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Kajian Pembangunan Indeks Akauntabiliti dan Keberkesanan Tadbir Urus Penyelidikan Bioteknologi Moden

Laporan Akhir

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PENGHARGAAN

Kajian ini dibiayai oleh Jabatan Biokeselamatan, Kementerian Sumber Asli, Alam Sekitar dan Perubahan Iklim, Malaysia.

ISI KANDUNGAN

SENARAI JADUAL

SENARAI RAJAH

SENARAI AKRONIM

BCH	Biosafety Clearing House
BSL	Aras Biokeselamatan
BSO	Pegawai Biokeselamatan
CBD	Konvensyen Kepelbagaian Biologi
CNBS	Majlis Biokeselamatan Kebangsaan
CTNBio	Suruhanjaya Teknikal Kebangsaan mengenai Biokeselamatan
CPB	Protokol Cartagena berkenaan Biokeselamatan
FGD	Perbincangan Kumpulan Bersasar
GMAC	Jawatankuasa Penasihat Pengubahsuaian Genetik
GMO	Organisma yang Diubahsuai Genetik
IBC	Jawatankuasa Keinstitusian Biokeselamatan
JBK	Jabatan Biokeselamatan
LMO	Organisma Hidup yang DiUbahsuai
NBB	Lembaga Biokeselamatan Kebangsaan
NIBM	Institut Bioteknologi Kebangsaan Malaysia
NRE	Kementerian Sumber Asli dan Alam Sekitar
MOSTI	Kementerian Sains, Teknologi & Inovasi

rDNA	DNA rekombinan
RAF	Rangka Kerja Analisis Risiko
RRT	Pasukan Tindak Balas Pantas
SOP	Prosedur Operasi Standard

BAB 1
RINGKASAN EKSEKUTIF

Peningkatan penggunaan bioteknologi dan kemajuan dalam kejuruteraan genetik, biokeselamatan telah menjadi isu kritikal bagi sesebuah organisasi yang berurusan dengan bahan biologi. Pelaksanaan amalan biokeselamatan yang berkesan dapat memastikan keselamatan pekerja, komuniti, dan alam sekitar disamping menggalakkan pembangunan produk yang inovatif. Malaysia telah membentuk rangka kerja, undang-undang, dan peraturan yang diperlukan untuk pelaksanaan biokeselamatan. Akta Biokeselamatan Kebangsaan 2007 dan peraturan-peraturan yang disertakan bertujuan untuk menggalakkan kemajuan bioteknologi disamping menjaga kesihatan manusia dan alam sekitar.

Indeks Akauntabiliti Biokeselamatan telah dibangunkan sebagai instrumen untuk membimbing institusi yang terlibat dalam penyelidikan bioteknologi ke arah pematuhan peraturan biokeselamatan. Indeks ini menyediakan rangka kerja bagi membolehkan sesebuah organisasi menilai pematuhan terhadap peraturan, merangka strategi penambahbaikan, dan melaksanakan langkah-langkah pembetulan. Ia juga merangkumi empat bidang utama dengan merujuk kepada Akta Biokeselamatan 2007 dan Peraturan Biokeselamatan (Kelulusan dan Pemberitahuan 2010:

Pengetahuan dan kapasiti manusia, pentadbiran dan institusi, pengurusan data dan bahan, serta amalan Biokeselamatan). Pengetahuan dan kapasiti manusia melibatkan penilaian terhadap pengetahuan am berkenaan latihan keselamatan dan biokeselamatan. Pentadbiran dan institusi melibatkan pematuhan terhadap peraturan biokeselamatan dan dasar sesebuah institusi. Pengurusan data dan bahan melibatkan penilaian ke atas pengendalian dan pergerakan bahan LMO/rDNA. Amalan biokeselamatan merujuk kepada prosedur yang diterima pakai semasa aktiviti LMO/rDNA.

Pelaksanaan Indeks Akauntabiliti Biokeselamatan bagi sesebuah organisasi adalah penting untuk memastikan pematuhan dengan keperluan kawal selia, mendorong ketelusan dan akauntabiliti, serta menggalakkan keyakinan awam dalam penyelidikan bioteknologi. Ini amat relevan di Malaysia, di mana sistem biokeselamatan berusaha untuk memastikan penyelidikan, pembangunan, pengendalian, pergerakan merentasi sempadan, transit, penggunaan, pelepasan, pengurusan GMO dan produk diuruskan dengan risiko yang minimum kepada kesihatan manusia, haiwan, biodiversiti, dan alam sekitar. Secara ringkasnya, Indeks Akauntabiliti Biokeselamatan merupakan instrumenyang penting bagi institusi yang terlibat dalam penyelidikan bioteknologi.

BAB 2

PENGENALAN

2.1 Latar Belakang Kajian

Biokeselamatan merangkumi prinsip, teknologi, dan amalan perlaksanaan bagi mengelakkan pendedahan yang tidak diingini kepada agen biologi atau pelepasan secara tidak sengaja. Ia telah mendapat perhatian global dalam beberapa dekad kebelakangan ini disebabkan kebimbangan yang semakin meningkat berkenaan insiden biologi yang disengajakan dan ancaman biologi yang berulang.

Dewasa kini, terdapat peningkatan dalam bidang penyelidikan, pembangunan, pengkomersilan, inovasi, serta perdagangan tempatan dan antarabangsa yang melibatkan Organisma Hidup Diubahsuai (LMO). Trend ini adalah kesan langsung daripada bioteknologi moden, termasuk teknologi penyuntingan gen termaju, gangguan RNA (RNAi) dan biologi sintetik. Bagi memastikan aktiviti ini dilaksanakan secara selamat dan bertanggungjawab, kerajaan diseluruh dunia perlu bekerjasama dalam meningkatkan strategi pengawalseliaan dan mengukuhkan pembinaan kapasiti tempatan bagi tujuan pengurusan dan pengawalan aktiviti LMO secara berkesan. Beberapa negara termasuk Malaysia, telah meratifikasi Protokol Cartagena mengenai biokeselamatan. Selaras dengan ini, Malaysia telah menggubal Akta

Biokeselamatan 2007 (juga dikenali sebagai Akta 678) bagi mengawal selia aktiviti import, eksport, penggunaan terkawal, serta ujian lapangan LMO dan produk terbitannya. Penggubalan akta ini selaras dengan dasar-dasar sedia ada kerajaan, iaitu Dasar Biodiversiti Negara (1998) dan Dasar Bioteknologi Negara (2005).

Usaha meningkatkan biokeselamatan di makmal memerlukan pengenalpastian kelemahan dan pelaksanaan penilaian risiko serta penyelesaian pengurusan risiko yang sesuai. Langkah-langkah penambahbaikan ini bertujuan untuk menghalang akses tanpa kebenaran kepada patogen, peralatan, maklumat, dan teknologi yang berkaitan. Walaupun dasar dan proses semasa telah wujud untuk memastikan pematuhan terhadap protokol biokeselamatan, namun keberkesanan protokol ini bergantung kepada penilaian tahap pematuhan yang tepat dan mudah.

Perlaksanaan sistem pengurusan biokeselamatan yang komprehensif haruslah merangkumi amalan biokeselamatan makmal dan mengekalkan keseimbangan fungsi antara mengakses bahan biologi dan memelihara persekitaran yang mampu memupuk penyelidikan asas dan gunaan. Tambahan pula, setiap organisasi perlu memberi tumpuan kepada kaedah untuk menangani punca ketidakpatuhan dan mencari jalan untuk meningkatkan prestasi kawalan bio-risiko dalam setiap operasi. Alat penilaian kendiri yang

berupaya untuk mengukur tahap pematuhan dan akauntabiliti perlu menjadi sebahagian daripada penyelesaian, pengenalpastian, serta penilaian sistematik bagi kemudahan dan prestasi amalan tertentu. Hasil penilaian ini boleh digunakan dalam menentukan langkah-langkah penambahbaikan, pengurangan risiko kepada tahap yang minima dan boleh diuruskan. Langkah-langkah ini kemudiannya boleh diterapkan ke dalam program pengurusan risiko biologi untuk tujuan peningkatan yang berterusan.

2.2 Objektif Kajian

Membangunkan alat penilaian kendiri yang membolehkan penilaian pematuhan terhadap protokol biokeselamatan, serta digunakan sebagai instrumen untuk membangunkan Indeks Akauntabiliti Biokeselamatan Kebangsaan. Skop penilaian dan objektif khusus adalah seperti berikut:

1. Menilai keberkesanan strategi kawal selia sedia ada dan usaha dalam membina kapasiti untuk pengurusan selamat Organisma Hidup Diubahsuai (LMO).
2. Menganalisa tahap pematuhan terhadap protokol biokeselamatan dan mengenal pasti cabaran dalam menilai dan memastikan pematuhan.

3. Mengkaji potensi penggunaan alat penilaian kendiri dalam mengukur pematuhan dan akauntabiliti.

4. Mengenal pasti jurang dan mencadangkan langkah penambahbaikan untuk meningkatkan pematuhan terhadap biokeselamatan.

2.3 Skop Kerja

Alat penilaian kendiri akan membolehkan sesebuah institusi (melalui IBC masing-masing) dan individu mengukur tahap pematuhan terhadap Akta Biokeselamatan Malaysia 2007, yang akan menggalakkan pematuhan yang lebih baik. Instrumen berbentuk soal selidik akan menjana indeks akauntabiliti. Pembangunan alat penilaian kendiri ini akan membolehkan penilaian pematuhan terhadap protokol biokeselamatan dan membangunkan Indeks Akauntabiliti Biokeselamatan Kebangsaan.

2.4 Kementerian, Badan Kawal Selia, Akta, dan Peraturan Dalam Penguatkuasaan Biokeselamatan di Malaysia

Pada September 2003, Malaysia telah meratifikasi Protokol Cartagena berkenaan biokeselamatan. Berikutan penerimaan Protokol Cartagena, Kementerian Sains, Teknologi, dan Alam Sekitar merangka langkah

pematuhan biokeselamatan. Pada tahun berikutnya, kementerian tersebut telah disusun semula dan bertukar kepada Kementerian Sains, Teknologi, dan Inovasi (MOSTI) serta Kementerian Sumber Asli dan Alam Sekitar. Kini, Kementerian Tenaga dan Sumber Asli menerajui penyeliaan dan penguatkuasaan terhadap Akta Biokeselamatan 2007, dengan peraturan-peraturan yang telah disediakan oleh empat pihak berkuasa iaitu Jabatan Biokeselamatan (JBK), Lembaga Biokeselamatan Negara (NBB), Jawatankuasa Penasihat Pengubahsuaian Genetik (GMAC), dan Institusi Jawatankuasa Biokeselamatan (IBC).

Penguatkuasaan Akta Biokeselamatan 2007 memerlukan kerjasama yang erat antara agensi kerajaan yang berkaitan. Beberapa Akta dan Peraturan Negara mempunyai implikasi terhadap Biokeselamatan di Malaysia seperti yang disenaraikan dalam **Jadual 2.1**.

Jadual 2.1: Agensi kerajaan yang terlibat dalam penguatkuasaan akta Biokeselamatan di Malaysia.

Kementerian	**Agensi Kerajaan**	**Akta Kebangsaan yang Berkaitan**
Kementerian Sumber Asli, Alam Sekitar, dan Perubahan Iklim (KASA)	Jabatan Biokeselamatan	Akta Biokeselamatan 2007 (Akta 678)
Kementerian Kesihatan	Bahagian Keselamatan dan Kualiti Makanan	Akta Makanan 1983 (Akta 281)
		Akta Makanan 1983 (Akta 281) dan Akta Biokeselamatan (Akta 678)
	Bahagian Perkhidmatan Farmasi	Akta Racun 1952 (Akta 366)
		Akta Penjualan Dadah 1952 (Akta 368)
	Bahagian Kawalan Penyakit	Akta Perlindungan dan Kawalan Penyakit Berjangkit 1988 (Akta 342)
Kementerian Pertanian dan Industri Makanan (MAFI)	Jabatan Perkhidmatan Veterinar	Akta Haiwan 1953 (pindaan 2006) (Akta 674)
		Akta Makanan Haiwan 2009 (Akta 698)
	Jabatan Perkhidmatan Kuarantin dan Pemeriksaan Malaysia (MAQIS)	Akta Perkhidmatan Kuarantin dan Pemeriksaan Malaysia 2011 (Akta 728)
	Jabatan Pertanian	Akta Kuarantin Tumbuhan 1976 (Akta 167)

		Akta Racun Perosak 1974 (Akta 149)
	Jabatan Perikanan	Akta Perikanan 1985 (Akta 317)
Kementerian Sains, Teknologi, dan Inovasi (MOSTI)	Jabatan Kimia Malaysia	Akta Biokeselamatan 2007 (Akta 678)
Kementerian Tenaga dan Sumber Asli (KeTSA)	Jabatan Perhutanan Semenanjung Malaysia	Akta Perhutanan Negara 1984 (Akta 313)
	Institut Penyelidikan Perhutanan Malaysia	Akta Biokeselamatan 2007 (Akta 678)
	Bahagian Pengurusan Biodiversity dan Perhutanan	Akta Perdagangan Antarabangsa Mengenai Spesis Terancam 2008 (Akta 686)
		Akta Akses kepada Sumber Biologi dan Perkongsian Faedah 2017 (Akta 795)

2.4.1 Akta Biokeselamatan (2007)

Objektif Akta 678, juga dikenali sebagai Akta Biokeselamatan (2007), adalah untuk mengawal pelepasan terkawal, pengimportan, pengeksportan, dan penggunaan terkawal organisma hidup diubah suai (LMO), serta pelepasan produk yang diperoleh daripada organisma tersebut. Matlamat utama akta ini adalah untuk menjaga kesihatan manusia, tumbuhan dan haiwan, melindungi alam sekitar, dan

memelihara kepelbagaian biologi (Undang-undang Malaysia, 2007).[1] Akta tersebut mendefinisikan bioteknologi moden (Bahagian I, Seksyen 3) sebagai teknik-teknik yang mengatasi halangan pembiakan semulajadi dan berbeza daripada pembiakan tradisional " Hasilnya, LMO ditakrifkan sebagai "mana-mana organisma hidup yang memiliki gabungan genetik baharu yang diperoleh melalui penggunaan bioteknologi moden." Di Malaysia, istilah LMO dan organisma diubah suai genetik (GMO) digunakan secara bergantian. Akta ini mengawal lima kategori aktiviti LMO, iaitu pelepasan, penggunaan terkawal, pengimportan untuk pelepasan, pengimportan untuk kegunaan terkawal, dan eksport (Kementerian Sumber Asli dan Alam Sekitar Malaysia, 2007).[2]

Akta ini dibahagikan kepada tujuh bahagian (Undang-undang Malaysia, 2007):

[1] Biosafety Act 2007 (Act 678), Laws of Malaysia

[2] Gurdial Singh Nijar, User's Guide to the Biosafety Act and Regulations (Putrajaya: The Ministry of Natural Resources and Environment Malaysia, 2010), 1-219.

(i) **Bahagian I** menyatakan perkara awal seperti petikan, permulaan, bukan permohonan, tafsiran, dan bayaran yang berkaitan dengan aktiviti yang akan dijalankan.

(ii) **Bahagian II** meliputi penubuhan dan fungsi Lembaga Biokeselamatan Kebangsaan (NBB), Jawatankuasa Penasihat Pengubahsuaian Genetik (GMAC), serta pelantikan Ketua Pengarah dan pegawai lain.

(iii) **Bahagian III** berkaitan dengan aktiviti yang melibatkan pelepasan dan pengimportan LMO, di mana penyerahan permohonan untuk kelulusan diperlukan.

(iv) **Bahagian IV** membincangkan keperluan pemberitahuan untuk acara khusus yang berkaitan dengan LMO, termasuk eksport, penggunaan terkawal, dan import.

(v) **Bahagian V** memberi tumpuan kepada aspek seperti penilaian risiko, laporan pengurusan risiko, dan pelan tindak balas kecemasan.

(vi) **Bahagian VI dan Bahagian VII** menyatakan penguatkuasaan, rayuan, dan pelbagai perkara lain yang berkaitan dengan akta.

Kebanyakan perkara praktikal yang berkaitan dengan akta dinyatakan melalui peraturan, kerana ia berfungsi sebagai rangka kerja undang-undang. Selepas rundingan dengan pihak berkepentingan, akta ini telah dikuat kuasakan pada 1 Disember 2009, dan Peraturan

Biokeselamatan (Kelulusan dan Pemberitahuan) telah dilaksanakan pada November 2010.

2.4.2 Peraturan Biokeselamatan (Kelulusan dan Pemberitahuan) 2010

Peraturan Biokeselamatan (Kelulusan dan Pemberitahuan) 2010 telah diperkenalkan untuk menangani dua kebimbangan utama (Undang-undang Malaysia, 2010). Pertama, ia bertujuan untuk memastikan keselamatan alam sekitar dan manusia disamping memupuk keyakinan orang ramai terhadap produk LMO. Ini dicapai melalui operasi Jawatankuasa Keinstitusian Biokeselamatan (IBC) di peringkat institusi. IBC menyediakan panduan untuk penggunaan bioteknologi moden dengan selamat, memantau aktiviti yang berkaitan dengan bioteknologi moden, mewujudkan serta mengawasi pelaksanaan dasar dan prosedur untuk mengendalikan LMO, dan juga menentukan tahap biokeselamatan untuk aktiviti penggunaan terkawal dalam penyelidikan dan pembangunan bioteknologi moden di fasiliti.

Kedua, peraturan mengawal proses kelulusan, pensijilan, serta pemberitahuan untuk pengeluaran dan pengimportan LMO dan produk LMO. Terutamanya, pertimbangan sosio-ekonomi, yang melibatkan penilaian terhadap kesan yang berpotensi terhadap corak sosial dan ekonomi sedia ada serta punca pencarian masyarakat yang terjejas

akibat pengenalan LMO, dan juga menilai kesan ke atas nilai agama, sosial, budaya, dan etika masyarakat hasil daripada penggunaan atau pelepasan LMO.

2.5 Penanda Aras

Untuk mengukuhkan rangka kerja kawalan dan pemantauan di Malaysia serta penguatkuasaan biokeselamatan, adalah jelas bahawa rangka kerja biokeselamatan negara perlu dikemas kini. Ini adalah bagi mengimbangi kemajuan terkini dalam bidang tersebut. Oleh itu, adalah penting untuk meneliti dan membandingkan langkah-langkah dasar yang sedang dibangunkan dan dilaksanakan oleh negara-negara yang lain. Untuk tujuan ini, rangka kerja pengawalan biokeselamatan di Australia, Brazil, dan Jepun telah dinilai. Ini berdasarkan pengalaman mereka yang meluas dan ketara dalam industri bioteknologi. Negara-negara ini mempunyai rangka kerja pengawalan yang baik pemantauan, pembangunan, penilaian risiko, pengurusan dan pengkomersilan LMO. Analisis ini memberikan gambaran menyeluruh untuk menentukan tahap fleksibiliti dan piawaian yang sesuai untuk dimasukkan ke dalam rangka kerja kawalan dan strategi pelaksanaan dalam bidang bioteknologi di Malaysia.

2.5.1 Australia

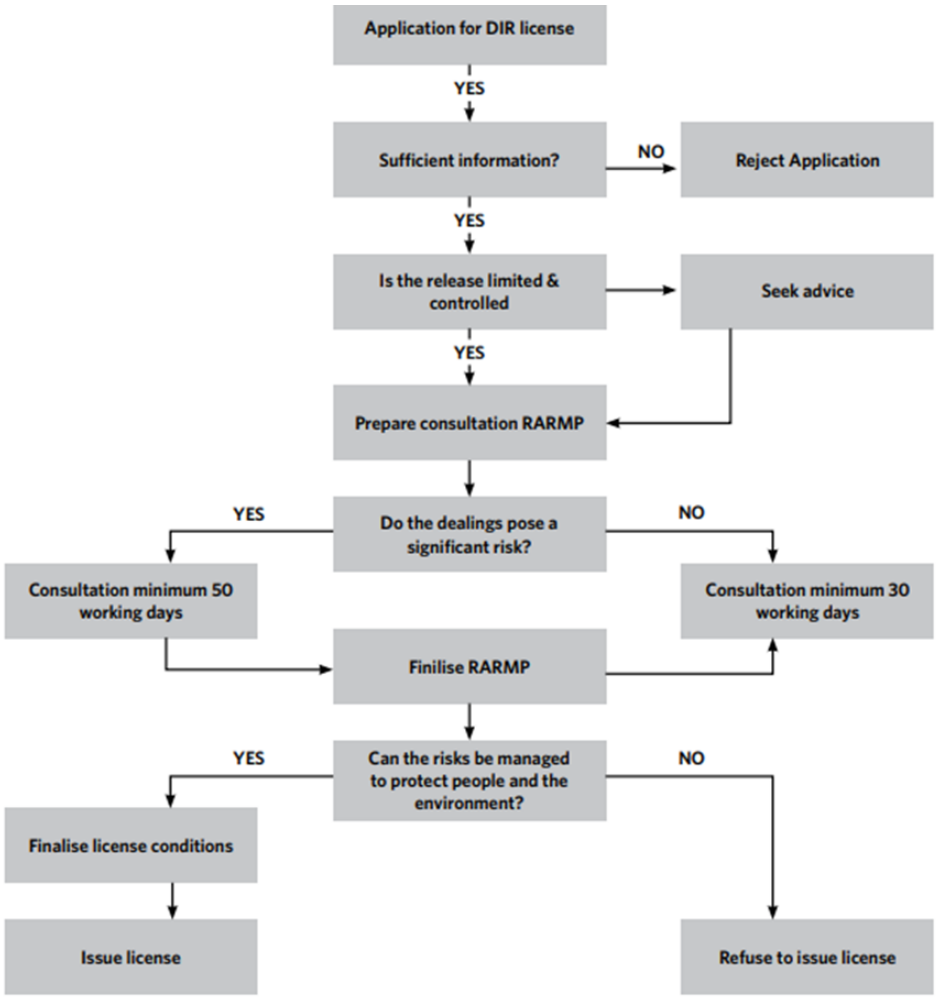
Rangka kerja pengawalan yang dipraktikkan oleh Australia bagi LMO telah diwujudkan melalui perundingan pakar, orang awam, model penilaian risiko sedia ada seperti Piawaian Pengurusan Risiko Australia New Zealand 4360:2004, dan dokumen garis panduan daripada Pertubuhan Kesihatan Sedunia, Pertubuhan Makanan dan Pertanian Pertubuhan Bangsa-Bangsa Bersatu, Lampiran III (Protokol Cartagena), "Buku Merah" Majlis Penyelidikan Kebangsaan Amerika Syarikat, dan Organisasi Kerjasama dan Pembangunan Ekonomi (Rajah 2.1). Akta ini menetapkan bahawa Pengawal Selia akan berunding dengan pakar saintifik serta dikehendaki untuk menyediakan bukti saintifik. Disamping itu, pakar saintifik boleh dirujuk apabila bukti yang tidak mencukupi atau tidak disediakan. Akhir sekali, kakitangan yang mengendali LMO dikehendaki mengikuti latihan yang terkini demi mengekalkan kepakaran saintifik dan amalan terbaik dalam menganalisis risiko.

Penggunaan maklumat saintifik yang kukuh adalah penting untuk proses kawalan LMO di Australia. Walaupun kebanyakan proses penilaian risiko LMO adalah bersifat kualitatif, bukti saintifik yang kukuh mesti digunakan untuk menganggarkan kemungkinan risiko, akibat, anggaran risiko keseluruhan dan pengurusan risiko. Rangka Kerja Analisis Risiko (RAF) menyenaraikan kriteria bagi menentukan

kualiti sumber dan maklumat saintifik. Selain itu, RAF Australia menyatakan bahawa ketelusan dan komunikasi risiko adalah penting dalam proses penilaian risiko LMO. Ketelusan dianggap sebagai salah satu "Prinsip kepada panduan analisis risiko". Dalam rangka kerja penilaian risiko Australia, komunikasi risiko "mewujudkan dialog interaktif antara Pengawal Selia dan pihak berkepentingan untuk menyediakan peraturan berasaskan risiko GMO yang terbuka, telus, dan secara rundingan", dan komponen penting komunikasi risiko ialah rasional yang digunakan oleh Pengawal Selia dalam membuat keputusan LMO.

Proses penilaian risiko LMO di Australia adalah proses yang sangat teliti dengan rasional, metodologi, dan contoh yang dibentangkan secara terperinci untuk hampir setiap langkah. Walaupun Australia mengambil pendekatan kualitatif untuk menganggar risiko LMO, setiap langkah proses analisis risiko dibentangkan secara terperinci dalam RAF dan RARMP untuk menjadikan proses membuat keputusan telus kepada pemohon dan pihak berkepentingan. RAF malah mewajarkan penggunaan penilaian risiko kualitatif dan bukannya kuantitatif. Walaupun RAF Australia tidak membezakan antara kumpulan LMO yang berlainan (seperti tumbuhan vs. mikroorganisma), kumpulan LMO ini diliputi secara berasingan dalam permohonan lesen LMO. Matriks anggaran risiko dan pertimbangan

untuk pelbagai jenis ketidakpastian adalah aspek penting lain dalam rangka kerja penilaian risiko Australia yang diterangkan secara eksplisit dalam dokumen garis panduan.



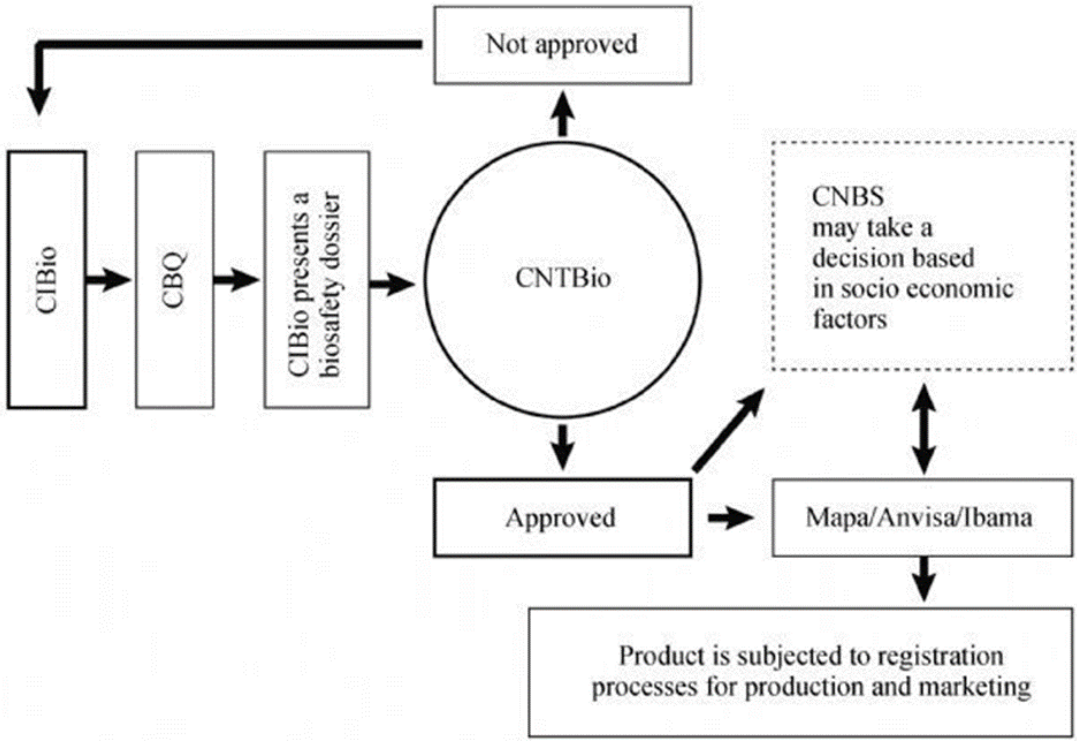
Rajah 2.1: Proses penilaian dalam rangka kerja penilaian risiko LMO Australia[3]

[3] Australia Risk Analysis Framework. 2009. Office of the Gene Technology Regulator. Appendix A, m/s 83.

2.5.2 Brazil

Rangka kerja penilaian risiko di Brazil adalah dengan menyerahkan penilaian risiko LMO kepada Suruhanjaya Teknikal Biokeselamatan Kebangsaan (CTNBio), dan Majlis Biokeselamatan Kebangsaan bertanggungjawab untuk menyemak keputusan dan mempertimbangkan rayuan keputusan CTNBio yang dibawa oleh pemohon (Rajah 2.2). Dokumen rangka kerja tidak memperincikan cara keputusan muktamad risiko dicapai, tetapi ia menggariskan keperluan asas untuk kelulusan LMO untuk dilepaskan ke alam sekitar. Pendekatan ini mempunyai kelebihan kerana membenarkan Suruhanjaya mengendalikan risiko dengan lebih fleksibel berdasarkan satu-satu kes, memperkemaskan prosedur untuk risiko minimum, dan menilai risiko yang kurang diketahui dengan lebih terperinci. Walaubagaimanapun, fleksibiliti ini mengakibatkan rangka kerja yang dipraktikkan oleh Brazil menjadi kurang telus. Untuk mengatasi perkara ini, pihak Brazil menerbitkankan keputusan risiko dan meminta ahli Suruhanjaya untuk bertanggungjawab terhadap pandangan mereka dengan membolehkan pendapat mereka boleh diakses. Walaupun Brazil nampaknya tidak mempunyai langkah untuk pemantauan selepas pengeluaran GMO, pemohon dikehendaki menyerahkan pelan pemantauan dan kemas kini tahunan tentang hasil pemantauan sepanjang 5 tahun selepas pengeluaran GMO.

Walaupun Brazil menekankan kepentingan penilaian risiko saintifik, namun kebimbangan sosial juga turut diambil kira. Namun begitu, rangka kerja Brazil tidak menjelaskan tentang ketidakpastian perlu dikendalikan atau kebarangkalian kesan buruk yang berlaku dianggarkan dan langkah-langkah pengurusan risiko hanya dinyatakan secara terperinci untuk penyelidikan dan ujian terkawal (makmal atau rumah hijau); langkah Biokeselamatan yang digunakan dalam ujian lapangan tidak diterangkan. Secara keseluruhannya, sistem pemberitahuan dan dokumentasi Brazil mengenai aplikasi dan keputusan LMO menjadikan penilaian risiko di Brazil boleh diakses, dan kebanyakan garis panduan adalah jelas. Walau bagaimanapun, penjelasan lanjut diperlukan mengenai jenis risiko yang dipertimbangkan, langkah-langkah Biokeselamatan yang boleh digunakan dalam ujian lapangan, jenis data yang boleh digunakan dalam penilaian risiko, dan kaedah data tersebut digunakan untuk membuat keputusan muktamad sama ada LMO diluluskan untuk pengeluaran atau tidak.



Rajah 2.2: Prosedur am untuk kelulusan kes demi kes LMO di Brazil[4]

2.5.3 Jepun

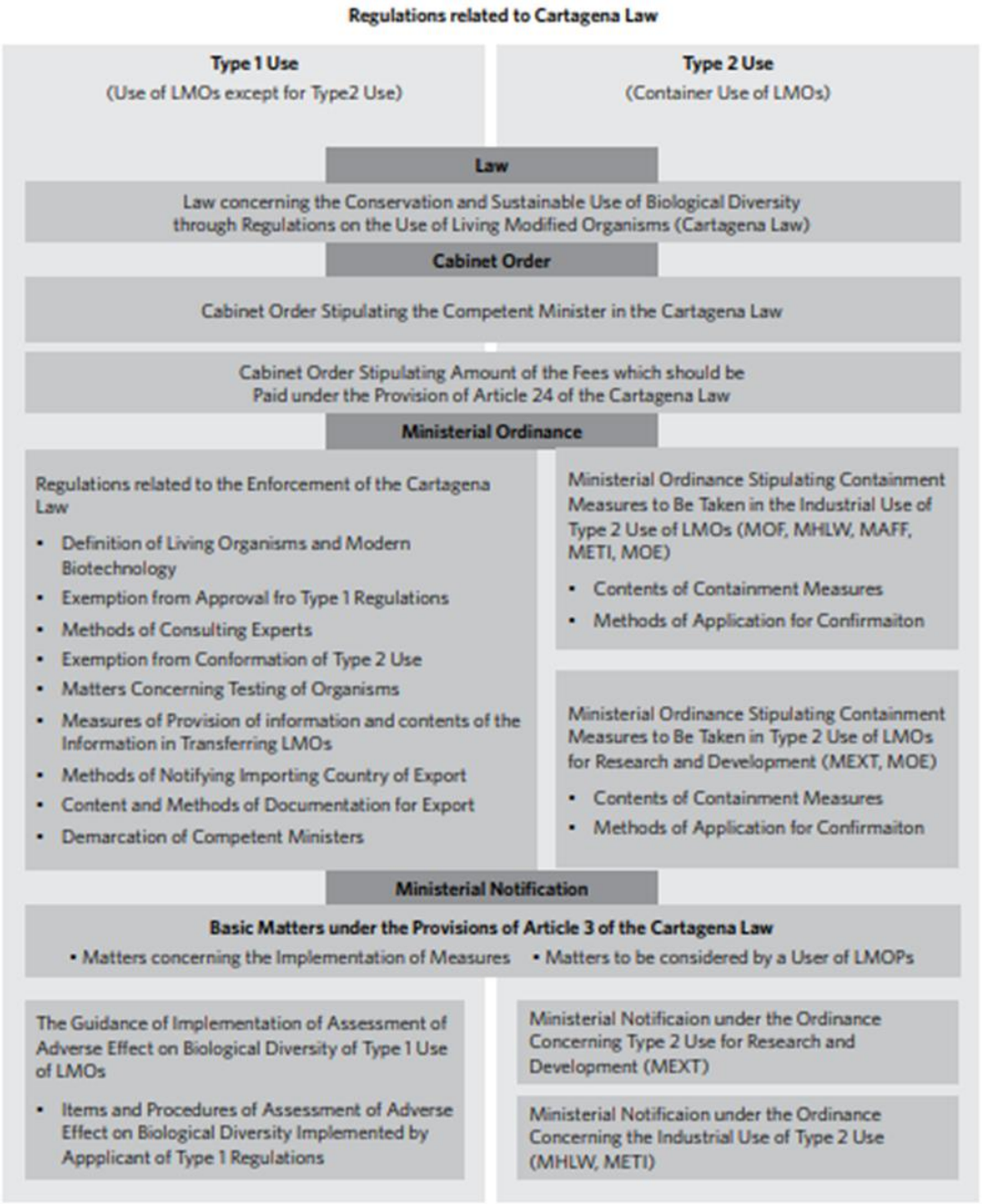
Peraturan LMO di Jepun adalah berdasarkan undang-undang kebangsaan (Akta 97/2003) dan dokumen panduan penilaian risiko, di mana kedua-duanya diselaraskan dengan Protokol Cartagena mengenai Biokeselamatan. Akta ini menetapkan bahawa keperluan penilaian risiko ditentukan terlebih dahulu sama ada penggunaan yang dimaksudkan adalah tidak terkandung (Jenis 1) atau terkandung (Jenis 2), kemudian oleh taksonomi luas organisma diubah suai hidup (LMO)

[4] Nepomuceno, Alexandre Lima, et al. "Brazilian Biosafety law and the new breeding technologies." Front Agr Sci Eng 7 (2020): 204-10.

(tumbuhan, haiwan, atau mikroorganisma), diikuti dengan gabungan organisma penerima, asid nukleik penderma, vektor, dan kaedah transformasi (Rajah 2.3). Kelulusan permohonan dibuat oleh menteri yang bersesuaian melalui rundingan bersama pakar saintifik. Anggaran risiko yang diperolehi melalui maklumat ini adalah berdasarkan data eksperimen atau ciri-ciri persekitaran penerima. Anggaran keseluruhan risiko yang diperolehi daripada penggunaan yang dicadangkan adalah kualitatif. Berdasarkan hasil penilaian risiko, menteri tersebut mungkin mensyaratkan pelaksanaan langkah pengurusan risiko dan pemantauan selepas pelepasan. Dua kategori khusus LMO - tumbuhan dan vaksin - termasuk dalam bidang kuasa Menteri Pertanian, Perhutanan, dan Perikanan disamping mengawal selia aplikasi untuk kegunaan LMO Jenis 1. LMO juga mungkin termasuk di bawah peraturan lain berdasarkan penggunaan yang dimaksudkan, seperti untuk makanan, atau jika LMO menyatakan ciri-ciri yang dikawal di bawah undang-undang lain (contohnya, tumbuhan dengan ciri racun serangga).

Peraturan Jepun adalah berdasarkan Protokol Cartagena mengenai Biokeselamatan dan rangka kerja penilaian risikonya mengikut Protokol Lampiran III. Terdapat beberapa cara di mana rangka kerja pengawalan digabungkan oleh Jepun. Pertama, perkara asas menetapkan bahawa pengetahuan saintifik terkini yang berkaitan

dengan aplikasi akan digunakan dalam penilaian risiko, dan kerajaan akan cuba mengumpul dan menganalisis data untuk mengukuhkan pengetahuan saintifik. Pakar akan dirujuk semasa proses kelulusan permohonan. Selain itu, dokumen panduan akan dikemaskini apabila terdapat keperluan untuk memasukkan kemajuan dalam pengetahuan saintifik mengenai kesan buruk LMO terhadap kepelbagaian biologi serta mempertimbangkan trend antarabangsadalam penilaian risiko LMO. Kedua, rangka kerja penilaian risiko Jepun menggabungkan ketelusan dari segi prosedur dan melalui pemberitahuan kepada umum. Penyediaan pangkalan data maklumat Biokeselamatan di mana data yang dijana oleh pelbagai kementerian kerajaan disusun dan disediakan untuk umum. Ketelusan melalui pemberitahuan awam dilakukan terlebih dahulu dimana senarai pakar yang dirujuk oleh menteri perlu dikeluarkan. Menteri juga mesti mengumumkan secara terbuka permohonan untuk penggunaan LMO dan mempertimbangkan pendapat umum mengenai permohonan tersebut walaupun maklumat teknikal atau penyelidikan yang skompleks mungkin tidak didedahkan oleh kerajaan. Selepas kelulusan, pemohon dijangka mengekalkan rekod mengenai "syarat penggunaan" dan maklumat yang berkaitan dengan LMO.



Rajah 2.3: Carta alir peraturan Jepun yang berkaitan dengan Protokol Cartagena mengenai Biokeselamatan[5]

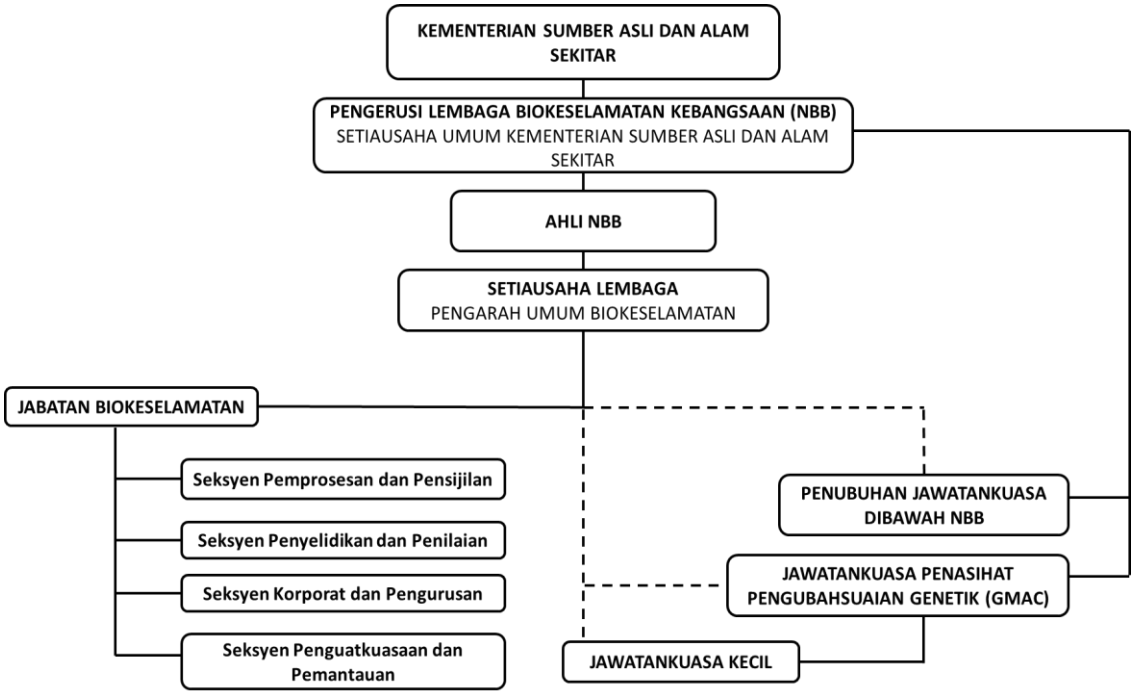
[5] Regulations Related to Cartagena Law. http://www.bch.biodic.go.jp/english/law.html

BAB 3

PERLAKSANAAN BIOKESELAMATAN

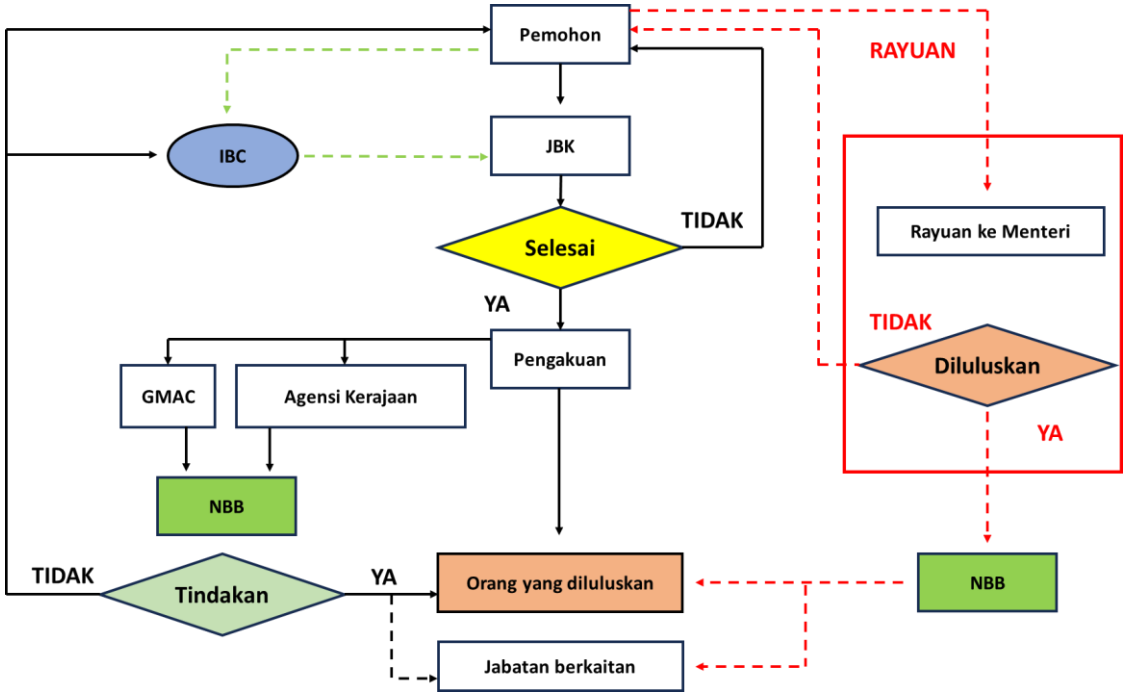
3.1 Tadbir Urus Biokeselamatan

Kementerian Tenaga dan Sumber Asli berfungsi sebagai Pusat Tumpuan Nasional CBD, manakala Kementerian Alam Sekitar dan Air memainkan peranan dalam Titik Tumpuan Kebangsaan dan Langkah-langkah Kecemasan (Artikel 17). Pentadbiran Biokeselamatan melibatkan pelbagai entiti penting, termasuk Lembaga Biokeselamatan Kebangsaan (NBB), Jabatan Biokeselamatan (JBK), dan Jawatankuasa Penasihat Pengubahsuaian Genetik (GMAC). Selain itu, terdapat beberapa jawatankuasa lain seperti yang disenaraikan dalam Rajah 3.1. Entiti ini menyumbang kepada semakan serta pengurusan Dasar dan Pelan Tindakan Biokeselamatan Kebangsaan untuk mengawal aktiviti yang melibatkan Organisma Hidup Diubahsuai (LMO).



