Workshop on the Development of a National Code of Conduct for

BIOSECURITY

in the Framework of Biological and Toxin Weapons Convention

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Science & Technology Research Institute for Defence (STRIDE)
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&
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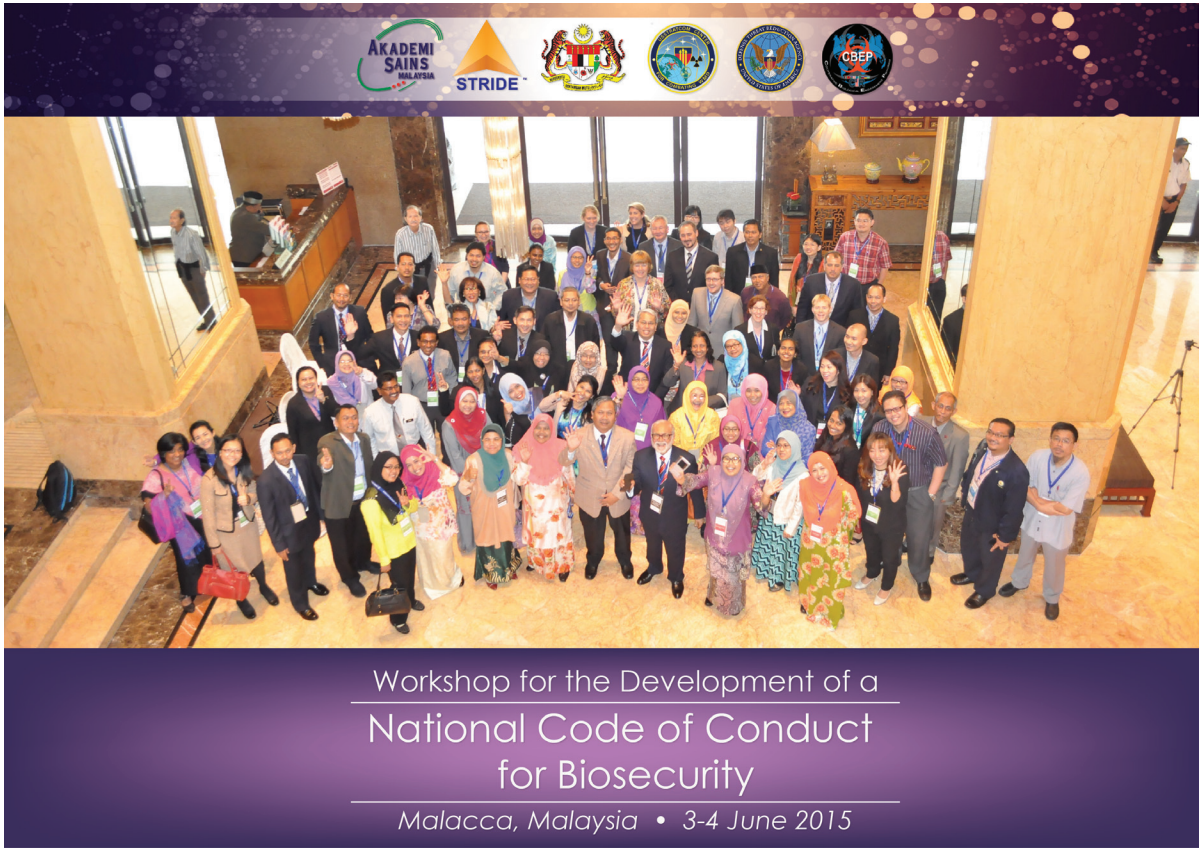
PREFACE

Biosafety and biosecurity measures must exist at all levels of scientific research and practice in order to be most effective and sustainable. These processes and guidelines can be operationalised through Codes of Practice for national-level laboratory biorisk management and responsible life sciences research. A Code of Conduct for Biosecurity promotes transparency of the risks of misuse of biological and other life sciences research and underscores and enforces already existing standards for ethical practices of accountability and communication. Codes of Conduct provide a country with a wide set of ideals that practitioners are encouraged to uphold, such as standards of research integrity, honesty, and objectivity. If further advanced, Codes of Conduct could provide guidelines in taking appropriate actions, and can become embedded within wider systems of professional or legal regulation to enable for an enforceable set of standards.

EXECUTIVE SUMMARY

Participants from science research, industry, and the academia convened on 3-4 June 2015, at the Ramada Plaza Hotel in Malacca, Malaysia, for a Workshop on the Development of a National Code of Conduct for Biosecurity in the Framework of Biological Weapons Convention. The Workshop was co-hosted by the Malaysia Ministry of Defence's Science and Technology Research Institute for Defence (STRIDE) and Academy of Sciences Malaysia (ASM), and co-organised with the USA Defence Threat Reduction Agency (DTRA) Cooperative Biological Engagement Programme (CBEP). The Workshop included presentations delivered by experts from the USA National Academy of Sciences, George Washington University (USA), Biosecure Ltd. (Switzerland), Eijkman Institute for Molecular Biology (Indonesia), National Bioethics Council (Malaysia), Institute of Medical Research (Malaysia), University of Manchester (UK), STRIDE (Malaysia), and the Royal Netherlands Academy of Arts and Sciences. The event was facilitated by international and national experts in biosecurity, biosafety, and bioethics from Malaysia, Indonesia, the USA, the Netherlands, and the U.K. For the event's agenda please refer to Annex A of this report.


AKADEMI SAINS MALAYSIA
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CBEP
Workshop for the Development of a
National Code of Conduct
for Biosecurity
Malacca, Malaysia • 3-4 June 2015

This Workshop provided a forum as a platform to discuss and present Malaysia's draft of the National Code of Conduct for Biosecurity as an instrument to extend the existing culture of responsibility in the life sciences to biosafety and biosecurity. Specifically, the workshop: (1) built awareness of Codes of Conduct as a policy option for addressing concerns about Dual Use research; (2) defined professional and ethical behaviours that can be encouraged through a Code of Conduct as an element of a comprehensive biosafety and biosecurity framework; and (3) ensured a sense of ownership and acceptance of Malaysia's draft National Code of Conduct for Biosecurity among participants and the broader community of life scientists.

Malaysia's adoption of a National Code of Conduct will assist the country in meeting its nonproliferation obligations under the Biological and Toxin Weapons Convention (BTWC). Additionally, implementation of the code at the institutional level extends guidelines of the BTWC to the broader scientific community, while promoting a safe and secure environment to conduct responsible life sciences work.

Overall, the workshop was a success (please refer to Annex B for the workshop feedback). Participants agreed that a strong culture of responsibility in their laboratories and institutions serves as a critical foundation of a shared commitment to advancing science and maintaining public trust in science. Over the two day event, it became apparent that a National Code of Conduct could enhance existing systems for biosecurity, and would include: (1) safety and security; (2) accountability and oversight; (3) communication; (4) transfer and control; and (5) response to potential misuse. All of the the participants agreed that if adopted, a National Code of Conduct would not serve as a body of law, but rather a framework by which Codes of Practice could be implemented at the institutional and laboratory level. The workshop ended with a facilitated discussion that provided a forum for participants to discuss a national path for Code of Conduct implementation and acceptance. All come to an understanding that a National Code of Conduct would

serve as a wide reaching framework and that implementation would require adopting Codes of Practice at the operational level and assuming personal responsibility. Some participants volunteered to serve as official messengers for the Code of Conduct as the document itself is moved through intensive review towards a final draft before the end of the year. For a full list of participating organisations please consult Annex C of this report.