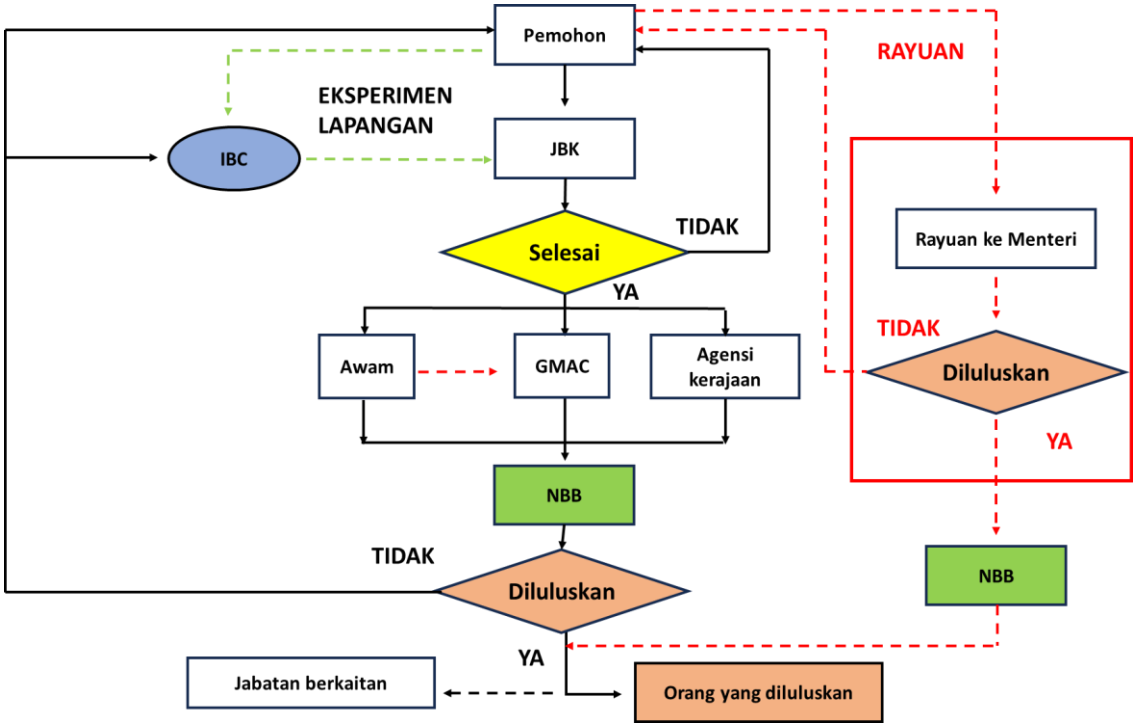
Rajah 3.1: Carta organisasi Biokeselamatan[6]

[6] Gurdial Singh Nijar, "Background Information About the National Regulatory Scheme for LMOs," in User's Guide to the Biosafety Act and Regulations, (Putrajaya: The Ministry of Natural Resources and Environment Malaysia, 2010), pg. 17.



Rajah 3.2: Proses pemberitahuan penerimaan daripada GMAC dan NBB

Aktiviti yang berkaitan dengan LMO/rDNA boleh dimulakan selepas mendapat perakuan daripada JBK. Pada masa yang sama, GMAC dan NBB akan menilai dan membuat keputusan dalam tempoh 90 hari dari tarikh permohonan. Penilaian NBB boleh menyebabkan tiada perintah, perintah pemberhentian, penentuan terma dan syarat, perintah pembetulan, dan perintah lain. Keputusan pemberitahuan akan disemak dari semasa ke semasa dan setiap kesalahan yang dilakukan akan dikenakan tindakan. Sebarang rayuan perlu dibuat kepada Menteri yang terlibat.



Rajah 3.3: Proses penerimaan kelulusan daripada NBB

NBB akan membuat keputusan dalam tempoh 180 hari. Keputusan mungkin berbeza bergantung kepada permohonansama ada diluluskan, diluluskan dengan terma dan syarat, atau ditolak. Sebarang aktiviti hanya boleh dimulakan selepas menerima sijil kelulusan daripada NBB. Pemohon yang diluluskan tidak boleh menjalankan apa-apa aktiviti pelepasan (termasuk mana-mana pengimportan LMO) selain daripada sijil yang telah dikeluarkan. Keputusan yang diluluskan boleh disemak dari semasa ke semasa dan sebarang kesalahan boleh dikenakan tindakan. Sebarang rayuan perlu dibuat kepada Menteri.

3.2 Isu dan Cabaran Dalam Pematuhan Biokeselamatan

Pematuhan kepada biokeselamatan merujuk kepada pematuhan undang-undang, peraturan, garis panduan, dan amalan terbaik berkaitan dengan pengendalian, penggunaan, dan pelupusan secara selamat bagi ejen biologi, termasuk patogen, organisma yang diubah suai secara genetik, dan produk bioteknologi. Pematuhan kepada biokeselamatan adalah penting untuk melindungi kesihatan manusia, alam sekitar, dan ekonomi daripada risiko berbahaya yang disebabkan oleh agen biologi.

Dari pihak berkepentingan yang terlibat, beberapa isu dan cabaran yang dihadapi dalam pematuhan Biokeselamatan telah dikenal pasti seperti berikut:

3.2.1 Kesedaran

Secara keseluruhannya, tahap kesedaran mengenai biokeselamatan dalam kalangan individu dan organisasi yang terlibat dalam kerja-kerja LMO adalah boleh dibanggakan. Walau bagaimanapun, terdapat jurang pengetahuan dalam kalangan kakitangan muda atau pengguna baharu mengenai peraturan, garis panduan dan amalan terbaik yang berkaitan dengan aktiviti-aktiviti LMO mereka. Selain itu, wujud kebimbangan apabiladalam kalangan penyelidik kanan yang menganggap bahawa organisma rekombinan

adalah selamat untuk dikendalikan. Tambahan pula, terdapat juga kekeliruan antara definisi "mutan" dan "GMO/LMO" dalam konteks biokeselamatan. Faktor-faktor ini secara tidak langsung akan menyebabkan ketidakpatuhan, menimbulkan risiko yang ketara, dan akibat yang mungkin timbul. Tambahan pula, isu kesedaran dan jurang pengetahuan dalam kalangan Penyelidik Utama baharu dan penyelidik yang terlibat dalam kerja-kerja LMO juga boleh menyumbang kepada ketidakpatuhan. Situasi ini adaalh perkara biasa bagi individu ini untuk tidak mengetahui keperluan pemberitahuan apabila memohon geran atau memulakan projek penyelidikan. Kekurangan kesedaran ini boleh menyebabkan projek dijalankan tanpa pemberitahuan yang sewajarnya, seterusnya memburukkan lagi cabaran dalam mengesan dan memantau aktiviti berkaitan LMO.

3.2.2 Sumber yang terhad

Pematuhan terhadap peraturan dan garis panduan biokeselamatan memerlukan sumber yang banyak, termasuk kakitangan, peralatandan latihan. Walau bagaimanapun, kebanyakan organisasi kecil dan sederhana mempunyai akses terhad kepada sumber yang diperlukanuntuk memahami dan mematuhi keperluan biokeselamatan secara menyeluruh. Institusi ini biasanya memberi tumpuan kepada langkah-langkah keselamatan am seperti latihan

kebakaran, tetapi kurang mendapat latihan khusus yang bersesuaian dengan amalan biokeselamatan. Akibatnya, sesetengah industri menggunakan proses percubaan dan kesilapan yang berulang disebabkan oleh kekurangan kakitangan berpengalaman yang berpengetahuan dalam protokol biokeselamatan. Selain itu, ketersediaan kursus biokeselamatan tahunan dan program latihan yang diperakui adalah terhad, memburukkan lagi cabaran yang dihadapi oleh sesebuah organisasi dalam meningkatkan amalan biokeselamatan mereka.

Walau bagaimanapun, situasi ini agak berbeza bagi institusi yang lebih besar. Antaranya ialah bilangan pegawai IBC yang terhad untuk menyemak, menilai, dan memantau projek dengan berkesan. Hal ini kerana, jumlah aktiviti penyelidikan dan projek serta memerlukan pengawasan adalah tidak seimbang dengan bilangan pegawai IBC yang sedia ada. Bilangan pegawai IBC yang terhad untuk mengendalikan beban kerja ini boleh menyebabkan kelewatan dalam semakan projek dan pemantauan yang tidak mencukupi terhadap aktiviti yang sedang dijalankan. Keadaan ini berpotensi menjejaskan ketelitian dan keberkesanan penilaian biokeselamatan dan proses pemantauan dalam institusi yang lebih besar.

Isu lain yang turut dihadapi oleh sesebuah organisasi dalam memastikan pematuhan biokeselamatan adalah kekangan peruntukan

untuk memastikan standard biokeselamatan dipenuhi. Proses untuk menyediakan fasiliti seperti insfrastruktur yang baik, sistem pengudaraan, langkah-langkah kawalan dan protocol pengurusan sisa yang memenuhi keperluan biokeselamatan boleh melibatkan kos perbelanjaan yang tinggi. Peruntukan yang terhad boleh menghalang keupayaan sesebuah organisasi dalam usaha untuk memastikan pematuhan terhadap protokol biokeselamatan secara menyeluruh. Kesimpulannya, kekurangan sumber dan sokongan tambahan telah menjadi salah satu cabaran terbesar bagi sesebuah organisasi dalam usaha untuk mematuhi protokol biokeselamatan secara menyeluruh.

3.2.3 Kerumitan

Peraturan dan garis panduan biokeselamatan boleh menjadi rumit dan sukar difahami, terutamanya bagi mereka yang tidak mempunyai latar belakang saintifik yang kukuh. Ini boleh menyebabkan cabaran kepada organisasi untuk memahami kewajipan mereka dan membangunkan strategi pematuhan yang sesuai. Kekurangan pihak berkuasa berpusat untuk prosedur tertentu juga menjadi satu cabaran besar dalam memastikan pengurusan biokeselamatan yang berkesan. Dalam beberapa kes, IBC mungkin tidak mempunyai hubungan atau integrasi yang kuat dengan ahli jawatankuasa yang lain, termasuk ahli akademik dan jawatankuasa etika. Kekangan ini boleh menghalang penyelarasan

dan komunikasi yang lancar antara entiti berbeza yang terlibat dalam pengawasan biokeselamatan.

Tambahan pula, ketiadaan integrasi antara pusat pengurusan penyelidikan dan jawatankuasa berkaitan biokeselamatan memburukkan lagi masalah ini. Aktiviti penyelidikan sering melibatkan pelbagai pihak berkepentingan, termasuk penyelidik, pentadbir, dan pegawai biokeselamatan. Tanpa integrasi dan kerjasama yang berkesan antara entiti ini, terdapat risiko untuk mengabaikan pertimbangan biokeselamatan yang penting sepanjang proses penyelidikan. Ketidak sepakatan ini boleh menjejaskan keberkesanan keseluruhan langkah biokeselamatan dan meningkatkan potensi ketidakpatuhan yang tidak disengajakan.

Satu lagi contoh cabaran dalam tadbir urus biokeselamatan ialah isu pengawasan peraturan apabila sel terapeutik dilepaskan ke pasaran. Dalam kes sedemikian, tanggungjawab untuk pemantauan dan pengawalseliaan mungkin beralih daripada JBK kepada NPRA, atau pihak berkuasa lain yang berkaitan. Peralihan ini boleh mengakibatkan kerumitan dan potensi jurang dalam pengawasan kerana rangka kerja dan mekanisme peraturan yang berbeza mungkin akan terjadi. Bagi memastikan penyelarasan yang lancar dan penerangan yang jelas tentang tanggungjawab antara badan-badanyang berkaitan, adalah penting untuk mengekalkan pemantauan biokeselamatan yang

konsisten dan kukuh sepanjang tempoh kitaran hayat produk atau intervensi.

3.2.4 Mengubah peraturan sedia ada

Landskap peraturan yang sentiasa berubah dalam bidang biokeselamatan memberikan cabaran yang ketara. Pematuhan peraturan yang sentiasa berubah menjadi semakin sukar adalah apabila maklumat dan garis panduan yang tersedia tidak mencukupi. Kekurangan maklumat yang boleh diakses dan komprehensif ini boleh menyebabkan kekeliruan dan ketidakpastian mengenai prosedur yang perlu diikuti. Peraturan dan garis panduan biokeselamatan yang sentiasa berkembang boleh menjadi cabaran buat organisasi untuk mengikuti keperluan dan prosedur terkini. Ini boleh mengakibatkan ketidakpatuhan yang tidak disengajakan dan berpotensi untuk berdepan dengan risiko undang-undang dan reputasi.

3.2.5 Perlaksanaan

Penguatkuasaan peraturan dan garis panduan biokeselamatan lebih mencabar terutamanya dalam institusi yang mempunyai sumber yang terhad atau struktur tadbir urus yang lemah. Ini boleh menyebabkan ketidakpatuhan dan berpotensi membahayakan kesihatan manusia, alam sekitar, dan ekonomi. Satu cabaran khusus

ialah kekurangan tindakan susulan ke atas permohonan dan pemberitahuan projek yang melibatkan LMO. Perkara ini lebih mencabar apabila penyelidikan dan kerjasama berlaku melibatkan pelbagai institusi. Tanpa sistem yang baik bagi proses pemantauan sesuatu projek, sukar untuk memastikan semua pemberitahuan yang diperlukan serta langkah biokeselamatan yang sesuai dilaksanakan.

Selain itu, kesukaran dalam pengesanan projek LMO berpunca daripada ketiadaan sistem berpusat yang cekap untuk mengumpul dan menyusun maklumat. Tanpa sistem sedemikian, ia menjadi sukar untuk menjejaki pelbagai projek, status, dan pematuhan terhadap peraturan biokeselamatan. Kekurangan proses pengesanan ini boleh menjejaskan keupayaan untuk menguatkuasakan garis panduan biokeselamatan secara berkesan dan bertindak balas terhadap sebarang potensi risiko atau ketidakpatuhan yang mungkin timbul.

Secara ringkasnya, pematuhan kepada biokeselamatan adalah penting untuk melindungi kesihatan manusia, alam sekitar dan ekonomi daripada potensi bahaya yang disebabkan oleh penyebaran agen biologi. Walau bagaimanapun, terdapat beberapa isu dan cabaran yang perlu ditangani untuk memastikan pematuhan yang berkesan, termasuk kekurangan kesedaran, sumber yang terhad, kerumitan, perubahan peraturan dan penguatkuasaan. Usaha untuk menangani

cabaran ini memerlukan kerjasama yang berteruskan antara kerajaan, organisasi dan individu yang terlibat dalam aktiviti Biokeselamatan.

3.3 Langkah-langkah Dalam Memastikan Pematuhan Kepada Biokeselamatan

Pematuhan protokol biokeselamatan didalam sesebuah organisasi adalah penting untuk melindungi kesihatan dan keselamatan pekerja dan orang awam, serta untuk mencegah kerosakan alam sekitar dan mengelakkan risiko undang-undang dan reputasi. Antara cadangan untuk memastikan pematuhan biokeselamatan dalam sesebuah organisasi termasuk:

3.3.1 Penubuhan sistem pemantauan dan penguatkuasaan berpusat

Adalah penting untuk mewujudkan pihak berkuasa atau mekanisme berpusat bagi memudahkan kerjasama dan penyelarasan dalam kalangan jawatankuasa dan pihak berkepentingan yang berbeza dalam bidang biokeselamatan. Pihak berkuasa pusat ini harus merapatkan jurang antara IBC, jawatankuasa etika, dan entiti lain yang berkaitan, menggalakkan komunikasi yang berkesan, perkongsian pengetahuan, dan penyelarasan amalan Biokeselamatan. Selain itu,

usaha perlu dibuat untuk memupuk integrasi antara pusat pengurusan penyelidikan dan jawatankuasa biokeselamatan untuk memastikan pendekatan holistik terhadap pengurusan biokeselamatan. Garis panduan dan protokol yang jelas juga harus diwujudkan untuk memudahkan peralihan yang lancar dan pengawasan kawal selia apabila tanggungjawab beralih antara badan kawal selia yang berbeza. Dengan menangani isu ini, organisasi boleh meningkatkan tadbir urus biokeselamatan mereka dan mengurangkan potensi risiko yang berkaitan dengan pengawasan dan ketidakpatuhan yang berpecah-belah.

Selain itu, adalah penting untuk mewujudkan sistem pemantauan berterusan dan pengemaskinian prosedur. Perkembangan pesat dalam bidang biokeselamatan, semakan dan pengemaskinian garis panduan dan SOP secara berkala adalah penting untuk mengimbangi perkembangan saintifik baharu dan keperluan kawal selia. Ini dapat memastikan semua pihak berkepentingan bekerja dengan maklumat terkini dan boleh dipercayai, mempromosikan konsistensi, dan pematuhan sepanjang proses kelulusan.

Ia juga penting untuk mengukuhkan mekanisme penguatkuasaan dan struktur tadbir urus yang mengelilingi peraturan biokeselamatan. Ini melibatkan memperuntukkan sumber yang mencukupi, termasuk kewangan dan kakitangan, untuk menyokong

usaha pematuhan. Mewujudkan pangkalan data atau sistem berpusat untuk mengesan dan memantau projek LMO akan meningkatkan keupayaan untuk menguatkuasakan peraturan dan memastikan ketelusan.

Kerjasama dan penyelarasan antara institusi, badan kawal selia, dan agensi pembiayaan penyelidikan adalah faktor utama dalam meningkatkan penguatkuasaan. Dengan kerjasama ini, garis panduan yang jelas dapat diwujudkan, memperkemas proses, dan melaksanakan mekanisme pemantauan yang berkesan untuk mengawasi projek LMO sepanjang kitaran hayat mereka.

3.3.2 Pembangunan program dan latihan biokeselamatan yang komprehensif

Meningkatkan kesedaran dan menyediakan latihan komprehensif kepada PI, penyelidik, dan pihak berkepentingan lain yang berkaitan adalah penting. Ini akan membantu mereka memahami kepentingan pematuhan peraturan biokeselamatan dan memperkasakannya demi memenuhi tanggungjawab dalam memaklumkan dan mematuhi protokol yang diperlukan.

Institusi yang terlibat dalam pengendalian LMO perlu membangunkan program biokeselamatan yang komprehensif serta

merangkumi dasar, prosedur dan garis panduan untuk pengendalian, penggunaan dan pelupusan agen biologi yang selamat. Program ini hendaklah disesuaikan dengan aktiviti khusus organisasi dan disemak serta dikemas kini secara berkala untuk mencerminkan perubahan peraturan dan amalan terbaik.

Semua pekerja yang mengendalikan ejen biologi hendaklah menerima latihan yang sesuai mengenai prosedur biokeselamatan, termasuk penggunaan peralatan pelindung diri yang betul, pengendalian dan pelupusan bahan biologi dengan selamat, serta prosedur tindak balas kecemasan. Latihan perlu diberikan kepada pekerja dan pengguna baharu pada permulaan serta diperbaharui secara berkala.

3.3.3 Menjalankan pemeriksaan dan audit secara berkala

Melaksanakan pemeriksaan dan audit secara berkala adalah komponen penting dalam program biokeselamatan yang berkesan. Institusi perlu sentiasa memantau dan menilai pematuhan kakitangan terhadap prosedur dan amalan biokeselamatan untuk memastikan persekitaran kerja yang selamat. Pemeriksaan mengejut yang kerap keatas kakitangan dijalankan untuk memastikan pematuhan mereka dengan prosedur biokeselamatan. Pemeriksaan mengejut ini melibatkan lawatan di tapak oleh Pegawai Biokeselamatan terlatih atau

pemeriksa yang menilai sama ada individu mematuhi protokol yang diperlukan semasa mengendalikan organisma hidup, bekerja dikawasan terkandung, atau menjalankan eksperimen. Melalui pemeriksaan ini, institusi boleh mengenal pasti sebarang kesilapan atau pelanggaran terhadap garis panduan biokeselamatan yang ditetapkan dan mengambil tindakan pembetulan dengan segera.

Selain itu, institusi juga perlu menjalankan pemeriksaan dan pengauditan terhadap keseluruhan program biokeselamatan. Penilaian ini melibatkan penilaian menyeluruh terhadap infrastruktur, kemudahan, peralatan, dan kawalan pentadbiran institusi bagi memastikan pematuhan kepada peraturan dan garis panduan. Semasa pemeriksaan dan audit, bahagian-bahagian tertentu dalam program biokeselamatan diperiksa untuk mengenal pasti bahagian yang berpotensi untuk diperbaiki. Ini termasuk menyemak dokumen seperti prosedur operasi standard, rekod latihan, laporan insiden, dan dokumenberkaitan keselamatan peralatan. Pasukan pemeriksa hendaklah menilai sama ada rekod ini adalah terkini, tepat, dan boleh diakses oleh kakitangan.

Selepas pemeriksaan dan pengauditan, institusi hendaklah membangunkan pelan tindakan pembetulan untuk menangani sebarang kelemahan yang telah dikenal pasti. Pelan ini menggariskan tindakan khusus yang perlu diambil untuk memperbaiki

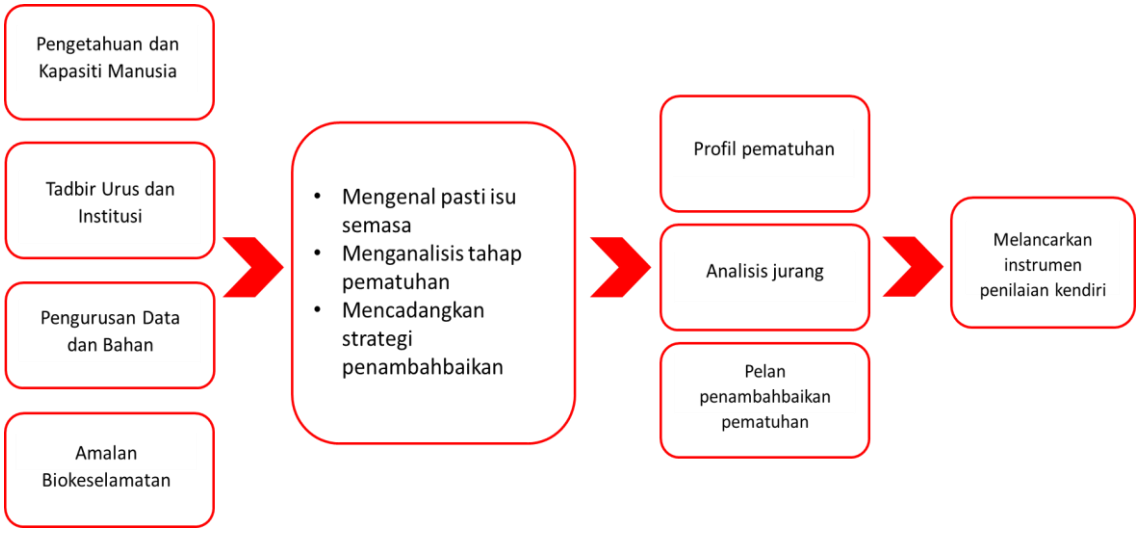
ketidakpatuhan atau menambah baik amalan sedia ada. Pemeriksaan dan audit susulan tetap dijalankan untuk memantau pelaksanaan tindakan pembetulan ini dan mengesahkan keberkesanannya dalam meningkatkan amalan biokeselamatan.

Perkembangan saintifik baharu, inovasi teknologi, dan perubahan dalam piawaian kawal selia boleh memberi kesan ketara kepada amalan biokeselamatan. Dengan menyemak dan mengemas kini prosedur secara berkala, pihak berkepentingan boleh mengintegrasikan pengetahuan dan panduan terkini ke dalam operasi mereka, mengurangkan kemungkinan risiko kesilapan, kemalangan atau ketidakpatuhan. Usaha untuk memastikan pematuhan kepada biokeselamatan dalam institusi dan organisasi memerlukan pendekatan komprehensif yang merangkumi dasar, prosedur, latihan, pemeriksaan, dan audit, serta memupuk budaya biokeselamatan. Pelaksanaan langkah-langkah ini membantu mengekalkan integriti rangka kerja biokeselamatan dan meningkatkan pematuhan keseluruhan terhadap peraturan.

BAB 4

PEMBANGUNAN INDEKS AKAUNTABILITI

4.1 Rangka Kerja Menyeluruh



Rajah 4.1: Pembangunan rangka kerja alat penilaian kendiri

Indeks akauntabiliti (alat penilaian kendiri) telah dibangunkan berpandukan bahagian yang disenaraikan dalam Akta Biokeselamatan 2007 dan Peraturan Biokeselamatan (Kelulusan dan Pemberitahuan) 2010. Ia boleh dikategorikan kepada bahagian-bahagian berikut:

a) Pengetahuan & kapasiti manusia: Penilaian tentang pengetahuan am mengenai latihan biokeselamatan dan latihan biokeselamatan.

b) Tadbir Urus dan institusi: Penilaian keatas peranan dan tanggungjawab individu diperingkat kumpulan yang berbeza berdasarkan pematuhan garis panduan biokeselamatan serta pemeriksaan makmal dan manual biokeselamatan.

c) Pengurusan data dan bahan: Penilaian tentang keselamatan bahan LMO/ rDNA, pelupusan dan pembungkusan, pengangkutan, serta import dan eksport bahan LMO/ rDNA.

d) Amalan Biokeselamatan: Penilaian ke atas aktiviti LMO/ rDNA, pelan tindak balas kecemasan, eksperimen lapangan LMO, dan amalan biokeselamatan.

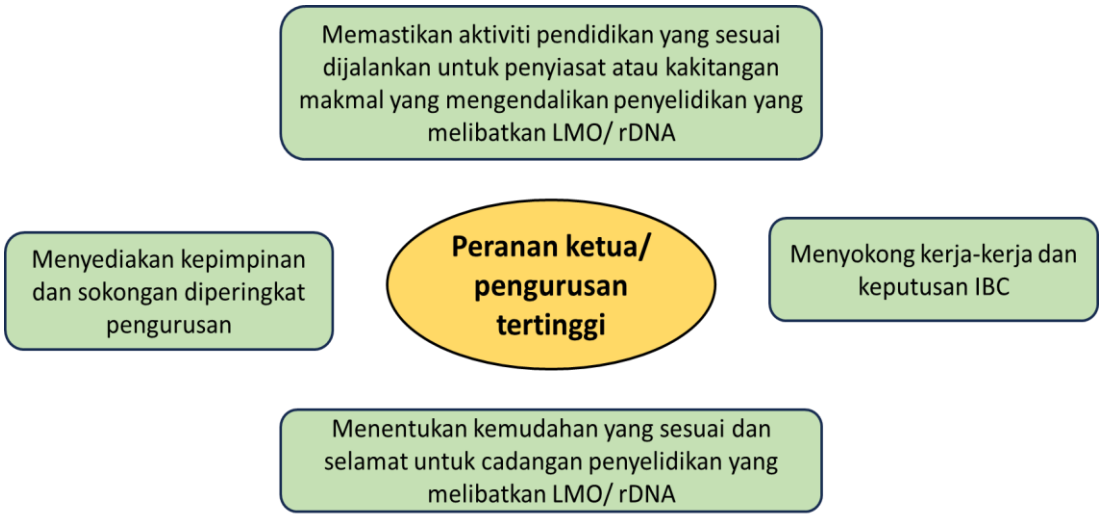
4.2 Peranan Pihak Berkepentingan

Pihak berkepentingan daripada institusi yang berbeza, mewakili peringkat kumpulan yang berbeza: Ketua/pengurusan tertinggi, Jawatankuasa Keinstitusian Biokeselamatan (IBC), Pegawai Biokeselamatan, Penyelidik Utama (PI), dan kakitangan makmal yang terdiri daripada pelbagai disiplin, geografi, dan latar belakang yang berurusan dengan kerja LMO telah direkrut untuk memberikan pendapat dan hujah asas mengenai pematuhan semasa terhadap biokeselamatan (Lampiran 1). Berikut dihuraikan peranan dan

tanggungjawab pihak berkepentingan diperingkat kumpulan yang berbeza **(Rajah 4.2 hingga 4.6)**.

4.2.1 Ketua/pengurusan tertinggi

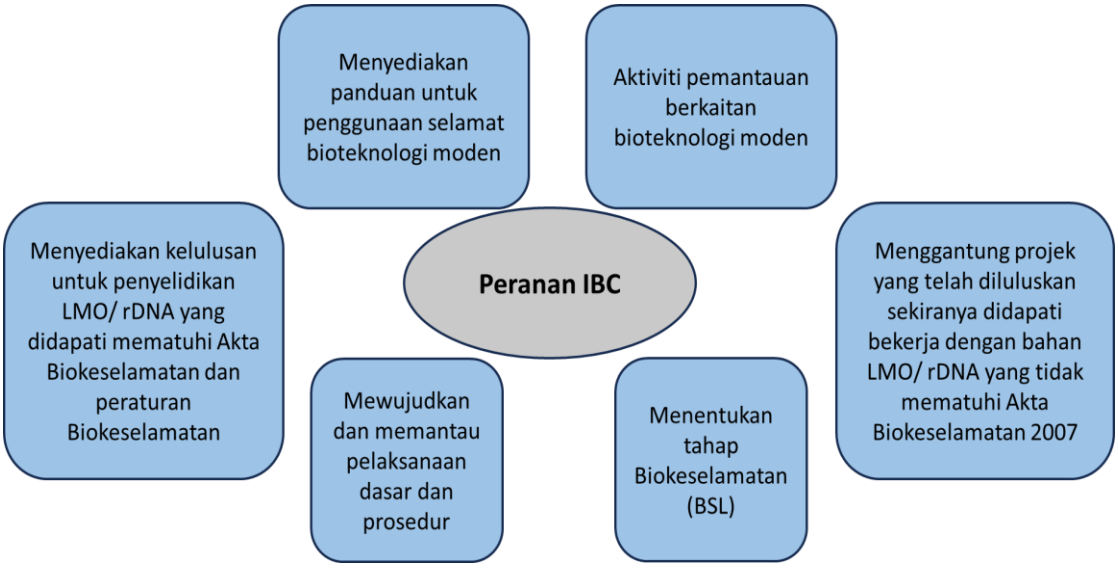
Ketua merujuk kepada Ketua organisasi yang terlibat dalam bioteknologi moden, seperti Naib Canselor/Rektor universiti atau institut pendidikan lain, Ketua Pegawai Eksekutif (CEO) pertubuhan perbadanan, Ketua Pengarah/Pengarah/Ketua Agensi, Koperasi Pusat Penyelidikan, Bahagian Jabatan, Institut, Unit Penyelidikan dan Pembangunan Perindustrian, atau yang setaraf dengannya.



Rajah 4.2: Peranan ketua/ pengurusan tertinggi

4.2.2 Jawatankuasa Keinstitusian Biokeselamatan (IBC)

IBC ialah jawatankuasa pakar rasmi sebuah organisasi yang menjalankan kerja bioteknologi moden yang melibatkan penggunaan mana-mana bahan LMO/ rDNA. Walau bagaimanapun, skop IBC boleh diperluaskan sebagaimana yang difikirkan perlu oleh organisasi masing-masing.



Rajah 4.3: Peranan Jawatankuasa Keinstitusian Biokeselamatan (IBC)

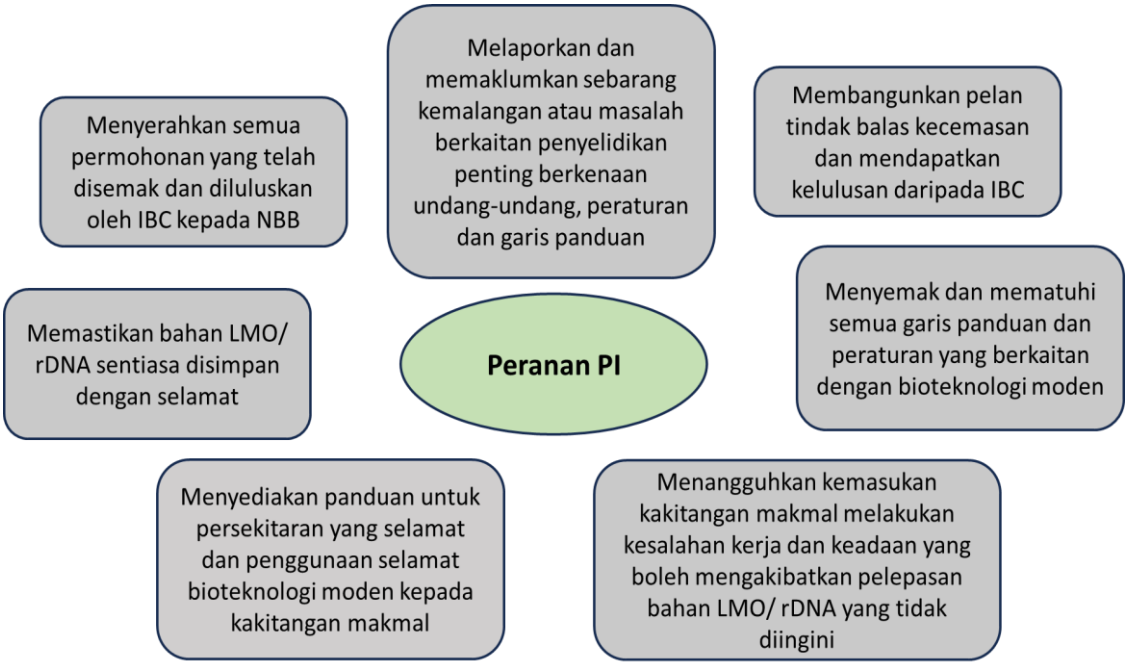
4.2.3 Pegawai Biokeselamatan (BSO)

BSO ialah ahli IBC yang dilantik oleh Ketua organisasi. BSO adalah pegawai yang dilantik bagi membantu dalam memastikan pematuhan kepada Akta Biokeselamatan 2007 dan Peraturan Biokeselamatan (Kelulusan dan Pemberitahuan) 2010 berkaitan penyelidikan LMO/ rDNA yang dijalankan disesebuah organisasi.

Rajah 4.4: Peranan Pegawai Biokeselamatan (BSO)

4.2.4 Penyelidik Utama (PI)

PI adalah individu yang terlibat dalam menjalankan penyelidikan bioteknologi moden dalam sesebuah organisasi atau institusi. PI bertanggungjawab kepada IBC dan harus mematuhi garis panduan penyelidikan yang sesuai dan menyediakan penyeliaan berdasarkan garis panduan biokeselamatan.



Rajah 4.5: Peranan Penyelidik Utama (PI)

4.2.5 Kakitangan makmal

Kakitangan makmal adalah termasuk juruteknik, juru teknologi, pelajar, dan pasca-kedoktoran yang bertanggungjawab untuk melaksanakan dan menjalankan kerja asas.

Rajah 4.6: Peranan kakitangan makmal

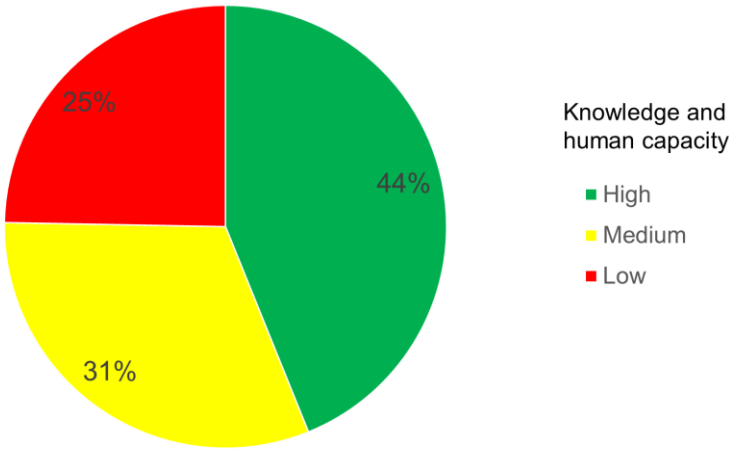
4.3 Profil index

Senarai semak indeks akauntabiliti telah dibentangkan dan disahkan semasa bengkel dengan kumpulan pemegang taruh (Lampiran 1) yang terdiri daripada pelbagai bidang dan latar belakang dan terlibat dengan kerja-kerja berkaitan dengan LMO. Pihak berkepentingan ini telah bersama-sama meneliti, mengesahkan dan menyumbang kepakaran dari perspektif masing-masing untuk mengesahkan kredibiliti Indeks Akauntabiliti Biokeselamatan. Bengkel ini berfungsi sebagai platform untuk mengesahkan ketepatan dan keberkesanan indeks akauntabiliti. Pihak berkepentingan telah dilibatkan dalam perbincangan menyeluruh untuk menilai dan menyelaras penjajaran metrik dan penanda aras indeks. Ini bermatlamat untuk menggalakkan akauntabiliti. Sepanjang

bengkel pengesahan (Lampiran 2), para peserta menekankan perkara penting daripada penemuan indeks akauntabiliti. Maklumbalas ini memberikan pemahaman yang komprehensif tentang keadaan semasa langkah-langkah akauntabiliti, mengenalpasti kekuatan dan kelemahan, serta peluang untuk peningkatan. Penganjuran bengkel telah menggalakkan dialog terbuka, membolehkan peserta berkongsi pandangan daripada perspektif yang pelbagai. Perbincangan ini telah membantu dalam pembentukan cadangan secara kolektif (Lampiran 3). Hasil yang diperolehi daripada bengkel pengesahan telah didokumenkan dalam bahagian seterusnya: 4.3.1, 4.3.2, 4.3.3, dan 4.3.4.

4.3.1 Pengetahuan dan kapasiti manusia

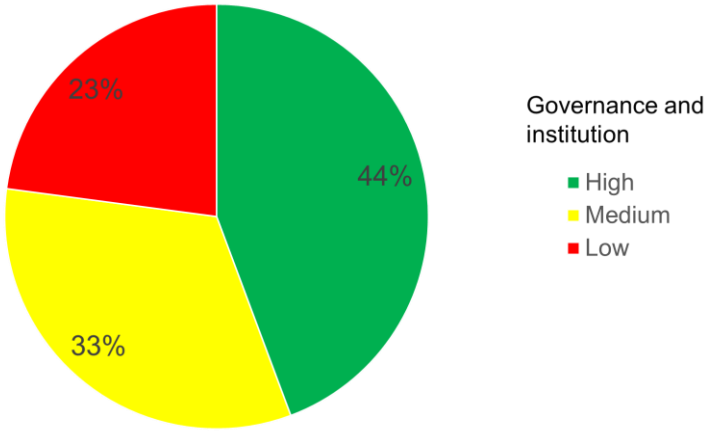
Bahagian ini menilai kesedaran dan pengetahuan pihak berkepentingan (IBC, pengurusan tertinggi, PI, pengguna makmal) tentang peraturan biokeselamatan di Malaysia dan untuk menilai sama ada kakitangan yang bekerja dengan bahan LMO/ rDNA telah menerima latihan biokeselamatan yang betul dan mencukupi. Bahagian ini disintesis berdasarkan Bahagian I dan II Akta Biokeselamatan 2007 dan Bahagian I dan II Peraturan-Peraturan Biokeselamatan (Kelulusan dan Pemberitahuan) 2010.



Rajah 4.7: Indeks akauntabiliti dibawah perspektif pengetahuan dan kapasiti manusia

4.3.2 Tadbir urus dan institusi

Bahagian ini menilai kefahaman pihak berkepentingan (IBC, pengurusan atasan, PI dan pengguna makmal) berkenaan peranan, tanggungjawab, dan fungsi masing-masing dalam mematuhi langkah biokeselamatan. Bahagian ini juga menilai peranan IBC, PI, dan kakitangan makmal dalam menjalankan pemeriksaan dan audit makmal di kemudahan yang berkaitan dengan LMO/rDNA. Bahagian ini disintesis berdasarkan Bahagian II dan VI Akta Biokeselamatan 2007 dan Bahagian IV dan V Peraturan-Peraturan Biokeselamatan (Kelulusan dan Pemberitahuan) 2010.

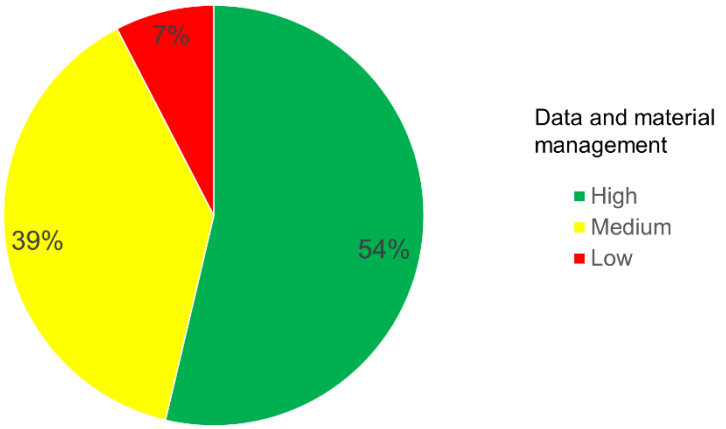


Rajah 4.8: Indeks akauntabiliti di bawah perspektif tadbir urus dan institusi

4.3.3 Pengurusan data dan bahan

Bahagian ini memberi tumpuan dalam menilai langkah keselamatan serta tanggungjawab pihak berkepentingan (IBC, PI, dan kakitangan makmal) semasa mengendali, menyimpan, membungkus, dan mengangkut bahan organisma hidup yang diubahsuai (LMO) dan DNA rekombinan (rDNA). Bahagian ini juga menilai kefahaman dan pemahaman tentang tanggungjawab pihak berkepentingan (pengguna PI dan makmal) dalam mendapatkan bahan LMO/ rDNA dan melindungi bahan tersebut daripada akses tanpa kebenaran, kehilangan, kecurian, atau penyalahgunaan serta kaedah dan protokol pelupusan LMO/ rDNA yang betul. Bahagian ini disintesis berdasarkan Bahagian III, IV, VII

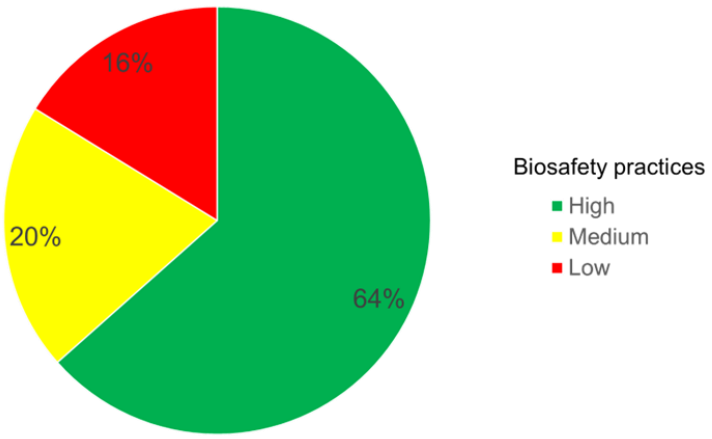
Akta Biokeselamatan 2007 dan Bahagian III Peraturan-Peraturan Biokeselamatan (Kelulusan dan Pemberitahuan) 2010.



Rajah 4.9: Indeks akauntabiliti di bawah perspektif pengurusan data dan bahan

4.3.4 Amalan Biokeselamatan

Bahagian ini menilai tahap pematuhan pihak berkepentingan (PI dan kakitangan makmal) kepada peraturan biokeselamatan semasa menjalankan ujian lapangan terkawal LMO. Bahagian ini mengumpulkan maklumat mengenai pengetahuan pihak berkepentingan (IBC, PI, dan kakitangan makmal) tentang proses dan prosedur yang diperlukan untuk aktiviti yang melibatkan LMO/ rDNA dan pelaksanaan pelan tindak balas kecemasan yang bersesuaian. Bahagian ini disintesis berdasarkan Bahagian V, VI, VII Akta Biokeselamatan 2007 dan Bahagian III dan VII Peraturan-Peraturan Biokeselamatan (Kelulusan dan Pemberitahuan) 2010.



Rajah 4.10: Indeks akauntabiliti dibawah perspektif amalan Biokeselamatan

4.4 Pemarkahan

Indeks akauntabiliti bertujuan untuk menyediakan cara yang standard dan objektif untuk menilai pematuhan biokeselamatan institusi dan individu yang berurusan dengan LMO. Ia juga boleh membantu mengenal pasti ruang untuk penambahbaikan dan menjejaki kemajuan pematuhan biokeselamatan dari semasa ke semasa. Sistem pemarkahan untuk indeks ini akan digunakan bagi menilai prestasi biokeselamatan sesebuah institusi terhadap satu set petunjuk atau kriteria yang telah ditetapkan (Lampiran 4). Sistem pemarkahan akan diberikan berdasarkan setiap bahagian penilaian kendiri. Markah tersebut kemudiannya diagregatkan untuk menghasilkan skor keseluruhan atau penarafan yang mencerminkan prestasi biokeselamatan organisasi (Jadual 4.1). Indeks ini juga harus sentiasa

disemak dan dikemas kini untuk mencerminkan perubahan dalam peraturan biokeselamatan dan amalan terbaik.

Jadual 4.1: Indeks pemarkahan

No.	Skala pemarkahan	Pengekodan warna	Klasifikasi untuk tahap dalam skor indeks Biokeselamatan
1	> 80	Hijau	Tahap tinggi akauntabiliti dan pematuhan pada setiap tahap Biokeselamatan
2	50 - 79	Kuning	Tahap sederhana akauntabiliti dan pematuhan pada tahap tertentu dan boleh dibaikpulih
3	< 50	Merah	Tahap rendah akauntabiliti dan pematuhan. Tindakan pantas harus diambil bagi mengelakkan pelanggaran secara sengaja atau tidak sengaja kepada Akta Biokeselamatan 2007.

4.5 Indeks akhir

Instrumen ini menggunakan satu siri soalan untuk mengukur pematuhan individu dan institusi terhadap protokol biokeselamatan yang disenaraikan dalam buku panduan biokeselamatan Malaysia sebagai pematuhan kepada Akta Biokeselamatan Malaysia 2007, Peraturan-Peraturan Biokeselamatan (Kelulusan dan Pemberitahuan) 2010. Ringkasan bahagian dan senarai semak adalah seperti berikut:

Bahagian 1 :		
Bahagian A	:	Pengetahuan Am tentang Biokeselamatan
Bahagian B	:	Peranan dan Tanggungjawab dalam Pematuhan Biokeselamatan
Bahagian C	:	Aktiviti LMO/rDNA
Bahagian D	:	Latihan
Bahagian E	:	Pelan Tindakan Kecemasan
Bahagian F	:	Pemeriksaan Makmal dan Manual Biokeselamatan
Bahagian G	:	Eksperimen Lapangan LMO (Percubaan Medan Terkurung LMO)
Bahagian H	:	Keselamatan Bahan LMO/rDNA
Bahagian I	:	Pelupusan
Bahagian J	:	Pembungkusan, Pengangkutan, Import dan Eksport Bahan LMO/rDNA
Bahagian 2		
Bahagian A	:	Amalan Biokeselamatan
Bahagian B	:	Peralatan Keselamatan
Bahagian C	:	Perlindungan Kemudahan
Bahagian D	:	Penyimpanan, Pergerakan dan Pengangkutan LMO dan Bahan Berkaitan

Accountability Index Version 1

KEMENTERIAN SUMBER ASLI, ALAM SEKITAR DAN PERUBAHAN IKLIM

Date	No.	N

BIOSAFETY ACCOUNTABILITY AND COMPLIANCE OF INSTITUTIONS

This instrument uses a series of questions to measure individual and institutional compliance with biosafety protocols and the Malaysian Biosafety Act 2007 and at the same time to suggest ways to improve biosafety compliance when handling LMOs.

Please be assured that all the information in this survey will be kept strictly PRIVATE and CONFIDENTIAL and will not be made public unless the law requires disclosure. The first part regards knowledge and opinions on biosafety. The second part focuses on biosafety practices. The third part is on general information about personnel.

Thank you for your time and generous contributions.

ABBREVIATIONS

BSL : Biosafety Level

BSO : Biological Safety Officer

IATA : International Air Transport Association

IBC : Institutional Biosafety Committee

LMO : Living Modified Organism

rDNA : Recombinant DNA

DNA : Deoxyribonucleic acid

NBB : National Biosafety Board

PI : Principal Investigator

PPE : Personal Protective Equipment

JBK : Jabatan Biokeselamatan

OHSC : Occupational Health and Safety Committee

ng : Nanogram

kg : Kilogram

SOP : Standard Operational Procedures

OHSC : Occupational Health and Safety Committee

PART 1: KNOWLEDGE AND AWARENESS

Please read each statement carefully and indicate your level of understanding by selecting one of the following options.

Yes	No	Not sure

Please ensure that you respond to each question. If you are unsure about a particular statement, select the option that most closely aligns with your view.
Before you start, please indicate the highest Biosafety Level (BSL) of your current research project involving LMO/rDNA activities.

( ) Biosafety Level 1 (BSL-1)
( ) Biosafety Level 2 (BSL-2)
( ) Biosafety Level 3 (BSL-3)
( ) Biosafety Level 4 (BSL-4)

SECTION A: General Knowledge about Biosafety				
The purpose of this section is to assess the basic understanding of all parties **(IBC, Head/top management, PI, laboratory users)** on Biosafety. This section is to be completed by **ALL** respondents.				
1.	Biosafety Act is only applicable for research related to LMO/ rDNA to manage relevant risks to human, animal, and plant life and associated risks for the environment.	**Yes**	**No**	**Not sure**
2.	Biosecurity is to protect, control, and accountability of LMO/ rDNA within facilities in order to prevent their loss, theft, misuse, diversion, unauthorized access, or intentional unauthorized release.	**Yes**	**No**	**Not sure**
3.	An LMO is any living organism that possesses a novel combination of genetic material obtained by modern biotechnology.	**Yes**	**No**	**Not sure**
4.	It is essential to obtain approval from the IBC prior to starting the cross-breeding activity between two breeds of animals to produce a new breed.	**Yes**	**No**	**Not sure**
5.	Selective breeding to produce individual crops with the most desirable traits does not necessarily obtain approval from the IBC prior to starting breeding activity.	**Yes**	**No**	**Not sure**

6.	Institutional policies or biosafety guidelines regarding the handling of LMO and related measures are intended to reduce the risks of unintentional and/or intentional release of LMOs.	**Yes**	**No**	**Not sure**
7.	The release activity of any intentional introduction of LMOs or products of such organisms into the environment is strictly prohibited and is only allowed in close contained areas.	**Yes**	**No**	**Not sure**
8.	A recombinant DNA (rDNA) molecule is a molecule that is constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell.	**Yes**	**No**	**Not sure**
9.	A risk assessment of LMO is performed to determine the appropriate containment facility, equipment, and work practices that will promote the safe conduct of the research project.	**Yes**	**No**	**Not sure**
10.	It is optional for organisations which undertake modern biotechnology research and development, to establish an Institutional Biosafety Committee (IBC) to ensure that any LMO/rDNA research complies with the Malaysian Biosafety Act 2007.	**Yes**	**No**	**Not sure**
11.	Reporting non-compliance with the Malaysia Biosafety Act in organizations undertaking modern biotechnology research and development is the responsibility of JBK and not the IBC.	**Yes**	**No**	**Not sure**
SECTION B: Roles and Responsibilities in Compliance with Biosafety				
This section is designed to assess the understanding and perspective of the IBC, top management, PIs, and laboratory users on their respective roles, responsibilities, and functions in compliance with Biosafety measures.				
No. 1 to 5 is to be completed by **ALL** *respondents.*				
1.	IBC is a formal expert committee of an organization undertaking modern biotechnology work which involves the use of any LMO/ rDNA materials.	**Yes**	**No**	**Not sure**
2.	IBC is composed of members who are appointed by the Head of the organization and approved by the National Biosafety Board (NBB).	**Yes**	**No**	**Not sure**

3.	A Biological Safety Officer (BSO) is a member of IBC appointed by the Head of the organization, responsible to submit all applications for approval and the annual report of IBC to the NBB, on behalf of the organization.	**Yes**	**No**	**Not sure**
4.	IBC is responsible to/for			
	a) Provide guidance to PI on biosafety policies and issues in the use of LMO/rDNA research.	**Yes**	**No**	**Not sure**
	b) Approve the LMO/rDNA research that was found to conform to Biosafety Act and Biosafety (Approval and Notification) Regulations.	**Yes**	**No**	**Not sure**
	c) Assess and monitor the facilities, procedures, practices, training, and expertise of personnel involved in LMO/rDNA research.	**Yes**	**No**	**Not sure**
	d) Allow continuation of projects dealing with LMO/rDNA materials that are not compliant with the Biosafety Act 2007 if the project has previously obtained approval from NBB.	**Yes**	**No**	**Not sure**
	e) Notify the PI of the results of the IBC's review, approval, or rejection of their application for approval and notification of all activities involving the use of LMO/rDNA to the NBB.	**Yes**	**No**	**Not sure**
	f) Assess and set containment levels for LMO/rDNA research and modify containment levels as necessary.	**Yes**	**No**	**Not sure**
	g) Assess field experiments to ensure that the proposed risk assessment, risk management and emergency response plan are sufficient.	**Yes**	**No**	**Not sure**
	h) Adopt and implement an emergency response plan covering accidental spills and personnel contamination, resulting from LMO/rDNA research.	**Yes**	**No**	**Not sure**
	i) Review and report to the Head of the organisation, but not to the NBB of any significant problems with non-compliance with the Biosafety Act 2007 and Biosafety (Approval and Notification) Regulations 2010 and any significant research-related accidents or illnesses.	**Yes**	**No**	**Not sure**
	j) Assist in the development of appropriate procedures as required by NBB only when unintended release and/or breach of	**Yes**	**No**	**Not sure**

	containment and/or spill or occupational exposure to LMO/rDNA materials occurred.			
5.	IBC approval is required for the following activities:			
	a) Deliberate transfer of a drug resistance trait to microorganisms.	**Yes**	**No**	**Not sure**
	b) Deliberate transfer of rDNA or DNA/ RNA derived from rDNA into human research participants (human gene transfer).	**Yes**	**No**	**Not sure**
	c) Use of Risk Group 2, Risk Group 3, or Risk Group 4 agents as host-vector systems.	**Yes**	**No**	**Not sure**
	d) Cloning of DNA from Risk Group 2 or greater agents into non-pathogenic prokaryotes or lower eukaryotic host-vector systems.	**Yes**	**No**	**Not sure**
	e) Use of infectious or defective Risk Group 2 or greater agents.	**Yes**	**No**	**Not sure**
	f) Use of whole animals in which the animal's genome has been altered by the stable introduction of rDNA or DNA/ RNA derived from rDNA into a germline (transgenic animal).	**Yes**	**No**	**Not sure**
	g) Viable rDNA-modified microorganism tested on whole animals.	**Yes**	**No**	**Not sure**
	h) Genetically engineered plants by rDNA methods with desirable traits.	**Yes**	**No**	**Not sure**
	i) Selective breeding plants through cross-pollination with desirable traits.	**Yes**	**No**	**Not sure**
	j) The formation of rDNA material containing one-third or more of the genome of a eukaryotic virus.	**Yes**	**No**	**Not sure**
No. 6 to 13 is to be completed by **BSO/IBC members ONLY**				
6.	IBC may not use external consultants for advice and information.	**Yes**	**No**	**Not sure**
7.	An IBC meeting shall be conducted at least once a year to review and approve projects as well as to conduct a project extension review of approved projects.	**Yes**	**No**	**Not sure**
8.	At least 80% of the IBC membership (excluding members with a conflict of interest) must be present during a meeting to approve or disapprove the non-exempt projects of LMO/rDNA materials.	**Yes**	**No**	**Not sure**
9.	A lost number of quorums at any time during the meeting will cause the meeting to be adjourned until a quorum is re-established.	**Yes**	**No**	**Not sure**

10.	Members who fail to attend IBC meetings on a regular basis or fail to contribute to the research review process may be removed from the committee.	**Yes**	**No**	**Not sure**
11.	All records which required the information for every approved project should be retained with IBC for at least three years after the completion of a research project.	**Yes**	**No**	**Not sure**
12.	IBC members who have conflicts of interest should at least be present during IBC's initial or project extension review.	**Yes**	**No**	**Not sure**
13.	BSO is responsible to:			
	a) Report to the IBC any significant problems, non-compliance with the Biosafety Act, and any significant research-related accidents or illness of which BSO become aware.	**Yes**	**No**	**Not sure**
	b) Guide PI in developing an emergency response plan for handling and investigating laboratory accidents involving LMO/rDNA materials.	**Yes**	**No**	**Not sure**
	c) Work with Rapid Response Team to provide technical advice on research safety and laboratory security procedures to PI, laboratory personnel and the IBC.	**Yes**	**No**	**Not sure**
	d) Serve as a liaison officer between the organization/institution and external regulatory agencies concerning the use of LMO/rDNA materials.	**Yes**	**No**	**Not sure**
	e) Serve as a voting member of the IBC.	**Yes**	**No**	**Not sure**
No. 14 is to be completed by **Top management ONLY** *(Vice Chancellor, CEO, Director General, Director, HOD)*				
14.	The head is responsible to			
	a) Have awareness of all requirements regarding compliance with the Biosafety Act and any related regulations regarding LMO/rDNA materials.	**Yes**	**No**	**Not sure**
	b) Provide leadership and support at the management level for laboratories.	**Yes**	**No**	**Not sure**
	c) Ensure that PI provides appropriate training for laboratory personnel prior to the initiation of research involving LMO/rDNA materials.	**Yes**	**No**	**Not sure**
	d) Support works and decisions of IBC.	**Yes**	**No**	**Not sure**

	e) Ensure that related educational activities are conducted to educate the investigators before the initiation of research involving LMO/rDNA materials.	**Yes**	**No**	**Not sure**
	f) Act as an observer in the case of determining which facilities are appropriate and safe for proposed research involving LMO/rDNA.	**Yes**	**No**	**Not sure**
No. 15 is to be completed by **laboratory personnel ONLY** *(technician, student, researchers, and everyone using the lab)*				
15.	Laboratory personnel must			
	a) Follow all safety practices, establish good laboratory techniques, work within the assigned BSL containment, and use PPE as recommended by PI.	**Yes**	**No**	**Not sure**
	b) Notify the Head/top management immediately of any health condition that may be compromised due to their work before the initiation of a research project.	**Yes**	**No**	**Not sure**
	c) Follow all practices and procedures as provided by the PI and BSO, as well as ensure strict compliance with all required biosafety regulations and guidelines.	**Yes**	**No**	**Not sure**
	d) Report non-compliance to			
	PI	**Yes**	**No**	**Not sure**
	IBC	**Yes**	**No**	**Not sure**
	JBK	**Yes**	**No**	**Not sure**
No. 16 is to be completed by **ALL** *respondents*				
16.	If the project/ research is non-compliance with the Biosafety Act, IBC may:			
	a) Suspend the use of LMO/rDNA materials.	**Yes**	**No**	**Not sure**
	b) Cease the approval for the use of the LMO/rDNA materials.	**Yes**	**No**	**Not sure**
	c) Confiscate the LMO/rDNA materials.	**Yes**	**No**	**Not sure**
	d) Destruct the LMO/rDNA materials.	**Yes**	**No**	**Not sure**
	e) Any other action necessary to protect the public and/or the organisation.	**Yes**	**No**	**Not sure**

	f) Report to head/top management only, not necessarily to NBB.	**Yes**	**No**	**Not sure**
No. 17 is to be completed by **PI ONLY**				
17.	PI is required to			
	a) Submit all applications for approval and notification directly to NBB without prior review and approval by IBC.	**Yes**	**No**	**Not sure**
	b) Change the research proposal involving LMO/rDNA materials if needed and do not need to inform the IBC.	**Yes**	**No**	**Not sure**
	c) Report any significant problems immediately with respect to the implementation of relevant laws, regulations, and guidelines.	**Yes**	**No**	**Not sure**
	d) Notify IBC promptly of any significant research-related accidents that have resulted or could result in human illness, unanticipated plant or animal disease, or an unintended release of an organism from intended confinement.	**Yes**	**No**	**Not sure**
	e) Complete Biosafety and Good Laboratory Practices training.	**Yes**	**No**	**Not sure**
	f) Develop and send directly to JBK for approval of the emergency response plan.	**Yes**	**No**	**Not sure**
	g) Comply with all legislative requirements when conducting research involving LMO/rDNA materials.	**Yes**	**No**	**Not sure**
	h) Ensure that the reporting requirements under the Biosafety Act are fulfilled.	**Yes**	**No**	**Not sure**
	i) Review the applicable guidelines and regulations related to LMO/ rDNA materials or other infectious materials involved in research activity.	**Yes**	**No**	**Not sure**
	j) Develop SOP incorporating biosafety procedures, or a biosafety manual prepared specifically for the laboratory.	**Yes**	**No**	**Not sure**
	k) Establish the policy and procedures to limit access to only individuals who are well-educated on the potential hazards and meet specific entry requirements (e.g., immunization, training on the use of PPE).	**Yes**	**No**	**Not sure**
	l) Instruct and educate the laboratory personnel on the potential hazards associated with the research, procedure of aseptic techniques, and	**Yes**	**No**	**Not sure**

	techniques required to ensure safety as well as procedures for dealing with accidents.			
	m) Provide PPE required for work with the specific LMO/rDNA materials.	**Yes**	**No**	**Not sure**
	n) Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.	**Yes**	**No**	**Not sure**
	o) Suspend the laboratory personnel's entrance into the laboratory with work errors and conditions that may result in the unintended release of LMO/rDNA materials.	**Yes**	**No**	**Not sure**
No. 18 to 20 are to be completed by **PI who is currently working in BSL-3 and BSL-4 ONLY**				
18.	PI is required to comply with all occupational health requirements including ensuring laboratory personnel know the reasons and provisions for precautionary medical practices implemented and ensure that they are offered (at no cost) appropriate immunisations or tests for the LMO/rDNA materials handled or potentially present in the laboratory.	**Yes**	**No**	**Not sure**
19.	The construction work and major changes to the BSL-3 facility can commence once certified by a competent authority/organisation and endorsed by the head of the department.	**Yes**	**No**	**Not sure**
20.	The BSL-3 facility should be tested and certified every 6 months.	**Yes**	**No**	**Not sure**
SECTION C: LMO/rDNA Activities				
This section is specifically for individuals involved in LMO and rDNA activities. The purpose of this section is to gather information about their knowledge of the processes and procedures required for LMO/rDNA activities. This section is to be completed by **ALL** respondents.				
1.	For the review of LMO/rDNA activity, project extension, and notice of termination, PI is required to			
	a) Submit the relevant application as prescribed by the NBB, the IBC assessment form and a copy of the document of the approved research grant for the LMO/rDNA project.	**Yes**	**No**	**Not sure**
	b) Submit the application form to NBB once approved by IBC.	**Yes**	**No**	**Not sure**

	c) Start an experiment with LMO/rDNA before notification of LMO work is submitted, if the work is very important.	**Yes**	**No**	**Not sure**
	d) Provide data reporting and adverse event reporting to monitor the proposed LMO/rDNA research, and the reports should be submitted to IBC.	**Yes**	**No**	**Not sure**
	e) Notify JBK of the proposed project if the research work falls into any of the exemptions.	**Yes**	**No**	**Not sure**
	f) Complete and submit the IBC Project Extension Review/ Notice of Termination Form to IBC Chair at least one week before the next scheduled IBC meeting or at the appropriate time intervals as stipulated by the IBC.	**Yes**	**No**	**Not sure**
	g) Complete the Notice of Termination Form and file the form in the laboratory record when the research project involving registered LMO/rDNA materials is completed/no longer active, or when the LMO/rDNA materials are properly disposed of or no longer in the possession of the PI.	**Yes**	**No**	**Not sure**
2.	Biosafety (Approval and Notification) Regulations 2010 forbid exemption for all types of LMO/rDNA.	**Yes**	**No**	**Not sure**
3.	For the review of LMO/rDNA activity, project extension, and notice of termination, IBC/ IBC Chair is required to			
	a) Review the proposed activity involving LMO/rDNA materials by referring to the Biosafety Guidelines for Contained Use Activity of LMOs and other relevant documents, including IBC policies and procedures for the organisation.	**Yes**	**No**	**Not sure**
	b) Assess the facilities, procedures, practices, training, and expertise of personnel involved in the LMP/rDNA research.	**Yes**	**No**	**Not sure**
	c) Provide written notification of the IBC's decision to PI.	**Yes**	**No**	**Not sure**
4.	Exempted work must also be carried out according to the Biosafety Act and should be periodically monitored by IBC.	**Yes**	**No**	**Not sure**
5.	The IBC should review all submitted research projects to determine their exemption or non-exemption status.	**Yes**	**No**	**Not sure**

6.	Access to the laboratory should be restricted when work with the LMO/rDNA materials is in progress.	**Yes**	**No**	**Not sure**
7.	In the case of an incident, follow the safety protocols outlined in the approved emergency response plan prepared by PI for the specific project and laboratory.	**Yes**	**No**	**Not sure**
8.	Ensure the LMO/rDNA materials are always kept secure.	**Yes**	**No**	**Not sure**
9.	The emergency response plan must be kept secure in a file at the designated laboratory.	**Yes**	**No**	**Not sure**
SECTION D: Training				
The purpose of this section is to know whether IBC members and individuals conducting research with LMO/rDNA materials received proper and adequate Biosafety training.				
No. 1 is to be completed by an **IBC member/ BSO ONLY**				
1.	a) IBC members should receive initial mandatory and refresher training on Biosafety, the Biosafety Act 2007, Biosafety (Approval and Notification) Regulations 2010 and related regulations as well as IBC policies.	**Yes**	**No**	**Not sure**
	b) IBC members should receive refresher training on any changes to national guidelines.	**Yes**	**No**	**Not sure**
	c) All training related to biosafety should be organized by JBK with commitment from the organisation and guidance from NBB.	**Yes**	**No**	**Not sure**
	d) IBC Chair is responsible to provide the training for the IBC members and BSO documents it.	**Yes**	**No**	**Not sure**
	e) BSO should attend biosafety training with commitment from the organisation and guidance from NBB.	**Yes**	**No**	**Not sure**
No. 2 is to be completed by **PI ONLY**				
2.	a) Ensure that the laboratory staff is supervised by the head/top management regarding the safety practices and techniques employed.	**Yes**	**No**	**Not sure**
	b) Provides training and educates the laboratory personnel on the potential hazards associated with the research, procedure of aseptic techniques, and techniques required to ensure safety as well as procedures for dealing with accidents.	**Yes**	**No**	**Not sure**
No. 3 is to be completed by **laboratory personnel ONLY**				

3.	a) All researchers handling LMO/rDNA materials including laboratory personnel must attend general biosafety training.	**Yes**	**No**	**Not sure**
	b) All researchers must provide proof to the IBC that they have undergone training and have adequate experience (as recognised by IBC) in Biosafety and Good Practices.	**Yes**	**No**	**Not sure**
	c) Successful completion of training is mandatory to receive an IBC approval (whether new or re-application).	**Yes**	**No**	**Not sure**
	d) For researchers who are proposing to work in BSL-3 containment, specific BSL-3 laboratory training is mandatory.	**Yes**	**No**	**Not sure**
SECTION E: Emergency Response Plan				
This section focuses on the role of IBC, PI, and laboratory personnel in creating an appropriate emergency response plan. This section is to be completed by **ALL** respondents.				
1.	The emergency response plan (and any revision thereof) must be formally adopted by the IBC pursuant to all National Biosafety policies and organisational policies.	**Yes**	**No**	**Not sure**
2.	The emergency response plan will be reviewed periodically based on new information from internal findings and/or external development.	**Yes**	**No**	**Not sure**
3.	Method and procedures for controlling the LMO(s) in case of unintentional release should be prepared by personnel involved in LMO research.	**Yes**	**No**	**Not sure**
4.	Details of any contingency measures should be in place for protecting human health and the environment in case of the occurrence of an undesirable effect caused by the unintentional release.	**Yes**	**No**	**Not sure**
5.	OHSC should coordinate the occupational health and safety services to ensure appropriate occupational health and safety surveillance for laboratory personnel involved in research approved by the IBC.	**Yes**	**No**	**Not sure**
6.	PI will use the Occupational Disease/Exposure Investigation Form to make a formal report within 24 hours to the OHSC, IBC, and NBB if there is any accidental exposure to LMO/rDNA materials.	**Yes**	**No**	**Not sure**
SECTION F: Laboratory Inspection and Biosafety Manuals				

This section focuses on the role of IBC, PI, and laboratory personnel in conducting laboratory inspection and preparation of biosafety manuals for proper documentation and inspection carried out at facilities working with LMO/rDNA. This section is to be completed by **ALL** respondents.				
1.	IBC members, as well as representatives and officers authorized by the NBB, are allowed to access the laboratories that are registered for activities with LMO/rDNA materials for inspection purposes by appointment only.	**Yes**	**No**	**Not sure**
2.	A collection of biosafety protocols and procedures (safety manual) at least one hard copy must be kept secure and not necessarily at the designated laboratory.	**Yes**	**No**	**Not sure**
3.	Detailed descriptions of all facilities being used for LMO-contained use activities should be properly documented.	**Yes**	**No**	**Not sure**
4.	PI should ensure the integrity of the biological and physical containment/ biosafety level.	**Yes**	**No**	**Not sure**
5.	IBC should review biosafety protocols during the inspection of facilities and laboratories.	**Yes**	**No**	**Not sure**
6.	IBC will inspect laboratories using a checklist according to the procedures outlined in the Biosafety (Approval and Notification) Regulations 2010.	**Yes**	**No**	**Not sure**
SECTION G: Field Experiments of LMOs (Confined Field Trial of LMO)				
This section is to evaluate PI and laboratory personnel that conduct confined field trials of LMO and whether they fulfil biosafety regulations.				
No. 1 to 6 is to be completed by **PI/personnel who involve in confined field trials ONLY**				
1.	All field experiments of LMO are considered a release activity.	**Yes**	**No**	**Not sure**
2.	All field experiments of LMO must obtain approval from NBB [procedures are outlined in Biosafety (Approval and Notification) Regulations 2010].	**Yes**	**No**	**Not sure**
3.	The application for field experiments should be vetted by IBC before submission to the NBB.	**Yes**	**No**	**Not sure**
4.	The application for field experiments can be directly submitted to NBB.	**Yes**	**No**	**Not sure**

5.	The PI does not need to obtain an endorsement from IBC and can start a field experiment before a certificate of approval is granted by the NBB.	**Yes**	**No**	**Not sure**
6.	Measures for control and confinement of fieldwork must comply with conditions imposed by NBB.	**Yes**	**No**	**Not sure**
SECTION H: Security of LMO/rDNA Materials				
This section is to evaluate the comprehension and understanding of the responsibility of PI and laboratory users in securing LMO/rDNA materials to safeguard LMO/rDNA materials from unauthorized access, loss, theft, or misuse. This section is to be completed by **ALL** respondents.				
1.	PI and/ or all associated personnel			
	a) Must be conscientious in controlling the biological materials and should be held accountable for them.	**Yes**	**No**	**Not sure**
	b) Should limit access to biological materials to authorised personnel only.	**Yes**	**No**	**Not sure**
	c) Should perform a risk vulnerability assessment and develop a plan to protect the security of the material in question, depending on the Risk Group the biological agent may pose.	**Yes**	**No**	**Not sure**
2.	Chain-of-custody forms within laboratories should be made available to track LMO/rDNA materials.	**Yes**	**No**	**Not sure**
3.	Log of access to areas where biological materials are in use should be in place.	**Yes**	**No**	**Not sure**
SECTION I: Disposal				
The purpose of this section is to assess the disposal methods and protocols in place and to evaluate the effectiveness of disposal procedures for the proper disposal of LMO/rDNA materials. This section is to be completed by **ALL** respondents.				
1.	Potentially hazardous biological material and LMO/rDNA materials are to be considered "regulated waste" and should be disposed of in a manner consistent with national regulations and related guidelines.	**Yes**	**No**	**Not sure**
2.	The laboratory supervisor or other person with operational responsibility should ensure compliance with requirements for proper segregation of laboratory waste to ensure a safe work environment.	**Yes**	**No**	**Not sure**

3.	The exempted LMO wastes are not necessarily to be inactivated prior to leaving the facility.	**Yes**	**No**	**Not sure**
4.	Each individual working with LMO material should be responsible for its sterilisation before disposal.	**Yes**	**No**	**Not sure**
5.	For disposal purposes, the exempted LMO material should be treated in the same way as infectious and potentially infectious material.	**Yes**	**No**	**Not sure**
6.	Ordinary waste should be placed into ordinary waste bins (these bins should not be yellow) that will be emptied by the cleaners in all rooms, except laboratories.	**Yes**	**No**	**Not sure**
7.	In laboratories, cleaners may be allowed to empty the bins for non-laboratory material (e.g., cardboard boxes, paper) only under supervision.	**Yes**	**No**	**Not sure**
SECTION J: Packaging, Transportation, Import, and Export of LMO/rDNA Materials				
This section focuses on assessing the security measures as well as responsibilities of IBC, PI, and laboratory personnel and protocols in place for the handling, storage, packaging, and transportation of LMO (Living Modified Organism) and rDNA (recombinant DNA) materials. This section is to be completed by **ALL** respondents.				
1.	Regulated LMO/rDNA materials will be packaged and transported in a manner compliant with national and international regulations and related guidelines.	**Yes**	**No**	**Not sure**
2.	PI is responsible to obtain permits when handling LMO materials or conducting activities which require additional permits (e.g., import permits etc.)	**Yes**	**No**	**Not sure**
3.	For the movement and transport of LMO and related materials, the following shall apply:			
	a) The regulatory authorities (IBC and NBB) shall be notified using the relevant forms.	**Yes**	**No**	**Not sure**
	b) LMO being transferred should be packaged in secure containers capable of preventing material loss during transportation.	**Yes**	**No**	**Not sure**
	c) LMO should be kept separate from other materials.	**Yes**	**No**	**Not sure**
	d) If an unintentional release of LMO during transport occurs, all attempts should be made to recover as much of the materials as possible.	**Yes**	**No**	**Not sure**

	e) The location of the unintentional release of LMO should be marked and treated in a manner that ensures that no additional release of materials occurs.	**Yes**	**No**	**Not sure**
	f) Corrective actions taken for unintentional release of LMO should be documented and the regulatory authorities notified.	**Yes**	**No**	**Not sure**
	g) Adequate records of the transport of LMO, as they move between research facilities, storage facilities and field trial sites, should be maintained by PI and not necessarily by IBC.	**Yes**	**No**	**Not sure**
	h) The shipper should notify the recipient of the date, kind and amount of material that will be sent before shipping.	**Yes**	**No**	**Not sure**
	i) Upon receiving the material, the recipient should confirm that the shipment has arrived intact, and that no material has been lost.	**Yes**	**No**	**Not sure**

PART 2: BIOSAFETY PRACTICES

Please indicate the proportion of time that your laboratory uses or performs the following BIOSAFETY MEASURES based on the scales provided below.

Rarely	Some of the time	Most of the time	All the time

SECTION A: Biosafety Practices					
No. 1 to 11 is to be completed by **ALL** *respondents.*					
1.	Decontaminating LMO waste before disposal	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
2.	Segregating LMO waste	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
3.	Use of appropriate PPE when handling LMOs	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
4.	Dedicated sharps containers for disposal of sharps used for handling LMOs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
5.	Assess and set containment levels of LMOs and modify them as necessary.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
6.	Use of Biological Safety Cabinet for work with LMOs materials.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
7.	Periodically review research projects that are recommended for approval.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
8.	Adopt and implement emergency response plans covering accidental spills and personnel contamination, resulting from LMO/rDNA research.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
9.	There is an up-to-date list available of personnel with authorized access to LMOs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
10.	Wear closed toes shoes	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
11.	Wear lab coats/lab gowns	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
No. 12 to 15 is to be completed by **BSL-3 users ONLY**					
12.	Wear N95 or N100 respirators	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
13.	Use mechanical pipetting aids	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
14.	Wear-powered air-purifying respirators	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
15.	Wear double gloves when handling infectious material	**Rarely**	**Some of the time**	**Most of the time**	**All the time**

SECTION B: Safety Equipment					
This section is to be completed by **ALL** *respondents.*					
1.	Electronic access control devices	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
2.	Guard at building entrance(s)	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
3.	Intrusion sensors and alarms	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
4.	A lighted building at night	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
5.	Locked cabinets	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
6.	Locked doors to building	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
7.	Locked doors to laboratory room(s)	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
8.	Locked refrigerators	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
9.	Security patrols	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
10.	Self-closing doors	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
11.	Unobstructed views of the entrance(s)	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
12.	Video monitors	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
SECTION C: Facility Safeguards					
This section is to be completed by **ALL** *respondents.*					
1.	Background screening for potential users.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
2.	Biosafety training for new users.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
3.	Security escort to the building for non-users or visitors.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
4.	List of users who have access to restricted areas.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
5.	Identification badges	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
6.	Records of key card/key assignments	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
7.	Restricted access to laboratory areas handling/storage of LMOs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
8.	Assess and monitor the facilities, procedures, practices, training, and expertise of personnel involved in LMO research.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**

9.	There is an updated list available of personnel with authorized access to biological agents.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
10.	There are procedures in place for decontamination and waste management.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
11.	Everyone in the facility decontaminates materials before disposing of contaminated materials.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
12.	Prior to being granted access to LMOs, workers are screened for appropriate credentials, skills, and personal traits for the job, and determined to be the best fit for the position.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
SECTION D: Storage, Movement, and Transport of LMOs and Related Materials					
This section is to be completed by **ALL** *respondents.*					
1.	Appropriate permission(s) obtained to share LMO materials with other investigators/labs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
2.	Current inventory of LMOs, and rDNA materials.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
3.	Inventory records are checked against actual LMOs, and/or rDNA materials in storage.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
4.	The PI is aware of all LMOs, and/or rDNA studied in the lab.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
5.	LMOs, and/or rDNA not in use are destroyed.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
6.	The laboratory head is aware of all LMOs, and/or rDNA studied in the lab.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
7.	Shipment of LMO materials using International Air Transport Association IATA Dangerous Goods Regulations.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**
8.	LMOs are kept securely in designated spaces.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**

PART 3: GENERAL INFORMATION

Please indicate your response by either checking the box (/) or completing the sentence with the most suitable answer.

1. Name of Institution/ Company / Lab/ Research Group:

_____

2. Select the most appropriate job category for your role. **(Multiple selections allowed)**

( ) Student/Research Assistant
( ) Laboratory technician/Medical technologist/Science officer
( ) Administrative and support staff
( ) Academic/Staff scientist/Postdoctoral fellow/Research Officer
( ) Principal Investigator
( ) Laboratory director/supervisor/coordinator
( ) Biosafety officer
( ) Mid-level manager
( ) Top-level manager
( ) Other (please specify) _____

3. Select the option that BEST describes your organization. **(Choose only one)**

( ) Public Organisation
( ) Private Sector
( ) Government-Linked Company (GLC)

4. In which area are you currently working?

( ) Living modified organism (LMO)
( ) Infectious agents
( ) Toxins
( ) Synthetic organism
( ) Other (please specify) _____

5. What is your level of experience and training in biosafety? **(Choose only one)**

( ) No experience or training
( ) Little experience. Attended one or two biosafety courses.
( ) Some experience. Attended more than two biosafety courses.
( ) High-level experience. Years of experience, I've attended many biosafety courses.
( ) Expert level of experience. For over five years, I have taught biosafety courses to other people.

****

Thank you for your feedback.

4.6 Indeks Akauntabiliti Untuk Biokeselamatan: Meningkatkan Pematuhan dan Prestasi

Untuk meningkatkan pematuhan peraturan biokeselamatan dan menggalakkan prestasi keseluruhan institusi, Indeks Akauntabiliti akan dijana berdasarkan instrumen penilaian kendiri. Indeks ini bertujuan untuk memberikan gambaran menyeluruh tentang pematuhan institusi terhadap peraturan dan garis panduan biokeselamatan, menilai pematuhannya dengan keperluan dan mengenal pasti bidang kekuatan dan penambahbaikan.

Indeks Akauntabiliti memberi tumpuan dalam memastikan institusi telah melaksanakan langkah berkesan untuk melindungi kesihatan manusia, menjaga alam sekitar, dan mengekalkan integriti penyelidikan saintifik yang melibatkan Organisma Hidup Diubahsuai (LMO). Dengan mengguna pakai kriteria dan tanda aras khusus, seperti keperluan kawal selia, piawaian industri, dan amalan terbaik dalam biokeselamatan, penilaian pematuhan dan akauntabiliti mengukur tahap pematuhan institusi.

Berdasarkan penemuan Indeks Akauntabiliti, laporan terperinci dijana, menegaskan bidang kekuatan pematuhan dan bidang yang memerlukan penambahbaikan. Laporan ini berfungsi sebagai sumber yang berharga, memberikan cadangan yang boleh diambil untuk meningkatkan amalan biokeselamatan institusi, menangani jurang

yang dikenal pasti dan mengurangkan potensi risiko. Cadangan itu mungkin termasuk menyemak semula Prosedur Operasi Standard (SOP), memperkukuh program latihan, menambah baik amalan dokumentasi atau meningkatkan infrastruktur fizikal.

Indeks Akauntabiliti berperanan sebagai penanda aras bagi institusi bagi membolehkan penilaian prestasi biokeselamatan dan membuat keputusan yang berinformasi untuk memastikan pematuhan berterusan. Ia membantu mengenal pasti sebarang kekurangan atau isu ketidakpatuhan yang memerlukan perhatian segera. Institusi boleh menggunakan indeks ini untuk memantau kemajuan dalam melaksanakan tindakan pembetulan dan mengekalkan program biokeselamatan yang baik, sekaligus memastikan biokeselamatan tetap menjadi keutamaan.

Pengemaskinian secara konsisten dan berkala kepada Indeks Akauntabiliti adalah penting untuk mencerminkan perubahan dalam peraturan, kemajuan dalam pengetahuan saintifik dan risiko yang muncul. Apabila peraturan dan garis panduan biokeselamatan berkembang, institusi perlu mengikuti perkembangan terkini dan menyesuaikan amalan dengan sewajarnya. Indeks Akauntabiliti membantu dalam memantau dan menjejaki kemajuan institusi dari semasa ke semasa, memberikan jaminan bahawa biokeselamatan terus diutamakan, dan usaha pematuhan terus berjaya.

Secara ringkasnya, Indeks Akauntabiliti untuk biokeselamatan memudahkan penilaian mendalam tentang pematuhan institusi terhadap peraturan dan garis panduan biokeselamatan. Ia merangkumi semakan menyeluruh tentang dasar, prosedur, infrastruktur dan amalan kakitangan. Dengan menjalankan penilaian tetap menggunakan indeks, institusi boleh mengenal pasti bidang kekuatan pematuhan dan bidang yang memerlukan penambahbaikan, membolehkan mereka mengekalkan tahap biokeselamatan yang tinggi dan memastikan kesejahteraan individu, melindungi alam sekitar, dan menegakkan integriti penyelidikan saintifik.

BAB 5

KESIMPULAN DAN HALA TUJU MASA DEPAN

Akauntabiliti biokeselamatan memainkan peranan penting dalam memastikan pengurusan biokeselamatan dan Organisma Hidup Diubahsuai (LMO) dilaksanakan secara bertanggungjawab dan telus merentasi pelbagai tetapan penyelidikan, klinikal, dan industri. Ia merangkumi pelbagai prinsip, proses, dan amalan yang bertujuan untuk mencegah atau mengurangkan kesan buruk agen biologi terhadap kesihatan manusia dan alam sekitar.

Akauntabiliti biokeselamatan yang berkesan bergantung pada komunikasi, ketelusan, dan kerjasama dikalangan pihak berkepentingan. Penilaian dan penilaian tetap langkah biokeselamatan adalah penting untuk memastikan keberkesanan dan kaitannya dalam bidang yang berkembang pesat. Mewujudkan mekanisme untuk pelaporan dan penyiasatan insiden adalah penting untuk mengenal pasti punca asas, menangani isu, dan mencegah kejadian yang tidak diingini pada masa hadapan.

Untuk menggalakkan akauntabiliti dalam pengurusan biokeselamatan, penggunaan indeks akauntabiliti disyorkan sebagai alat penilaian kendiri dan latihan yang standard. Indeks ini

memberikan pandangan berharga tentang jurang dan peluang untuk menambah baik amalan makmal dan meningkatkan pengetahuan serta pematuhan kepada peraturan dan piawaian biokeselamatan. Dengan mengenal pasti dan menilai prestasi kemudahan dan amalan sedia ada secara sistematik, institusi dan individu yang terlibat dalam mengendalikan LMO boleh menilai pematuhan mereka dan mengenal pasti bidang untuk penambahbaikan. Keputusan penilaian tersebut membantu dalam mengutamakan langkah-langkah untuk mengurangkan risiko ke tahap yang boleh diterima dan terurus.

Melaksanakan indeks akauntabiliti membolehkan institusi mengenal pasti jurang, kelemahan atau kekurangan dalam program biokeselamatan mereka. Dengan menangani isu ini, institusi boleh meningkatkan amalan biokeselamatan mereka, mengurangkan risiko, dan mengutamakan kesejahteraan kakitangan, serta perlindungan terhadap alam sekitar dan kesihatan awam.

Memandang ke hadapan, usaha berterusan diperlukan untuk memperhalusi dan mengemas kini indeks akauntabiliti agar sejajar dengan peraturan yang berkembang, kemajuan dalam pengetahuan saintifik, dan cabaran biokeselamatan yang muncul. Program latihan dan kesedaran yang kerap perlu dijalankan untuk memastikan pihak berkepentingan sentiasa mengikuti perkembangan amalan dan piawaian terbaik. Selain itu, memupuk budaya bertanggungjawab dan

akauntabiliti dalam institusi akan menyumbang kepada peningkatan berterusan amalan biokeselamatan dan perlindungan keseluruhan individu dan alam sekitar.

Kesimpulannya, meningkatkan akauntabiliti biokeselamatan adalah penting untuk pengurusan LMO secara bertanggungjawab. Indeks akauntabiliti, sebagai alat penilaian kendiri dan latihan yang komprehensif, memberi kuasa kepada institusi dan individu untuk mengenal pasti bidang untuk penambahbaikan dan mengutamakan langkah bagi mengurangkan risiko. Dengan menggalakkan ketelusan, kerjasama dan penilaian berterusan, akauntabiliti biokeselamatan dapat memastikan kesejahteraan kakitangan, melindungi alam sekitar dan mengekalkan kesihatan awam.

LAMPIRAN

Lampiran 1 Senarai ahli berkepentingan

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Lampiran 1 Senarai ahli berkepentingan

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Lampiran 2 Bengkel pengesahan indeks (24 Ogos 2023)

Lampiran 3 Keputusan bengkel pengesahan

Biosafety Accountability and Compliance of Institutions

20 responses

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PART 1: KNOWLEDGE AND AWARENESS

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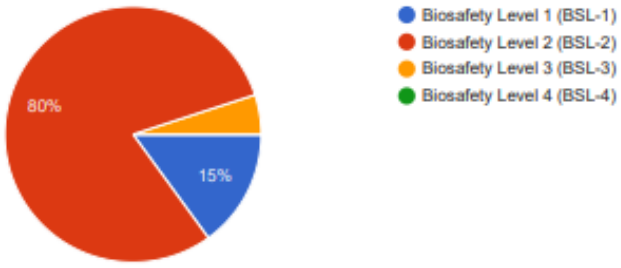
Before you start, please indicate the Biosafety Level (BSL) of your current facilities/research projects/LMO activities.

20 responses



What is the Biosafety Act 2007 for? (Explain in less than 30 words)

20 responses

To ensure the correct handling of living modified organism that it does not harm or affect the environment by identifying the risks and mitigating the risk..

An act that regulate activities involving genetically modification of organisms/plant

This Act's mandate is to safeguard the health of people, plants, and animals, as well as the environment and biological variety by regulating the release, importation, exportation, and use of live modified organisms. The National Biosafety Board's establishment, as well as its makeup and duties, are all outlined in the Act.

The purpose of the Act is to regulate the release, importation, exportation and contained use of living modified organisms, and the release of products of such organisms, with the objectives of protecting human, plant and animal health, the environment and biological diversity

An act to regulate the activities of LMOs, including handling LMO materials, field experiment, import and export and to establish NBB

An Act to establish the National Biosafety Board; to regulate the release, importation, exportation and contained use of living modified organisms, and the release of products of such organisms, with the objectives of protecting human, plant and animal health, the environment and biological diversity, and where there are threats of irreversible damage, lack of full scientific evidence may not be used as a reason not to take action to prevent such damage; and to provide for matters connected therewith.

Act to regulate the activity of importation, exportation and release of living modified microorganism to avoid risks to human, animal, plant and environment

for regulation, release, export and import of living modified organism for the protection of human and environment.

Biosafety Act is a law established to ensure the safety and proper governance on the use of genetically modified organism

A Malaysian Act to regulate the release, importation, exportation and use and release LMO, and related products, with the aim of protecting human, plant, animal health, environment and biological diversity.

Biosafety Act is an regulation complied for any genetically modified organism .

To regulate & enforce the laws related to modern biotechnology activities.

To regulate living modified organisms related activities with the objective to protect human, animal and environmental biodiversity.

The act that explain usage of LMO & GMO rules and regulation

The act that oversee and enforce the safe and proper handling and disposal of LMO in Malaysia.

To regulate import, export and release of GMO into the environment in the country

To ensure the safety of the public towards the risks of the LMOs

an act to establish the national biosafety board, to regulate the release, importation, exportation and contained use of LMO, to protect our health and environment

It's an Act to regulate/ contain all activities (release/exposure/import, etc) that involving LMO/GMO to make sure it can minimize the risk that can causing harm (health) of human, environment, biodiversity

The Act aims to ensure that modern biotechnology applications, including the use of genetically modified crops, are carried out responsibly and in compliance with safety measures to prevent any potential adverse effects on human health, biodiversity, and the environment.

Please read each statement carefully and indicate your level of agreement or disagreement by selecting one of the following options.

1 - Strongly disagree

2 - Disagree

3 - Agree

4 - Strongly agree

Please ensure that you respond to each question. If you are unsure about a particular statement, select the option that most closely aligns with your view.

SECTION A: General Knowledge about Biosafety

1. Biosafety Act is a strategic and integrated approach to managing relevant risks to human, animal, and plant life and associated risks for the environment.

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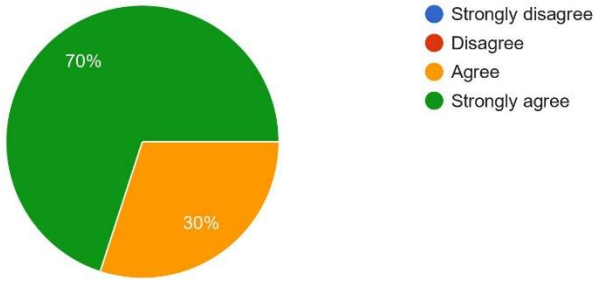

2. Biosecurity is the protection, control, and accountability for biological agents and toxins within facilities in order to prevent their loss, theft, misuse, diversion, unauthorized access, or intentional unauthorized release.

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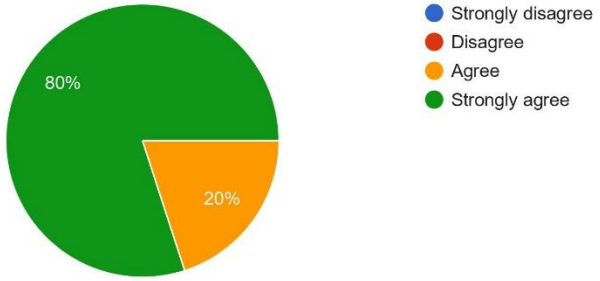

3. A Living Modified Organism (LMO) is any living organism that possesses a novel combination of genetic material obtained by modern biotechnology.

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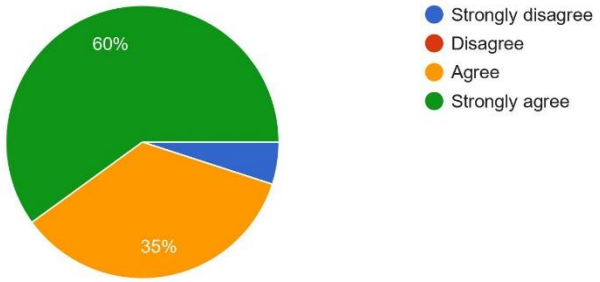

4. It is mandatory to obtain approval from the IBC prior to starting the cross-breeding activity between two breeds of animals to produce a new breed.