GLOSSARY

Accountability

Accountability ensures that biological materials are controlled and traced as intended, by formally associating the specified materials with the individuals who provide oversight and are held responsible for them.

Biological laboratory

A facility within which microorganisms, their components or their derivatives are collected handled and/or stored. Biological laboratories include clinical laboratories, diagnostic facilities, regional and/national reference centres, public health laboratories, research centres (academic, pharmaceutical, environmental, etc.) and production facilities (manufacturers of vaccines, pharmaceuticals, large scale GMOs, etc) for human, veterinary and agricultural purposes

Biological materials

Biological materials may include pathogens and toxins, as well as non-pathogenic organisms, vaccine strains, foods, genetically modified organisms (GMOs), cell components, genetic elements, and extraterrestrial samples.

Biological agent

Any microbial, micro-organism, or infectious substance or any substance derived from them naturally or artificially, as well as their components and whatever their origin or method of production which can cause illness, injury or death.

Biological and toxin weapons

Any microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes and weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

Biorisk

The probability or chance that a particular adverse event (accidental infection or unauthorised access, loss, theft, misuse, diversion or intentional release), possibly leading to harm, will occur.

Biorisk assessment

The process to identify acceptable and unacceptable risks, embracing biosafety risks (risks of accidental infection) and laboratory biosecurity risks (risks of unauthorised access, loss, theft, misuse, diversion or intentional release) and their potential consequences.

Biorisk management

The analysis of ways and development of strategies minimised the likelihood of the occurrence of biorisks. The management of biorisk places responsibility on the facility and its manager to demonstrate that appropriate and valid biorisk minimisation procedures have been established and are implemented. A biorisk management committee should be established to assist the facility manager in identifying, developing and reaching biorisk management goals.

Biosafety

Laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release.

Code of conduct, code of ethics, code of practice

Non-legislated guidelines which organisations and individuals voluntarily agree to abide by, that set out the standard of conduct or behaviour with respect to a particular activity.

Dual Use

Initially used to refer to the aspects of certain materials, information and technologies that are useful in both military and civilian spheres. The expression is increasingly being used to refer not only to military and civilian purposes, but also research that can be reasonably anticipated to provide knowledge, products or technologies that could be directly

misapplied by others to pose a threat to public health, agriculture, plants, animals, the environment or material.

Laboratory biosecurity

Laboratory biosecurity describes the protection, control and accountability for biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release.

Misuse

The misuse of biological materials describes their inappropriate or illegitimate use, despite existing and subscribed agreements, treaties and conventions.

Recombinant DNA technology

The ability to combine DNA molecules from different sources into one molecule in a test tube.

Threat

The likelihood for an adverse event to occur, as an expression of intention to inflict evil, injury, disruption or damage.

Transport of Biological Materials

Procedures and practices to correctly categorize, package, document and safely and securely transport biological materials from one place to another, following applicable national and/or international regulations.

THE WORKSHOP IN PERSPECTIVE

COLLABORATION BACKGROUND

THE SCIENCE & TECHNOLOGY RESEARCH INSTITUTE FOR DEFENCE (STRIDE)

STRIDE is a department in the Ministry of Defence, Malaysia. Its role is to provide technical support and scientific expertise to the Malaysian Armed forces. STRIDE's history began with the formation of the Defence Technical Centre in 1968. After several expansions of its original scope, it was eventually elevated from a Division to a Department under the Ministry of Defence through an act of the Malaysian Cabinet in 2001. Construction of the new STRIDE main laboratory complex was completed in 2005. STRIDE's mission is to lead science and technology initiatives for Malaysian Defence and Security through innovative solutions. This mission is accomplished through: 1) strengthening of science and technology support for Malaysian Defence and Security requirements; 2) spearheading research, development, and innovation in defence domains and their exploitation; 3) collaborating with industry and institutions, and defence technology initiatives; and 4) accelerating the development of scientific, technological and human capital resources in compliance with defence requirements.

THE ACADEMY OF SCIENCES MALAYSIA (ASM)

The ASM came into force on 1 February 1995, and was established under the Academy of Sciences Act 1994. ASM strives to be a "think tank" for the nation by bringing together experts in all areas of scientific and technological endeavour to address critical national issues relating to Science, Engineering, Technology and Innovation for the benefit of all.

THE COOPERATIVE BIOLOGICAL ENGAGEMENT PROGRAMME

The Cooperative Biological Engagement Programme (CBEP) is the biological threat-reduction component of the US Cooperative Threat Reduction Programme (CTR). It seeks the establishment of sustainable capabilities and capacities within appropriate regional organisations and partner countries that effectively mitigate global biological threats, while imposing minimal disruption to the advancement of life sciences. CBEP directly supports CTR strategic objectives by working cooperatively with partner governments to 1) reverse biological weapons (BW) programs by dismantling and destroying stockpiles, equipment, and means of delivery; 2) account for, secure, and safeguard biological material, equipment, and expertise, which, if vulnerable to theft or diversion, could result in weapons of mass destruction (WMD) threats; and 3) prevent and detect the acquisition, proliferation, and use of biological weapons, weapons-usable material, equipment, means of delivery, and expertise. CBEP enhances partner country/region's capability to rapidly and

accurately survey, detect diagnose, and report biological terrorism and outbreaks of pathogens and diseases of security concern in accordance with international reporting requirements. Some of the implementation activities include strengthening and deploying biosurveillance and information systems to rapidly confirm, and report deliberate biological attacks, including differentiating endemic pathogens from those introduced by accident or nefarious intent and enhancing capacity for and linkages between disease surveillance and reporting systems to national, regional, and global outbreak response systems, including emergency operations centres; and multi-sectoral engagement to enhance discussion and exercise the system across the health, foreign affairs, law enforcement, responder, and other relevant communities.