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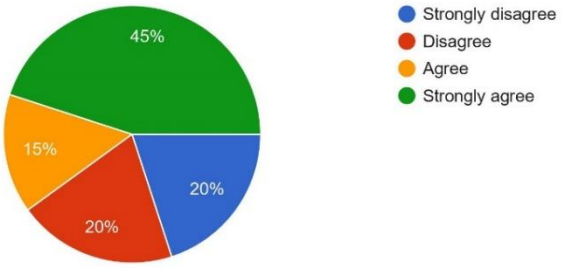

5. Selective breeding to produce individual crops with the most desirable traits does not necessarily obtain approval from the IBC prior to starting breeding activity.

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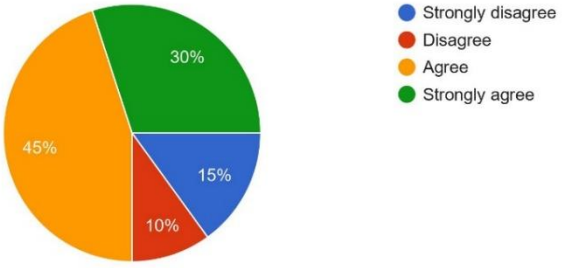

6. Institutional policies or biosafety guidelines regarding the handling of LMO and related measures are intended to reduce the risks of unintentional and/or intentional release of LMOs.

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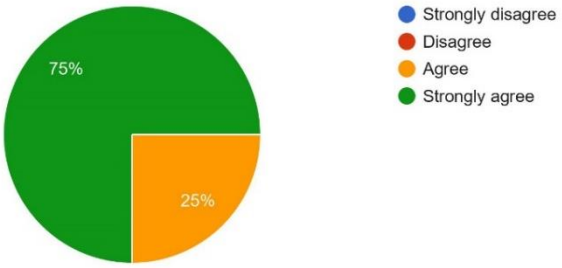

7. The release activity of any intentional introduction of LMOs or products of such organisms into the environment is strictly prohibited and is only allowed in close contained areas.

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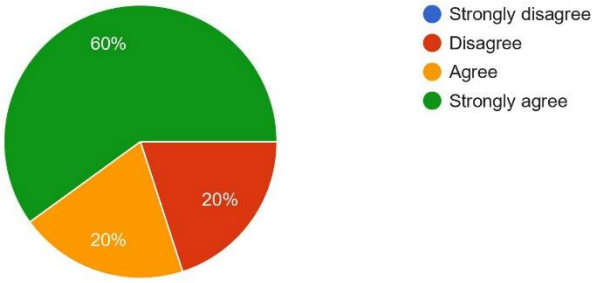

8. A recombinant DNA (rDNA) molecule is a molecule that is constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell.

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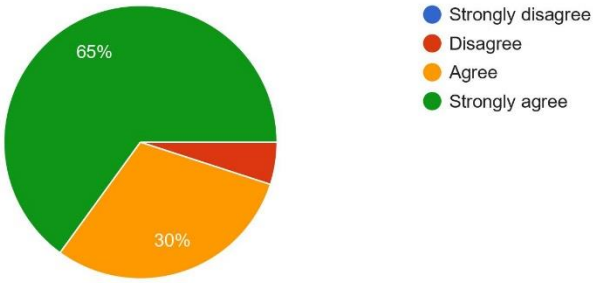

9. A risk assessment of the known infectious agent or toxin is performed to determine the appropriate containment facility, equipment, and work practices that will promote the safe conduct of the research project.

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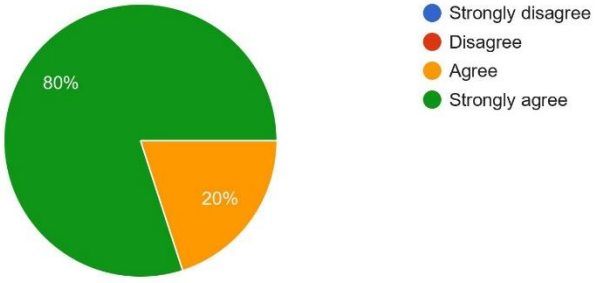

10. It is optional for organizations which undertake modern biotechnology research and development, to establish an Institutional Biosafety Committee (IBC) to ensure that any LMO/rDNA research complies with the Malaysian Biosafety Act 2007.

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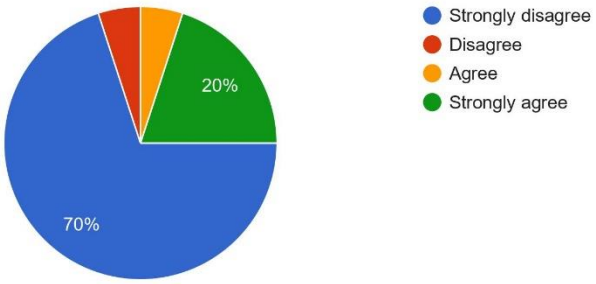

11. Reporting non-compliance with the Malaysia Biosafety Act in organizations undertaking modern biotechnology research and development is the responsibility of JBK and not the Institutional Biosafety Committee (IBC).

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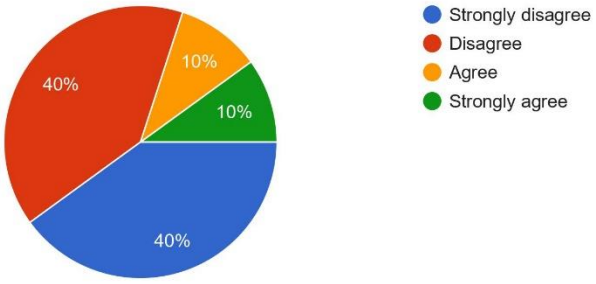

SECTION B: Roles and Responsibilities in Compliance with Biosafety

No. 1 to 5 are to be completed by **ALL** *respondents*

1. IBC is a formal expert committee of an organization undertaking modern biotechnology work which involves the use of any LMO/ rDNA materials.

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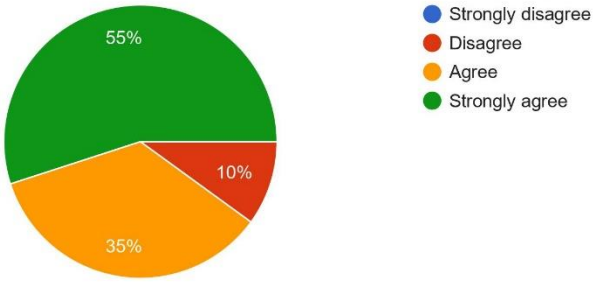

2. IBC is composed of members who are appointed by the Head of the organization and approved by the National Biosafety Board (NBB).

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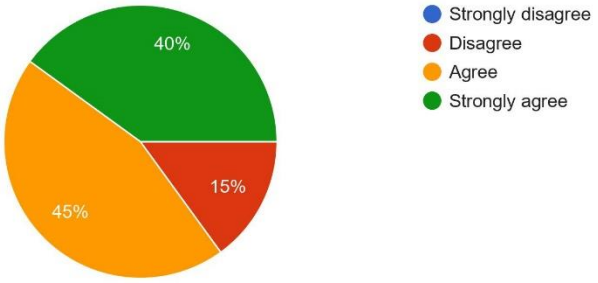

3. A Biosafety officer (BSO) is a member of IBC appointed by the Head of the organization, responsible to submit all applications for approval and the annual report of IBC to the NBB, on behalf of the organization.

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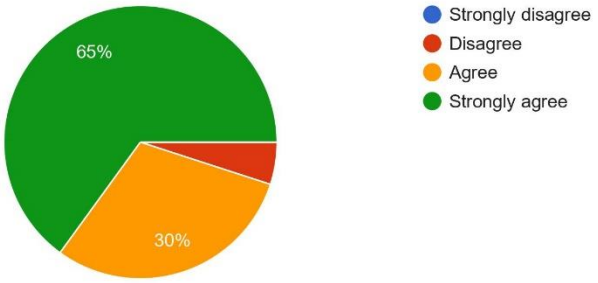
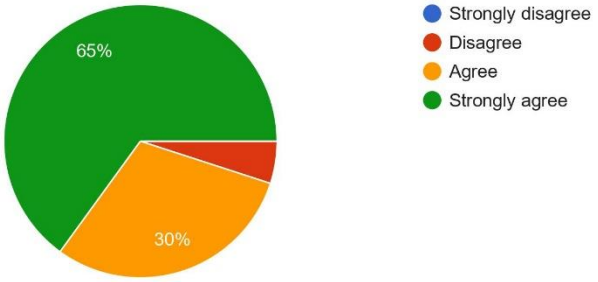


4. IBC is responsible to/ for: Copy

a) Provide guidance to PI on biosafety policies and issues in the use of LMO/rDNA research.

20 responses



4. IBC is responsible to/ for: Copy

b) Approve the LMO/rDNA research that was found to conform to Biosafety Act and Biosafety (Approval and Notification) Regulations.

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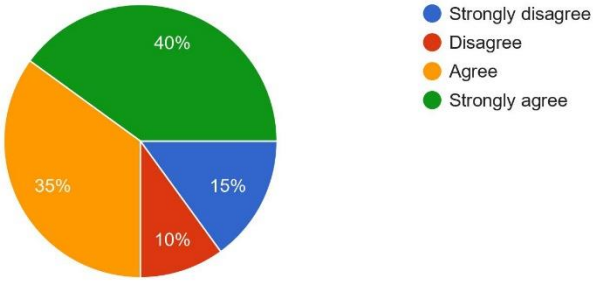

4. IBC is responsible to/ for: Copy

c) Assess and monitor the facilities, procedures, practices, training, and expertise of personnel involved in LMO/rDNA research.

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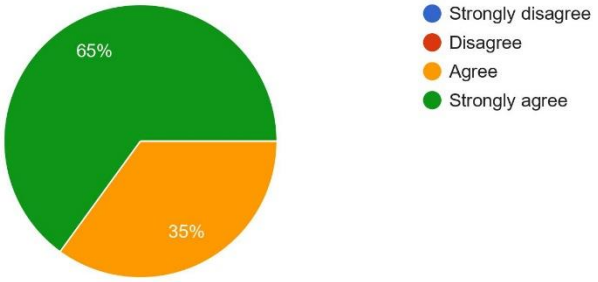
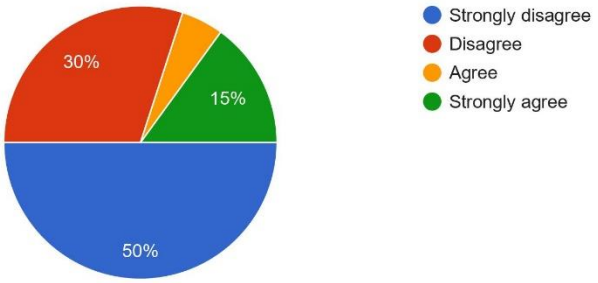


4. IBC is responsible to/ for: Copy

d) Allow continuation of projects dealing with LMO/rDNA materials that are not compliant with the Biosafety Act 2007 if the project has previously obtained approval from NBB.

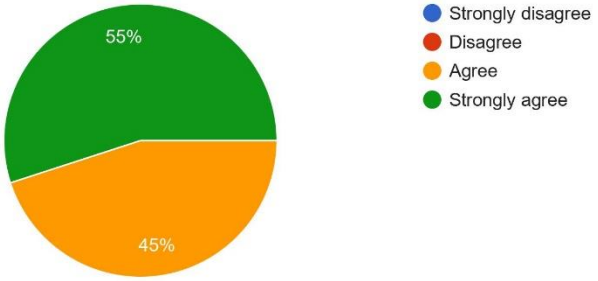
20 responses



4. IBC is responsible to/ for: Copy

e) Notify the PI of the results of the IBC's review, approval, or rejection of their application for approval and notification of all activities involving the use of LMO/rDNA to the NBB.

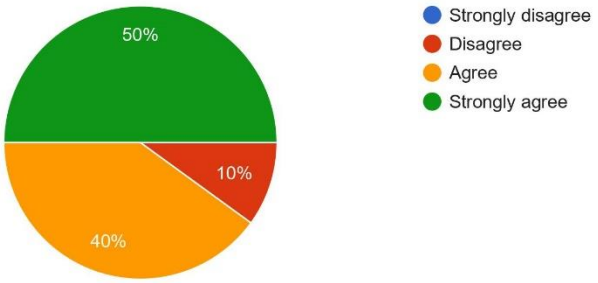
20 responses



4. IBC is responsible to/ for: Copy

f) Assess and set containment levels for LMO/rDNA research and modify containment levels as necessary.

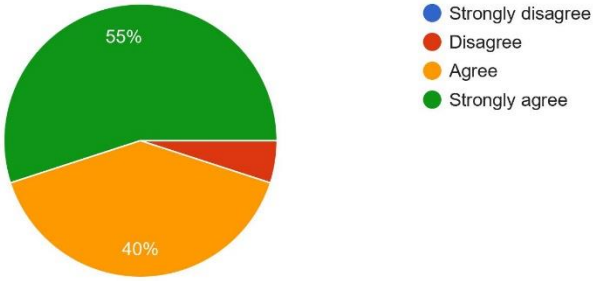
20 responses



4. IBC is responsible to/ for: Copy

g) Assess field experiments to ensure that the proposed risk assessment, risk management and emergency response plan are sufficient.

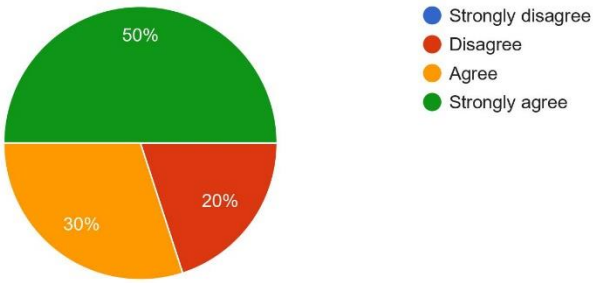
20 responses



4. IBC is responsible to/ for: Copy

h) Adopt and implement an emergency response plan covering accidental spills and personnel contamination, resulting from LMO/rDNA research.

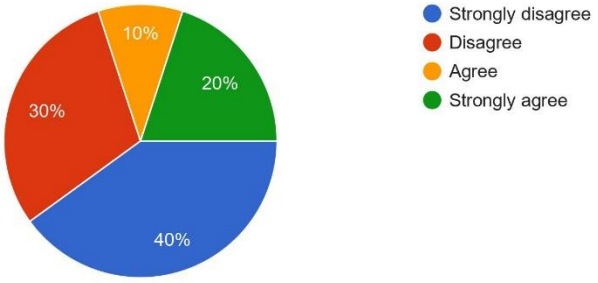
20 responses



4. IBC is responsible to/ for: Copy

i) Review and report to the Head of the organization, but not to the NBB of any significant problems with non-compliance with the Biosafety Act 2007 and Biosafety (Approval and Notification) Regulations 2010 and any significant research-related accidents or illnesses.

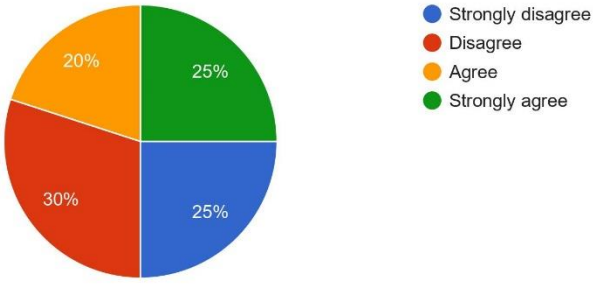
20 responses



4. IBC is responsible to/ for: Copy

j) Assist in the development of appropriate procedures as required by NBB only when unintended release, breach of containment, spill or occupational exposure to LMO/rDNA materials occurred.

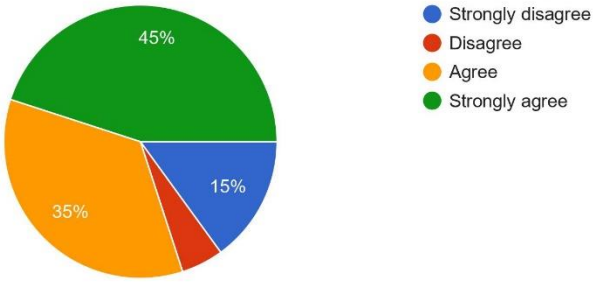
20 responses



5. IBC approval is required for the following activities: Copy

a) Deliberate transfer of a drug resistance trait to microorganisms.

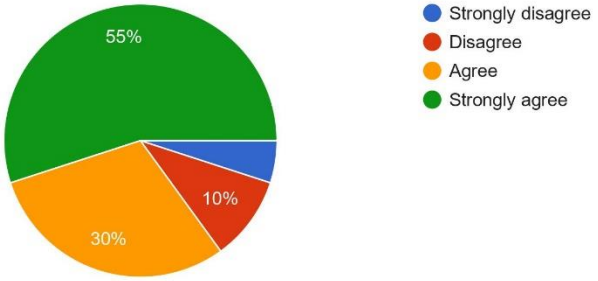
20 responses



5. IBC approval is required for the following activities: Copy

b) Deliberate transfer of rDNA or DNA/ RNA derived from rDNA into human research participants (human gene transfer).

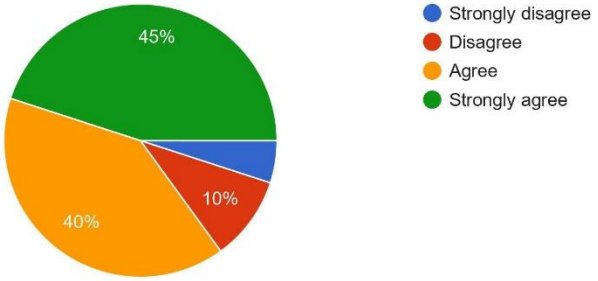
20 responses



5. IBC approval is required for the following activities: Copy

c) Deliberate formation of rDNA-containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100 ng/kg body weight.

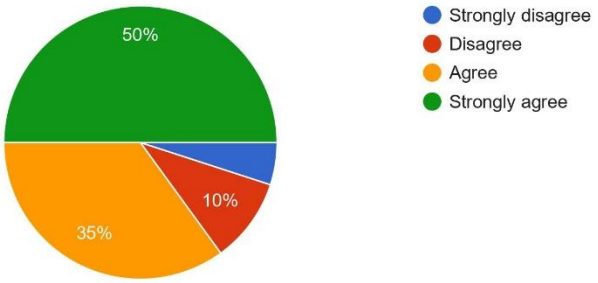
20 responses



5. IBC approval is required for the following activities: Copy

d) Use of Risk Group 2, Risk Group 3, or Risk Group 4 agents as host-vector systems.

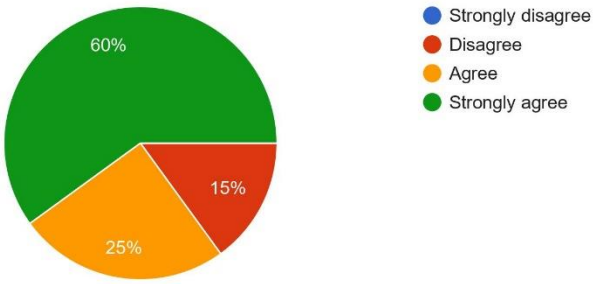
20 responses



5. IBC approval is required for the following activities: Copy

e) Cloning of DNA from Risk Group 2 or greater agents into non-pathogenic prokaryotes or lower eukaryotic host-vector systems.

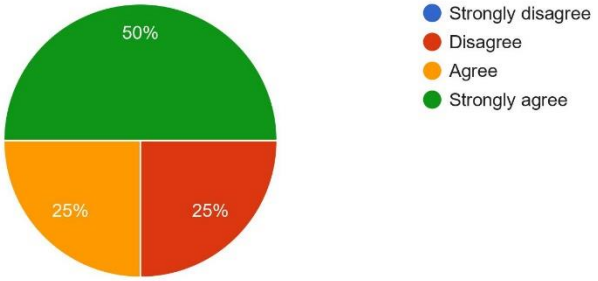
20 responses



5. IBC approval is required for the following activities: Copy

f) Use of infectious or defective Risk Group 2 or greater agents.

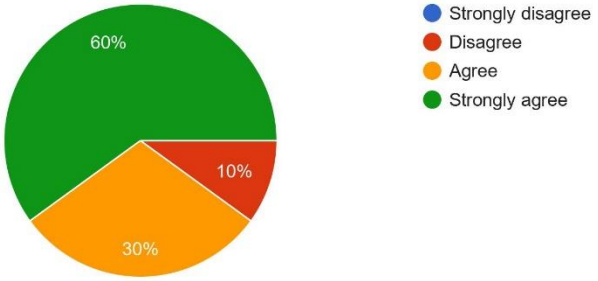
20 responses



5. IBC approval is required for the following activities: Copy

g) Use of whole animals in which the animal's genome has been altered by the stable introduction of rDNA or DNA/ RNA derived from rDNA into a germline (transgenic animal).

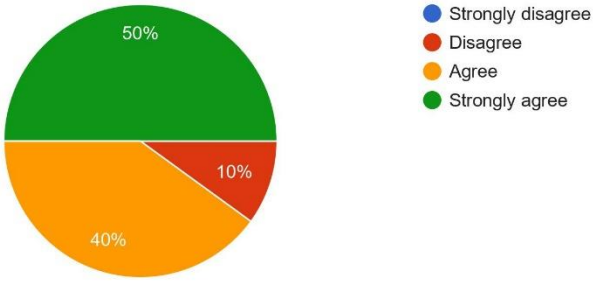
20 responses



5. IBC approval is required for the following activities: Copy

h) Viable rDNA-modified microorganism tested on whole animals.

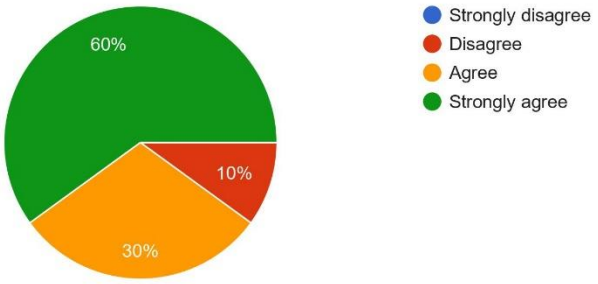
20 responses



5. IBC approval is required for the following activities: Copy

i) Genetically engineered plants by rDNA methods with desirable traits.

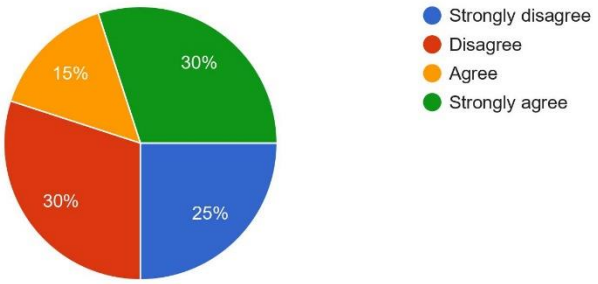
20 responses



5. IBC approval is required for the following activities: Copy

j) Selective breeding plants through cross-pollination with desirable traits.

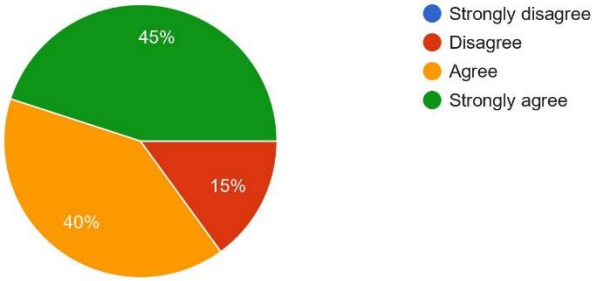
20 responses



5. IBC approval is required for the following activities: Copy

k) The formation of rDNA material containing one-third or more of the genome of a eukaryotic virus.

20 responses

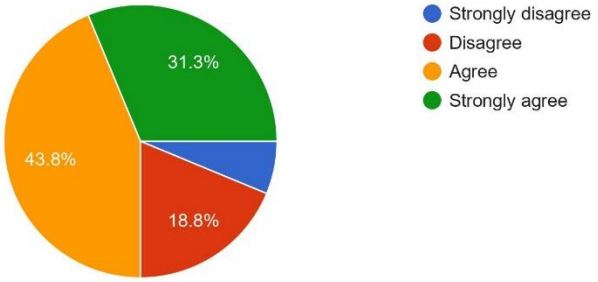


No. 6 to 13 are to be completed by **BSO/ IBC member ONLY**

6. IBC use only locally qualified consultants for advice and information, as and when required.

Copy

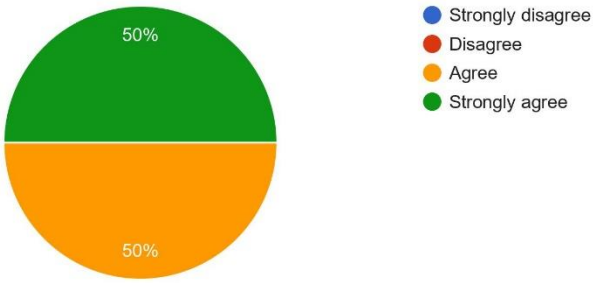
16 responses



7. An IBC meeting shall be conducted at least once a year to review and approve projects as well as to conduct a project extension review of approved projects.

Copy

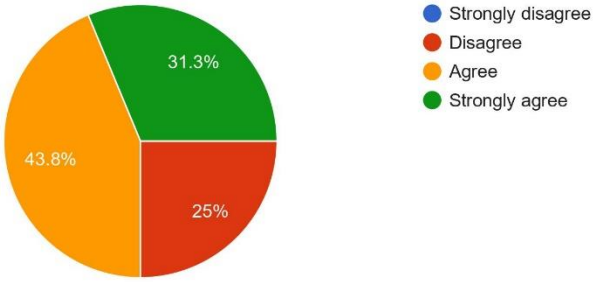
16 responses



8. At least 80% of the IBC membership (excluding members with a conflict of interest) must be present during a meeting to approve or disapprove the non-exempt projects of LMO/rDNA materials.

Copy

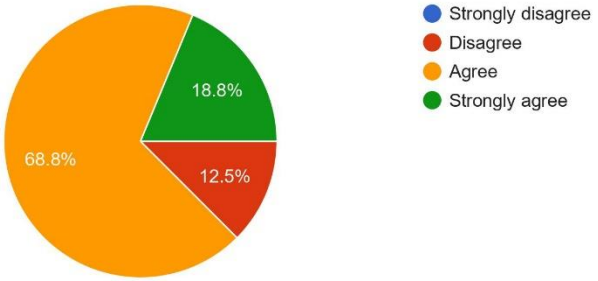
16 responses



9. A lost number of quorums at any time during the meeting will cause the meeting to be adjourned until a quorum is re-established.

Copy

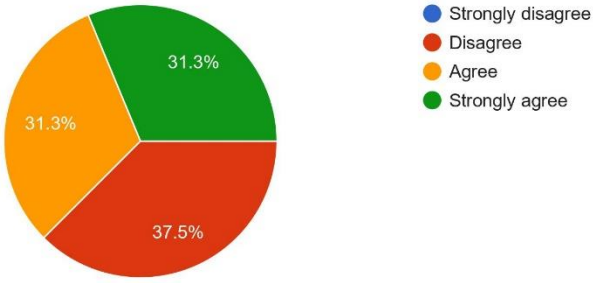
16 responses



10. Attendance of every IBC member at IBC meetings on a regular basis is mandatory.

Copy

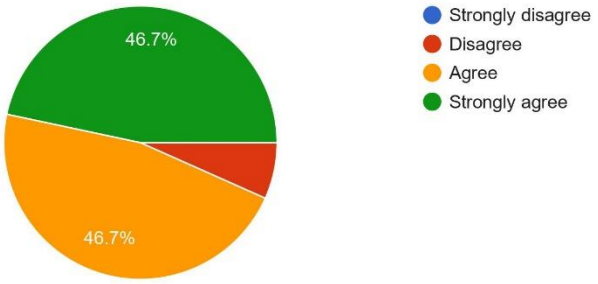
16 responses



11. All records which required the information for every approved project should be retained with IBC for at least three years after the completion of a research project.

Copy

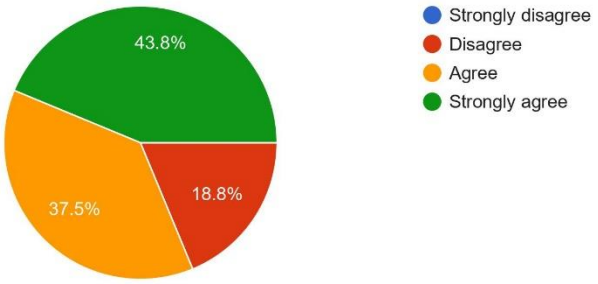
15 responses



12. IBC members who have conflicts of interest should at least be present during IBC's initial or project extension review.

Copy

16 responses

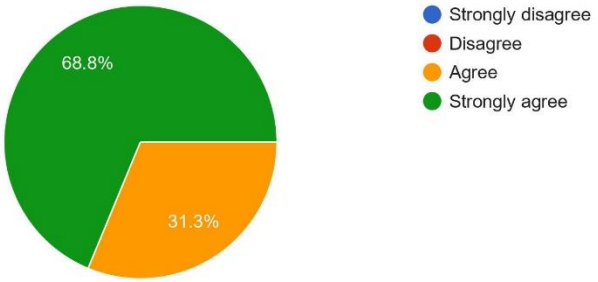


13. BSO is responsible to:

Copy

a) Report to the IBC any significant problems, non-compliance with the Biosafety Act, and any significant research-related accidents or illness of which BSO become aware.

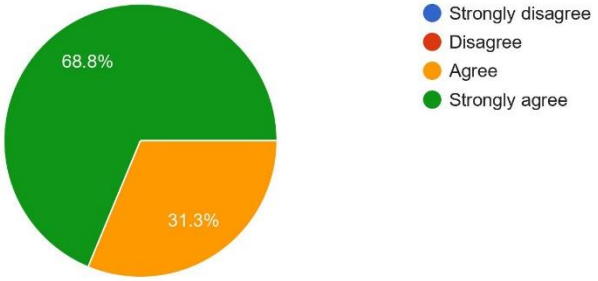
16 responses



13. BSO is responsible to: Copy

b) Provide guidance to PI in developing an emergency response plan for handling and investigating laboratory accidents involving LMO/rDNA materials.

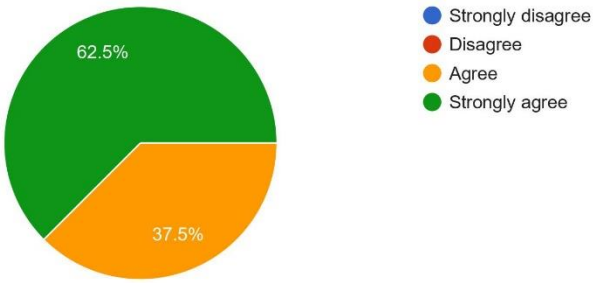
16 responses



13. BSO is responsible to: Copy

c) Work with Rapid Response Team to provide technical advice on research safety and laboratory security procedures to PI, laboratory personnel and the IBC.

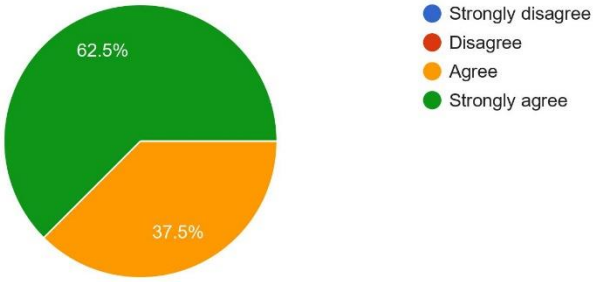
16 responses



13. BSO is responsible to: Copy

d) Serve as a liaison officer between the organization/institution and external regulatory agencies concerning the use of LMO/rDNA materials.

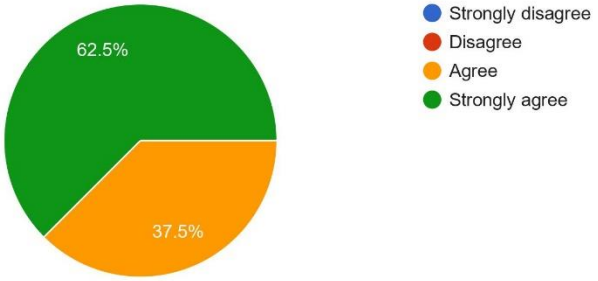
16 responses



13. BSO is responsible to: Copy

e) Serve as a voting member of the IBC.

16 responses



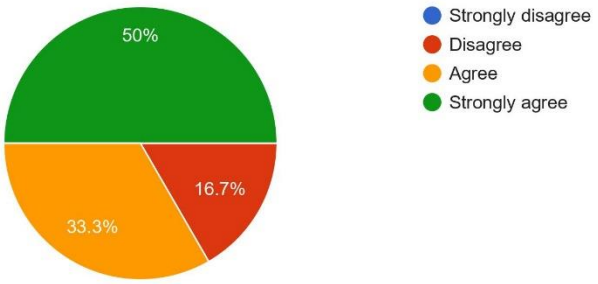
No. 14 is to be completed by **Top management ONLY** *(Vice Chancellor, CEO, Director General, Director, HOD)*

14. The head is responsible to/ for

Copy

a) Have awareness of all requirements regarding compliance with the Biosafety Act and any related regulations regarding LMO/rDNA materials.

6 responses

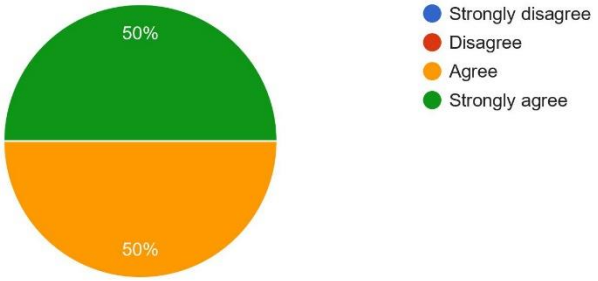


14. The head is responsible to/ for:

Copy

b) Provide leadership and support at the management level for laboratories.

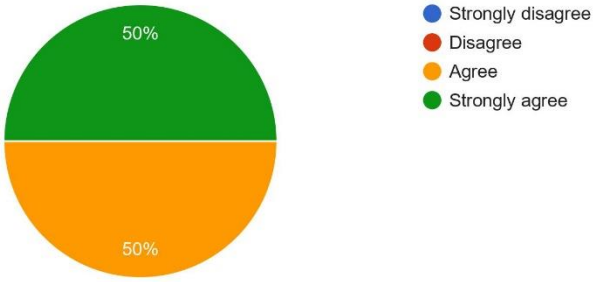
6 responses



14. The head is responsible to/ for: Copy

c) Ensure that PI provides appropriate training for laboratory personnel prior to the initiation of research involving LMO/rDNA materials.

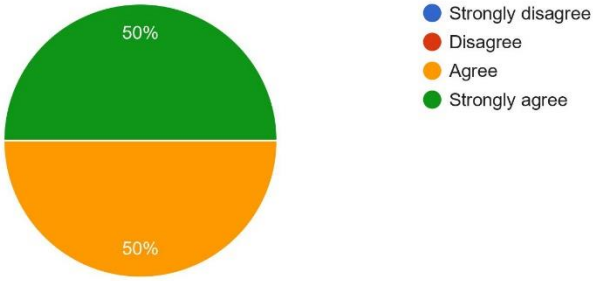
6 responses



14. The head is responsible to/ for: Copy

d) Support works and decisions of IBC.

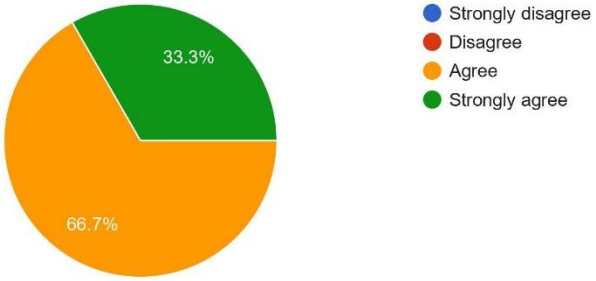
6 responses



14. The head is responsible to/ for: Copy

e) Ensure that related educational activities are conducted to educate the investigators prior to the initiation of research involving LMO/rDNA materials.

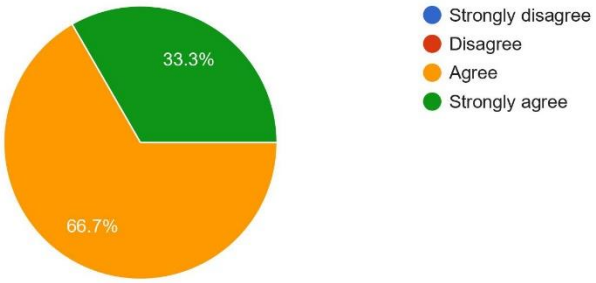
6 responses



14. The head is responsible to/ for: Copy

f) Act as an observer in the case of determining which facilities are appropriate and safe for proposed research involving LMO/rDNA.

6 responses



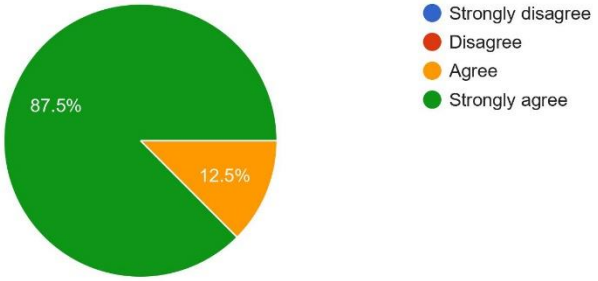
No. 15 is to be completed by **laboratory personnel ONLY** *(technician, student, researchers, and everyone using the lab)*

15. Laboratory personnel **MUST**

Copy

a) Follow all safety practices, establish good laboratory techniques, work within the assigned BSL containment, and use PPE as recommended by PI.

16 responses

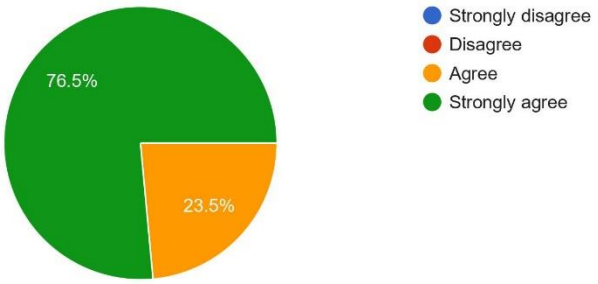


15. Laboratory personnel **MUST**

Copy

b) Immediately notify the Head/Top Management of any health condition that may be compromised due to their work before the initiation of a research project.

17 responses

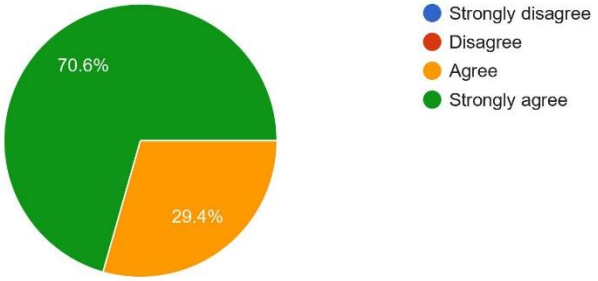


15. Laboratory personnel **MUST**

Copy

c) Follow all practices and procedures as provided by the PI and BSO, as well as ensure strict compliance with all required biosafety regulations and guidelines.

17 responses

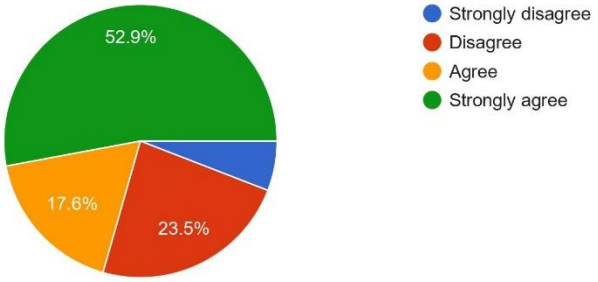


15. Laboratory personnel **MUST**

Copy

d) Report problems, procedural mistakes, spills etc. to the JBK or Head/Top Management as soon as they occur to obtain an immediate solution.

17 responses

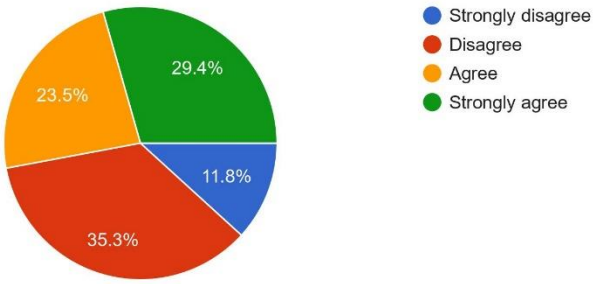


15. Laboratory personnel **MUST**

Copy

e) Report to the PI only on non-compliance with the biosafety guidelines or policies.

17 responses



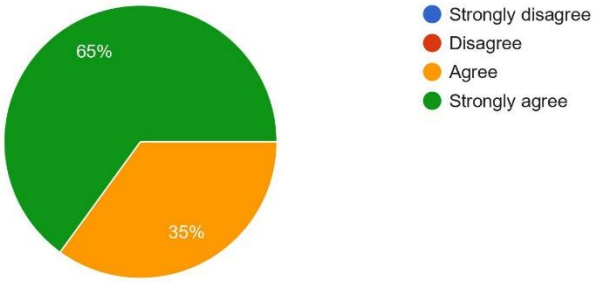
No. 16 to be answered by* ALL *respondents

16. If the project/ research is non-compliance with the Biosafety Act, IBC can:

Copy

a) Suspend the use of LMO/rDNA materials.

20 responses

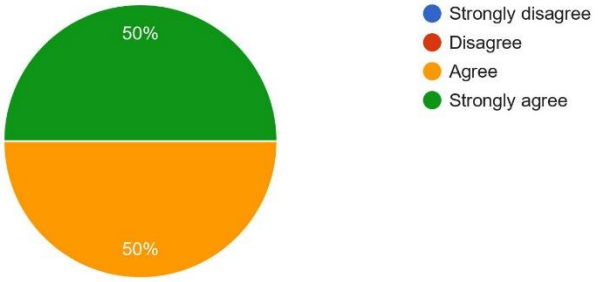


16. If the project/ research is non-compliance with the Biosafety Act, IBC can:

Copy

b) Cease the approval for the use of the LMO/rDNA materials.

20 responses

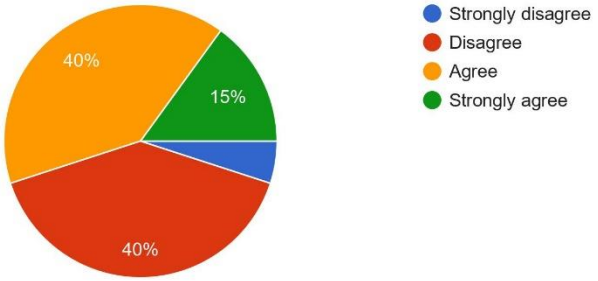


16. If the project/ research is non-compliance with the Biosafety Act, IBC can:

Copy

c) Confiscate the LMO/rDNA materials.

20 responses

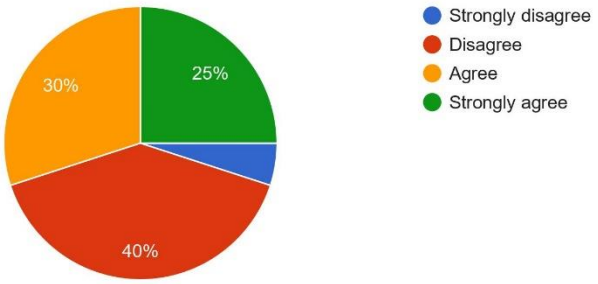


16. If the project/ research is non-compliance with the Biosafety Act, IBC can:

Copy

d) Destruct the LMO/rDNA materials.

20 responses

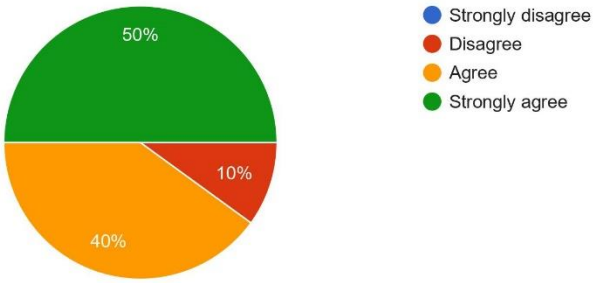


16. If the project/ research is non-compliance with the Biosafety Act, IBC can:

Copy

e) Any other action necessary to protect the public and/or the organization.

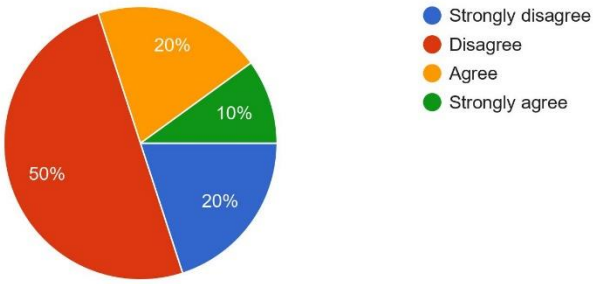
20 responses



16. If the project/ research is non-compliance with the Biosafety Act, IBC can: Copy

f) Report to head/top management only, not necessarily to NBB.

20 responses

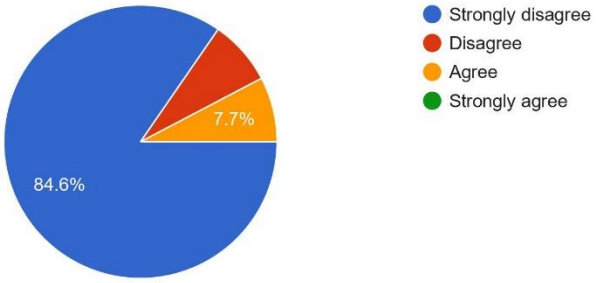


***No. 17 is to be completed by* PI ONLY**

17. PI should Copy

a) Submit all applications for approval and notification directly to NBB without prior review and approval by IBC.

13 responses



17. PI should

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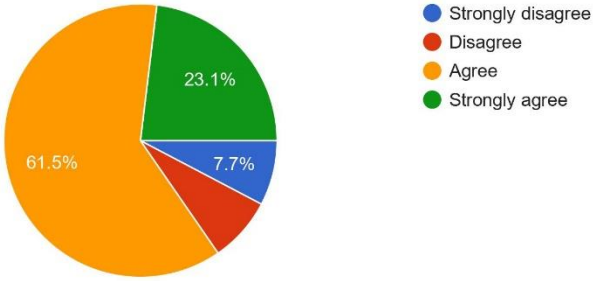
b) Should modify the research project involving LMO/rDNA materials such that it requires a change from the BSL and/ or Risk Group or change a premise which has been assessed by IBC.

13 responses



17. PI should

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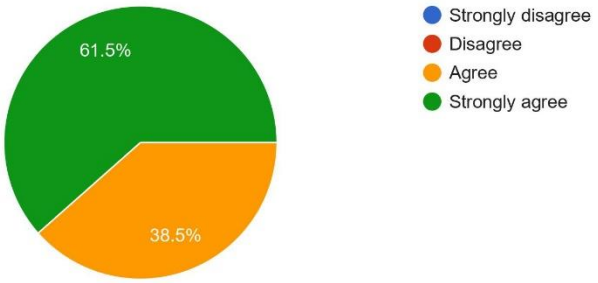
c) Report any significant problems immediately with respect to the implementation of relevant laws, regulations, and guidelines.

13 responses



17. PI should

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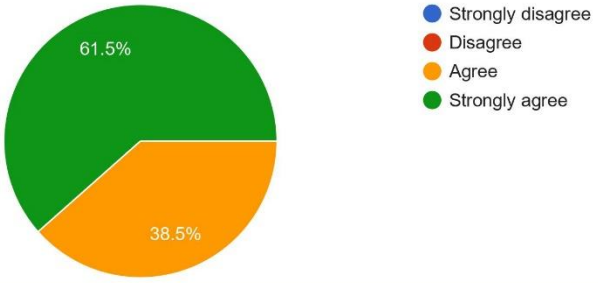
d) Notify IBC promptly of any significant research-related accidents that have resulted or could result in human illness, unanticipated plant or animal disease, or an unintended release of an organism from intended confinement.

13 responses

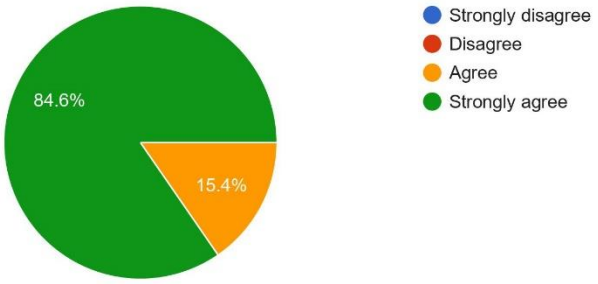


17. PI should

Copy

e) Complete Biosafety and Good Laboratory Practices training.

13 responses

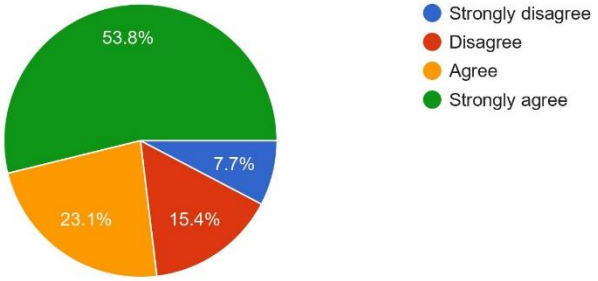


17. PI should

Copy

f) Develop and obtain JBK approval for an emergency response plan to handle accidental spills and personnel contamination, and to adhere strictly to such plans.

13 responses



17. PI should

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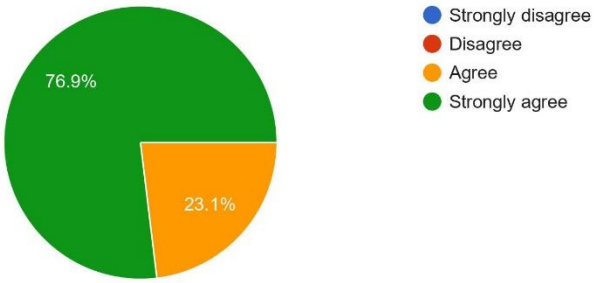
g) Comply with all legislative requirements when conducting research involving LMO/rDNA materials.

13 responses

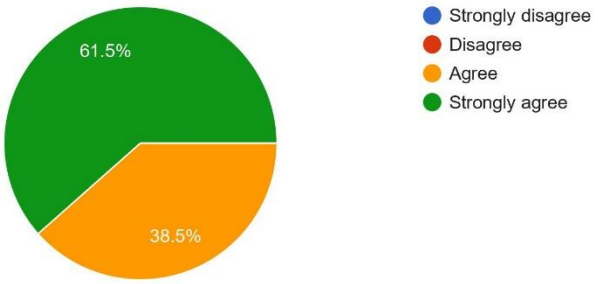


17. PI should

Copy

h) Ensure that the reporting requirements under the Biosafety Act are fulfilled.

13 responses



17. PI should

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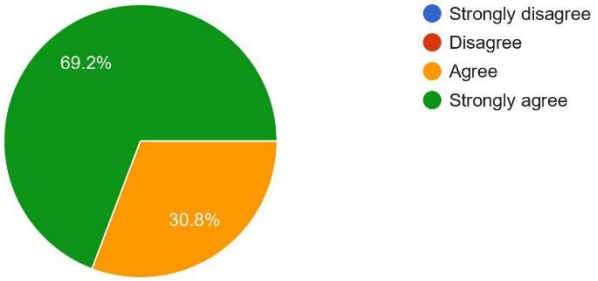
i) Review the applicable guidelines and regulations related to LMO/ rDNA materials or other infectious materials involved in research activity.

13 responses



17. PI should

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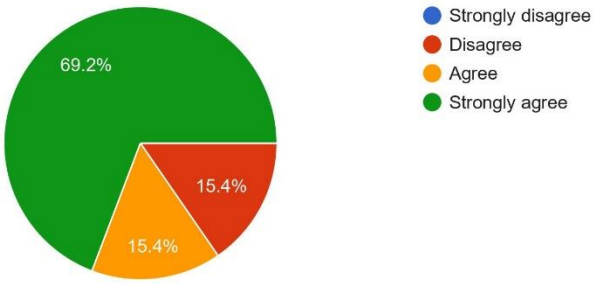
j) Develop SOP incorporating biosafety procedures, or a biosafety manual prepared specifically for the laboratory.

13 responses



17. PI should

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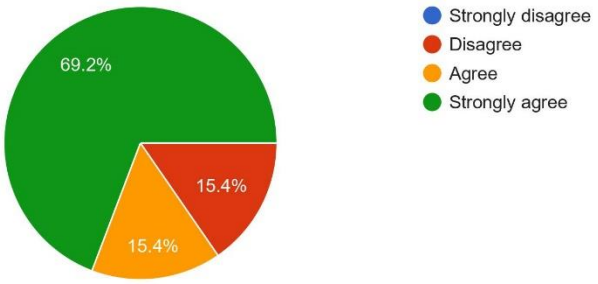
k) Establishes the policy and procedures to limit access to only individuals who are well-educated on the potential hazards and meet specific entry requirements (e.g., immunization, training on the use of PPE).

13 responses



17. PI should

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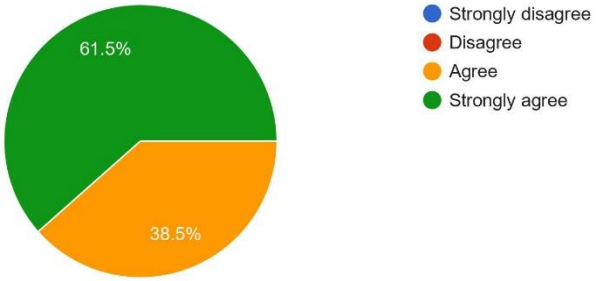
l) Instruct and educate the laboratory personnel on the potential hazards associated with the research, procedure of aseptic techniques, and techniques required to ensure safety as well as procedures for dealing with accidents.

13 responses



17. PI should

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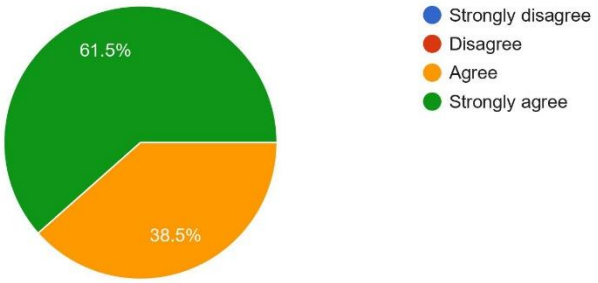
m) Provide PPE required for work with the specific LMO/rDNA materials.

13 responses

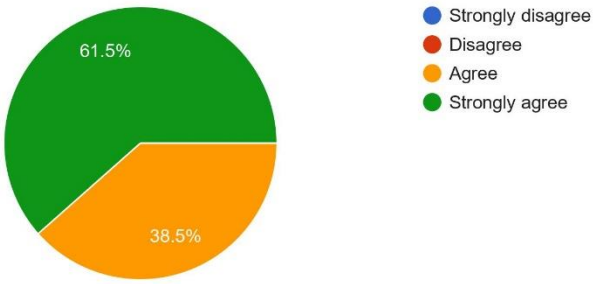


17. PI should

Copy

n) Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.

13 responses

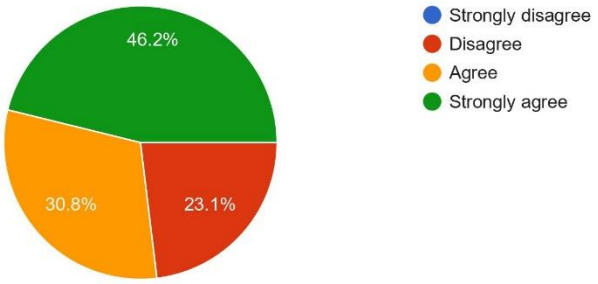


17. PI should

Copy

o) Suspend the laboratory personnel's entrance into the laboratory with work errors and conditions that may result in the unintended release of LMO/rDNA materials.

13 responses

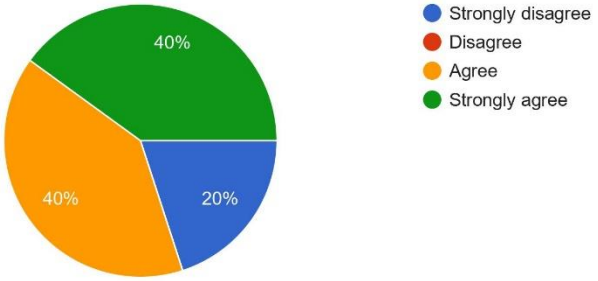


No. 18 to 20 are to be completed by **PI who is currently working in BSL-3 and BSL-4 ONLY**

18. PI should comply with all required occupational health requirements including ensuring laboratory personnel know the reasons and provisions for precautionary medical practices implemented and ensure that they are offered (at no cost) appropriate immunizations or tests for the LMO/rDNA materials handled or potentially present in the laboratory.

Copy

5 responses



19. The construction work and major changes to the BSL-3 facility can commence once certified by a competent authority/organization and endorsed by the head of the department.

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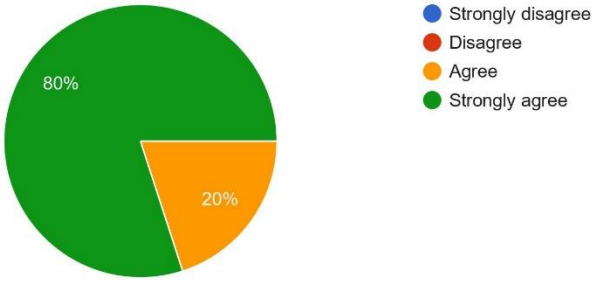
5 responses



20. The BSL-3 facility should be tested and certified every 6 months.

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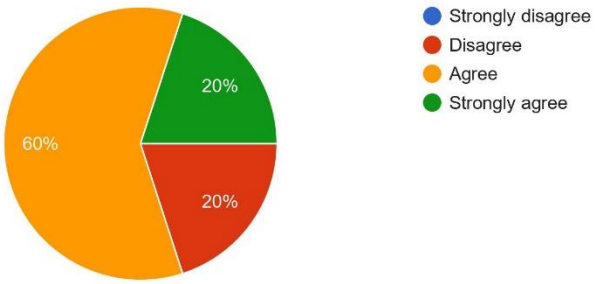
5 responses



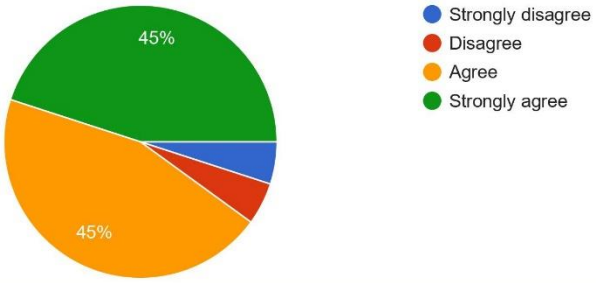
SECTION C: LMO/ rDNA Activities

1. For the review of LMO/ rDNA activity, project extension, and notice of termination, PI should

Copy

a) Submit the relevant application as prescribed by the NBB, the IBC assessment form and a copy of the document of the approved research grant for the LMO/rDNA project.

20 responses

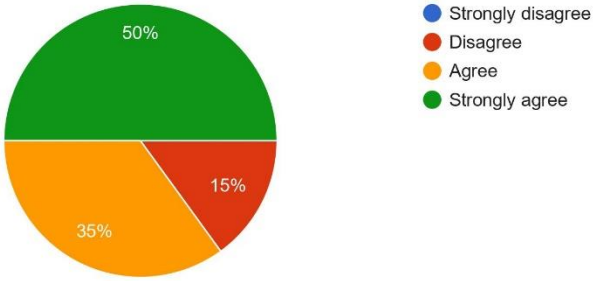


1. For the review of LMO/ rDNA activity, project extension, and notice of termination, PI should

Copy

b) Submit the application form to NBB once approved by IBC.

20 responses

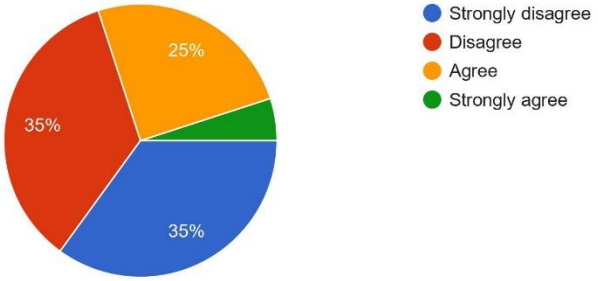


1. For the review of LMO/ rDNA activity, project extension, and notice of termination, PI should

Copy

c) Can start an experiment with LMO/rDNA before a certificate of approval is granted by NBB, if the work is very important.

20 responses

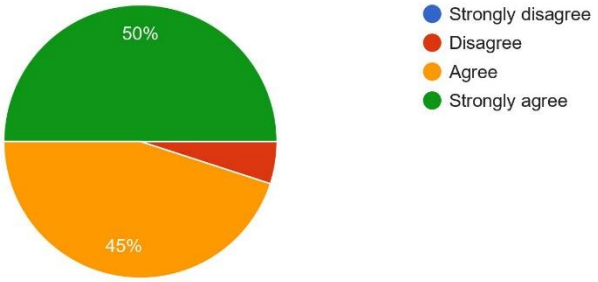


1. For the review of LMO/ rDNA activity, project extension, and notice of termination, PI should

Copy

d) Provide data reporting and adverse event reporting to monitor the proposed LMO/rDNA research, and the reports should be submitted to IBC.

20 responses

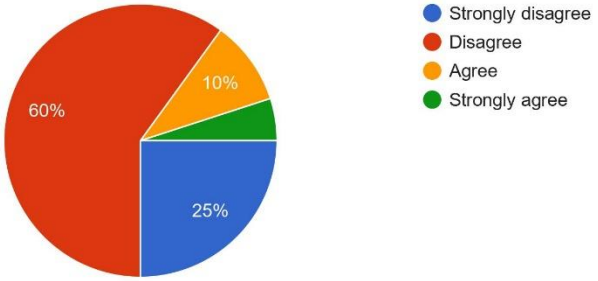


1. For the review of LMO/ rDNA activity, project extension, and notice of termination, PI should

Copy

e) Not required to notify IBC of the proposed project if the research work falls into any of the exemptions.

20 responses

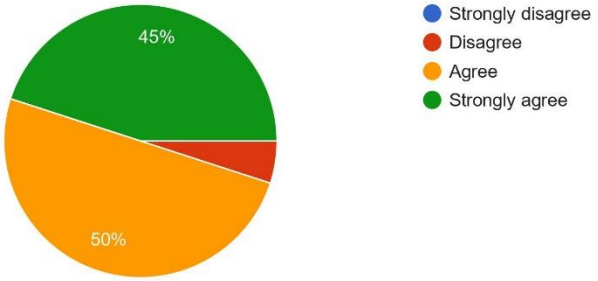


1. For the review of LMO/ rDNA activity, project extension, and notice of termination, PI should

Copy

f) Complete and submit the IBC Project Extension Review/ Notice of Termination Form to IBC Chair at least one week before the next scheduled IBC meeting or at the appropriate time intervals as stipulated by the IBC.

20 responses

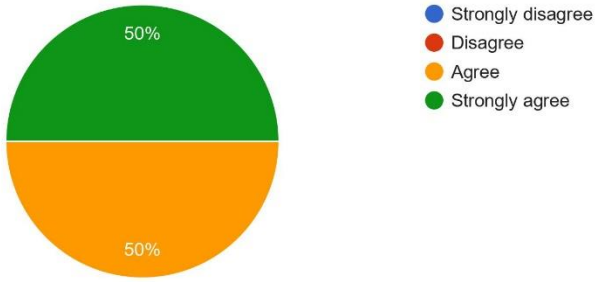


1. For the review of LMO/ rDNA activity, project extension, and notice of termination, PI should

Copy

g) Complete the Notice of Termination Form and file the form in the laboratory record when the research project involving registered LMO/rDNA materials is completed/no longer active, or when the LMO/rDNA materials are properly disposed of or no longer in the possession of the PI.

20 responses



2. Biosafety (Approval and Notification) Regulations 2010 forbid exemption for all types of LMO/rDNA.

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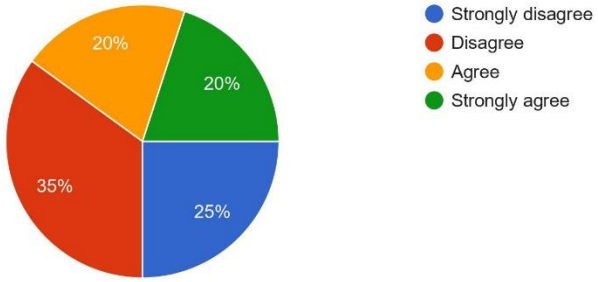
20 responses



3. For the review of LMO/rDNA activity, project extension, and notice of termination, IBC/ IBC Chair should

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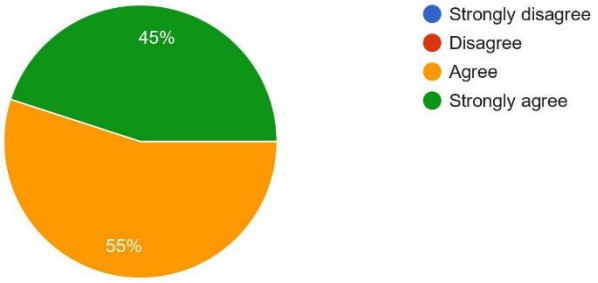
a) Review the proposed activity involving LMO/rDNA materials by referring to the Biosafety Guidelines for Contained Use Activity of LMOs and other relevant documents, including IBC policies and procedures for the organization.

20 responses



3. For the review of LMO/rDNA activity, project extension, and notice of termination, IBC/ IBC Chair should

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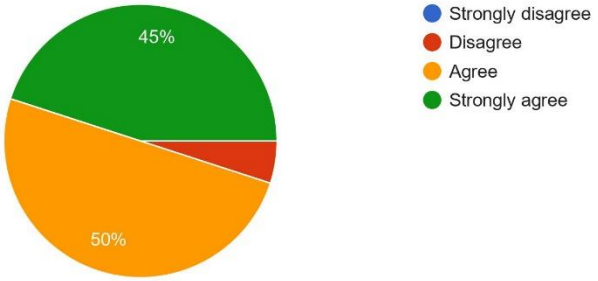
b) Assess the facilities, procedures, practices, training, and expertise of personnel involved in the LMP/rDNA research.

20 responses

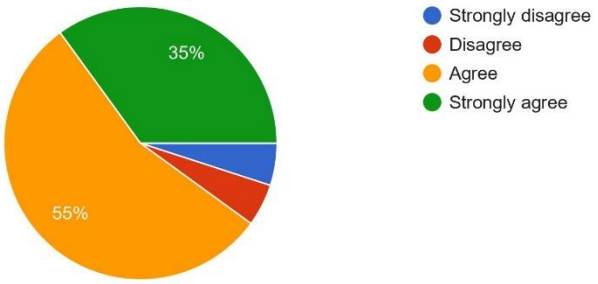


3. For the review of LMO/rDNA activity, project extension, and notice of termination, IBC/ IBC Chair should

Copy

c) Provide written notification of the IBC's decision to PI.

20 responses



4. Exempted work also must be carried out according to the Biosafety Act and should be periodically monitored by IBC.

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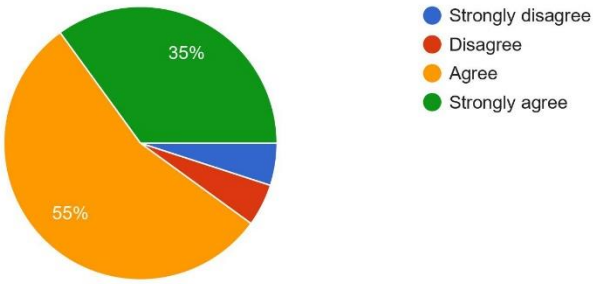
20 responses



5. The ad-hoc subcommittee should review all submitted research projects to determine their exemption or non-exemption status.

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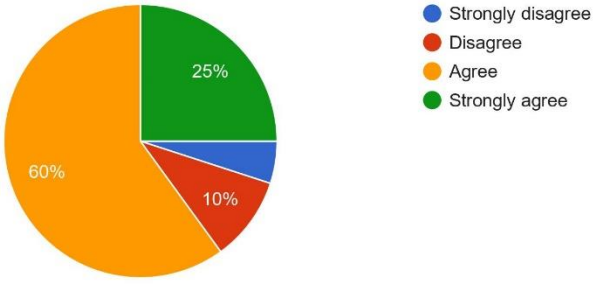
20 responses



6. Limit or restrict access to the laboratory when work with the LMO/rDNA materials is in progress.

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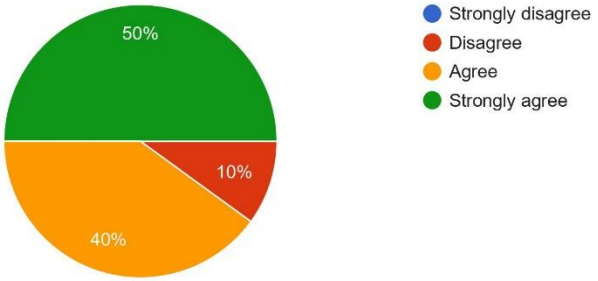
20 responses



7. Follow safety protocols outlined in the approved emergency response plan prepared by PI for the specific project and laboratory.

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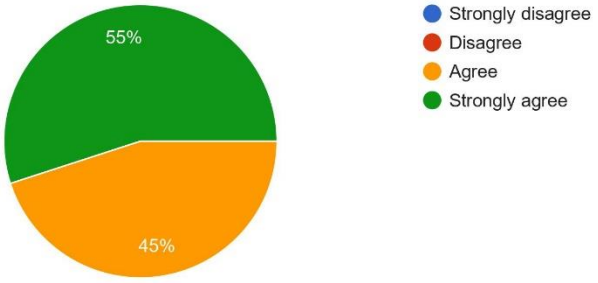
20 responses



8. Ensure the LMO/rDNA materials are always kept secure.

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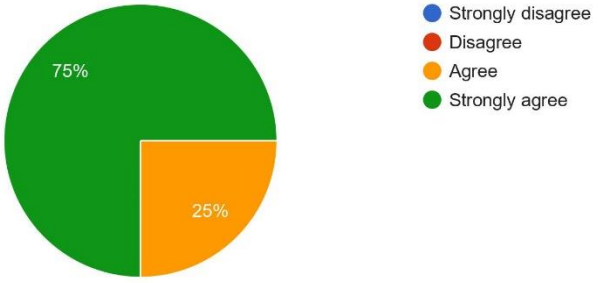
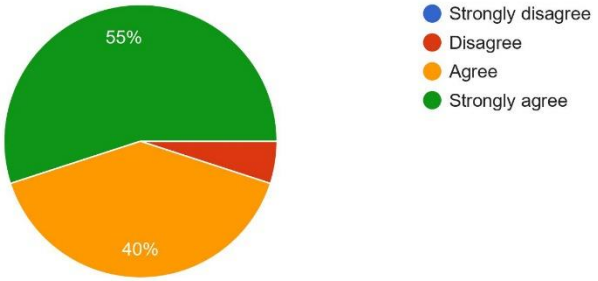
20 responses



9. The emergency response plan must be kept secure in a file at the designated laboratory.

Copy

20 responses



SECTION D: Training

No. 1 is to be completed by an **BSO/ IBC member ONLY**

1 a) IBC members should receive initial mandatory and refresher training on Biosafety, the Biosafety Act 2007, Biosafety (Approval and Notification) Regulations 2010 and related regulations as well as IBC policies.

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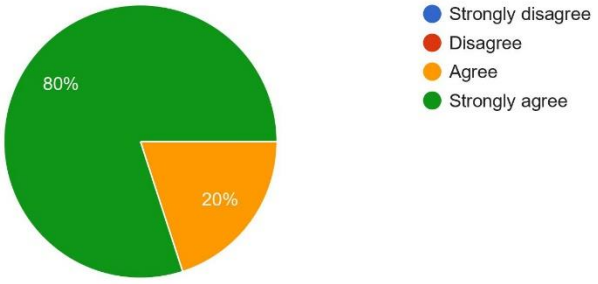
15 responses



1 b) IBC members should receive refresher training on any changes to national guidelines.

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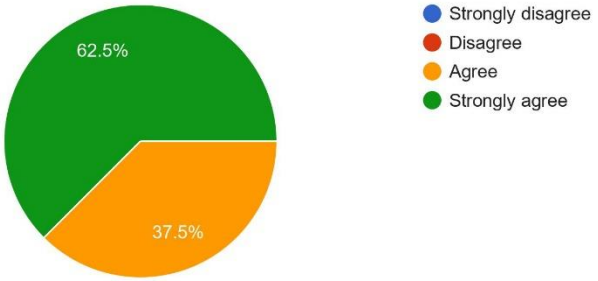
16 responses



1 c) All training related to biosafety should be organized by JBK with commitment from the organization and guidance from NBB.

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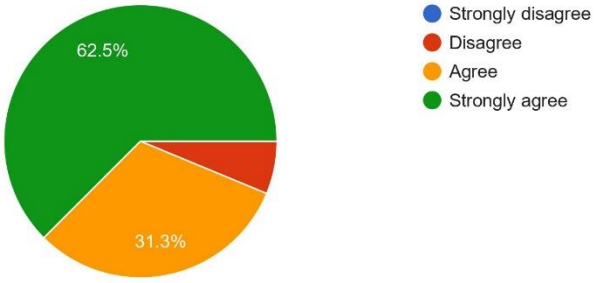
16 responses



1 d) IBC Chair is responsible to provide the training and BSO documents it.

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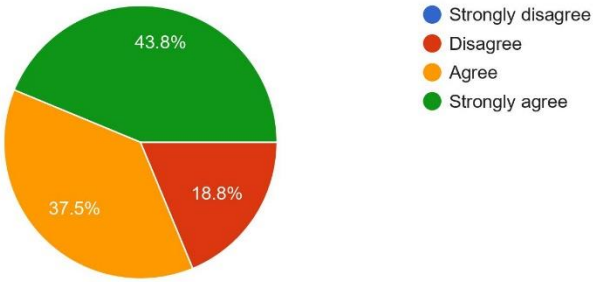
16 responses



1 e) BSO should attend biosafety training with commitment from the organization and guidance from NBB.

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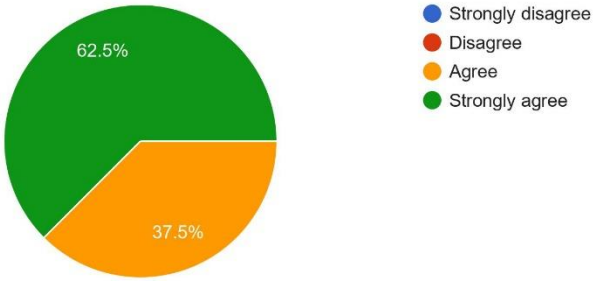
16 responses

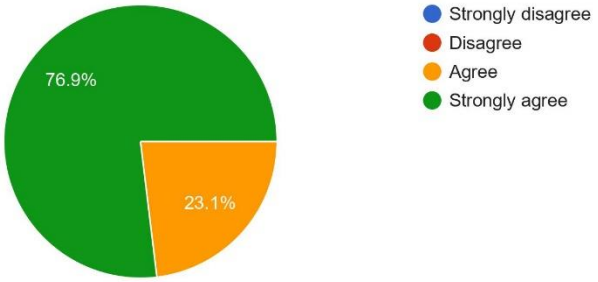


No. 2 is to be completed by **PI ONLY**

2 a) Complete Biosafety and Good Laboratory Practices training.

Copy

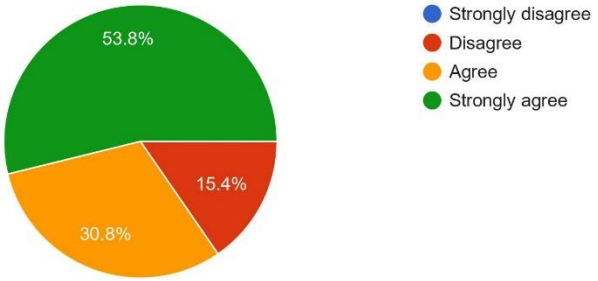
13 responses



2 b) Ensure that the laboratory staff is supervised by the head/top management regarding the safety practices and techniques employed.

Copy

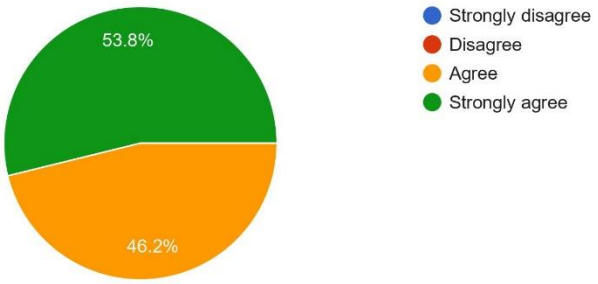
13 responses



2 c) Provides training and educates the laboratory personnel on the potential hazards associated with the research, procedure of aseptic techniques, and techniques required to ensure safety as well as procedures for dealing with accidents.

Copy

13 responses



No. 3 is to be completed by **laboratory personnel ONLY**

3 a) All researchers handling LMO/rDNA materials including laboratory personnel must attend general biosafety training.

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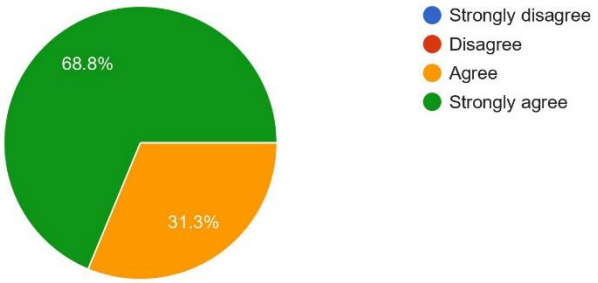
16 responses



3 b) All researchers must provide proof to the IBC that they have undergone training and have adequate experience (as recognized by IBC) in Biosafety and Good Practices.

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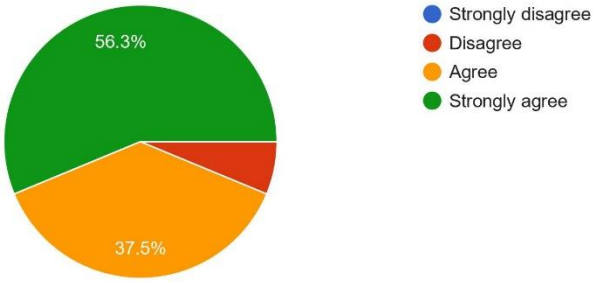

3 c) Successful completion of training is mandatory to receive an IBC approval (whether new or re-application).

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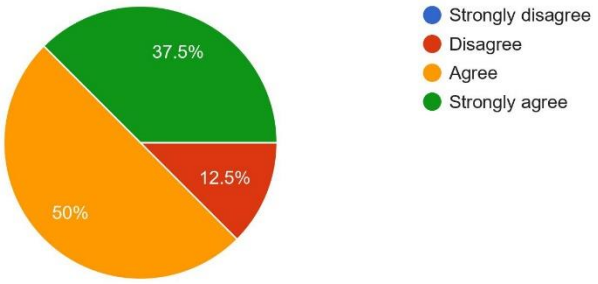

3 d) For researchers who are proposing to work in BSL-3 containment, specific BSL-3 laboratory training is mandatory.

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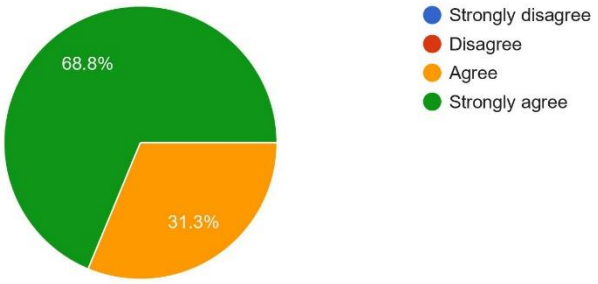

SECTION E: Emergency Response Plan

1. The emergency response plan (and any revision thereof) must be formally adopted by the IBC pursuant to all National Biosafety policies and organizational policies.

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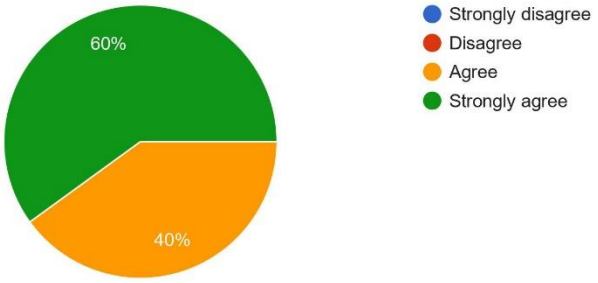

2. The emergency response plan will be reviewed periodically based on new information from internal findings and/or external development.

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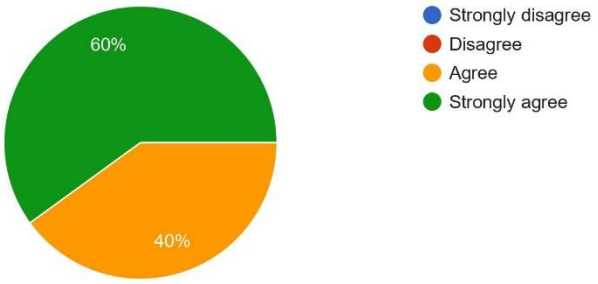

3. Method and procedures for controlling the LMO(s) in case of unintentional release should be prepared by personnel involved in LMO research.

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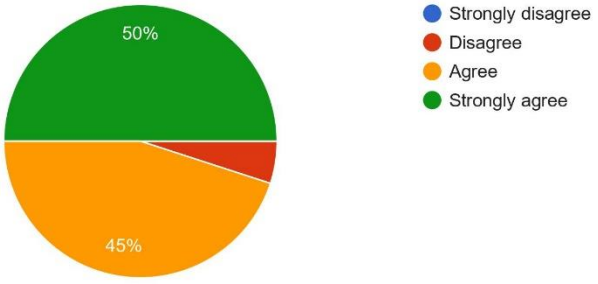

4. Details of any contingency measures should be in place for protecting human health and the environment in case of the occurrence of an undesirable effect caused by the unintentional release.

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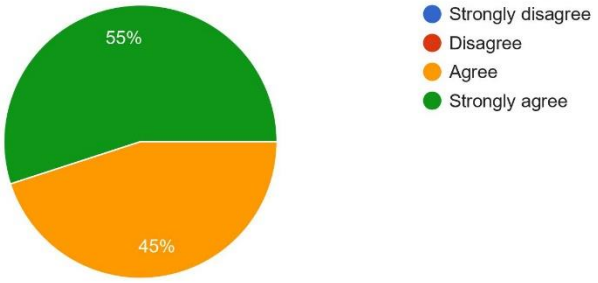

5. OHSC should coordinate the occupational health and safety services to ensure appropriate occupational health and safety surveillance for laboratory personnel involved in research approved by the IBC.

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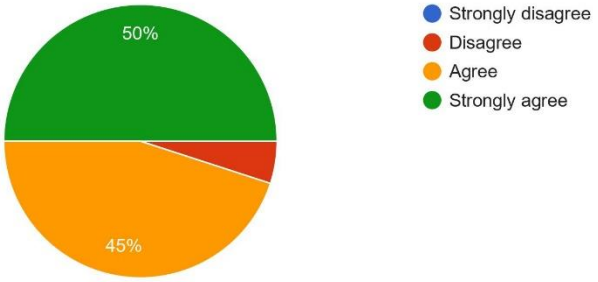

6. PI will use the Occupational Disease/Exposure Investigation Form to make a formal report within 24 hours to the OHSC, IBC, and NBB if there is any occupational exposure to LMO/rDNA materials.

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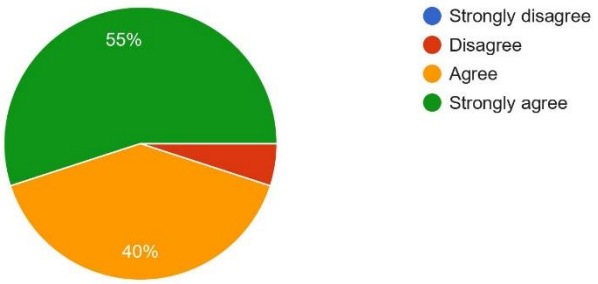

SECTION F: Laboratory Inspection and Biosafety Manuals

1. IBC members, as well as representatives and officers authorized by the NBB, are allowed to access the laboratories that are registered for activities with LMO/rDNA materials for inspection purposes by appointment only.

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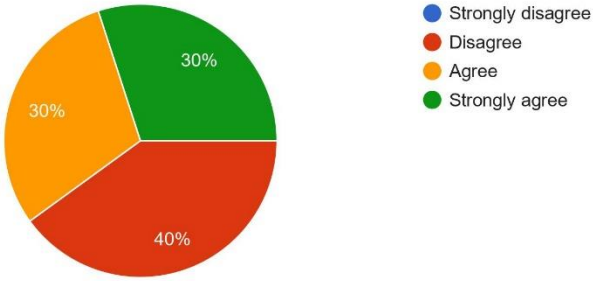

2. A collection of biosafety protocols and procedures (safety manual) must be kept secure and not necessarily at the designated laboratory.

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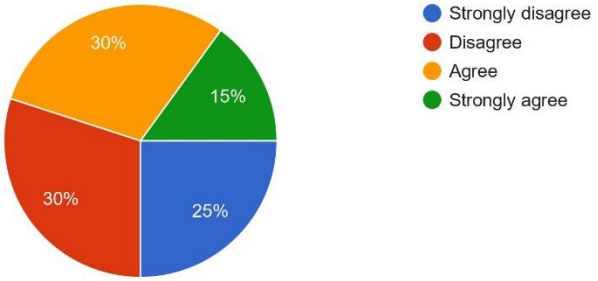

3. Detailed descriptions of all facilities being used for LMO-contained use activities should be properly documented.

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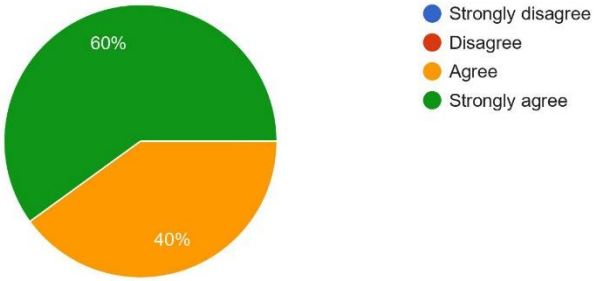

4. PI should ensure the integrity of the biological and physical containment/ biosafety level.

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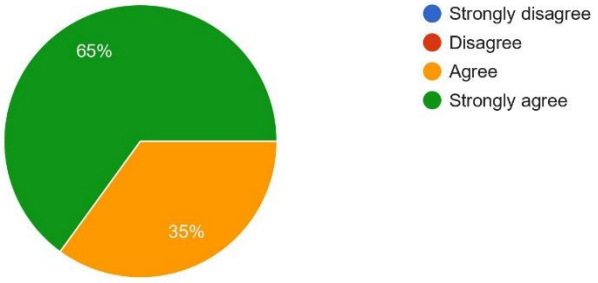

5. IBC should review biosafety protocols during the inspection of facilities and laboratories.

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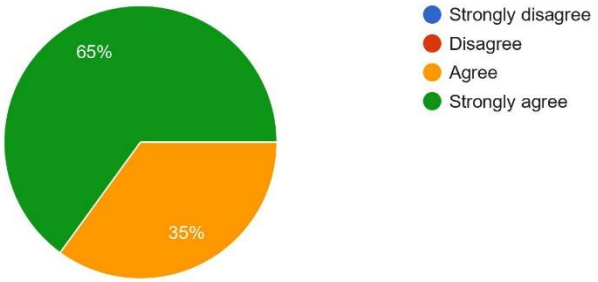

6. IBC will inspect laboratories using a checklist according to the procedures outlined in the Biosafety (Approval and Notification) Regulations 2010.

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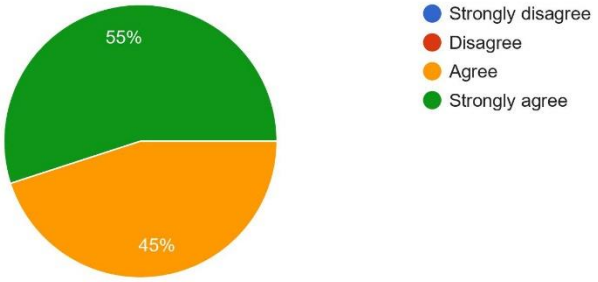

SECTION G: Field Experiments of LMOs (Confined Field Trial of LMO)

No. 1 to 6 are to be completed by **PI/ personnel who involve in confined field trials ONLY**

1. All field experiments of LMO are considered a release activity.

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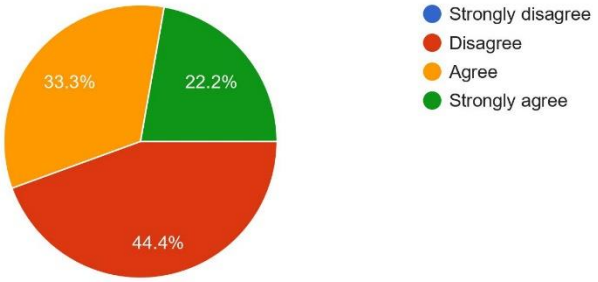

2. All field experiments of LMO must obtain approval from NBB [procedures are outlined in Biosafety (Approval and Notification) Regulations 2010].

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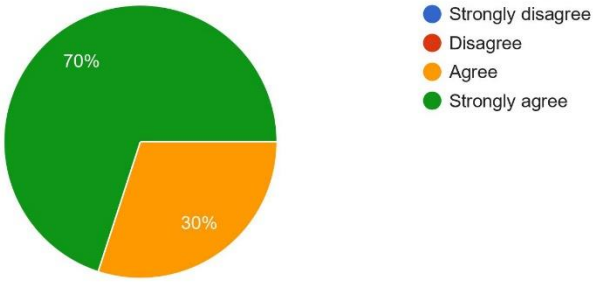

3. The application for field experiments should be vetted by IBC before submission to the NBB.

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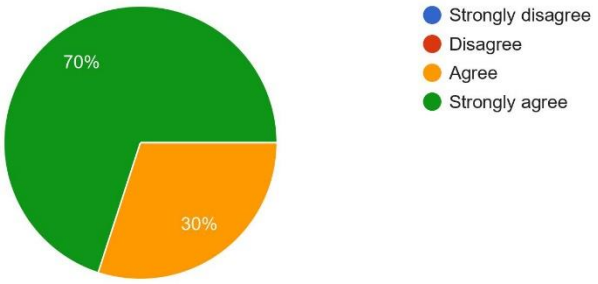

4. The application for field experiments can be directly submitted to NBB

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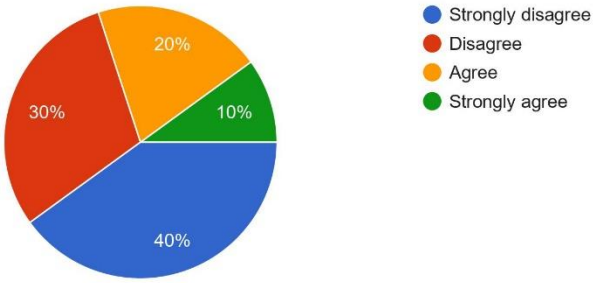

5. The PI need not obtain an endorsement from IBC and can start a field experiment before a certificate of approval is granted by the NBB.