PREVIOUS WORKSHOPS

- Workshop on the Development and the Implementation of Biosecurity and Biorisk Management Programme, 26 –29 November 2012, Kompleks Induk STRIDE, Kajang
- Workshop on the Development of Biorisk Assessment Toolkits, 26 –28 February 2013, Kompleks Induk STRIDE, Kajang
- Workshop on Collaborating Across Sectors to prepare for and respond to biological incidents, 19 -22 August 2013, Holiday Inn Hotel, Melaka
- Bioterrorism: Introductory Science Training Workshop for the Law Enforcement, 2-4 June 2014, Forensic Laboratory, Royal Malaysia Police College Cheras
- Exercise BLAZING TIGER 2014 a Multisectoral Bioincident Coordination Table Top Exercise, 23-24 June 2014, Putrajaya International Convention Centre (PICC)
- National Academic Seminar on Biothreats and Biorisk: Bridging Science and Security, 27-28 October 2014, Golden Sands Resort Penang
- Southeast Asia Discussion (SEA Dragons 2015) Biothreats and Biosecurity : Multisectoral Regional Coordination, 29-31 October 2014, Golden Sands Resort Penang

WORKSHOP PRESENTATIONS

The event opened with introductory comments from YBhg Academician Tan Sri Dato' Ir (Dr) Haji Ahmad Zaidee bin Laidin FASc, Secretary General of ASM and Major Kevin Tran, Deputy Chief of the DTRA Regional Cooperative Engagement Office - Asia Pacific, both of whom set the scene for the workshop and highlighted the importance of the event. Event facilitators and presenters then introduced participants to global and national concerns about Dual Use research and gain-of-function, by presenting a scenario that emphasised risks to communities and to the research enterprise. They presented the concept of a Code of Conduct as a policy option that could mitigate concerns of unethical practice in research and also fit into Malaysia's new biosafety and biosecurity legal/regulatory framework. Participants reviewed specific examples of internationally accepted Codes of Conduct and were introduced to the historical purposes and the role of Codes in the context of the Biological Weapons Convention. (Workshop presenters and facilitators biographies are summarised in Annex D)

SESSION 1

DR PIERS MILLETT
Biosecure Ltd.
Biosecurity and Dual Use Research: Possibility, Intentions and Threats

Dr Millett began his presentation with an overview of the historical acquisition and use of biological weapons. He set a threat context through a history of state run offensive biological weapons programmes and non-state actor efforts to acquire / develop and deploy biological weapons; thus emphasising the important role which scientists play in combatting biological threats (both emerging and intentional). He explored the need for a robust framework to help strengthen a culture of responsibility, which, he opined, can clearly demarcate acceptable from unacceptable scientific research. Dr Millett concluded his presentation by outlining three contemporary examples of Dual Use research: gain-of-function experiments; opiate biosynthesis and human germline editing.

PROFESSOR DATIN DR AZIZAN BINTI BAHARUDDIN
National Bioethics Council, Malaysia
Bioethics, Biotechnology, and the Future of Human Nature: the Dilemma

Professor Datin Dr Baharuddin presented on the needs for convergence between bioethics and current developments in biotechnology. She emphasised the critical relationship between science and religion, noting that some of the ways by which these two forces may come to work together are currently articulated via the emerging noetic science and international protocols, such as the Universal Declaration on Bioethics and Human Rights (UDBHR) and other internationally agreed upon agreements. Dr Azizan stressed that the best scenario perhaps would be to encourage dialogue between people and leaders professing differing ideologies.

DR GERALD WALTHER
University of Manchester, U.K.
Biological Weapons Convention and Code of Conduct

Dr Gerald Walther began his presentation by outlining the Dual Use threat, alerting participants on how ostensibly benign scientific research could provide the blueprint for production of a biological weapon when acquired by criminal-

minded and nonethical actors. He stated that Codes of Conduct are not a panacea for the Dual Use issue; rather, they should be supplemented by educational reforms, such as efforts to implement ethics training into scientific curricula. He also emphasised that scientists should be caring human beings, as scientists by nature want to contribute to the benefit of society. Thus, implementing and sustaining a Code of Conduct helps scientists to protect their work against misuse; by tapping into their personal convictions and their drive to contribute to the advancement of science for the betterment of society.

SESSION 2

MS SARASWATHY SUBRAMANIAM
Ministry of Health, Malaysia
Setting the Scene for Biosecurity: Legislations, Self regulation and Code of Conduct

Ms Saraswathy Subramaniam described the evolution of biorisk, highlighting international obligations to mitigate risk. She discussed Malaysia's pending national legislation and the concept of personal-regulatory measures (i.e. Codes of Conduct) as tools for managing biosecurity to prevent the hostile use of science. She also dwelt on some legal

instruments that are applicable to enforce biosecurity, including punitive measures and penalties. Ms Subramaniam emphasised that a comprehensive biorisk management framework must include a balance between legislative measures and self-regulation.

DR ZALINI YUNUS
STRIDE, MinDef
Setting the Scene on Biorisk: BTWC Article IV - National Implementation Measures

Dr Zalini Yunus opened her presentation by drawing upon the scenario today, where it is difficult to determine whether major disease outbreaks or biological incidents are spread naturally or occurred deliberately. Without proper oversight and precautionary measures, it is not impossible that the agents could be released intentionally or misused by non-state actors or terrorists. The Biological and Toxin Weapons Convention (BTWC) is an instrument that can help prevent risks from major disease outbreaks, biological warfare and bioterrorism brought about by technological advancements in the field of life sciences and biotechnology. She stated that the BTWC implementation in Malaysia is essential for biological arms control in the country; it ensures that the development and use of biological weapons is to be prohibited, and any biological agent and toxin shall be

handled safely and securely. Dr Zalini also highlighted that the key to a reduction in biorisk is through national measures. She outlined Malaysia's draft BTWC Bill throughout her presentation, highlighting its importance as part of an overall national framework for standards of practice.

ICE-BREAKING FORUM

Facilitated by Dr Piers Millett and Dr Jo Husbands
Key Aspects of a Code of Conduct for Biosecurity in the Framework of BWC

Dr Piers Millett and Dr Jo Husbands facilitated an open discussion among participants on the historical origin, purpose and intent of Codes of Conduct (CoC), especially with respect to Malaysia. Questions centred on topics related to implementation, sustainability, and enforcement of a CoC. Facilitators emphasised that the main objective of a CoC is shared responsibility among science professionals. Dr Husbands noted that in the USA. there is no national level Code of Conduct; however, there are guidelines, regulations, many Codes of Conduct from professional societies, and Codes of Practice that are common in industry (e.g. conditions of employment), but no national-level code. Dr Zalini weighed in on the conversation and highlighted the important role that ASM will play in building outreach

and promotion of the Code to institutions and labs. Dr Piers Millett stated that Codes of Conduct might also expedite the process of applying for grant funding from the USA as it would strengthen the submissions.

DR JO HUSBANDS
National Academy of Sciences, USA
Codes of Conduct: A Comparative Overview

Dr Jo Husbands' presentation discussed Codes of Conduct within the context of the Biological Weapons Convention and how different types of Codes can contribute to biosafety and biosecurity. She emphasised on the importance of the Code as a tool for supporting a Culture of Responsibility that provides engagement and commitment that moves everyone in an organisation beyond mere compliance with rules and regulations. She identified and outlined lessons learned from her experience with BWC's 2005 work on Codes of Conduct for scientists and discussed the underlying principles of Codes. Dr Husbands provided some background to Codes of Conduct and went on to distinguish three types of Codes: (1) aspirational Codes (often designated as "Codes of Ethics"), which set out ideals that practitioners should uphold, such as standards of research, integrity, or objectivity; (2) educational / advisory codes (often designated as "Codes of Conduct"),

which go further than merely setting aspirations by providing guidelines suggesting how to act appropriately; and (3) enforceable Codes (often designated as 'Codes of Practice'), which seek to further classify what is regarded as acceptable behaviour, this is generally embedded within wider systems of professional or legal regulation. She reviewed some of the attempts made by international scientific organisations in creating Codes and the underlying principles of Codes. Dr Husbands briefly discussed the examples of a recent initiative within the Chemical Weapons Convention and BWC to integrate Codes of Conduct for biology with Codes of Conduct for chemistry.