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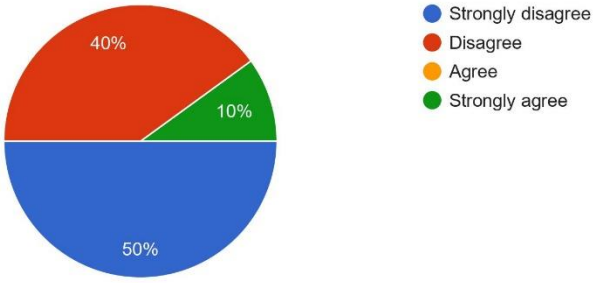

6. Measures for control and confinement of fieldwork must comply with conditions imposed by NBB.

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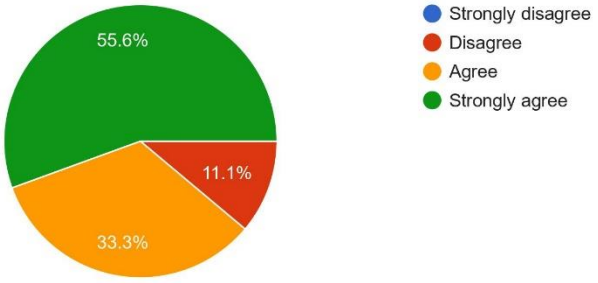

SECTION H: Security of LMO/rDNA Materials

1. PI and/or all associated personnel

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a) Must be conscientious in controlling the biological materials and should be held accountable for them.

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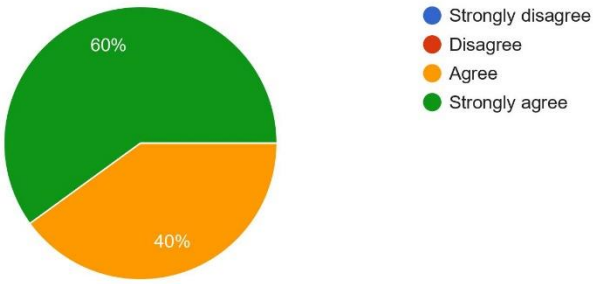

1. PI and/or all associated personnel

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b) Should limit access to biological materials to authorized personnel only.

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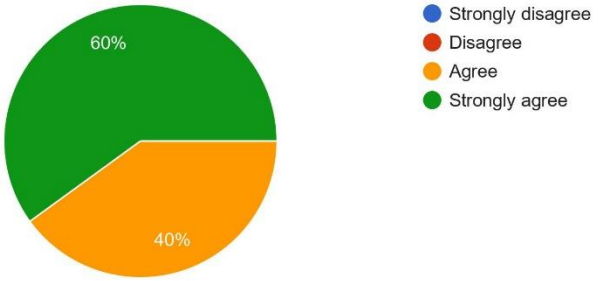

1. PI and/or all associated personnel

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c) Should perform a risk vulnerability assessment and develop a plan to protect the security of the material in question, depending on the Risk Group the biological agent may pose.

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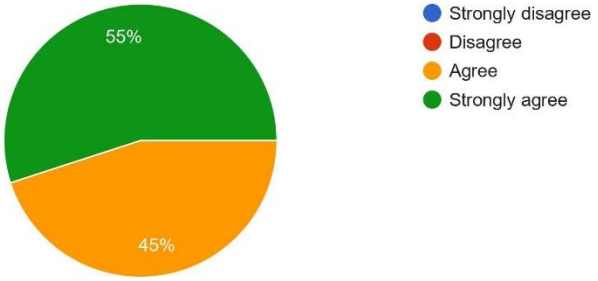

2. Chain-of-custody forms within laboratories should be made available to track LMO/rDNA materials.

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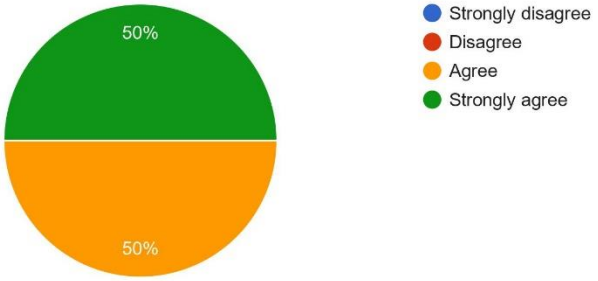

3. Log of access to areas where biological materials are in use should be in place.

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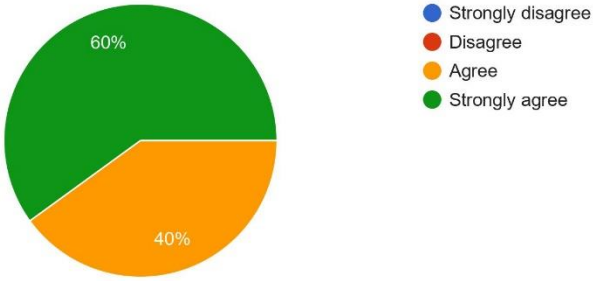

SECTION I: Disposal

1. Potentially hazardous biological material and LMO/rDNA materials are to be considered "regulated waste" and should be disposed of in a manner consistent with national regulations and related guidelines.

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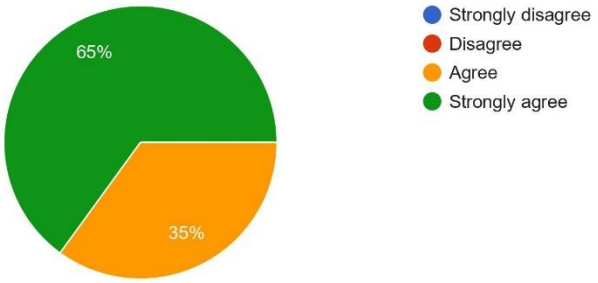

2. The laboratory supervisor or other person with operational responsibility should ensure compliance with requirements for proper segregation of laboratory waste to ensure a safe work environment.

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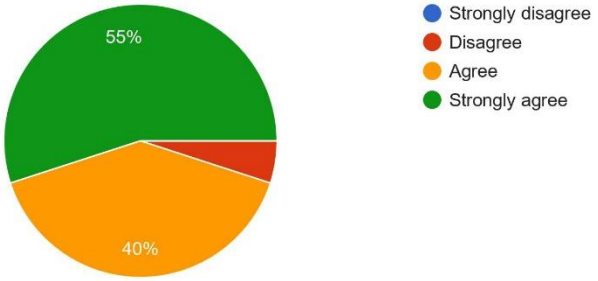

3. The exempted LMO wastes are not necessarily to be inactivated prior to leaving the facility.

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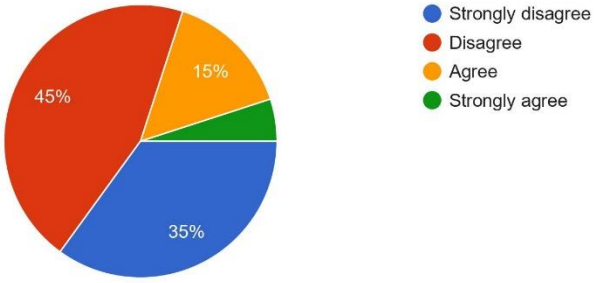

4. Each individual working with biohazardous material should be responsible for its sterilization before disposal.

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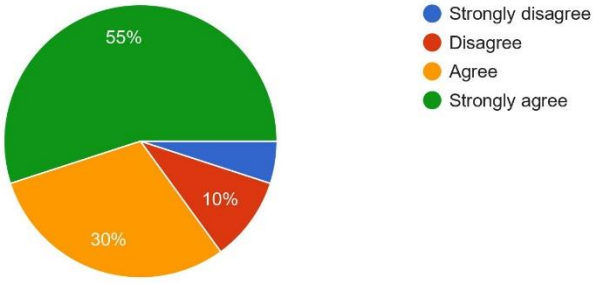

5. For disposal purposes, the exempted LMO material also should be treated in the same way as infectious and potentially infectious material.

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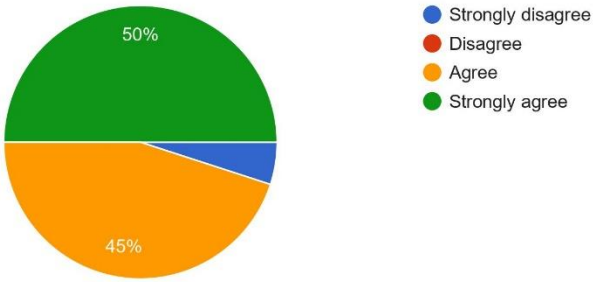

6. Ordinary waste should be placed into ordinary waste bins (these bins should not be yellow) that will be emptied by the cleaners in all rooms, except laboratories.

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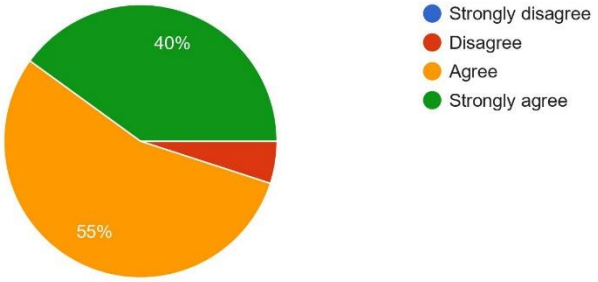

7. In laboratories, cleaners may be allowed to empty the bins for non-laboratory material (e.g., cardboard boxes, paper) only under supervision.

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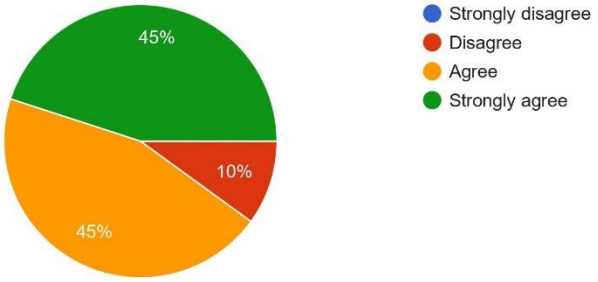

SECTION J: Packaging, Transportation, Import, and Export of LMO/ rDNA Materials

1. Regulated LMO/rDNA materials will be packaged and transported in a manner compliant with national and international regulations and related guidelines.

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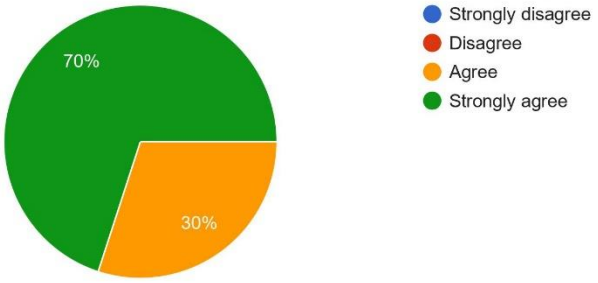

2. PI is responsible to obtain permits when handling biological materials or conducting activities which require additional permits (e.g., import permits etc.)

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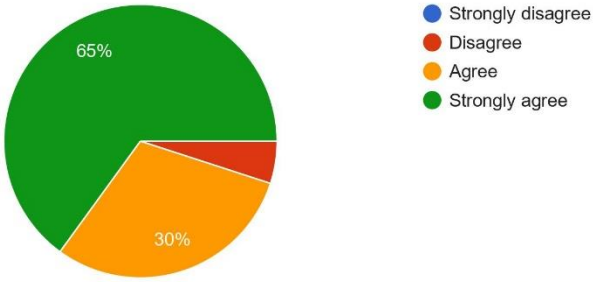

3. For the movement and transport of LMO and related materials, the following shall apply:

a) The regulatory authorities (IBC and NBB) shall be notified using the relevant forms.

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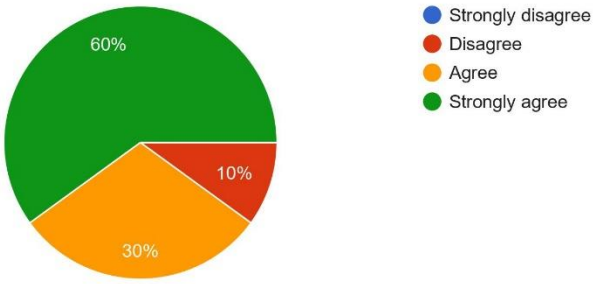

3. For the movement and transport of LMO and related materials, the following shall apply:

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b) LMO being transferred should be packaged in secure containers capable of preventing material loss during transportation.

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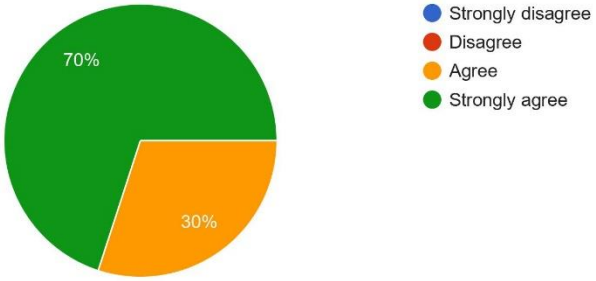

3. For the movement and transport of LMO and related materials, the following shall apply:

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c) LMO should be kept separate from other materials.

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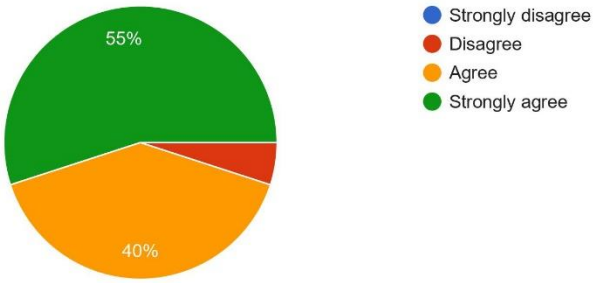

3. For the movement and transport of LMO and related materials, the following shall apply:

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d) If an unintentional release of LMO during transport occurs, all attempts should be made to recover as much of the materials as possible.

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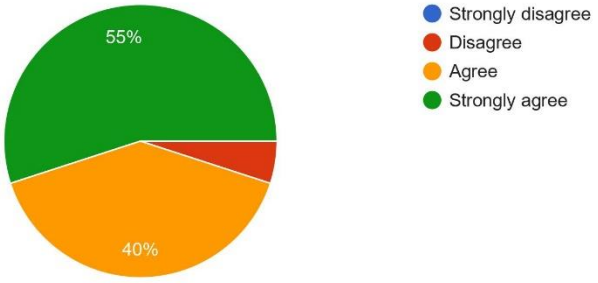

3. For the movement and transport of LMO and related materials, the following shall apply:

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e) The location of the unintentional release of LMO should be marked and treated in a manner that ensures that no additional release of materials occurs.

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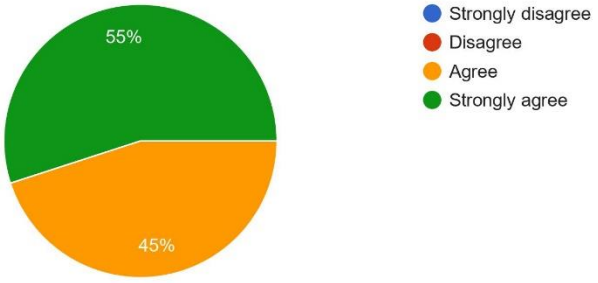

3. For the movement and transport of LMO and related materials, the following shall apply:

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f) Corrective actions taken for unintentional release of LMO should be documented and the regulatory authorities notified.

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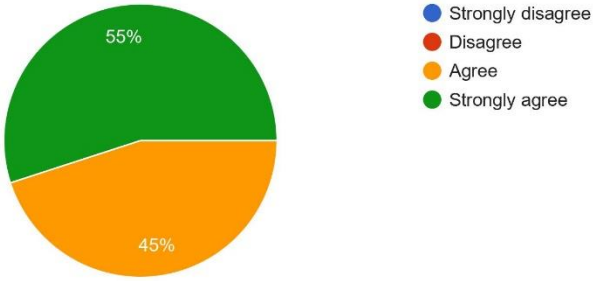

3. For the movement and transport of LMO and related materials, the following shall apply:

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g) Adequate records of the transport of LMO as they move between research facilities, storage facilities and field trial sites should be maintained by PI and not necessarily by IBC, to ensure an adequate system is in place for tracking the movement of this material.

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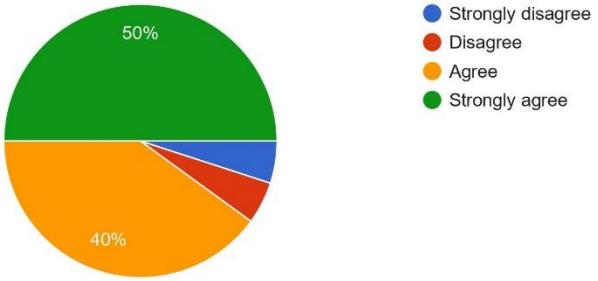

3. For the movement and transport of LMO and related materials, the following shall apply:

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h) The shipper should notify the recipient of the date, kind and amount of material that will be sent before shipping.

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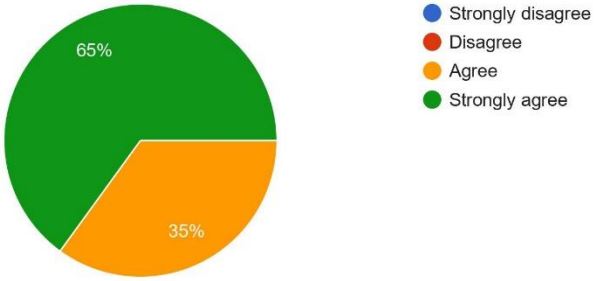

3. For the movement and transport of LMO and related materials, the following shall apply:

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i) Upon receiving the material, the recipient should confirm that the shipment has arrived intact, and that no material has been lost.

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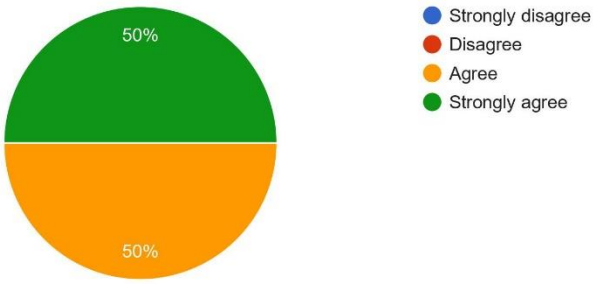

PART 2: BIOSAFETY PRACTICES

SECTION A: Biosafety Practices

No. 1 to 11 are to be completed by **ALL** *respondents*

1. Decontaminating LMO waste before disposal

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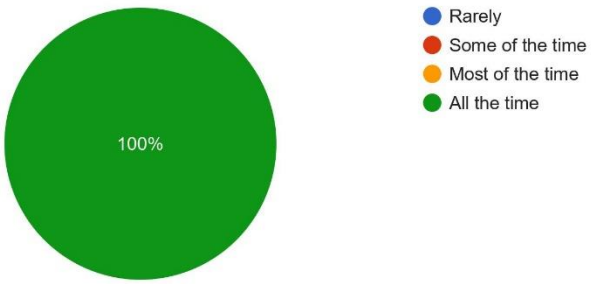

2. Segregating LMO waste

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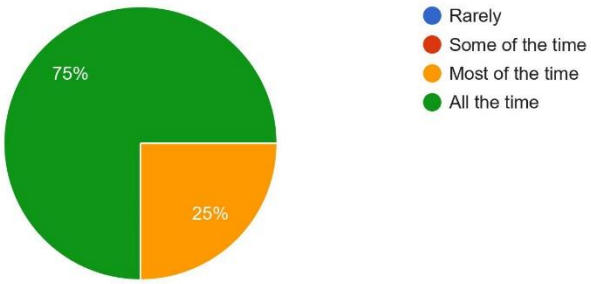
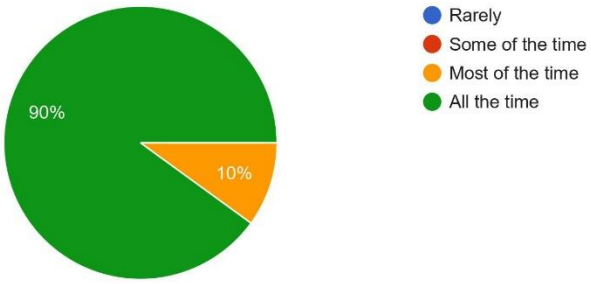


3. Use of appropriate PPE when handling LMOs

Copy

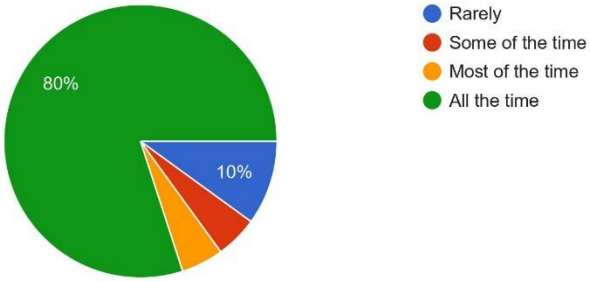
20 responses



4. Dedicated sharps containers for disposal of sharps used for handling LMOs.

Copy

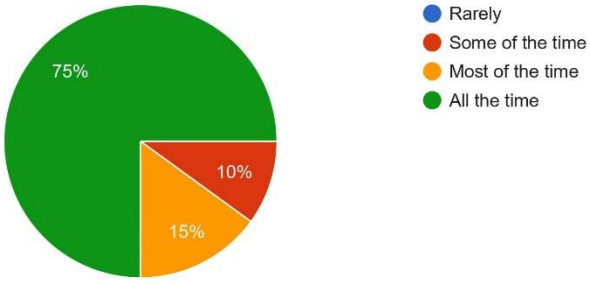
20 responses



5. Assess and set containment levels of LMOs and modify them as necessary.

Copy

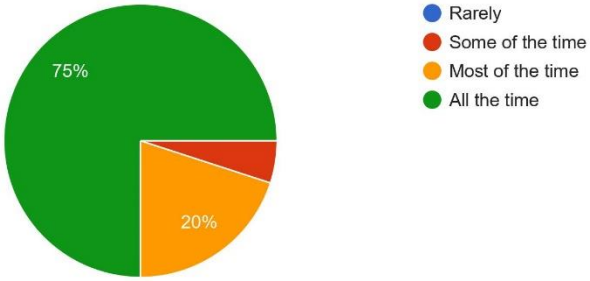
20 responses



6. Use of Biological Safety Cabinet for work with LMOs materials.

Copy

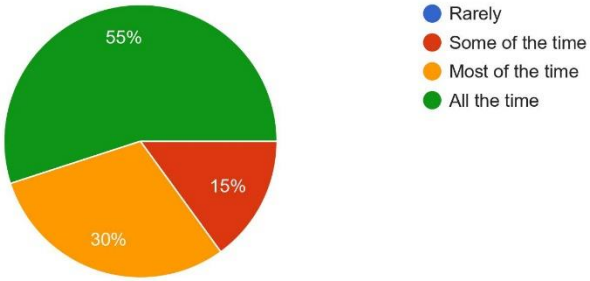
20 responses



7. Periodically review research projects that are recommended for approval.

Copy

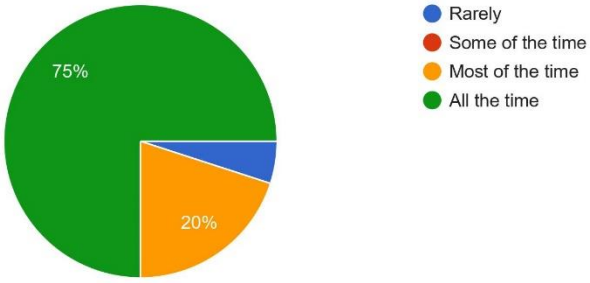
20 responses



8. Adopt and implement emergency response plans covering accidental spills and personnel contamination, resulting from LMO/rDNA research.

Copy

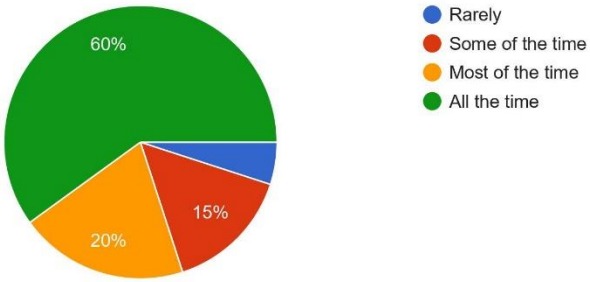
20 responses



9. There is an up-to-date list available of personnel with authorized access to LMOs.

Copy

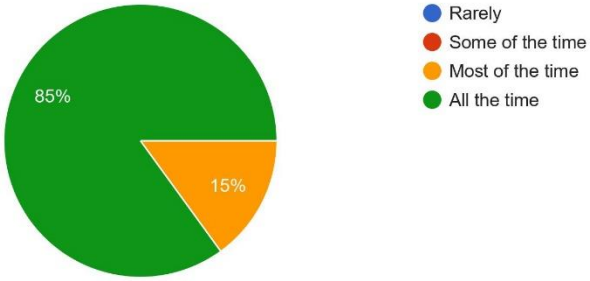
20 responses



10. Wear Closed toes shoes

Copy

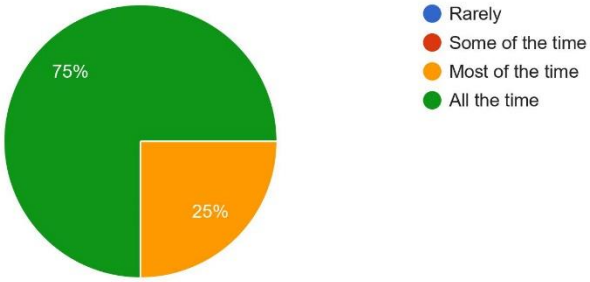
20 responses



11. Wear Lab coats/lab gowns

Copy

20 responses

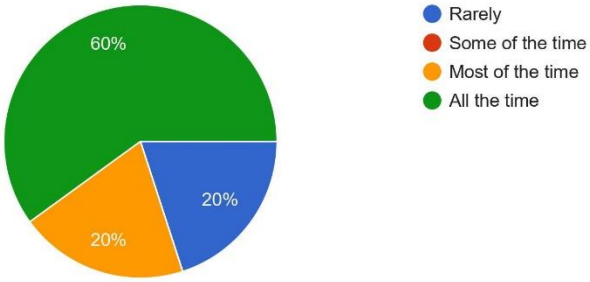


No. 12 to 15 are to be completed by **BSL-3 users ONLY**

12. Wear N95 or N100 respirators

Copy

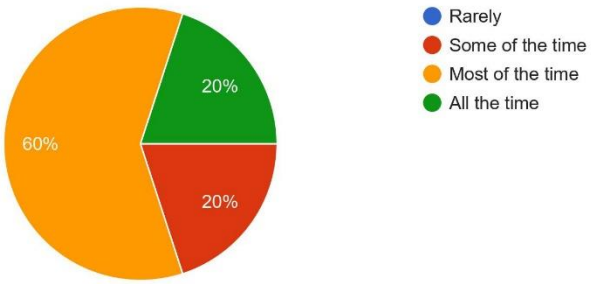
5 responses



13. Wear mechanical pipetting aids

Copy

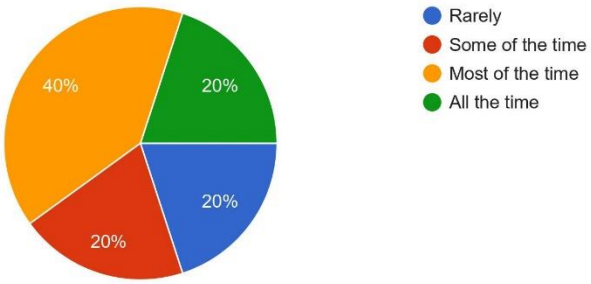
5 responses



14. Wear powered air-purifying respirators

Copy

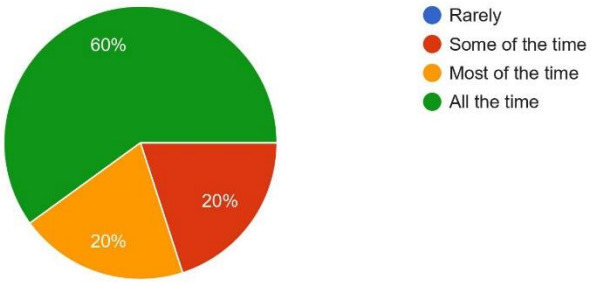
5 responses



15. Wear double gloves when handling infectious material.

Copy

5 responses

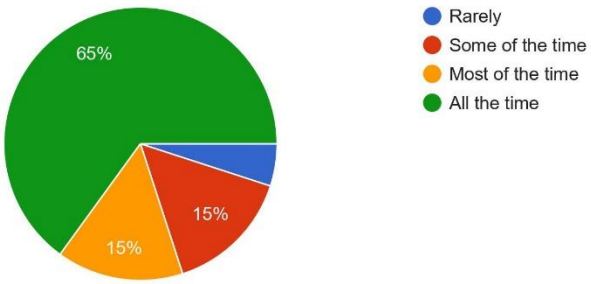


SECTION B: Safety Equipment

1. Electronic access control devices

Copy

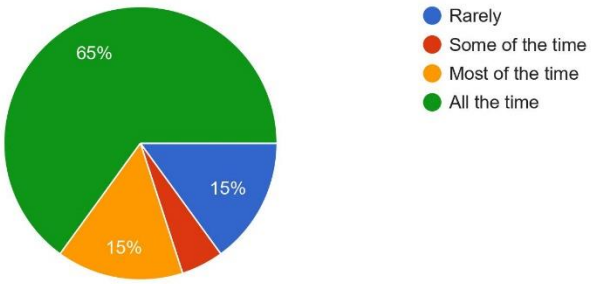
20 responses



2. Guard at building entrance(s)

Copy

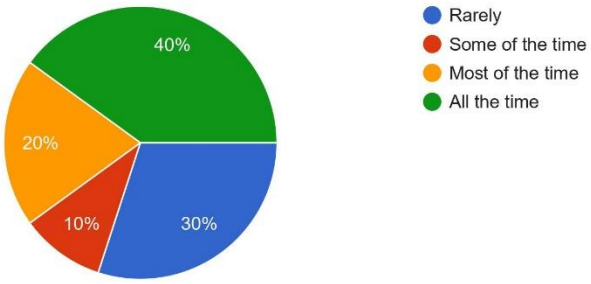
20 responses



3. Intrusion sensors and alarms

Copy

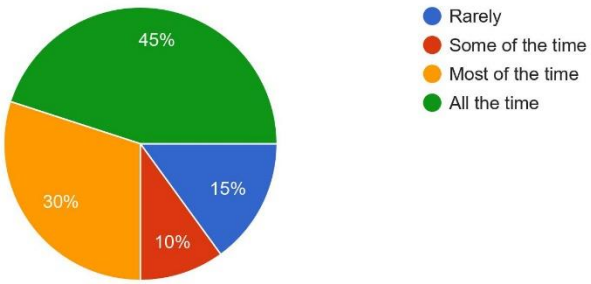
20 responses



4. A lighted building at night

Copy

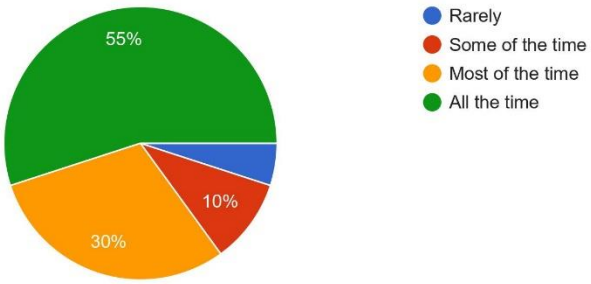
20 responses



5. Locked cabinets

Copy

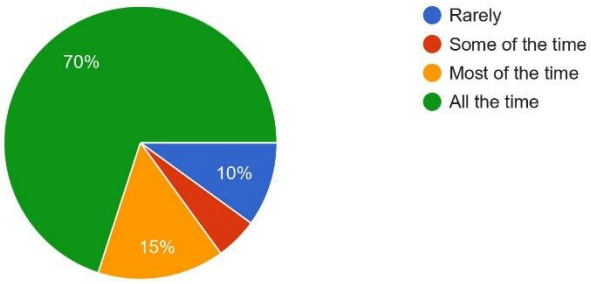
20 responses



6. Locked doors to building

Copy

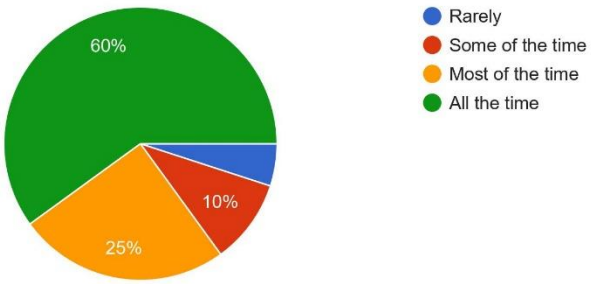
20 responses



7. Locked doors to laboratory room(s)

Copy

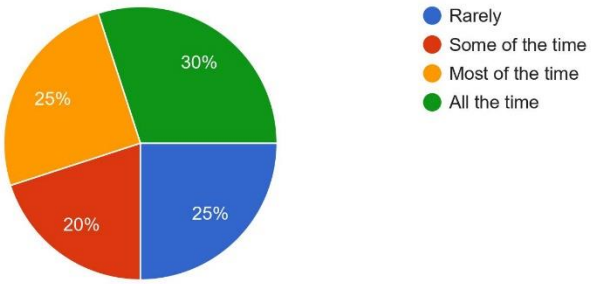
20 responses



8. Locked refrigerators

Copy

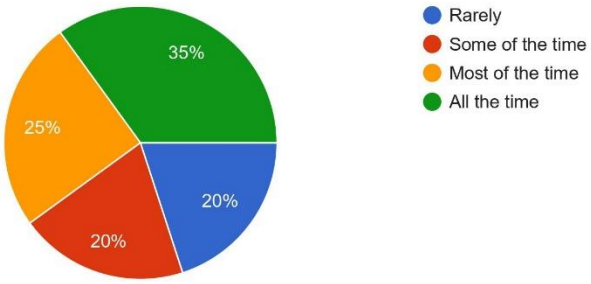
20 responses



9. Security patrols

Copy

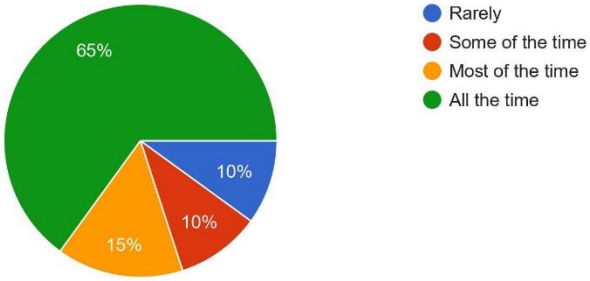
20 responses



10. Self-closing doors

Copy

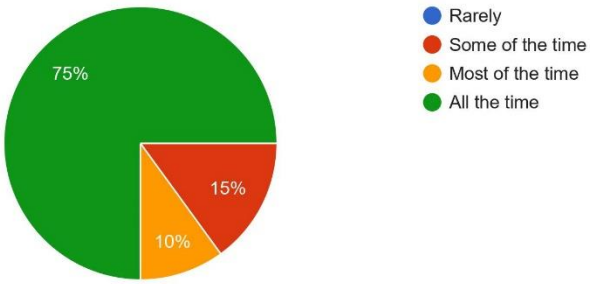
20 responses



11. Unobstructed views of the entrance(s)

Copy

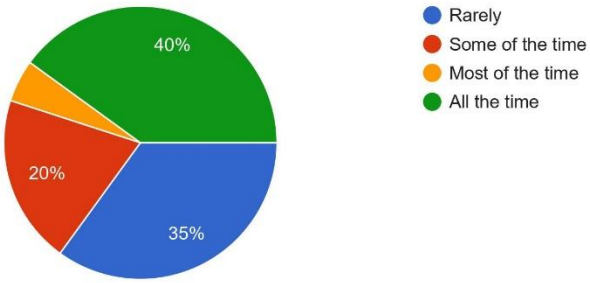
20 responses



12. Video monitors

Copy

20 responses

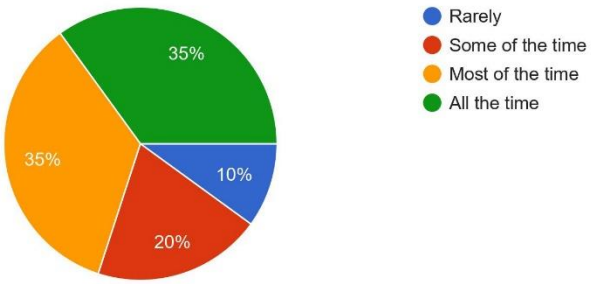


SECTION C: Facility Safeguards

1. Background screening for potential employees

Copy

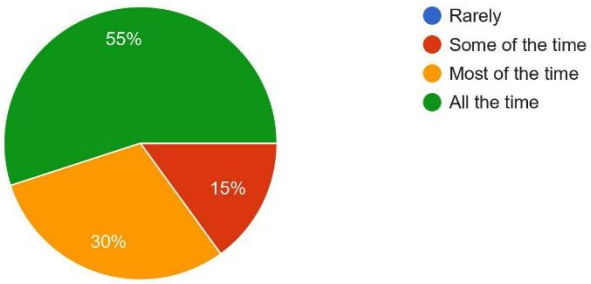
20 responses



2. Biosafety training for new employees

Copy

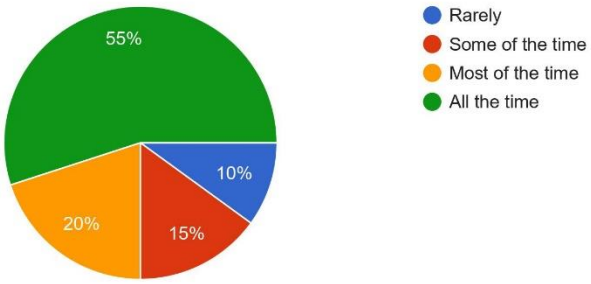
20 responses



3. Building escorts for nonemployees

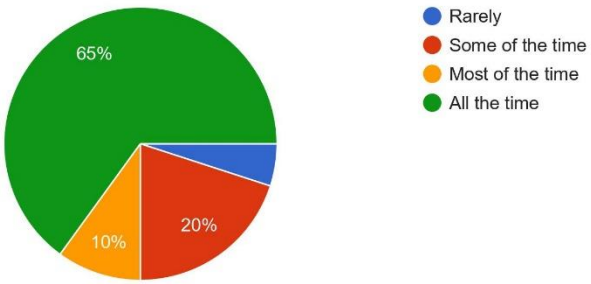
Copy

20 responses



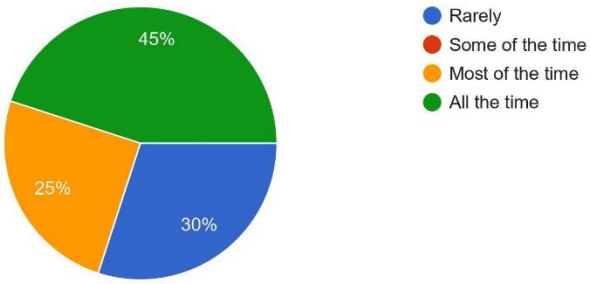
4. List of employees who have access to restricted areas. Copy

20 responses



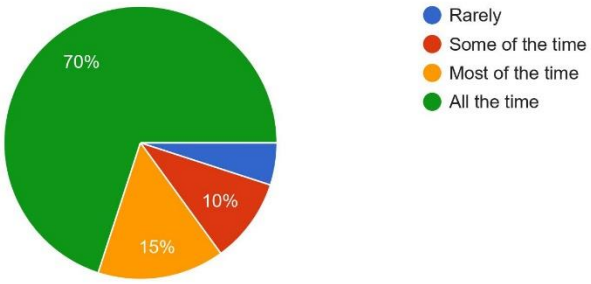
5. Identification badges Copy

20 responses



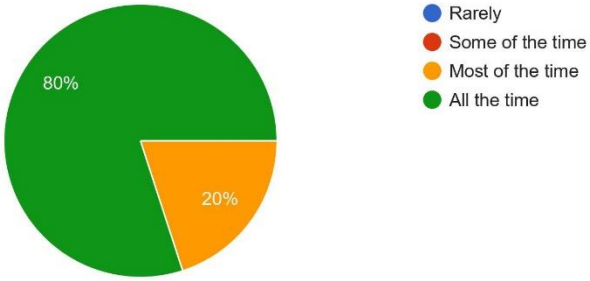
6. Records of key card/key assignments Copy

20 responses



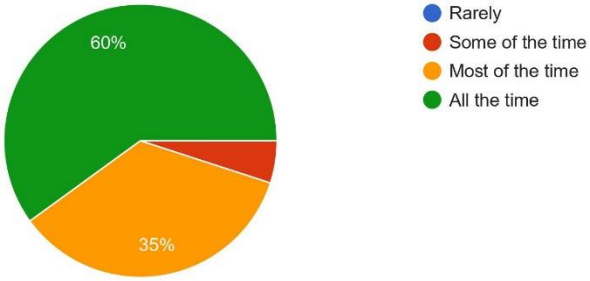
7. Restricted access to laboratory areas handling/storage of LMOs. Copy

20 responses



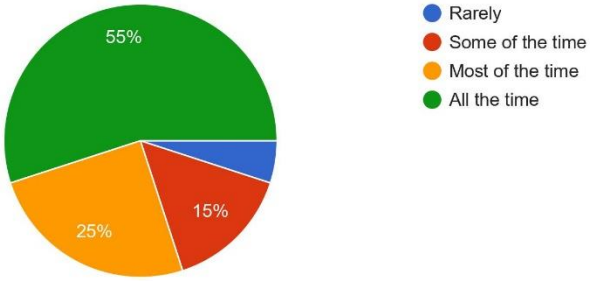
8. Assess and monitor the facilities, procedures, practices, training, and expertise of personnel involved in LMO research. Copy

20 responses



9. There is an updated list available of personnel with authorized access to biological agents. Copy

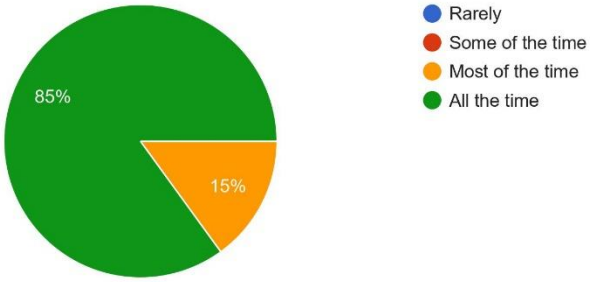
20 responses



10. There are procedures in place for decontamination and waste management.

Copy

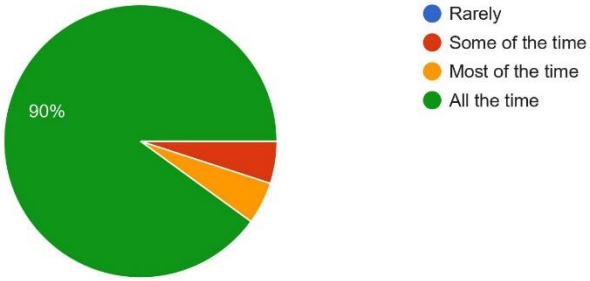
20 responses



11. Everyone in the facility decontaminates materials before disposing of contaminated materials.

Copy

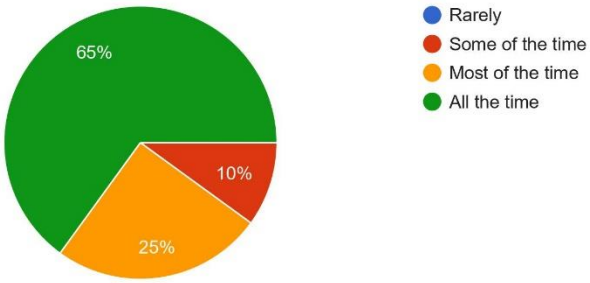
20 responses



12. Prior to being granted access to pathogens and toxins, workers are screened for appropriate credentials, skills, and personal traits for the job, and determined to be the best fit for the position.