SESSION 3

PROFESSOR DR HERAWATI SUDOYO
Eijkman Institute for Molecular Biology, Indonesia
The Development of Indonesia's Code of Conduct for Biosecurity: Challenges and Lessons Learned

Professor Dr Herawati Sudoyo outlined the origin of the CoC for Biosecurity in Indonesia, which grew as a response to the anthrax attacks in the USA in 2001. The Indonesian CoC, or better known as "Pedoman Perilaku Keamanan Hayati", was developed in order to introduce a security culture for life sciences within the bioscience community. She stated that

their Code of Conduct is connected to daily practices and includes an extensive plan of outreach including discussions and workshops that engages university and government participants in an open dialogue on biosecurity issues and concerns. One of the challenges that were evident during the development of the CoC was in dealing with diversity. There was a need to consider the huge diversity of the archipelago with reference to social-cultural settings, level of development, and in biological research capability and knowledge.

Professor Dr Herawati also explained about the lessons learnt from the process, which included a lack of awareness of biosecurity issues among stakeholders in the life sciences. In particular, they were unaware that bioterrorism or bioweapons could constitute a substantial threat to security nor that research in the life sciences could contribute to bio-threats. They were also unaware of the current debates and concerns about Dual Use research or with the BTWC. According to her, the most possible explanation of the lack of biosecurity awareness is the fact that it is not featured in Indonesia's university education. One of the key best practices advocated for the implementation of a National Code in Indonesia was raising awareness throughout the country and providing specialised training for key personnel in lab management.

SESSION 4

DR KOOS VAN DER BRUGGEN
Royal Netherlands Academy of Arts and Sciences
Practicalities of the Implementation of a Code of Conduct

Dr Koos van der Bruggen provided an overview of the Dutch Code of Conduct, which has been in place since 2007. He stated that when the Royal Academy of Arts and Sciences agreed to develop a National Code, it was understood that it would not be a panacea and would not replace existing rules and laws; rather, the Code would be used to raise awareness and make good people better. He also elaborated on the vigorous and encouraging aftermaths from the publication of the CoC. This included dissemination of the CoC in both Dutch and English editions, debates and meetings with stakeholders in research institutes, universities and companies, and the development of audio-visual materials pertaining to the Code. Dr van der Bruggen stated that the Code is linked to the daily practices of the relevant persons and organisations. In conclusion, the speaker reemphasised that the Code was developed through intensive and extensive discussions with stakeholders which he felt was critical for full implementation, adoption, and sustainability of the Code.

SESSION 5

DR JULIE FISCHER
George Washington University
Codes into Action: Institutional Threat and Vulnerability Assessment

Dr Julie Fischer provided a presentation on the value of a Code of Conduct at the institutional-level. She opened with a brief profile of the freshman class of 2019; providing a look at the cultural touchstones and experiences that shape the worldview of students entering college and university. For this group of students, gene therapy has always been feasible, and eukaryotic genomes have always been sequenced. Therefore, she identified the need for practices that enhance responsible science and stressed that a Code of Conduct can be used to realise awareness about Dual Use research concerns. She provided the example of a published framework for management and training in high-containment laboratories developed by US academic scientists, which stresses the importance of combining formal training and mentoring for laboratory workers to ensure that they are not only technically well-prepared but knowledgeable about institutional and national biosafety and biosecurity requirements. She further outlined the importance of a living Code and a willingness on the part of implementers to revisit and revise the Code as needed.

BREAKOUT GROUP AND ROUNDTABLE SESSIONS

The participants broke out into four (4) groups, facilitated by regional and international subject matter experts on biosecurity, biosafety, and bioethics. Facilitators used a case study with two turns to promote discussion and response. The purpose of these sessions was to: (1) increase participant awareness of Dual Use research of concern risks and related ethical and regulatory issues; (2) emphasise the utility of a Code of Conduct in addressing these issues; (3) familiarise participants with key terms, concepts, and definitions to prepare for discussion of Malaysia's draft Code of Conduct.

BREAKOUT SESSION 1

The first session was designed to orient participants to the importance of a National Code of Conduct. Facilitators introduced a scenario in two turns based on research of a fictional pathogen, Niba. It is important to note that this session was designed to introduce the concept of a Code of Conduct and facilitate discussion about the value of personal responsibility and accountability for the science community. At this point, participants had not reviewed Malaysia's draft National Code of Conduct.

1. Turn 1 – The Unexpected Result

Researchers working to understand virulence factors of 'Niba' virus combine / manipulate live virus. The manipulation of this virus produces recombinant strains with unexpected characteristics. The lab is now in possession of a novel

virus strain and interesting observations, which could have significance to public health, as well as for publications. However, this action could also pose biosafety and biosecurity risks for workers and the community. The goal of this Turn was to discuss what to do with an unexpected result and explore how a Code of Conduct could play within this situation.

Facilitator Questions:

- Would you deem these experiments, Dual Use Research of Concern (DURC)?
- Who should be responsible for assessing and managing biosecurity risks that appear in the course of research?
    - At the laboratory level?
    - At the institutional level?
- What would be needed to implement safety and security for:
    - Communication with and between institutions?
    - Presentations and publications?
    - Access to materials and information?
    - Accountability and oversight?

Key Responses / Discussions:

- Most participants agreed that the research should be considered as dual-use since the research could cause harm or be misused.
- Some participants asked for clarification on when the experiment would have shifted from moderate risk to DURC; stating that it might be helpful to understand the

trigger for re-evaluating the research:
    - Some asked about the term, "Dual Use research of concern," specifically the word, concern, and whether it could be less subjective for future use in plans and Codes.
- Participants were able to easily identify responsible parties for assessing and managing biosecurity risks at both the laboratory and institutional level:
    - Lab: principal investigators, laboratory manager, researchers
    - Institution: primary investigators, laboratory managers, biosafety officers, institutional biosafety committees, bioethics committees, senior institutional leadership, and funding agencies
    - When asked what would be needed to implement appropriate safety and security measures, participants provided the following responses:
    - Communication within and between institutions would require agreements (such as an Materials Transfer Agreement (MTA)), government regulations, and standard policies and procedures
    - Development of presentations and publications would require input from a sponsor and a clearance process similar to existing processes within government
    - Access to materials and information would require processes for peer review and institution / leadership approval
    - Accountability and oversight would require full participation of the institution, leadership,

principal investigator, and research team; formal acknowledgement of responsibilities within and / or among institutions; and a flow chart or decision tree algorithm.

2. Turn 2 – Malicious Intent

A foreign graduate student working within the research team has ties to groups with anti-elitist/anti-wealth extremist views. He is part of the team that unintentionally develops the novel strain with unexpected characteristics. This nefarious individual impulsively hides several vials within the lab, anticipating an opportunity for malicious use. The goal of this Turn was to discuss the additional systems that are needed to prevent intentional theft and misuse and explore how a Code of Conduct could play within this situation.

Facilitator Questions:

- What are the key features of a "culture of responsibility"?
  - At the laboratory level?
  - At the institutional level?
- What roles can a Code of Conduct play in extending the culture of responsibility to biosecurity?
- When and how would you introduce biosecurity responsibilities during education and training?

Key Responses / Discussions:

- Participants agreed that the key features of a "culture of responsibility" include implementing guidelines at the institutional level (e.g peer counselling and anonymous

reporting mechanisms); developing education and engagement at an early age to build and grow ethical research practices; and integrating a culture into meetings, workshops, and training opportunities

- When asked what roles could a Code of Conduct perform in extending the culture of responsibility to biosecurity, participants provided the following responses:
  - Safety and security require instituting security measures, access controls, systems for monitoring, and formal personnel reliability checks
  - Accountability and oversight require the development of Standard Operating Procedures for communication and safekeeping of specimens;
  - Recognising and responding to potential misuse require education at every level, from the highest authorities to students;
  - Protecting pathogens and materials in and between laboratories require proper practices for documentation, inventory, safe packaging, and transportation; and
  - Participants agreed that biosecurity responsibilities should be introduced early into education and training (primary through advanced) and that it should build on standards of ethics in science; they further stated that ethics and biosafety/biosecurity should be part of compulsory curriculum for undergraduate students, new staff in labs, and as refresher training to existing staff.

MALAYSIA'S DRAFT CODE OF CONDUCT REVIEW

During the evening session, Dr Zalini Yunus (STRIDE, MinDef) introduced Malaysia's draft Code Conduct to all participants. The Code was based on other established Codes of Conduct and Ethics from the Netherlands and American Society for Microbiology respectively. Dr Zalini emphasised that the National Code was established to facilitate a long-term culture of responsibility. She outlined ten draft elements for the National Code:

1. Biorisk Management
2. Raising Awareness
3. Safety and Security
4. Education and Information
5. Accountability
6. Oversight
7. Reporting Misuse
8. Internal and External Communication
9. Research and Sharing Knowledge
10. Accessibility
11. Supply, Shipment and Transport

Dr Zalini provided a physical copy of the Code of Conduct for participants to mark up. She also provided an electronic copy of the code and asked participants to share the document with other cohorts and stakeholders. She stated her intention to collect, collate and incorporate all relevant edits, suggestions, and comments and further emphasised her desire to finalise the National Code of Conduct in 2016.

BREAKOUT SESSION 2

A second breakout group session was designed to gather feedback on the Draft Code of Conduct. This session occurred on day two of the event, after participants were given time to review and edit the draft Code of Conduct. Participants split into the same four groups to respond to a series of questions concerning content, layout, and an action plan for Malaysia's National Code of Conduct.

Facilitator Questions:

- Introduction and Scope of the draft
  - Is the material clear and easy to understand?
  - Is the material focused and relevant to the issue?
- For each element covered in the draft Code of Conduct
  - Are the recommendations clear and consistent?
  - Are the recommendations sufficient?
  - If additional elements or terms are needed, please state and describe.
- What do you see as the most effective first steps in the implementation strategy
  - At the national level?
  - At the institutional level?
  - At the laboratory level?

Participants were also asked to develop two to three specific recommendations for an action plan to implement Malaysia's National Code of Conduct.

Key Responses / Discussions:

- Participants recommended the addition of a preamble or background section to the document, which defines: (1) the targeted audience and fields for use; (2) the operational objectives for the document; (3) the scope of the document; and (4) a glossary for key terms such as biosafety, biosecurity and DURC, including commonly used (biological materials, biosafety, etc.) and ambiguous (culture of responsibility, third parties, etc. terms);
- Some added that identification of the committed target audience and their stakeholders (e.g. life scientists and their assistants) could be a critical step in building awareness for the Code;
- A process for "raising awareness" is needed and could include a roadmap, approach, or best practices for how to raise awareness;
- The document should be in simple English and/or could be multilingual so that it could be easily digested by a wider audience;
- The sequence of the document needs rearrangement for a better readability and thought flow. In general, it was suggested that the document be restructured to follow the sequence "Knowledge, Awareness, and Research", each to be treated separately but flowing together in a logical manner;
- Participants questioned if there should be a time frame associated with reporting protocols for misuse, because

many were concerned with how to execute a process for reporting misuse an and stated that it could be a different process for different communities

- All agreed that it would be important for participants of the workshop to report back to their respective organisations and describe the actions, discussions and recommendations from the event
- The key to implementing the National Level Code of Conduct will be to make a very general code and allow for the specific institution to develop an implementation strategy– this would eliminate the debate across communities (e.g. Health, Defense…)
- Each type of facility will have different rules regarding safety and security- this needs to be flexible at a national level and specific at the institutional level
- With regards to reporting misuse, there was some concern with overloading biosafety officers with additional duties of monitoring and oversight and that independent verification and oversight, while important, could be enforced through committee
- Some participants asked for explanatory notes for each of the elements of the Code of Conduct, within the overall concept of biosecurity and raising awareness, they stated that this could be accomplished through an addendum or reference section that could include case study examples for each of the elements.

- Participants suggested train-the-trainer workshop(s) for implementation, which could ensure that all institutions in Malaysia have a trainer and a One-Stop-Information Centre.
- The document should also mention training needs complete with information about the content, frequency and how to measure/review effectiveness of the training.
- Participants recommended including the role of institutions, its obligations and compliance of the code in the document, specifically in gathering and disseminating the information, and making it publicly available to everyone. Furthermore, the possible role and involvement of the institutional biosafety committee (IBC) and/or the ethics committees as the overseeing bodies for the CoC should be clearly spelt out in the document.
- The term 'Scientist' should be replaced with a more appropriate word to cover all personnel working in laboratories, such as science officers, laboratory technicians, researchers and even students

CODE OF CONDUCT PATH TO IMPLEMENTATION

The participants deliberated on the implementation of the Code; finding an approach suitable for nation-wide operational execution of the Code of Conduct. Many agreed that implementation would require transparent and

open communication to all Code stakeholders, which would ensure implementation and compliance. They requested for another consensus meeting, workshop, or seminar with more stakeholders as a recommendation for building awareness on content and intent. The participants also suggested a high profile launch (which could include press announcement/ conference) of the final National Code of Conduct, which could be attended by primary stakeholders in industry, government, and academia.

STRIDE will oversee collection of edits and comments for the National Code of Conduct from the scientific community and move the document through a revision process to final draft. They will work with ASM, which will assist with outreach and messaging the intent of the Code. There is a tentative plan in place for a second workshop in 2017 or 2018 to be co-hosted by STRIDE and ASM, to further transition the National Code of Conduct from its broad framework into personal responsibility for science professionals and Codes of Practice at both the institution and laboratory levels.