Copy

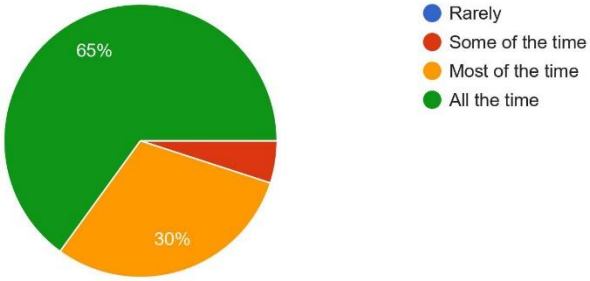
20 responses



SECTION D: Data Security

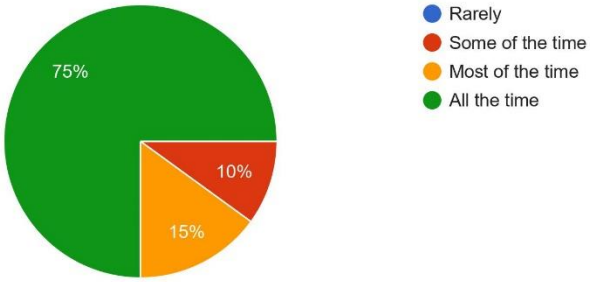
1. Computer/network security should always be maintained. Copy

20 responses



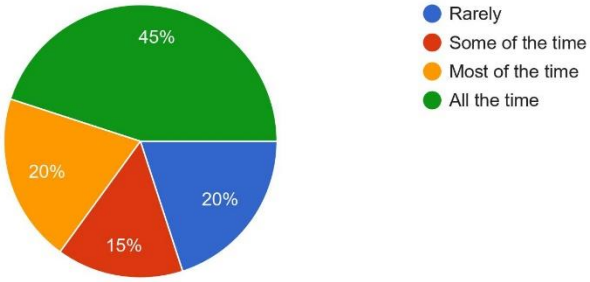
2. Computers and/or computer files are password protected. Copy

20 responses



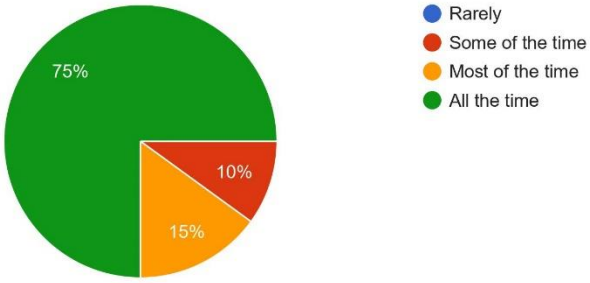
3. All data are stored in personal cloud storage (e.g., Google Drive, Microsoft OneDrive) Copy

20 responses



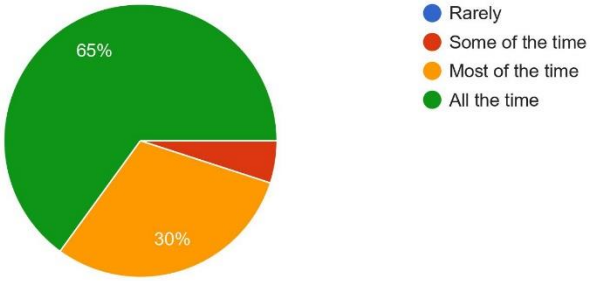
4. Sensitive and confidential documentation is destroyed before putting in the trash. Copy

20 responses



5. Secure storage of sensitive and confidential documents. Copy

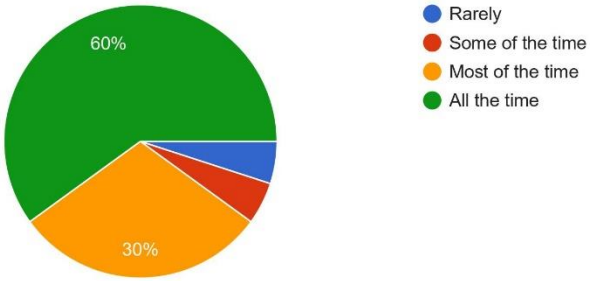
20 responses



SECTION E: Storage, Movement, and Transport of LMOs and Related Materials

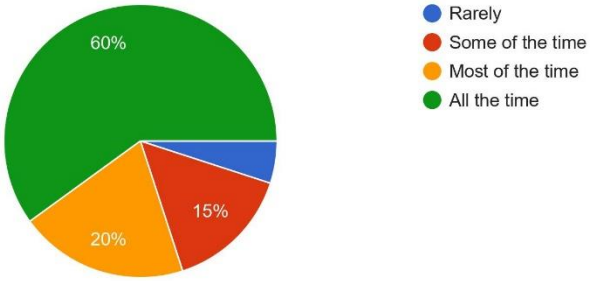
1. Appropriate permission(s) obtained to share infectious agents and/or toxins with other investigators/labs. Copy

20 responses



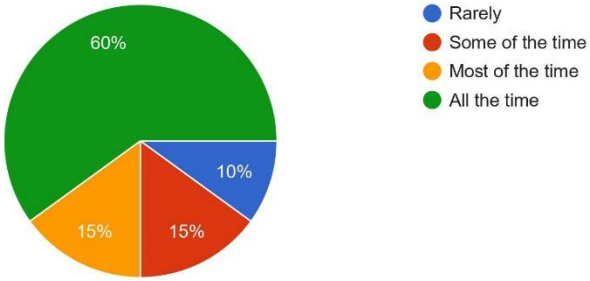
2. Current inventory of LMOs, infectious agents and/or toxins. Copy

20 responses



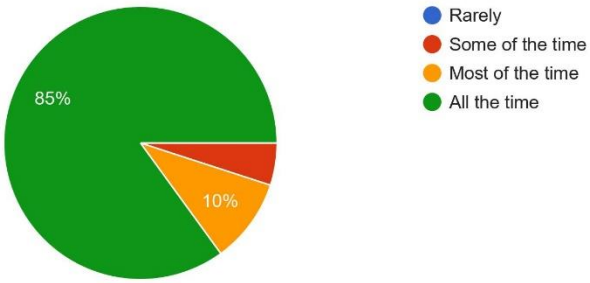
3. Inventory records are checked against actual LMOs, and infectious agents in storage. Copy

20 responses



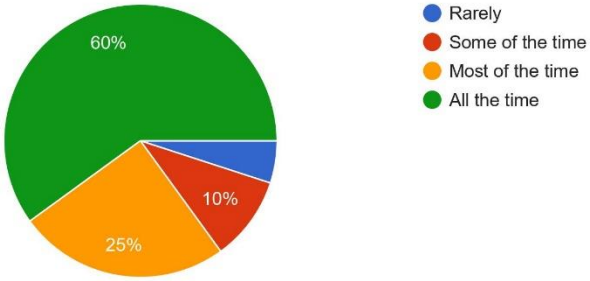
4. The direct supervisor is aware of all LMOs, infectious agents and/or toxins studied in the lab. Copy

20 responses



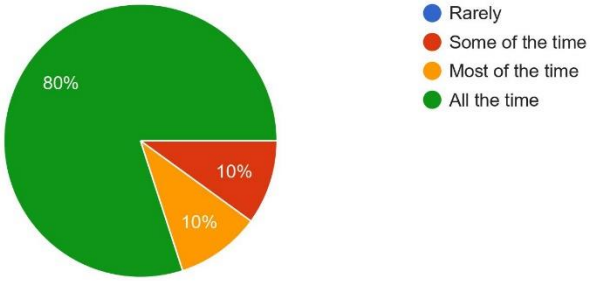
5. LMOs, Infectious agents and/or toxins not in use are destroyed. Copy

20 responses



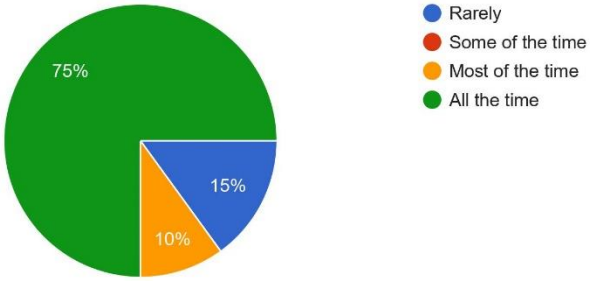
6. The laboratory head is aware of all LMOs, infectious agents and/or toxins studied in the lab. Copy

20 responses



7. Shipment of LMO, infectious agents and/or toxins using International Air Transport Association IATA Dangerous Goods Regulations. Copy

20 responses



8. LMOs are kept securely in designated spaces.

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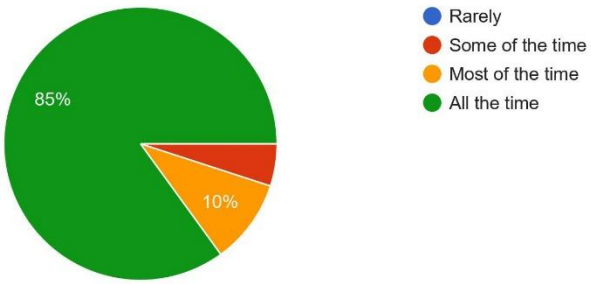
20 responses



PART 3: GENERAL INFORMATION

1. Name of Institution/ Company / Lab/ Research Group:

20 responses

IBX ProTech Sdn. Bha.

Malaysian Vaccines and Pharmaceuticals Sdn Bhd

International Medical University

lembaga

Universiti Malaya

Universiti Malaysia Pahang

Malaysia Genome & Vaccine Institute

Malaysian Palm Oil Board

CRYOCORD

CEBAR, UM

Malaysian Vaccines and Pharmaceuticals

CJ Bio Malaysia Sdn. Bhd.

ACGT Sdn. Bhd.

Institute For Medical Research (IMR)

IBX Protech Sdn Bhd

Universiti Kebangsaan Malaysia

siti suhaila binti a rahman/forest research institute malaysia (FRIM)/Genetic lab & Tissue Culture LabBSL 1 and 2

Universiti Tunku Abdul Rahman

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2. Select the most appropriate job category for your role (multiple selection allowed).

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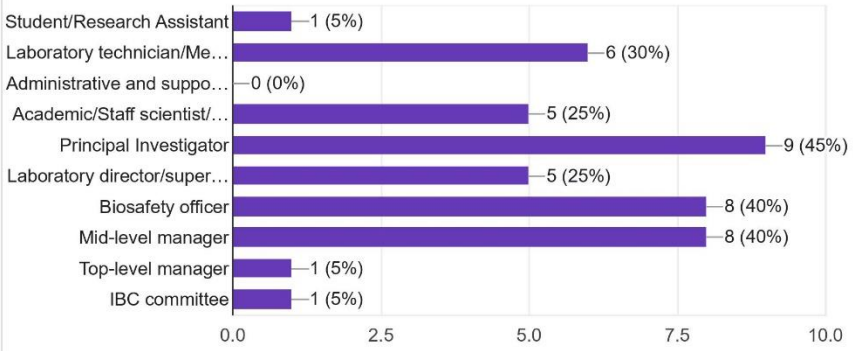
20 responses



3. Select the option that BEST describes your organization. (Choose only one)

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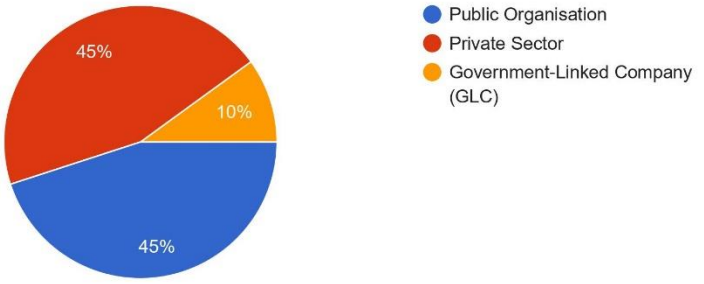

4. What is your level of experience and training in biosafety? (Choose only one)

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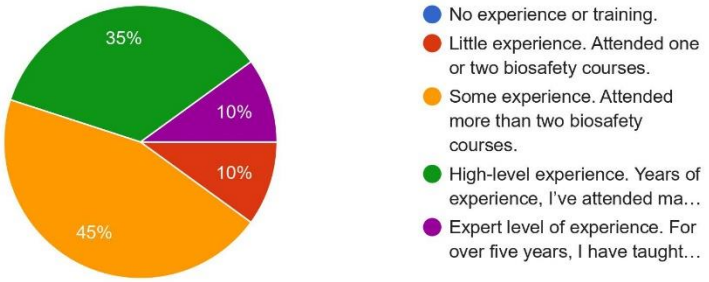

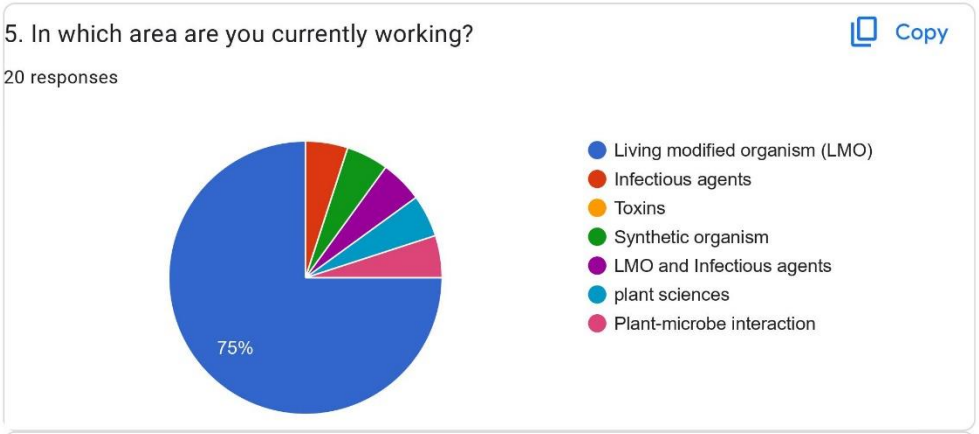

Thank you for your feedback. We really appreciate your time.

Lapiran 4 Skema jawapan dan pemarkahan

Checklist for IBC

PART 1: KNOWLEDGE AND AWARENESS

Please read each statement carefully and indicate your level of understanding by selecting one of the following options.

Yes	No	Not sure

Please ensure that you respond to each question. If you are unsure about a particular statement, select the option that most closely aligns with your view.

Before you start, please indicate the highest Biosafety Level (BSL) of your current research project involving LMO/rDNA activities.

( ) Biosafety Level 1 (BSL-1)
( ) Biosafety Level 2 (BSL-2)
( ) Biosafety Level 3 (BSL-3)
( ) Biosafety Level 4 (BSL-4)

SECTION A: General Knowledge about Biosafety					
The purpose of this section is to assess the basic understanding of all parties **(IBC, Head/top management, PI, laboratory users)** on Biosafety. This section is to be completed by **ALL** respondents.					
1.	Biosafety Act is only applicable for research related to LMO/ rDNA to manage relevant risks to human, animal, and plant life and associated risks for the environment.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
2.	Biosecurity is to protect, control, and accountability of LMO/ rDNA within facilities in order to prevent their loss, theft, misuse, diversion, unauthorized access, or intentional unauthorized release.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	An LMO is any living organism that possesses a novel combination of genetic material obtained by modern biotechnology.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
4.	It is essential to obtain approval from the IBC prior to starting the cross-breeding activity between two breeds of animals to produce a new breed.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
5.	Selective breeding to produce individual crops with the most desirable traits does not necessarily obtain approval from the IBC prior to starting breeding activity.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**

6.	Institutional policies or biosafety guidelines regarding the handling of LMO and related measures are intended to reduce the risks of unintentional and/or intentional release of LMOs.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
7.	The release activity of any intentional introduction of LMOs or products of such organisms into the environment is strictly prohibited and is only allowed in close contained areas.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
8.	A recombinant DNA (rDNA) molecule is a molecule that is constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
9.	A risk assessment of LMO is performed to determine the appropriate containment facility, equipment, and work practices that will promote the safe conduct of the research project.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
10.	It is optional for organisations which undertake modern biotechnology research and development, to establish an Institutional Biosafety Committee (IBC) to ensure that any LMO/rDNA research complies with the Malaysian Biosafety Act 2007.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
11.	Reporting non-compliance with the Malaysia Biosafety Act in organizations undertaking modern biotechnology research and development is the responsibility of JBK and not the IBC.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
SECTION B: Roles and Responsibilities in Compliance with Biosafety					
This section is designed to assess the understanding and perspective of the IBC, top management, PIs, and laboratory users on their respective roles, responsibilities, and functions in compliance with Biosafety measures.					
No. 1 to 5 is to be completed by **ALL** *respondents.*					
1.	IBC is a formal expert committee of an organization undertaking modern biotechnology work which involves the use of any LMO/ rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	IBC is composed of members who are appointed by the Head of the organization and	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1;**

	approved by the National Biosafety Board (NBB).				**Not sure = 0**
3.	A Biological Safety Officer (BSO) is a member of IBC appointed by the Head of the organization, responsible to submit all applications for approval and the annual report of IBC to the NBB, on behalf of the organization.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
4.	IBC is responsible to/for				
	k) Provide guidance to PI on biosafety policies and issues in the use of LMO/rDNA research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	l) Approve the LMO/rDNA research that was found to conform to Biosafety Act and Biosafety (Approval and Notification) Regulations.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	m) Assess and monitor the facilities, procedures, practices, training, and expertise of personnel involved in LMO/rDNA research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	n) Allow continuation of projects dealing with LMO/rDNA materials that are not compliant with the Biosafety Act 2007 if the project has previously obtained approval from NBB.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	o) Notify the PI of the results of the IBC's review, approval, or rejection of their application for approval and notification of all activities involving the use of LMO/rDNA to the NBB.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	p) Assess and set containment levels for LMO/rDNA research and modify containment levels as necessary.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	q) Assess field experiments to ensure that the proposed risk assessment, risk management and emergency response plan are sufficient.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	r) Adopt and implement an emergency response plan covering accidental spills and personnel contamination, resulting from LMO/rDNA research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	s) Review and report to the Head of the organisation, but not to the NBB of any significant problems with non-compliance with the Biosafety Act 2007	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**

	and Biosafety (Approval and Notification) Regulations 2010 and any significant research-related accidents or illnesses.				
	t) Assist in the development of appropriate procedures as required by NBB only when unintended release and/or breach of containment and/or spill or occupational exposure to LMO/rDNA materials occurred.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
5.	IBC approval is required for the following activities:				
	k) Deliberate transfer of a drug resistance trait to microorganisms.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	l) Deliberate transfer of rDNA or DNA/ RNA derived from rDNA into human research participants (human gene transfer).	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	m) Use of Risk Group 2, Risk Group 3, or Risk Group 4 agents as host-vector systems.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	n) Cloning of DNA from Risk Group 2 or greater agents into non-pathogenic prokaryotes or lower eukaryotic host-vector systems.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	o) Use of infectious or defective Risk Group 2 or greater agents.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	p) Use of whole animals in which the animal's genome has been altered by the stable introduction of rDNA or DNA/ RNA derived from rDNA into a germline (transgenic animal).	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	q) Viable rDNA-modified microorganism tested on whole animals.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	r) Genetically engineered plants by rDNA methods with desirable traits.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**

	s) Selective breeding plants through cross-pollination with desirable traits.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	t) The formation of rDNA material containing one-third or more of the genome of a eukaryotic virus.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
No. 6 to 13 is to be completed by **BSO/IBC members ONLY**					
6.	IBC may not use external consultants for advice and information.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
7.	An IBC meeting shall be conducted at least once a year to review and approve projects as well as to conduct a project extension review of approved projects.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
8.	At least 80% of the IBC membership (excluding members with a conflict of interest) must be present during a meeting to approve or disapprove the non-exempt projects of LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
9.	A lost number of quorums at any time during the meeting will cause the meeting to be adjourned until a quorum is re-established.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
10.	Members who fail to attend IBC meetings on a regular basis or fail to contribute to the research review process may be removed from the committee.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
11.	All records which required the information for every approved project should be retained with IBC for at least three years after the completion of a research project.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
12.	IBC members who have conflicts of interest should at least be present during IBC's initial or project extension review.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
13.	BSO is responsible to:				
	f) Report to the IBC any significant problems, non-compliance with the Biosafety Act, and any significant research-related accidents or illness of which BSO become aware.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	g) Guide PI in developing an emergency response plan for handling and	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1;**

	investigating laboratory accidents involving LMO/rDNA materials.				**Not sure = 0**
	h) Work with Rapid Response Team to provide technical advice on research safety and laboratory security procedures to PI, laboratory personnel and the IBC.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	i) Serve as a liaison officer between the organization/institution and external regulatory agencies concerning the use of LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	j) Serve as a voting member of the IBC.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
No. 14 is to be completed by **ALL** *respondents*					
14.	If the project/ research is non-compliance with the Biosafety Act, IBC may:				
	g) Suspend the use of LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	h) Cease the approval for the use of the LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	i) Confiscate the LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	j) Destruct the LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	k) Any other action necessary to protect the public and/or the organisation.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	l) Report to head/top management only, not necessarily to NBB.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
SECTION C: LMO/rDNA Activities					
This section is specifically for individuals involved in LMO and rDNA activities. The purpose of this section is to gather information about their knowledge of the processes and procedures required for LMO/rDNA activities. This section is to be completed by **ALL** respondents.					

1.	For the review of LMO/rDNA activity, project extension, and notice of termination, PI is required to				
	h) Submit the relevant application as prescribed by the NBB, the IBC assessment form and a copy of the document of the approved research grant for the LMO/rDNA project.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	i) Submit the application form to NBB once approved by IBC.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	j) Start an experiment with LMO/rDNA before notification of LMO work is submitted, if the work is very important.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	k) Provide data reporting and adverse event reporting to monitor the proposed LMO/rDNA research, and the reports should be submitted to IBC.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	l) Notify JBK of the proposed project if the research work falls into any of the exemptions.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	m) Complete and submit the IBC Project Extension Review/ Notice of Termination Form to IBC Chair at least one week before the next scheduled IBC meeting or at the appropriate time intervals as stipulated by the IBC.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	n) Complete the Notice of Termination Form and file the form in the laboratory record when the research project involving registered LMO/rDNA materials is completed/no longer active, or when the LMO/rDNA materials are properly disposed of or no longer in the possession of the PI.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
2.	Biosafety (Approval and Notification) Regulations 2010 forbid exemption for all types of LMO/rDNA.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
3.	For the review of LMO/rDNA activity, project extension, and notice of termination, IBC/ IBC Chair is required to				

	d) Review the proposed activity involving LMO/rDNA materials by referring to the Biosafety Guidelines for Contained Use Activity of LMOs and other relevant documents, including IBC policies and procedures for the organisation.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	e) Assess the facilities, procedures, practices, training, and expertise of personnel involved in the LMP/rDNA research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	f) Provide written notification of the IBC's decision to PI.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
4.	Exempted work must also be carried out according to the Biosafety Act and should be periodically monitored by IBC.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
5.	The IBC should review all submitted research projects to determine their exemption or non-exemption status.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
6.	Access to the laboratory should be restricted when work with the LMO/rDNA materials is in progress.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
7.	In the case of an incident, follow the safety protocols outlined in the approved emergency response plan prepared by PI for the specific project and laboratory.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
8.	Ensure the LMO/rDNA materials are always kept secure.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
9.	The emergency response plan must be kept secure in a file at the designated laboratory.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
SECTION D: Training					
The purpose of this section is to know whether IBC members and individuals conducting research with LMO/rDNA materials received proper and adequate Biosafety training.					
No. 1 is to be completed by an **IBC member/ BSO ONLY**					

1.	f) IBC members should receive initial mandatory and refresher training on Biosafety, the Biosafety Act 2007, Biosafety (Approval and Notification) Regulations 2010 and related regulations as well as IBC policies.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	g) IBC members should receive refresher training on any changes to national guidelines.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	h) All training related to biosafety should be organized by JBK with commitment from the organisation and guidance from NBB.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	i) IBC Chair is responsible to provide the training for the IBC members and BSO documents it.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	j) BSO should attend biosafety training with commitment from the organisation and guidance from NBB.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION E: Emergency Response Plan					
This section focuses on the role of IBC, PI, and laboratory personnel in creating an appropriate emergency response plan. This section is to be completed by **ALL** respondents.					
1.	The emergency response plan (and any revision thereof) must be formally adopted by the IBC pursuant to all National Biosafety policies and organisational policies.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	The emergency response plan will be reviewed periodically based on new information from internal findings and/or external development.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	Method and procedures for controlling the LMO(s) in case of unintentional release should be prepared by personnel involved in LMO research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

4.	Details of any contingency measures should be in place for protecting human health and the environment in case of the occurrence of an undesirable effect caused by the unintentional release.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
5.	OHSC should coordinate the occupational health and safety services to ensure appropriate occupational health and safety surveillance for laboratory personnel involved in research approved by the IBC.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
6.	PI will use the Occupational Disease/Exposure Investigation Form to make a formal report within 24 hours to the OHSC, IBC, and NBB if there is any accidental exposure to LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION F: Laboratory Inspection and Biosafety Manuals					
This section focuses on the role of IBC, PI, and laboratory personnel in conducting laboratory inspection and preparation of biosafety manuals for proper documentation and inspection carried out at facilities working with LMO/rDNA. This section is to be completed by **ALL** respondents.					
1.	IBC members, as well as representatives and officers authorized by the NBB, are allowed to access the laboratories that are registered for activities with LMO/rDNA materials for inspection purposes by appointment only.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
2.	A collection of biosafety protocols and procedures (safety manual) at least one hard copy must be kept secure and not necessarily at the designated laboratory.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
3.	Detailed descriptions of all facilities being used for LMO-contained use activities should be properly documented.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
4.	PI should ensure the integrity of the biological and physical containment/ biosafety level.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
5.	IBC should review biosafety protocols during the inspection of facilities and laboratories.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
6.	IBC will inspect laboratories using a checklist according to the procedures outlined in the Biosafety (Approval and Notification) Regulations 2010.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION H: Security of LMO/rDNA Materials					

This section is to evaluate the comprehension and understanding of the responsibility of PI and laboratory users in securing LMO/rDNA materials to safeguard LMO/rDNA materials from unauthorized access, loss, theft, or misuse. This section is to be completed by **ALL** respondents.					
1.	PI and/ or all associated personnel				
	d) Must be conscientious in controlling the biological materials and should be held accountable for them.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	e) Should limit access to biological materials to authorised personnel only.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	f) Should perform a risk vulnerability assessment and develop a plan to protect the security of the material in question, depending on the Risk Group the biological agent may pose.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	Chain-of-custody forms within laboratories should be made available to track LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	Log of access to areas where biological materials are in use should be in place.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION I: Disposal					
The purpose of this section is to assess the disposal methods and protocols in place and to evaluate the effectiveness of disposal procedures for the proper disposal of LMO/rDNA materials. This section is to be completed by **ALL** respondents.					
1.	Potentially hazardous biological material and LMO/rDNA materials are to be considered "regulated waste" and should be disposed of in a manner consistent with national regulations and related guidelines.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	The laboratory supervisor or other person with operational responsibility should ensure compliance with requirements for proper segregation of laboratory waste to ensure a safe work environment.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	The exempted LMO wastes are not necessarily to be inactivated prior to leaving the facility.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**

4.	Each individual working with LMO material should be responsible for its sterilisation before disposal.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
5.	For disposal purposes, the exempted LMO material should be treated in the same way as infectious and potentially infectious material.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
6.	Ordinary waste should be placed into ordinary waste bins (these bins should not be yellow) that will be emptied by the cleaners in all rooms, except laboratories.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
7.	In laboratories, cleaners may be allowed to empty the bins for non-laboratory material (e.g., cardboard boxes, paper) only under supervision.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION J: Packaging, Transportation, Import, and Export of LMO/rDNA Materials					
This section focuses on assessing the security measures as well as responsibilities of IBC, PI, and laboratory personnel and protocols in place for the handling, storage, packaging, and transportation of LMO (Living Modified Organism) and rDNA (recombinant DNA) materials. This section is to be completed by **ALL** respondents.					
1.	Regulated LMO/rDNA materials will be packaged and transported in a manner compliant with national and international regulations and related guidelines.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	PI is responsible to obtain permits when handling LMO materials or conducting activities which require additional permits (e.g., import permits etc.)	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	For the movement and transport of LMO and related materials, the following shall apply:				
	j) The regulatory authorities (IBC and NBB) shall be notified using the relevant forms.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	k) LMO being transferred should be packaged in secure containers capable of preventing material loss during transportation.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	l) LMO should be kept separate from other materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

	m) If an unintentional release of LMO during transport occurs, all attempts should be made to recover as much of the materials as possible.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	n) The location of the unintentional release of LMO should be marked and treated in a manner that ensures that no additional release of materials occurs.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	o) Corrective actions taken for unintentional release of LMO should be documented and the regulatory authorities notified.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	p) Adequate records of the transport of LMO, as they move between research facilities, storage facilities and field trial sites, should be maintained by PI and not necessarily by IBC.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	q) The shipper should notify the recipient of the date, kind and amount of material that will be sent before shipping.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	r) Upon receiving the material, the recipient should confirm that the shipment has arrived intact, and that no material has been lost.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

PART 2: BIOSAFETY PRACTICES

Please indicate the proportion of time that your laboratory uses or performs the following BIOSAFETY MEASURES based on the scales provided below.

Rarely	**Some of the time**	**Most of the time**	**All the time**

SECTION A: Biosafety Practices						
No. 1 to 11 is to be completed by **ALL** *respondents.*						
1.	Decontaminating LMO waste before disposal	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
2.	Segregating LMO waste	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**

3.	Use of appropriate PPE when handling LMOs	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
4.	Dedicated sharps containers for disposal of sharps used for handling LMOs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
5.	Assess and set containment levels of LMOs and modify them as necessary.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
6.	Use of Biological Safety Cabinet for work with LMOs materials.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
7.	Periodically review research projects that are recommended for approval.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
8.	Adopt and implement emergency response plans covering accidental spills and personnel contamination, resulting from LMO/rDNA research.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
9.	There is an up-to-date list available of personnel with authorized access to LMOs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
10.	Wear closed toes shoes	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
11.	Wear lab coats/lab gowns	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
SECTION B: Safety Equipment						
This section is to be completed by **ALL** *respondents.*						
1.	Electronic access control devices	**Rarely**	**Some of**	**Most of**	**All the time**	**All the time = 4; Most of the time = 3; Some of the**

			the time	**the time**		**time = 2; Rarely = 1**
2.	Guard at building entrance(s)	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
3.	Intrusion sensors and alarms	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
4.	A lighted building at night	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
5.	Locked cabinets	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
6.	Locked doors to building	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
7.	Locked doors to laboratory room(s)	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
8.	Locked refrigerators	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
9.	Security patrols	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
10.	Self-closing doors	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
11.	Unobstructed views of the entrance(s)	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**

12.	Video monitors	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
SECTION C: Facility Safeguards						
This section is to be completed by **ALL** *respondents.*						
1.	Background screening for potential users.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
2.	Biosafety training for new users.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
3.	Security escort to the building for non-users or visitors.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
4.	List of users who have access to restricted areas.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
5.	Identification badges	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
6.	Records of key card/key assignments	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
7.	Restricted access to laboratory areas handling/storage of LMOs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
8.	Assess and monitor the facilities, procedures, practices, training, and expertise of personnel involved in LMO research.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
9.	There is an updated list available of personnel with authorized access to biological agents.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the**

						time = 2; Rarely = 1
10.	There are procedures in place for decontamination and waste management.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
11.	Everyone in the facility decontaminates materials before disposing of contaminated materials.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
12.	Prior to being granted access to LMOs, workers are screened for appropriate credentials, skills, and personal traits for the job, and determined to be the best fit for the position.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
SECTION D: Storage, Movement, and Transport of LMOs and Related Materials						
This section is to be completed by **ALL** *respondents.*						
1.	Appropriate permission(s) obtained to share LMO materials with other investigators/labs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
2.	Current inventory of LMOs, and rDNA materials.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
3.	Inventory records are checked against actual LMOs, and/or rDNA materials in storage.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
4.	The PI is aware of all LMOs, and/or rDNA studied in the lab.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
5.	LMOs, and/or rDNA not in use are destroyed.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
6.	The laboratory head is aware of all LMOs, and/or rDNA studied in the lab.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the**

						time = 2; Rarely = 1
7.	Shipment of LMO materials using International Air Transport Association IATA Dangerous Goods Regulations.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
8.	LMOs are kept securely in designated spaces.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**

Checklist for Head/Top management

PART 1: KNOWLEDGE AND AWARENESS

Please read each statement carefully and indicate your level of understanding by selecting one of the following options.

Yes	No	Not sure

Please ensure that you respond to each question. If you are unsure about a particular statement, select the option that most closely aligns with your view.

Before you start, please indicate the highest Biosafety Level (BSL) of your current research project involving LMO/rDNA activities.

( ) Biosafety Level 1 (BSL-1)
( ) Biosafety Level 2 (BSL-2)
( ) Biosafety Level 3 (BSL-3)
( ) Biosafety Level 4 (BSL-4)

SECTION A: General Knowledge about Biosafety					
The purpose of this section is to assess the basic understanding of all parties **(IBC, Head/top management, PI, laboratory users)** on Biosafety. This section is to be completed by **ALL** respondents.					
1.	Biosafety Act is only applicable for research related to LMO/ rDNA to manage relevant risks to human, animal, and plant life and associated risks for the environment.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
2.	Biosecurity is to protect, control, and accountability of LMO/ rDNA within facilities in order to prevent their loss, theft, misuse, diversion, unauthorized access, or intentional unauthorized release.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

3.	An LMO is any living organism that possesses a novel combination of genetic material obtained by modern biotechnology.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
4.	It is essential to obtain approval from the IBC prior to starting the cross-breeding activity between two breeds of animals to produce a new breed.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
5.	Selective breeding to produce individual crops with the most desirable traits does not necessarily obtain approval from the IBC prior to starting breeding activity.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
6.	Institutional policies or biosafety guidelines regarding the handling of LMO and related measures are intended to reduce the risks of unintentional and/or intentional release of LMOs.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
7.	The release activity of any intentional introduction of LMOs or products of such organisms into the environment is strictly prohibited and is only allowed in close contained areas.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
8.	A recombinant DNA (rDNA) molecule is a molecule that is constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
9.	A risk assessment of LMO is performed to determine the appropriate containment facility, equipment, and work practices that will promote the safe conduct of the research project.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
10.	It is optional for organisations which undertake modern biotechnology research and development, to establish an Institutional Biosafety Committee (IBC) to ensure that any LMO/rDNA research complies with the Malaysian Biosafety Act 2007.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
11.	Reporting non-compliance with the Malaysia Biosafety Act in organizations undertaking modern biotechnology research and development is the responsibility of JBK and not the IBC.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
SECTION B: Roles and Responsibilities in Compliance with Biosafety					

This section is designed to assess the understanding and perspective of the IBC, top management, PIs, and laboratory users on their respective roles, responsibilities, and functions in compliance with Biosafety measures.					
No. 1 to 5 is to be completed by **ALL** *respondents.*					
1.	IBC is a formal expert committee of an organization undertaking modern biotechnology work which involves the use of any LMO/ rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	IBC is composed of members who are appointed by the Head of the organization and approved by the National Biosafety Board (NBB).	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
3.	A Biological Safety Officer (BSO) is a member of IBC appointed by the Head of the organization, responsible to submit all applications for approval and the annual report of IBC to the NBB, on behalf of the organization.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
4.	IBC is responsible to/for				
	a) Provide guidance to PI on biosafety policies and issues in the use of LMO/rDNA research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) Approve the LMO/rDNA research that was found to conform to Biosafety Act and Biosafety (Approval and Notification) Regulations.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) Assess and monitor the facilities, procedures, practices, training, and expertise of personnel involved in LMO/rDNA research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	d) Allow continuation of projects dealing with LMO/rDNA materials that are not compliant with the Biosafety Act 2007 if the project has previously obtained approval from NBB.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	e) Notify the PI of the results of the IBC's review, approval, or rejection of their application for approval and notification of all activities involving the use of LMO/rDNA to the NBB.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	f) Assess and set containment levels for LMO/rDNA research and modify containment levels as necessary.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	g) Assess field experiments to ensure that the proposed risk assessment, risk	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1;**

	management and emergency response plan are sufficient.				**Not sure = 0**
	h) Adopt and implement an emergency response plan covering accidental spills and personnel contamination, resulting from LMO/rDNA research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	i) Review and report to the Head of the organisation, but not to the NBB of any significant problems with non-compliance with the Biosafety Act 2007 and Biosafety (Approval and Notification) Regulations 2010 and any significant research-related accidents or illnesses.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	j) Assist in the development of appropriate procedures as required by NBB only when unintended release and/or breach of containment and/or spill or occupational exposure to LMO/rDNA materials occurred.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
5.	IBC approval is required for the following activities:				
	a) Deliberate transfer of a drug resistance trait to microorganisms.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) Deliberate transfer of rDNA or DNA/ RNA derived from rDNA into human research participants (human gene transfer).	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) Use of Risk Group 2, Risk Group 3, or Risk Group 4 agents as host-vector systems.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	d) Cloning of DNA from Risk Group 2 or greater agents into non-pathogenic prokaryotes or lower eukaryotic host-vector systems.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	e) Use of infectious or defective Risk Group 2 or greater agents.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	f) Use of whole animals in which the animal's genome has been altered by the stable introduction of rDNA or DNA/ RNA derived from rDNA into a germline (transgenic animal).	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

	g) Viable rDNA-modified microorganism tested on whole animals.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	h) Genetically engineered plants by rDNA methods with desirable traits.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	i) Selective breeding plants through cross-pollination with desirable traits.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	j) The formation of rDNA material containing one-third or more of the genome of a eukaryotic virus.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
No. 6 is to be completed by **Top management ONLY** *(Vice Chancellor, CEO, Director General, Director, HOD)*					
6.	The head is responsible to				
	g) Have awareness of all requirements regarding compliance with the Biosafety Act and any related regulations regarding LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	h) Provide leadership and support at the management level for laboratories.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	i) Ensure that PI provides appropriate training for laboratory personnel prior to the initiation of research involving LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	j) Support works and decisions of IBC.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	k) Ensure that related educational activities are conducted to educate the investigators before the initiation of research involving LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	l) Act as an observer in the case of determining which facilities are	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

	appropriate and safe for proposed research involving LMO/rDNA.				
No. 7 is to be completed by **ALL** *respondents*					
7	If the project/ research is non-compliance with the Biosafety Act, IBC may:				
	a) Suspend the use of LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) Cease the approval for the use of the LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) Confiscate the LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	d) Destruct the LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	e) Any other action necessary to protect the public and/or the organisation.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	f) Report to head/top management only, not necessarily to NBB.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
SECTION C: LMO/rDNA Activities					
This section is specifically for individuals involved in LMO and rDNA activities. The purpose of this section is to gather information about their knowledge of the processes and procedures required for LMO/rDNA activities. This section is to be completed by **ALL** respondents.					
1.	For the review of LMO/rDNA activity, project extension, and notice of termination, PI is required to				
	a) Submit the relevant application as prescribed by the NBB, the IBC assessment form and a copy of the document of the approved research grant for the LMO/rDNA project.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

	b) Submit the application form to NBB once approved by IBC.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) Start an experiment with LMO/rDNA before notification of LMO work is submitted, if the work is very important.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	d) Provide data reporting and adverse event reporting to monitor the proposed LMO/rDNA research, and the reports should be submitted to IBC.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	e) Notify JBK of the proposed project if the research work falls into any of the exemptions.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	f) Complete and submit the IBC Project Extension Review/ Notice of Termination Form to IBC Chair at least one week before the next scheduled IBC meeting or at the appropriate time intervals as stipulated by the IBC.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	g) Complete the Notice of Termination Form and file the form in the laboratory record when the research project involving registered LMO/rDNA materials is completed/no longer active, or when the LMO/rDNA materials are properly disposed of or no longer in the possession of the PI.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
2.	Biosafety (Approval and Notification) Regulations 2010 forbid exemption for all types of LMO/rDNA.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
3.	For the review of LMO/rDNA activity, project extension, and notice of termination, IBC/ IBC Chair is required to				
	a) Review the proposed activity involving LMO/rDNA materials by referring to the Biosafety Guidelines for Contained Use Activity of LMOs and other relevant documents, including IBC policies and procedures for the organisation.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) Assess the facilities, procedures, practices, training, and expertise of personnel involved in the LMP/rDNA research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

	c) Provide written notification of the IBC's decision to PI.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
4.	Exempted work must also be carried out according to the Biosafety Act and should be periodically monitored by IBC.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
5.	The IBC should review all submitted research projects to determine their exemption or non-exemption status.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
6.	Access to the laboratory should be restricted when work with the LMO/rDNA materials is in progress.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
7.	In the case of an incident, follow the safety protocols outlined in the approved emergency response plan prepared by PI for the specific project and laboratory.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
8.	Ensure the LMO/rDNA materials are always kept secure.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
9.	The emergency response plan must be kept secure in a file at the designated laboratory.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
SECTION E: Emergency Response Plan					
This section focuses on the role of IBC, PI, and laboratory personnel in creating an appropriate emergency response plan. This section is to be completed by **ALL** respondents.					
1.	The emergency response plan (and any revision thereof) must be formally adopted by the IBC pursuant to all National Biosafety policies and organisational policies.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	The emergency response plan will be reviewed periodically based on new information from internal findings and/or external development.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	Method and procedures for controlling the LMO(s) in case of unintentional release should be prepared by personnel involved in LMO research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

4.	Details of any contingency measures should be in place for protecting human health and the environment in case of the occurrence of an undesirable effect caused by the unintentional release.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
5.	OHSC should coordinate the occupational health and safety services to ensure appropriate occupational health and safety surveillance for laboratory personnel involved in research approved by the IBC.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
6.	PI will use the Occupational Disease/Exposure Investigation Form to make a formal report within 24 hours to the OHSC, IBC, and NBB if there is any accidental exposure to LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION F: Laboratory Inspection and Biosafety Manuals					
This section focuses on the role of IBC, PI, and laboratory personnel in conducting laboratory inspection and preparation of biosafety manuals for proper documentation and inspection carried out at facilities working with LMO/rDNA. This section is to be completed by **ALL** respondents.					
1.	IBC members, as well as representatives and officers authorized by the NBB, are allowed to access the laboratories that are registered for activities with LMO/rDNA materials for inspection purposes by appointment only.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
2.	A collection of biosafety protocols and procedures (safety manual) at least one hard copy must be kept secure and not necessarily at the designated laboratory.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
3.	Detailed descriptions of all facilities being used for LMO-contained use activities should be properly documented.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
4.	PI should ensure the integrity of the biological and physical containment/ biosafety level.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
5.	IBC should review biosafety protocols during the inspection of facilities and laboratories.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
6.	IBC will inspect laboratories using a checklist according to the procedures outlined in the Biosafety (Approval and Notification) Regulations 2010.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION H: Security of LMO/rDNA Materials					

This section is to evaluate the comprehension and understanding of the responsibility of PI and laboratory users in securing LMO/rDNA materials to safeguard LMO/rDNA materials from unauthorized access, loss, theft, or misuse. This section is to be completed by **ALL** respondents.					
1.	PI and/ or all associated personnel				
	a) Must be conscientious in controlling the biological materials and should be held accountable for them.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) Should limit access to biological materials to authorised personnel only.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) Should perform a risk vulnerability assessment and develop a plan to protect the security of the material in question, depending on the Risk Group the biological agent may pose.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	Chain-of-custody forms within laboratories should be made available to track LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	Log of access to areas where biological materials are in use should be in place.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION I: Disposal					
The purpose of this section is to assess the disposal methods and protocols in place and to evaluate the effectiveness of disposal procedures for the proper disposal of LMO/rDNA materials. This section is to be completed by **ALL** respondents.					
1.	Potentially hazardous biological material and LMO/rDNA materials are to be considered "regulated waste" and should be disposed of in a manner consistent with national regulations and related guidelines.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	The laboratory supervisor or other person with operational responsibility should ensure compliance with requirements for proper segregation of laboratory waste to ensure a safe work environment.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	The exempted LMO wastes are not necessarily to be inactivated prior to leaving the facility.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**

4.	Each individual working with LMO material should be responsible for its sterilisation before disposal.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
5.	For disposal purposes, the exempted LMO material should be treated in the same way as infectious and potentially infectious material.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
6.	Ordinary waste should be placed into ordinary waste bins (these bins should not be yellow) that will be emptied by the cleaners in all rooms, except laboratories.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
7.	In laboratories, cleaners may be allowed to empty the bins for non-laboratory material (e.g., cardboard boxes, paper) only under supervision.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION J: Packaging, Transportation, Import, and Export of LMO/rDNA Materials					
This section focuses on assessing the security measures as well as responsibilities of IBC, PI, and laboratory personnel and protocols in place for the handling, storage, packaging, and transportation of LMO (Living Modified Organism) and rDNA (recombinant DNA) materials. This section is to be completed by **ALL** respondents.					
1.	Regulated LMO/rDNA materials will be packaged and transported in a manner compliant with national and international regulations and related guidelines.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	PI is responsible to obtain permits when handling LMO materials or conducting activities which require additional permits (e.g., import permits etc.)	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	For the movement and transport of LMO and related materials, the following shall apply:				
	a) The regulatory authorities (IBC and NBB) shall be notified using the relevant forms.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) LMO being transferred should be packaged in secure containers capable of preventing material loss during transportation.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) LMO should be kept separate from other materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

	d) If an unintentional release of LMO during transport occurs, all attempts should be made to recover as much of the materials as possible.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	e) The location of the unintentional release of LMO should be marked and treated in a manner that ensures that no additional release of materials occurs.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	f) Corrective actions taken for unintentional release of LMO should be documented and the regulatory authorities notified.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	g) Adequate records of the transport of LMO, as they move between research facilities, storage facilities and field trial sites, should be maintained by PI and not necessarily by IBC.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	h) The shipper should notify the recipient of the date, kind and amount of material that will be sent before shipping.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	i) Upon receiving the material, the recipient should confirm that the shipment has arrived intact, and that no material has been lost.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

PART 2: BIOSAFETY PRACTICES

Please indicate the proportion of time that your laboratory uses or performs the following BIOSAFETY MEASURES based on the scales provided below.