4.0 DRAFT CODE OF CONDUCT FOR BIOSECURITY IN THE FRAMEWORK OF BIOLOGICAL WEAPONS CONVENTION

4.1 PREAMBLE

Accumulated and advancing knowledge on biological systems offers substantial benefits to mankind, while also opening vast opportunities for research and development covering both basic and applied aspects within the fields of biomedical sciences and biotechnology. However, this improved knowledge is intrinsically associated with the potential for dual applications: for beneficial or malicious purpose. The possibility of using scientific knowledge for peaceful or non-peaceful purposes reflects the Dual Use dilemma and confers a responsibility on both those with the knowledge and those with the biological resources. Additionally, those engaged in the life sciences have the responsibility for in-depth implementation of the Biological and Toxin Weapons

Convention (BTWC). Scientific openness and a sense of security are prerequisites for freedom of scientific work, publication of findings and exchange of bio-resources to carry out activities in the life sciences. This Code of Conduct for Biosecurity aims to help researchers and scientists working with pathogens to have a basic ethical understanding of science compliant with the BTWC and to promote and raise awareness that would prevent misuse within the life-sciences.

It is not the aim of this Code to influence the life science activities performed at their facilities. Above all, this Biosecurity Code of Conduct is meant to complement legislative procedures. This Code intends: (1) to raise awareness of potential dual use and the need to prevent malicious misuse; (2) to help research institutions to avoid any direct or indirect contributions to the development and production of potential biological weapons; and (3) to clearly demonstrate that research institutions in the country are fully compliant with national and international legislation and support the BTWC as an international norm prohibiting biological weapons. As such, his Biosecurity Code of Conduct is also to support the statement and principles from the *InterAcademy Panel (IAP) Statement on Biosecurity*, namely, (1) Awareness, (2) Safety and Security, (3) Education and Information, (4) Accountability and (5) Oversight.

4.2 DUAL USE RESEARCH

In the life sciences, Dual Use research encompasses biological research with legitimate scientific purpose, of which the resulting new technologies or information have the potential for both benevolent and malevolent applications. The Dual Use research dilemma in life sciences refers to the challenge of producing and publishing research within the life sciences that is intended to improve public health, animal health, or agricultural productivity However, in the hands of a rogue state, terrorist group, or individual, it could be used to damage public health, as well as economic and country stability. Hence, this Dual Use research dilemma confers a responsibility on both those with the knowledge and with the biological resources.

Dual Use researches of concern are those that would: (a) demonstrate how to render a vaccine ineffective; (b) confer resistance to therapeutically useful antibiotics or antiviral agents; (c) enhance the virulence of a pathogen or render a non-pathogen virulent; (d) increase the transmissibility of a pathogen; (e) alter the host range of a pathogen; (f) enable the evasion of diagnosis and/or detection by established methods; (g) enable the weaponisation of a biological agent or toxin; (h) involve genetic sequencing of pathogens; (i) deal with the synthesis of pathogenic microorganisms; (j) cover

any experiment with variola virus (smallpox); or (k) involve attempts to recover/revive past pathogens.

In contrast with other weapons, the materials and equipment required to create and propagate a biological attack using naturally occurring or genetically manipulated pathogens are 'low-tech', inexpensive and widely available. In addition, much of the same equipment that can be used to create a dangerous biological agent is also a key part of benign biological research programmes. Moreover, in the case of life sciences research, it is not just that the materials and equipment can be used for illegal and benign research, but also that biological research can produce agents and knowledge which in the right hands can contribute beneficially to human health and welfare, but when in the wrong may be used for harm.

4.3 SELF-GOVERNANCE VERSUS REGULATION

The principle of open science is to make scientific research accessible to the public, which in turn stimulates discussion and furthers the advancement of the scientific enterprise. However, there is concern that the ability of terrorists to gather information from scientific publications poses a severe risk to the public. It is possible that bioterrorists could directly or indirectly use published scientific information related to

pathogens or the delivery of pathogens to plan a terrorist attack. Different opinions have been formed regarding whether Dual Use research should be openly published and disseminated. While some may argue that publishing such data is irresponsible, the prevailing view among many scientists is that, generally, the risk of bioterrorism is far outweighed by the benefit of further scientific work based upon openly disseminated information.
Nevertheless, there may be special cases in which open publication of research would not be in the best interest of national security and, therefore, some form of government regulations or restrictions would be needed. It has been suggested that to determine the type of mechanism to govern dual–use research, whether regulations or restrictions, or other lesser measures such as guidelines, code of conduct or self-governance, the mechanism used should be proportional to the probability and magnitude of harm, whereby the greater the risk, the more need there would be for formal regulation and oversight.

4.4. LOCAL OVERSIGHT AND ASSURANCE

Local oversight by the institution through its Institutional Biosafety Committee (IBCs) ensures biosafety guidelines are met, in particular, with regard to recombinant DNA research. It has been suggested that IBCs responsibilities should be

expanded to include biosecurity and Dual Use concerns. Local oversight is a key component in providing scientific and risk-based evaluation of biosafety and biosecurity, including Dual Use concerns.

4.5 CODES OF CONDUCT AND BTWC

The 1972 Biological and Toxin Weapons Convention (BTWC) reinforced the international norm prohibiting biological weapons, stating in its provisions:

"Each state party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain: microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic or other peaceful purposes."

This statement presents principles to guide individual scientists and local scientific communities that may wish to define a code of conduct for their own use. These principles, more importantly, represent fundamental issues that should be taken into account when formulating codes of conduct. The responsibilities of those engaged in the life sciences have an increasing role for in-depth implementation of the BTWC.

Scientific openness and a sense of security are prerequisites for freedom of scientific work, publication of findings and exchange of bio-resources to carry out activities in the life sciences. This Code of Conduct on Biosecurity is to help research agencies, universities and industries to promote a basic ethical understanding of science compliant with the BTWC and raise awareness to prevent misuse in the life-sciences context.

This Code intends to raise awareness on biosecurity within and outside research agencies, universities and industries, and to clearly demonstrate that they are fully compliant with the national and international treaties, as well as to support the BTWC as an international norm prohibiting biological weapons. Nonetheless, it is not the aim of this Code to influence the range of bio-resources maintained or life science activities performed at research premises. Above all, this Biosecurity Code of Conduct is meant to complement legislative procedures.