Rarely	**Some of the time**	**Most of the time**	**All the time**

SECTION A: Biosafety Practices						
No. 1 to 11 is to be completed by **ALL** *respondents.*						
1.	Decontaminating LMO waste before disposal	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
2.	Segregating LMO waste	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
3.	Use of appropriate PPE when handling LMOs	**Rarely**	**Some of**	**Most of**	**All the time**	**All the time = 4;**

			the time	**the time**		**Most of the time = 3; Some of the time = 2; Rarely = 1**
4.	Dedicated sharps containers for disposal of sharps used for handling LMOs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
5.	Assess and set containment levels of LMOs and modify them as necessary.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
6.	Use of Biological Safety Cabinet for work with LMOs materials.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
7.	Periodically review research projects that are recommended for approval.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
8.	Adopt and implement emergency response plans covering accidental spills and personnel contamination, resulting from LMO/rDNA research.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
9.	There is an up-to-date list available of personnel with authorized access to LMOs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
10.	Wear closed toes shoes	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
11.	Wear lab coats/lab gowns	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
SECTION B: Safety Equipment						
This section is to be completed by **ALL** *respondents.*						
1.	Electronic access control devices	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
2.	Guard at building entrance(s)	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
3.	Intrusion sensors and alarms	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**

4.	A lighted building at night	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
5.	Locked cabinets	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
6.	Locked doors to building	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
7.	Locked doors to laboratory room(s)	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
8.	Locked refrigerators	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
9.	Security patrols	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
10.	Self-closing doors	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
11.	Unobstructed views of the entrance(s)	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
12.	Video monitors	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
SECTION C: Facility Safeguards						
This section is to be completed by **ALL** *respondents.*						
1.	Background screening for potential users.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
2.	Biosafety training for new users.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
3.	Security escort to the building for non-users or visitors.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**

4.	List of users who have access to restricted areas.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
5.	Identification badges	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
6.	Records of key card/key assignments	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
7.	Restricted access to laboratory areas handling/storage of LMOs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
8.	Assess and monitor the facilities, procedures, practices, training, and expertise of personnel involved in LMO research.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
9.	There is an updated list available of personnel with authorized access to biological agents.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
10.	There are procedures in place for decontamination and waste management.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
11.	Everyone in the facility decontaminates materials before disposing of contaminated materials.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
12.	Prior to being granted access to LMOs, workers are screened for appropriate credentials, skills, and personal traits for the job, and determined to be the best fit for the position.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
SECTION D: Storage, Movement, and Transport of LMOs and Related Materials						
This section is to be completed by **ALL** *respondents.*						
1.	Appropriate permission(s) obtained to share LMO materials with other investigators/labs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
2.	Current inventory of LMOs, and rDNA materials.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**

3.	Inventory records are checked against actual LMOs, and/or rDNA materials in storage.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
4.	The PI is aware of all LMOs, and/or rDNA studied in the lab.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
5.	LMOs, and/or rDNA not in use are destroyed.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
6.	The laboratory head is aware of all LMOs, and/or rDNA studied in the lab.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
7.	Shipment of LMO materials using International Air Transport Association IATA Dangerous Goods Regulations.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
8.	LMOs are kept securely in designated spaces.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**

Checklist for PI

PART 1: KNOWLEDGE AND AWARENESS

Please read each statement carefully and indicate your level of understanding by selecting one of the following options.

Yes	No	Not sure

Please ensure that you respond to each question. If you are unsure about a particular statement, select the option that most closely aligns with your view.

Before you start, please indicate the highest Biosafety Level (BSL) of your current research project involving LMO/rDNA activities.

( ) Biosafety Level 1 (BSL-1)
( ) Biosafety Level 2 (BSL-2)
( ) Biosafety Level 3 (BSL-3)
( ) Biosafety Level 4 (BSL-4)

SECTION A: General Knowledge about Biosafety					
The purpose of this section is to assess the basic understanding of all parties **(IBC, Head/top management, PI, laboratory users)** on Biosafety. This section is to be completed by **ALL** respondents.					
1.	Biosafety Act is only applicable for research related to LMO/ rDNA to manage relevant risks	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1;**

	to human, animal, and plant life and associated risks for the environment.				**Not sure = 0**
2.	Biosecurity is to protect, control, and accountability of LMO/ rDNA within facilities in order to prevent their loss, theft, misuse, diversion, unauthorized access, or intentional unauthorized release.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	An LMO is any living organism that possesses a novel combination of genetic material obtained by modern biotechnology.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
4.	It is essential to obtain approval from the IBC prior to starting the cross-breeding activity between two breeds of animals to produce a new breed.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
5.	Selective breeding to produce individual crops with the most desirable traits does not necessarily obtain approval from the IBC prior to starting breeding activity.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
6.	Institutional policies or biosafety guidelines regarding the handling of LMO and related measures are intended to reduce the risks of unintentional and/or intentional release of LMOs.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
7.	The release activity of any intentional introduction of LMOs or products of such organisms into the environment is strictly prohibited and is only allowed in close contained areas.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
8.	A recombinant DNA (rDNA) molecule is a molecule that is constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
9.	A risk assessment of LMO is performed to determine the appropriate containment facility, equipment, and work practices that will promote the safe conduct of the research project.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
10.	It is optional for organisations which undertake modern biotechnology research and development, to establish an Institutional Biosafety Committee (IBC) to ensure that any LMO/rDNA research complies with the Malaysian Biosafety Act 2007.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**

11.	Reporting non-compliance with the Malaysia Biosafety Act in organizations undertaking modern biotechnology research and development is the responsibility of JBK and not the IBC.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
SECTION B: Roles and Responsibilities in Compliance with Biosafety					
This section is designed to assess the understanding and perspective of the IBC, top management, PIs, and laboratory users on their respective roles, responsibilities, and functions in compliance with Biosafety measures.					
No. 1 to 5 is to be completed by **ALL** *respondents.*					
1.	IBC is a formal expert committee of an organization undertaking modern biotechnology work which involves the use of any LMO/ rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	IBC is composed of members who are appointed by the Head of the organization and approved by the National Biosafety Board (NBB).	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
3.	A Biological Safety Officer (BSO) is a member of IBC appointed by the Head of the organization, responsible to submit all applications for approval and the annual report of IBC to the NBB, on behalf of the organization.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
4.	IBC is responsible to/for				
	a) Provide guidance to PI on biosafety policies and issues in the use of LMO/rDNA research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) Approve the LMO/rDNA research that was found to conform to Biosafety Act and Biosafety (Approval and Notification) Regulations.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) Assess and monitor the facilities, procedures, practices, training, and expertise of personnel involved in LMO/rDNA research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	d) Allow continuation of projects dealing with LMO/rDNA materials that are not compliant with the Biosafety Act 2007 if the project has previously obtained approval from NBB.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	e) Notify the PI of the results of the IBC's review, approval, or rejection of their application for approval and notification of	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1;**

	all activities involving the use of LMO/rDNA to the NBB.				**Not sure = 0**
	f) Assess and set containment levels for LMO/rDNA research and modify containment levels as necessary.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	g) Assess field experiments to ensure that the proposed risk assessment, risk management and emergency response plan are sufficient.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	h) Adopt and implement an emergency response plan covering accidental spills and personnel contamination, resulting from LMO/rDNA research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	i) Review and report to the Head of the organisation, but not to the NBB of any significant problems with non-compliance with the Biosafety Act 2007 and Biosafety (Approval and Notification) Regulations 2010 and any significant research-related accidents or illnesses.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	j) Assist in the development of appropriate procedures as required by NBB only when unintended release and/or breach of containment and/or spill or occupational exposure to LMO/rDNA materials occurred.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
5.	IBC approval is required for the following activities:				
	a) Deliberate transfer of a drug resistance trait to microorganisms.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) Deliberate transfer of rDNA or DNA/ RNA derived from rDNA into human research participants (human gene transfer).	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) Use of Risk Group 2, Risk Group 3, or Risk Group 4 agents as host-vector systems.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	d) Cloning of DNA from Risk Group 2 or greater agents into non-pathogenic	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1;**

	prokaryotes or lower eukaryotic host-vector systems.				**Not sure = 0**
	e) Use of infectious or defective Risk Group 2 or greater agents.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	f) Use of whole animals in which the animal's genome has been altered by the stable introduction of rDNA or DNA/ RNA derived from rDNA into a germline (transgenic animal).	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	g) Viable rDNA-modified microorganism tested on whole animals.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	h) Genetically engineered plants by rDNA methods with desirable traits.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	i) Selective breeding plants through cross-pollination with desirable traits.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	j) The formation of rDNA material containing one-third or more of the genome of a eukaryotic virus.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
No. 6 is to be completed by **ALL** *respondents*					
6.	If the project/ research is non-compliance with the Biosafety Act, IBC may:				
	a) Suspend the use of LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) Cease the approval for the use of the LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) Confiscate the LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	d) Destruct the LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

	e) Any other action necessary to protect the public and/or the organisation.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	f) Report to head/top management only, not necessarily to NBB.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
No. 7 is to be completed by **PI ONLY**					
7.	PI is required to				
	p) Submit all applications for approval and notification directly to NBB without prior review and approval by IBC.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	q) Change the research proposal involving LMO/rDNA materials if needed and do not need to inform the IBC.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	r) Report any significant problems immediately with respect to the implementation of relevant laws, regulations, and guidelines.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	s) Notify IBC promptly of any significant research-related accidents that have resulted or could result in human illness, unanticipated plant or animal disease, or an unintended release of an organism from intended confinement.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	t) Complete Biosafety and Good Laboratory Practices training.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

	u) Develop and send directly to JBK for approval of the emergency response plan.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	v) Comply with all legislative requirements when conducting research involving LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	w) Ensure that the reporting requirements under the Biosafety Act are fulfilled.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	x) Review the applicable guidelines and regulations related to LMO/ rDNA materials or other infectious materials involved in research activity.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	y) Develop SOP incorporating biosafety procedures, or a biosafety manual prepared specifically for the laboratory.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	z) Establish the policy and procedures to limit access to only individuals who are well-educated on the potential hazards and meet specific entry requirements (e.g., immunization, training on the use of PPE).	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	aa) Instruct and educate the laboratory personnel on the potential hazards associated with the research, procedure of aseptic techniques, and techniques required to ensure safety as well as procedures for dealing with accidents.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	bb) Provide PPE required for work with the specific LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	cc) Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	dd) Suspend the laboratory personnel's entrance into the laboratory with work errors and conditions that may result in the unintended release of LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

No. 8 to 10 are to be completed by **PI who is currently working in BSL-3 and BSL-4 ONLY**					
8.	PI is required to comply with all occupational health requirements including ensuring laboratory personnel know the reasons and provisions for precautionary medical practices implemented and ensure that they are offered (at no cost) appropriate immunisations or tests for the LMO/rDNA materials handled or potentially present in the laboratory.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
9.	The construction work and major changes to the BSL-3 facility can commence once certified by a competent authority/organisation and endorsed by the head of the department.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
10.	The BSL-3 facility should be tested and certified every 6 months.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
SECTION C: LMO/rDNA Activities					
This section is specifically for individuals involved in LMO and rDNA activities. The purpose of this section is to gather information about their knowledge of the processes and procedures required for LMO/rDNA activities. This section is to be completed by **ALL** respondents.					
1.	For the review of LMO/rDNA activity, project extension, and notice of termination, PI is required to				
	a) Submit the relevant application as prescribed by the NBB, the IBC assessment form and a copy of the document of the approved research grant for the LMO/rDNA project.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) Submit the application form to NBB once approved by IBC.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) Start an experiment with LMO/rDNA before notification of LMO work is submitted, if the work is very important.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	d) Provide data reporting and adverse event reporting to monitor the proposed LMO/rDNA research, and the reports should be submitted to IBC.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	e) Notify JBK of the proposed project if the research work falls into any of the exemptions.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**

	f) Complete and submit the IBC Project Extension Review/ Notice of Termination Form to IBC Chair at least one week before the next scheduled IBC meeting or at the appropriate time intervals as stipulated by the IBC.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	g) Complete the Notice of Termination Form and file the form in the laboratory record when the research project involving registered LMO/rDNA materials is completed/no longer active, or when the LMO/rDNA materials are properly disposed of or no longer in the possession of the PI.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
2.	Biosafety (Approval and Notification) Regulations 2010 forbid exemption for all types of LMO/rDNA.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
3.	For the review of LMO/rDNA activity, project extension, and notice of termination, IBC/ IBC Chair is required to				
	a) Review the proposed activity involving LMO/rDNA materials by referring to the Biosafety Guidelines for Contained Use Activity of LMOs and other relevant documents, including IBC policies and procedures for the organisation.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) Assess the facilities, procedures, practices, training, and expertise of personnel involved in the LMP/rDNA research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) Provide written notification of the IBC's decision to PI.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
4.	Exempted work must also be carried out according to the Biosafety Act and should be periodically monitored by IBC.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
5.	The IBC should review all submitted research projects to determine their exemption or non-exemption status.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
6.	Access to the laboratory should be restricted when work with the LMO/rDNA materials is in progress.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

7.	In the case of an incident, follow the safety protocols outlined in the approved emergency response plan prepared by PI for the specific project and laboratory.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
8.	Ensure the LMO/rDNA materials are always kept secure.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
9.	The emergency response plan must be kept secure in a file at the designated laboratory.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
SECTION D: Training					
The purpose of this section is to know whether IBC members and individuals conducting research with LMO/rDNA materials received proper and adequate Biosafety training.					
No. 1 is to be completed by **PI ONLY**					
1.	c) Ensure that the laboratory staff is supervised by the head/top management regarding the safety practices and techniques employed.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	d) Provides training and educates the laboratory personnel on the potential hazards associated with the research, procedure of aseptic techniques, and techniques required to ensure safety as well as procedures for dealing with accidents.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION E: Emergency Response Plan					
This section focuses on the role of IBC, PI, and laboratory personnel in creating an appropriate emergency response plan. This section is to be completed by **ALL** respondents.					
1.	The emergency response plan (and any revision thereof) must be formally adopted by the IBC pursuant to all National Biosafety policies and organisational policies.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	The emergency response plan will be reviewed periodically based on new information from internal findings and/or external development.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	Method and procedures for controlling the LMO(s) in case of unintentional release should be prepared by personnel involved in LMO research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

4.	Details of any contingency measures should be in place for protecting human health and the environment in case of the occurrence of an undesirable effect caused by the unintentional release.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
5.	OHSC should coordinate the occupational health and safety services to ensure appropriate occupational health and safety surveillance for laboratory personnel involved in research approved by the IBC.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
6.	PI will use the Occupational Disease/Exposure Investigation Form to make a formal report within 24 hours to the OHSC, IBC, and NBB if there is any accidental exposure to LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION F: Laboratory Inspection and Biosafety Manuals					
This section focuses on the role of IBC, PI, and laboratory personnel in conducting laboratory inspection and preparation of biosafety manuals for proper documentation and inspection carried out at facilities working with LMO/rDNA. This section is to be completed by **ALL** respondents.					
1.	IBC members, as well as representatives and officers authorized by the NBB, are allowed to access the laboratories that are registered for activities with LMO/rDNA materials for inspection purposes by appointment only.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
2.	A collection of biosafety protocols and procedures (safety manual) at least one hard copy must be kept secure and not necessarily at the designated laboratory.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
3.	Detailed descriptions of all facilities being used for LMO-contained use activities should be properly documented.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
4.	PI should ensure the integrity of the biological and physical containment/ biosafety level.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
5.	IBC should review biosafety protocols during the inspection of facilities and laboratories.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
6.	IBC will inspect laboratories using a checklist according to the procedures outlined in the Biosafety (Approval and Notification) Regulations 2010.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION G: Field Experiments of LMOs (Confined Field Trial of LMO)					

This section is to evaluate PI and laboratory personnel that conduct confined field trials of LMO and whether they fulfil biosafety regulations.					
No. 1 to 6 is to be completed by **PI/personnel who involve in confined field trials ONLY**					
1.	All field experiments of LMO are considered a release activity.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	All field experiments of LMO must obtain approval from NBB [procedures are outlined in Biosafety (Approval and Notification) Regulations 2010].	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	The application for field experiments should be vetted by IBC before submission to the NBB.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
4.	The application for field experiments can be directly submitted to NBB.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
5.	The PI does not need to obtain an endorsement from IBC and can start a field experiment before a certificate of approval is granted by the NBB.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
6.	Measures for control and confinement of fieldwork must comply with conditions imposed by NBB.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION H: Security of LMO/rDNA Materials					
This section is to evaluate the comprehension and understanding of the responsibility of PI and laboratory users in securing LMO/rDNA materials to safeguard LMO/rDNA materials from unauthorized access, loss, theft, or misuse. This section is to be completed by **ALL** respondents.					
1.	PI and/ or all associated personnel				
	a) Must be conscientious in controlling the biological materials and should be held accountable for them.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) Should limit access to biological materials to authorised personnel only.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) Should perform a risk vulnerability assessment and develop a plan to protect the security of the material in question,	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

	depending on the Risk Group the biological agent may pose.				
2.	Chain-of-custody forms within laboratories should be made available to track LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	Log of access to areas where biological materials are in use should be in place.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION I: Disposal					
The purpose of this section is to assess the disposal methods and protocols in place and to evaluate the effectiveness of disposal procedures for the proper disposal of LMO/rDNA materials. This section is to be completed by **ALL** respondents.					
1.	Potentially hazardous biological material and LMO/rDNA materials are to be considered "regulated waste" and should be disposed of in a manner consistent with national regulations and related guidelines.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	The laboratory supervisor or other person with operational responsibility should ensure compliance with requirements for proper segregation of laboratory waste to ensure a safe work environment.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	The exempted LMO wastes are not necessarily to be inactivated prior to leaving the facility.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
4.	Each individual working with LMO material should be responsible for its sterilisation before disposal.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
5.	For disposal purposes, the exempted LMO material should be treated in the same way as infectious and potentially infectious material.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
6.	Ordinary waste should be placed into ordinary waste bins (these bins should not be yellow) that will be emptied by the cleaners in all rooms, except laboratories.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
7.	In laboratories, cleaners may be allowed to empty the bins for non-laboratory material (e.g., cardboard boxes, paper) only under supervision.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION J: Packaging, Transportation, Import, and Export of LMO/rDNA Materials					

This section focuses on assessing the security measures as well as responsibilities of IBC, PI, and laboratory personnel and protocols in place for the handling, storage, packaging, and transportation of LMO (Living Modified Organism) and rDNA (recombinant DNA) materials. This section is to be completed by **ALL** respondents.					
1.	Regulated LMO/rDNA materials will be packaged and transported in a manner compliant with national and international regulations and related guidelines.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	PI is responsible to obtain permits when handling LMO materials or conducting activities which require additional permits (e.g., import permits etc.)	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	For the movement and transport of LMO and related materials, the following shall apply:				
	a) The regulatory authorities (IBC and NBB) shall be notified using the relevant forms.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) LMO being transferred should be packaged in secure containers capable of preventing material loss during transportation.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) LMO should be kept separate from other materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	d) If an unintentional release of LMO during transport occurs, all attempts should be made to recover as much of the materials as possible.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	e) The location of the unintentional release of LMO should be marked and treated in a manner that ensures that no additional release of materials occurs.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	f) Corrective actions taken for unintentional release of LMO should be documented and the regulatory authorities notified.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	g) Adequate records of the transport of LMO, as they move between research facilities, storage facilities and field trial sites, should be maintained by PI and not necessarily by IBC.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	h) The shipper should notify the recipient of the date, kind and amount of material that will be sent before shipping.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

	i) Upon receiving the material, the recipient should confirm that the shipment has arrived intact, and that no material has been lost.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

PART 2: BIOSAFETY PRACTICES

Please indicate the proportion of time that your laboratory uses or performs the following BIOSAFETY MEASURES based on the scales provided below.

Rarely	**Some of the time**	**Most of the time**	**All the time**

SECTION A: Biosafety Practices						
No. 1 to 11 is to be completed by **ALL** *respondents.*						
1.	Decontaminating LMO waste before disposal	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
2.	Segregating LMO waste	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
3.	Use of appropriate PPE when handling LMOs	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
4.	Dedicated sharps containers for disposal of sharps used for handling LMOs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
5.	Assess and set containment levels of LMOs and modify them as necessary.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
6.	Use of Biological Safety Cabinet for work with LMOs materials.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
7.	Periodically review research projects that are recommended for approval.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
8.	Adopt and implement emergency response plans covering accidental spills and personnel	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**

	contamination, resulting from LMO/rDNA research.					
9.	There is an up-to-date list available of personnel with authorized access to LMOs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
10.	Wear closed toes shoes	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
11.	Wear lab coats/lab gowns	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
No. 12 to 15 is to be completed by **BSL-3 users ONLY**						
12.	Wear N95 or N100 respirators	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
13.	Use mechanical pipetting aids	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
14.	Wear-powered air-purifying respirators	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
15.	Wear double gloves when handling infectious material	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
SECTION B: Safety Equipment						
This section is to be completed by **ALL** *respondents.*						
1.	Electronic access control devices	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
2.	Guard at building entrance(s)	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
3.	Intrusion sensors and alarms	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**

4.	A lighted building at night	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
5.	Locked cabinets	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
6.	Locked doors to building	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
7.	Locked doors to laboratory room(s)	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
8.	Locked refrigerators	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
9.	Security patrols	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
10.	Self-closing doors	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
11.	Unobstructed views of the entrance(s)	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
12.	Video monitors	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
SECTION C: Facility Safeguards						
This section is to be completed by **ALL** *respondents.*						
1.	Background screening for potential users.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
2.	Biosafety training for new users.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
3.	Security escort to the building for non-users or visitors.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**

4.	List of users who have access to restricted areas.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
5.	Identification badges	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
6.	Records of key card/key assignments	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
7.	Restricted access to laboratory areas handling/storage of LMOs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
8.	Assess and monitor the facilities, procedures, practices, training, and expertise of personnel involved in LMO research.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
9.	There is an updated list available of personnel with authorized access to biological agents.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
10.	There are procedures in place for decontamination and waste management.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
11.	Everyone in the facility decontaminates materials before disposing of contaminated materials.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
12.	Prior to being granted access to LMOs, workers are screened for appropriate credentials, skills, and personal traits for the job, and determined to be the best fit for the position.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
SECTION D: Storage, Movement, and Transport of LMOs and Related Materials						
This section is to be completed by **ALL** *respondents.*						
1.	Appropriate permission(s) obtained to share LMO materials with other investigators/labs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
2.	Current inventory of LMOs, and rDNA materials.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**

3.	Inventory records are checked against actual LMOs, and/or rDNA materials in storage.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
4.	The PI is aware of all LMOs, and/or rDNA studied in the lab.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
5.	LMOs, and/or rDNA not in use are destroyed.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
6.	The laboratory head is aware of all LMOs, and/or rDNA studied in the lab.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
7.	Shipment of LMO materials using International Air Transport Association IATA Dangerous Goods Regulations.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
8.	LMOs are kept securely in designated spaces.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**

Checklist for Laboratory Users

PART 1: KNOWLEDGE AND AWARENESS

Please read each statement carefully and indicate your level of understanding by selecting one of the following options.

Yes	No	Not sure

Please ensure that you respond to each question. If you are unsure about a particular statement, select the option that most closely aligns with your view.

Before you start, please indicate the highest Biosafety Level (BSL) of your current research project involving LMO/rDNA activities.

( ) Biosafety Level 1 (BSL-1)
( ) Biosafety Level 2 (BSL-2)
( ) Biosafety Level 3 (BSL-3)
( ) Biosafety Level 4 (BSL-4)

SECTION A: General Knowledge about Biosafety					
The purpose of this section is to assess the basic understanding of all parties **(IBC, Head/top management, PI, laboratory users)** on Biosafety. This section is to be completed by **ALL** respondents.					
1.	Biosafety Act is only applicable for research related to LMO/ rDNA to manage relevant risks to human, animal, and plant life and associated risks for the environment.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
2.	Biosecurity is to protect, control, and accountability of LMO/ rDNA within facilities in order to prevent their loss, theft, misuse, diversion, unauthorized access, or intentional unauthorized release.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	An LMO is any living organism that possesses a novel combination of genetic material obtained by modern biotechnology.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
4.	It is essential to obtain approval from the IBC prior to starting the cross-breeding activity between two breeds of animals to produce a new breed.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
5.	Selective breeding to produce individual crops with the most desirable traits does not necessarily obtain approval from the IBC prior to starting breeding activity.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
6.	Institutional policies or biosafety guidelines regarding the handling of LMO and related measures are intended to reduce the risks of	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

	unintentional and/or intentional release of LMOs.				
7.	The release activity of any intentional introduction of LMOs or products of such organisms into the environment is strictly prohibited and is only allowed in close contained areas.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
8.	A recombinant DNA (rDNA) molecule is a molecule that is constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
9.	A risk assessment of LMO is performed to determine the appropriate containment facility, equipment, and work practices that will promote the safe conduct of the research project.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
10.	It is optional for organisations which undertake modern biotechnology research and development, to establish an Institutional Biosafety Committee (IBC) to ensure that any LMO/rDNA research complies with the Malaysian Biosafety Act 2007.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
11.	Reporting non-compliance with the Malaysia Biosafety Act in organizations undertaking modern biotechnology research and development is the responsibility of JBK and not the IBC.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
SECTION B: Roles and Responsibilities in Compliance with Biosafety					
This section is designed to assess the understanding and perspective of the IBC, top management, PIs, and laboratory users on their respective roles, responsibilities, and functions in compliance with Biosafety measures.					
No. 1 to 5 is to be completed by **ALL** *respondents.*					
1.	IBC is a formal expert committee of an organization undertaking modern biotechnology work which involves the use of any LMO/ rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	IBC is composed of members who are appointed by the Head of the organization and approved by the National Biosafety Board (NBB).	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**

3.	A Biological Safety Officer (BSO) is a member of IBC appointed by the Head of the organization, responsible to submit all applications for approval and the annual report of IBC to the NBB, on behalf of the organization.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
4.	IBC is responsible to/for				
	a) Provide guidance to PI on biosafety policies and issues in the use of LMO/rDNA research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) Approve the LMO/rDNA research that was found to conform to Biosafety Act and Biosafety (Approval and Notification) Regulations.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) Assess and monitor the facilities, procedures, practices, training, and expertise of personnel involved in LMO/rDNA research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	d) Allow continuation of projects dealing with LMO/rDNA materials that are not compliant with the Biosafety Act 2007 if the project has previously obtained approval from NBB.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	e) Notify the PI of the results of the IBC's review, approval, or rejection of their application for approval and notification of all activities involving the use of LMO/rDNA to the NBB.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	f) Assess and set containment levels for LMO/rDNA research and modify containment levels as necessary.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	g) Assess field experiments to ensure that the proposed risk assessment, risk management and emergency response plan are sufficient.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	h) Adopt and implement an emergency response plan covering accidental spills and personnel contamination, resulting from LMO/rDNA research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	i) Review and report to the Head of the organisation, but not to the NBB of any significant problems with non-compliance with the Biosafety Act 2007 and Biosafety (Approval and Notification) Regulations 2010 and any significant research-related accidents or illnesses.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**

	j) Assist in the development of appropriate procedures as required by NBB only when unintended release and/or breach of containment and/or spill or occupational exposure to LMO/rDNA materials occurred.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
5.	IBC approval is required for the following activities:				
	a) Deliberate transfer of a drug resistance trait to microorganisms.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) Deliberate transfer of rDNA or DNA/ RNA derived from rDNA into human research participants (human gene transfer).	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) Use of Risk Group 2, Risk Group 3, or Risk Group 4 agents as host-vector systems.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	d) Cloning of DNA from Risk Group 2 or greater agents into non-pathogenic prokaryotes or lower eukaryotic host-vector systems.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	e) Use of infectious or defective Risk Group 2 or greater agents.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	f) Use of whole animals in which the animal's genome has been altered by the stable introduction of rDNA or DNA/ RNA derived from rDNA into a germline (transgenic animal).	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	g) Viable rDNA-modified microorganism tested on whole animals.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	h) Genetically engineered plants by rDNA methods with desirable traits.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	i) Selective breeding plants through cross-pollination with desirable traits.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**

	j) The formation of rDNA material containing one-third or more of the genome of a eukaryotic virus.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
No. 6 is to be completed by **laboratory personnel ONLY** *(technician, student, researchers, and everyone using the lab)*					
6.	Laboratory personnel must				
	e) Follow all safety practices, establish good laboratory techniques, work within the assigned BSL containment, and use PPE as recommended by PI.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	f) Notify the Head/top management immediately of any health condition that may be compromised due to their work before the initiation of a research project.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	g) Follow all practices and procedures as provided by the PI and BSO, as well as ensure strict compliance with all required biosafety regulations and guidelines.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	h) Report non-compliance to				
	PI	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	IBC	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	JBK	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
No. 6 is to be completed by **ALL** *respondents*					

6.	If the project/ research is non-compliance with the Biosafety Act, IBC may:				
	a) Suspend the use of LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) Cease the approval for the use of the LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) Confiscate the LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	d) Destruct the LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	e) Any other action necessary to protect the public and/or the organisation.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	f) Report to head/top management only, not necessarily to NBB.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
SECTION C: LMO/rDNA Activities					
This section is specifically for individuals involved in LMO and rDNA activities. The purpose of this section is to gather information about their knowledge of the processes and procedures required for LMO/rDNA activities. This section is to be completed by **ALL** respondents.					
1.	For the review of LMO/rDNA activity, project extension, and notice of termination, PI is required to				
	a) Submit the relevant application as prescribed by the NBB, the IBC assessment form and a copy of the document of the approved research grant for the LMO/rDNA project.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) Submit the application form to NBB once approved by IBC.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) Start an experiment with LMO/rDNA before notification of LMO work is submitted, if the work is very important.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**

	d) Provide data reporting and adverse event reporting to monitor the proposed LMO/rDNA research, and the reports should be submitted to IBC.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	e) Notify JBK of the proposed project if the research work falls into any of the exemptions.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	f) Complete and submit the IBC Project Extension Review/ Notice of Termination Form to IBC Chair at least one week before the next scheduled IBC meeting or at the appropriate time intervals as stipulated by the IBC.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	g) Complete the Notice of Termination Form and file the form in the laboratory record when the research project involving registered LMO/rDNA materials is completed/no longer active, or when the LMO/rDNA materials are properly disposed of or no longer in the possession of the PI.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
2.	Biosafety (Approval and Notification) Regulations 2010 forbid exemption for all types of LMO/rDNA.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
3.	For the review of LMO/rDNA activity, project extension, and notice of termination, IBC/ IBC Chair is required to				
	a) Review the proposed activity involving LMO/rDNA materials by referring to the Biosafety Guidelines for Contained Use Activity of LMOs and other relevant documents, including IBC policies and procedures for the organisation.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) Assess the facilities, procedures, practices, training, and expertise of personnel involved in the LMP/rDNA research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) Provide written notification of the IBC's decision to PI.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
4.	Exempted work must also be carried out according to the Biosafety Act and should be periodically monitored by IBC.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

5.	The IBC should review all submitted research projects to determine their exemption or non-exemption status.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
6.	Access to the laboratory should be restricted when work with the LMO/rDNA materials is in progress.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
7.	In the case of an incident, follow the safety protocols outlined in the approved emergency response plan prepared by PI for the specific project and laboratory.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
8.	Ensure the LMO/rDNA materials are always kept secure.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
9.	The emergency response plan must be kept secure in a file at the designated laboratory.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
SECTION D: Training					
The purpose of this section is to know whether IBC members and individuals conducting research with LMO/rDNA materials received proper and adequate Biosafety training.					
No. 1 is to be completed by **laboratory personnel ONLY**					
1.	e) All researchers handling LMO/rDNA materials including laboratory personnel must attend general biosafety training.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	f) All researchers must provide proof to the IBC that they have undergone training and have adequate experience (as recognised by IBC) in Biosafety and Good Practices.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	g) Successful completion of training is mandatory to receive an IBC approval (whether new or re-application).	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	h) For researchers who are proposing to work in BSL-3 containment, specific BSL-3 laboratory training is mandatory.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION E: Emergency Response Plan					
This section focuses on the role of IBC, PI, and laboratory personnel in creating an appropriate emergency response plan. This section is to be completed by **ALL** respondents.					

1.	The emergency response plan (and any revision thereof) must be formally adopted by the IBC pursuant to all National Biosafety policies and organisational policies.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	The emergency response plan will be reviewed periodically based on new information from internal findings and/or external development.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	Method and procedures for controlling the LMO(s) in case of unintentional release should be prepared by personnel involved in LMO research.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
4.	Details of any contingency measures should be in place for protecting human health and the environment in case of the occurrence of an undesirable effect caused by the unintentional release.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
5.	OHSC should coordinate the occupational health and safety services to ensure appropriate occupational health and safety surveillance for laboratory personnel involved in research approved by the IBC.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
6.	PI will use the Occupational Disease/Exposure Investigation Form to make a formal report within 24 hours to the OHSC, IBC, and NBB if there is any accidental exposure to LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION F: Laboratory Inspection and Biosafety Manuals					
This section focuses on the role of IBC, PI, and laboratory personnel in conducting laboratory inspection and preparation of biosafety manuals for proper documentation and inspection carried out at facilities working with LMO/rDNA. This section is to be completed by **ALL** respondents.					
1.	IBC members, as well as representatives and officers authorized by the NBB, are allowed to access the laboratories that are registered for activities with LMO/rDNA materials for inspection purposes by appointment only.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
2.	A collection of biosafety protocols and procedures (safety manual) at least one hard copy must be kept secure and not necessarily at the designated laboratory.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
3.	Detailed descriptions of all facilities being used for LMO-contained use activities should be properly documented.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
4.	PI should ensure the integrity of the biological and physical containment/ biosafety level.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1;**

					Not sure = 0
5.	IBC should review biosafety protocols during the inspection of facilities and laboratories.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
6.	IBC will inspect laboratories using a checklist according to the procedures outlined in the Biosafety (Approval and Notification) Regulations 2010.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION G: Field Experiments of LMOs (Confined Field Trial of LMO)					
This section is to evaluate PI and laboratory personnel that conduct confined field trials of LMO and whether they fulfil biosafety regulations.					
No. 1 to 6 is to be completed by **PI/personnel who involve in confined field trials ONLY**					
1.	All field experiments of LMO are considered a release activity.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	All field experiments of LMO must obtain approval from NBB [procedures are outlined in Biosafety (Approval and Notification) Regulations 2010].	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	The application for field experiments should be vetted by IBC before submission to the NBB.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
4.	The application for field experiments can be directly submitted to NBB.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
5.	The PI does not need to obtain an endorsement from IBC and can start a field experiment before a certificate of approval is granted by the NBB.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
6.	Measures for control and confinement of fieldwork must comply with conditions imposed by NBB.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION H: Security of LMO/rDNA Materials					
This section is to evaluate the comprehension and understanding of the responsibility of PI and laboratory users in securing LMO/rDNA materials to safeguard LMO/rDNA materials from unauthorized access, loss, theft, or misuse. This section is to be completed by **ALL** respondents.					
1.	PI and/ or all associated personnel				

	a) Must be conscientious in controlling the biological materials and should be held accountable for them.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) Should limit access to biological materials to authorised personnel only.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) Should perform a risk vulnerability assessment and develop a plan to protect the security of the material in question, depending on the Risk Group the biological agent may pose.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	Chain-of-custody forms within laboratories should be made available to track LMO/rDNA materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	Log of access to areas where biological materials are in use should be in place.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION I: Disposal					
The purpose of this section is to assess the disposal methods and protocols in place and to evaluate the effectiveness of disposal procedures for the proper disposal of LMO/rDNA materials. This section is to be completed by **ALL** respondents.					
1.	Potentially hazardous biological material and LMO/rDNA materials are to be considered "regulated waste" and should be disposed of in a manner consistent with national regulations and related guidelines.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	The laboratory supervisor or other person with operational responsibility should ensure compliance with requirements for proper segregation of laboratory waste to ensure a safe work environment.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	The exempted LMO wastes are not necessarily to be inactivated prior to leaving the facility.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
4.	Each individual working with LMO material should be responsible for its sterilisation before disposal.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
5.	For disposal purposes, the exempted LMO material should be treated in the same way as infectious and potentially infectious material.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1;**

					Not sure = 0
6.	Ordinary waste should be placed into ordinary waste bins (these bins should not be yellow) that will be emptied by the cleaners in all rooms, except laboratories.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
7.	In laboratories, cleaners may be allowed to empty the bins for non-laboratory material (e.g., cardboard boxes, paper) only under supervision.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
SECTION J: Packaging, Transportation, Import, and Export of LMO/rDNA Materials					
This section focuses on assessing the security measures as well as responsibilities of IBC, PI, and laboratory personnel and protocols in place for the handling, storage, packaging, and transportation of LMO (Living Modified Organism) and rDNA (recombinant DNA) materials. This section is to be completed by **ALL** respondents.					
1.	Regulated LMO/rDNA materials will be packaged and transported in a manner compliant with national and international regulations and related guidelines.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
2.	PI is responsible to obtain permits when handling LMO materials or conducting activities which require additional permits (e.g., import permits etc.)	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
3.	For the movement and transport of LMO and related materials, the following shall apply:				
	a) The regulatory authorities (IBC and NBB) shall be notified using the relevant forms.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	b) LMO being transferred should be packaged in secure containers capable of preventing material loss during transportation.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	c) LMO should be kept separate from other materials.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	d) If an unintentional release of LMO during transport occurs, all attempts should be made to recover as much of the materials as possible.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	e) The location of the unintentional release of LMO should be marked and treated in a	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1;**

	manner that ensures that no additional release of materials occurs.				**Not sure = 0**
	f) Corrective actions taken for unintentional release of LMO should be documented and the regulatory authorities notified.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	g) Adequate records of the transport of LMO, as they move between research facilities, storage facilities and field trial sites, should be maintained by PI and not necessarily by IBC.	**Yes**	**No**	**Not sure**	**Yes = -1; No = 1; Not sure = 0**
	h) The shipper should notify the recipient of the date, kind and amount of material that will be sent before shipping.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**
	i) Upon receiving the material, the recipient should confirm that the shipment has arrived intact, and that no material has been lost.	**Yes**	**No**	**Not sure**	**Yes = 1; No = -1; Not sure = 0**

PART 2: BIOSAFETY PRACTICES

Please indicate the proportion of time that your laboratory uses or performs the following BIOSAFETY MEASURES based on the scales provided below.

Rarely	Some of the time	Most of the time	All the time

SECTION A: Biosafety Practices						
No. 1 to 11 is to be completed by **ALL** *respondents.*						
1.	Decontaminating LMO waste before disposal	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
2.	Segregating LMO waste	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
3.	Use of appropriate PPE when handling LMOs	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**

4.	Dedicated sharps containers for disposal of sharps used for handling LMOs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
5.	Assess and set containment levels of LMOs and modify them as necessary.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
6.	Use of Biological Safety Cabinet for work with LMOs materials.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
7.	Periodically review research projects that are recommended for approval.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
8.	Adopt and implement emergency response plans covering accidental spills and personnel contamination, resulting from LMO/rDNA research.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
9.	There is an up-to-date list available of personnel with authorized access to LMOs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
10.	Wear closed toes shoes	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
11.	Wear lab coats/lab gowns	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
No. 12 to 15 is to be completed by **BSL-3 users ONLY**						
12.	Wear N95 or N100 respirators	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
13.	Use mechanical pipetting aids	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
14.	Wear-powered air-purifying respirators	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
15.	Wear double gloves when handling infectious material	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**

SECTION B: Safety Equipment						
This section is to be completed by **ALL** *respondents.*						
1.	Electronic access control devices	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
2.	Guard at building entrance(s)	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
3.	Intrusion sensors and alarms	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
4.	A lighted building at night	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
5.	Locked cabinets	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
6.	Locked doors to building	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
7.	Locked doors to laboratory room(s)	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
8.	Locked refrigerators	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
9.	Security patrols	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
10.	Self-closing doors	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
11.	Unobstructed views of the entrance(s)	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
12.	Video monitors	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**

SECTION C: Facility Safeguards						
This section is to be completed by **ALL** *respondents.*						
1.	Background screening for potential users.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
2.	Biosafety training for new users.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
3.	Security escort to the building for non-users or visitors.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
4.	List of users who have access to restricted areas.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
5.	Identification badges	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
6.	Records of key card/key assignments	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
7.	Restricted access to laboratory areas handling/storage of LMOs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
8.	Assess and monitor the facilities, procedures, practices, training, and expertise of personnel involved in LMO research.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
9.	There is an updated list available of personnel with authorized access to biological agents.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
10.	There are procedures in place for decontamination and waste management.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
11.	Everyone in the facility decontaminates materials before disposing of contaminated materials.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**

12.	Prior to being granted access to LMOs, workers are screened for appropriate credentials, skills, and personal traits for the job, and determined to be the best fit for the position.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
SECTION D: Storage, Movement, and Transport of LMOs and Related Materials						
This section is to be completed by **ALL** *respondents.*						
1.	Appropriate permission(s) obtained to share LMO materials with other investigators/labs.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
2.	Current inventory of LMOs, and rDNA materials.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
3.	Inventory records are checked against actual LMOs, and/or rDNA materials in storage.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
4.	The PI is aware of all LMOs, and/or rDNA studied in the lab.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
5.	LMOs, and/or rDNA not in use are destroyed.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
6.	The laboratory head is aware of all LMOs, and/or rDNA studied in the lab.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
7.	Shipment of LMO materials using International Air Transport Association IATA Dangerous Goods Regulations.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**
8.	LMOs are kept securely in designated spaces.	**Rarely**	**Some of the time**	**Most of the time**	**All the time**	**All the time = 4; Most of the time = 3; Some of the time = 2; Rarely = 1**

Lampiran 5 Hasil dan pencapaian

Fasa	Hantaran	Tempoh masa
1	• Laporan awal • Rangka kerja untuk instrumen penilaian kendiri	6-8 minggu
2	• Ulasan terperinci hasil kajian literatur dan analisis jurang • Penglibatan dengan pihak berkepentingan dan pengumpulan data	2-4 bulan
3	• Laporan interim berkenaan analisis data awal dan hasil sesi perundingan bersama pihak berkepentingan • Draft study report document	5 bulan
4	• Laporan akhir	10 bulan
5.	• Laporan kemajuan	2 bulan sekali sepanjang projek berjalan

Lampiran 6 Carta Perbatuan

No.	Item	2022					2023							
		Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	April	May	Jun	July	Aug
1	Penyelarasan Kerjasama / MOA													
2	Penyerahan laporan insepsi (konsep/cadangan/pelan) secara terperinci selepas perjanjian ditandatangani													
3	Menyediakan ulasan terperinci daripada hasil tinjauan pustaka dan analisis jurang.													
4	Menjalankan perbincangan bersama pihak berkepentingan dan pengumpulan data.													
5	Menyediakan laporan interim berkenaan analisis data awalan dan hasil sesi konsultasi bersama pihak berkepentingan.													
6	Menghasilkan draf dokumen laporan hasil kajian.													
7	Melaksanakan pembentangan dan menyerahkan dokumen akhir laporan hasil kajian.													

Lampiran 7 Berkenaan kumpulan penyelidik

Profesor Dr Saiful Anuar Karsani (Ketua Projek)

Fokus dan Tekad; dilahirkan dengan semangat akademik, dan jiwa peneroka; Profesor Dr. Saiful menerima PhD dalam Parasitologi Molekul dari Imperial College, London pada tahun 2006 selepas itu beliau segera menyertai Universiti Malaya sebagai ahli akademik. Pada masa ini, beliau adalah seorang profesor Biokimia di Fakulti Sains. Lebih daripada 12 pelajar PhD dan 15 MSc telah menamatkan pengajian di bawah seliaan beliau. Dengan lebih 70 penerbitan (WOS) dan indeks H sebanyak 18, Profesor Dr Saiful ialah pihak berkuasa yang diiktiraf dalam bidang proteomik dan mempunyai pelbagai kerjasama dengan penyelidik di seluruh dunia. Beliau telah menerima lebih RM 5 juta geran penyelidikan. Profesor Dr Saiful juga memegang pelbagai tanggungjawab pengurusan. Nota khusus ialah peranan beliau sebagai Timbalan Dekan (2015-2017) dan Dekan (2017--2022) bagi Kluster Penerokaan Ilmu Alam Semulajadi (dahulunya dikenali sebagai Frontier Science Research Cluster), dan kini sebagai Pengarah IPPP. Tanggungjawab beliau termasuklah memastikan peningkatan dan pembangunan penyelidikan dalam UM, pengurusan geran penyelidikan, memperkasakan penyelidik UM, membangunkan niche dan bidang teras UM, melibatkan pihak berkepentingan, dan pelbagai tugas lain yang berkaitan dengan penyelidikan dan inovasi.

Profesor Dr Yusniza Kamarulzaman

Profesor

Jabatan Pengurusan dan Pemasaran, Fakulti Perniagaan dan Ekonomi, Universiti Malaya

Profesor Dr Jennifer Ann Harikrishna

Profesor

Institut Sains Biologi, Fakulti Sains, Universit Malaya

Prof Madya Dr Norhaniza Aminudin

Profesor Madya

Institut Sains Biologi, Fakulti Sains, Universiti Malaya

Dr Jasmine Elanie Khairat

Pensyarah Kanan

Institut Sains Biologi, Fakulti Sains, Universiti Malaya

Dr Yvonne Liew Jing Mei

Pensyarah

Pejabat Timbalan Naib Canselor (Penyelidikan dan Inovasi), Universiti Malaya

Dr Noor Liana Mat Yajit

Pegawai Penyelidik

Kluster Penerokaan Ilmu Alam Semulajadi, Universiti Malaya

Puan Haryana Rozana Abdul Rahim

Pegawai Penyelidik Sosial

Bahagian Pengurusan Geran Penyelidikan (BPGP), Universiti Malaya

Puan Nor Hidayah Ismail

Pegawai Penyelidik

Bahagian Pengurusan Geran Penyelidikan (BPGP), Universiti Malaya