4.6 PROPOSED CODES OF CONDUCT FOR BIOSECURITY IN THE FRAMEWORK OF BWC FOR LIFE SCIENCES

The aim of this Code of Conduct is to prevent microbial at research facilities from directly or indirectly contributing to the malicious misuse of biological agents and toxins, including the development or production of biological weapons. Many research facilities are entrusted with the collection and controlled supply of potentially hazardous bioresources. This requires high responsibility, well-established biorisk analyses and management, and appropriate research facility internal infrastructures, profound knowledge of relevant bio-legislation including export control and respective protective measures. This Code calls for implementation and compliance of awareness, accountability and oversight and targets all those engaged in life sciences activities, laboratory workers, managers, stakeholders and others. The code of conduct is intended for organisations, institutes and companies that work or deal with biological agents with potential risk. As such, the code lays down rules of conduct related to the following issues:

a. Biorisk assessment and risk management
b. Raising awareness
c. Safety and security
d. Education and information

e. Accountability and oversight
f. Reporting misuse
g. Internal and external communication
h. Research and sharing knowledge
i. Accessibility
j. Supply, shipment and transport

5.0 THE MAIN ELEMENTS OF THE DRAFT CODE OF CONDUCT

(1) BIORISK ASSESSMENT(BRA) AND BIORISK MANAGEMENT (BRM)

For BRA and BRM attention is drawn to the following:

- Abuse of biological materials in hazardous applications is possible in two ways only: Intentionally, and by failures in risk assessment and management.
- The technology of handling biological materials requires specific and complex procedures which by their nature are self-contained and tightly controlled under existing standards of good practice.
- For biosecurity, risk assessment entails the screening of potential misuse of the biological materials which can be intentionally abused, for example, in terrorist activities, whereas risk management entails the restriction of access to biological materials to legitimate users.
- Biorisk management should be introduced throughout the organisation and regularly reviewed for continuous improvement.

– Adequate resources and responsibility for BRA and BRM needs to be assigned to guarantee compliance with legal requirements,
– There should be good communication of all relevant information to staff and relevant third parties to facilitate reliable and appropriate risk assessment.

(2) RAISING AWARENESS

Raising Awareness requires the following:

– Devote specific attention in the education and further training of all staff on:
- the dual use dilemma, i.e. the risks from misuse of biological information and material in life sciences research; and
- the requirement in the above context, for adequate biosecurity regulations.

– Provide regular training and carry out auditing to maintain up to date knowledge on biosecurity.
– Raise awareness of related third parties on their responsibilities.
– Since scientists have an obligation to do no harm, they should always take into consideration the reasonably foreseeable consequences of their own activities. To do this they should:

- always bear in mind the potential consequences – possibly harmful – of their research and recognise that individual good conscience does not justify ignoring the possible misuse of their scientific endeavours;
- refuse to undertake research that has only harmful consequences for humankind.

(3) SAFETY AND SECURITY

Scientists working with agents such as pathogenic organisms or dangerous toxins have a responsibility to use good, safe and secure laboratory procedures, whether codified by law or common practice.

(4) EDUCATION AND INFORMATION

– Scientists should be aware of, disseminate information about and teach national and international laws and regulations, as well as policies and principles aimed at preventing the misuse of biological research.
– Faithfully transmit this code and the ethical principles upon which it is based to all who are or may be engaged in the conduct of science.

(5) ACCOUNTABILITY

Scientists who become aware of activities that violate the Biological and Toxin Weapons Convention or other international treaties should raise their concerns with appropriate people, authorities and agencies.

(6) OVERSIGHT

Scientists with responsibility for oversight of research or for evaluation of projects or publications should promote adherence to these principles by those under their control, supervision or evaluation and act as role models in this regard.

(7) REPORTING MISUSE

- A culture of reporting misuse should be encouraged.
- Any finding or suspicion of misuse of biological material, information or technology should be reported directly to competent persons or commissions.
- Persons reporting on misuse should be protected and ensured that they would not suffer any harassment as a consequence.

(8) INTERNAL AND EXTERNAL COMMUNICATION

- Access by unauthorised persons to internal and external e-mails, post, telephone calls and data concerning information about potential Dual Use research or potential Dual Use materials should be prevented.
- Communication of sensitive information should be regulated.

(9) RESEARCH AND SHARING KNOWLEDGE

- All possible Dual Use aspects of research should be assessed during the application for and the execution of research projects.

- The risk that publication of results on potential Dual Use organisms that would contribute to misuse of that knowledge should be minimised.
- Biosecurity implications should be considered when sharing knowledge.

(10) ACCESSIBILITY

- Physical security of and access control to stored potential Dual Use material in accordance with its risk classification should be ensured.
- Access control for staff and visitors where potential Dual Use biological materials are stored or used should be implemented.

(11) SUPPLY, SHIPMENT AND TRANSPORT

- Recipients of potential Dual Use biological materials should be screened in consultation with the relevant authorities and parties.
- Transporters to handle potential Dual Use biological materials should be carefully selected.
- Export control should be performed in accordance with applicable regulations.

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Royal Netherlands Academy of Arts and Sciences 2007, A Code of Conduct for Biosecurity. Report by the Biosecurity Working Group, Amsterdam.

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ANNEX A: AGENDA

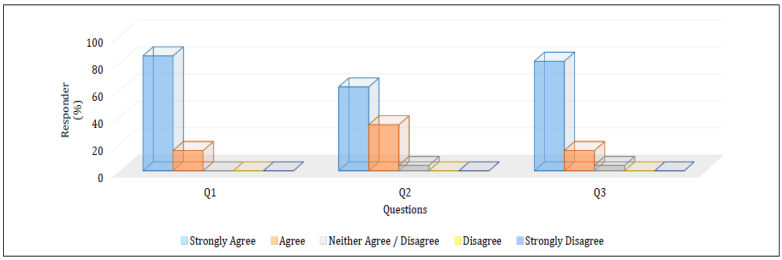
3 JUNE 2015 (WEDNESDAY)	
Time	Program
0730 – 0830	REGISTRATION
0830 – 0900 O	PENING CEREMONY Recitation of Doa Welcoming Speech Major Kevin Tran, Deputy Chie f DTRA Regional Cooperative Engagement Office, Asia Pacific Opening Speech YBhg. Tan Sri Dato' Ir (Dr.) Zaidee bin Laidin, Secretary General Academy of Sciences Malaysia
Session Moderators: Dr. Julie Fischer (GWU) and Prof. Dato' Dr. Mohd Jamil Maah (UM)	
0900 – 0930	Keynotes Addresses Biosecurity and Dual-Use Research: Possible Intentions and Threats Dr. Piers D. Millett, Biosecure Ltd.
0930 – 0950 B	ioethics, Biotechnology and the Future of Human Nature: the Dilemma Prof Datin Dr. Azizan binti Baharuddi Chairman of National Bioethics Council of Malaysia
0950 – 1010	Biological Weapons and Codes of Conduct Dr. Gerald Walther, University of Manchester
1010 – 1040	Tea Break
INTRODUCTION	
Session Moderators: Dr. Jo Husbands (US NAS) and Prof Datin Dr. Zahurin Mohamed, UM	
1040 – 1100 W	elcome and Introduction to the Workshop Goals Dr Zalini Yunus, STRIDE, (MinDef) Mr. Randy Thur, CBEP, (U.S. DoD)
1100 – 1130	Setting the Scene on Biosecurity: Legislation, Sel f-Regulation and Code of Conduct Dr. Zalini Yunus, STRIDE (MinDef) Ms. Saraswathy Subramani am, IMR (MOH)
1130 – 1200	Ice Breaking Forum: Key Aspects of a Code of Conduct for Biosecurity in the Framework of BWC Dr. Piers D. Millett, Biosecure Ltd Dr. Jo Husbands, US NAS

Time	Program
1130 – 1200	Ice Breaking Forum: Key Aspects of a Code of Conduct for Biosecurity in the Framework of BWC Dr. Piers D. Millett, Biosecure Ltd Dr. Jo Husbands, US NAS
1200 – 1230	Codes of Conduct: A Comparative Overview Dr. Jo Husbands, US NAS
1230 – 1400	Lunch
DEVELOPMENT OF A DRAFT NATIONAL CODE OF CONDUC T (PART I)	
1400 – 1420	Overview of Breakout Group Sessions and Presentation of Case Study (Turn 1) Dr. Julie Fisher, GWU / Dr. Jo Husbands, US NA S
1420 – 1500	Breakout Group Session 1
1500 – 1515	Presentation of Case Study (Turn 2) Dr. Julie Fischer, GWU / Dr. Jo Husbands, U.S. National Academy of Science s
1515 – 1600	Breakout Group Session 2
1600 – 1615	Tea Break
1615 - 1730	Internal Discussion for Breakout Group Rapporteurs
1930 – 2030	Dinner
2030 – 2100	Presentations from Breakout Group Rapporte urs
2100 – 2130	Presentation of the Draft National Code of Conduct for Biosecurit y Dr. Zalini Yunus, STRIDE (MinDef)
2130 – 2200	Group Discussion: Initial Feedback on the Draft National Code of Conduc t
2200	Supper

4 JUNE 2015 (THURSDAY)	
Time	Program
	Session Moderators: Dr. Jo Husbands (U.S. NAS) and Prof Dr. Helen Nair (ASM)
0830 – 0900	The Development of an Indonesian Code of Conduct for Biosecurity: Challenges and Lessons Learned Prof Herawati Sudoyo, Eijkman Institute for Molecular Biol ogy, Indonesia
0900 – 1000	Round Table Discussion: Implementation of a Code of Conduct at the Institutional Level Facilitators: Prof Dato' Dr. Mohd Jamil bin Maah, UM Dr. Julie Fischer, GWU Dr. Anita Anthonysamy, DOB (NRE)
0900 – 1000	Round Table Discuss sion: Implementation of a Code of Conduct at the Institutional Level Facilitators: Prof Dato' Dr. Mohd Jamil bin Maah, UM Dr. Julie Fischer, GWU Dr. Anita Anthonysamy, DOB (NRE)
1000 – 1030	Tea Break
	DEVELOPMENT OF A DRAFT NATIONAL CODE OF CONDUCT (PART II)
	Session Moderators: Dr. Julie Fischer (GWU) and Ms. Saraswathy Subramaniam (IMR, MOH)
1030 – 1100	Practicalities of Implementing a Code of Conduct Dr. Koos van der Bruggen, KNAW, Netherlands
1100 – 1230	Breakout Group Discussion Based on Draft of National Code of Conduct Specifically related to the focus elements of the Code of Conduct
1230 – 1400	Lunch
1400 – 1430	Summary and Discussion
	DEVELOPMENT OF A DRAFT NATIONAL CODE OF CONDUCT (PART III)
	Session Moderators: Dr. Jo Husbands (U.S. NAS) a nd Dr. Mohana Anita Anthonysamy (DOB NRE)
1430 – 1500	Codes into Action: Institutional Threat and Vulnerability Assessment Dr. Julie Fischer, GWU

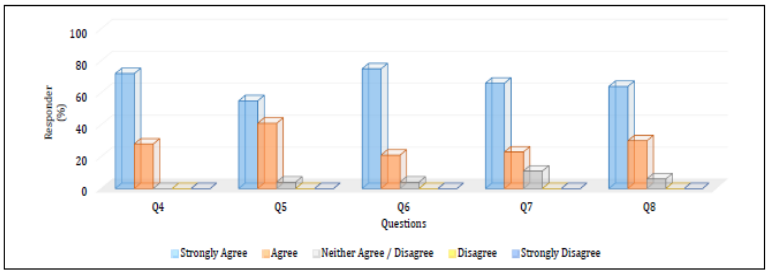
Time	Program
1500 – 1530	Breakout Group Discussion: Continued Discussion on Draft National Code of Conduct Dr. Julie Fischer, GWU Dr. Jo Husbands, US NAS
1530 – 1600	Group Discussion: Presentation of Formulated Recommendations and Specific Steps Forward
1600 – 1630	Tea Break
DEVELOPMENT OF DRAFT CODE OF CONDUCT (PART III) (CONTINUED)	
1630 – 1730	Open Discussion: Presentation of Formulated Recommendations and Specific Steps Forward
1730 – 1815	Summary: Discussion and Development of an Action Plan Dr. Zalini Yunus, STRIDE, (MinDef)
1815 – 1845	Recitation of Doa Welcoming Speech Major Kevin Tran, Deputy Chief Regional Cooperative Engagement Office, Asia Pacific Closing Speech YBhg. Dato' Salim bin Parlan, Director Management Services Division STRIDE
1930 – 2030	Dinner

ANNEX B: WORKSHOP FEEDBACK



Q1: Build awareness of Codes of Conduct as a policy option for addressing concerns about dual-use research
Q2: Define professional and ethical behaviors that can be encouraged through a code of conduct as an element of a comprehensive biosafety and biosecurity framework
Q3: Ensure a sense of ownership and acceptance of Malaysia's draft National Code of Conduct among participants and the broader community of life scientists

Figure 1: Participants' feedback on whether the workshop has achieved its purpose and goals.



Q4: Introduce the Code of Conduct as a policy option for addressing concerns about dual-use research
Q5: Describe the historical purposes/roles of COC in the context of BWC
Q6: Define objectives and elements of COC by reviewing specific examples developed by various countries and institutions
Q7: Define potential uses of COC in awareness-building, education, and governance
Q8: Set the stage for discussing how a COC might fit into Malaysia's new biosafety and biosecurity legal/regulatory framework

Figure 2: Participants' feedback on the workshop effectiveness

ANNEX C: PARTICIPATING ORGANISATIONS

MINISTRIES, GOVERNMENT AGENCIES & NGOs

- Ministry of Health
- Ministry of Defence
- Royal Malaysia Police
- Malaysian Armed Forces
- Institute of Medical Research
- Science & Technology Research Institute for Defence
- Department of Chemistry
- Department of Veterinary Services
- Department of Biosafety
- Department of Fisheries
- Veterinary Research Institute
- Fisheries Research Institute
- Academy of Sciences Malaysia
- Malaysian Society for Microbiology
- Malaysian Biosafety & Biosecurity Association
- Sime Darby Sdn Bhd
- BioValence Sdn Bhd
- Microwell Bio Solutions Sdn Bhd

UNIVERSITIES

- University of Malaya
- Universiti Kebangsaan Malaysia
- Universiti Sains Malaysia
- Universiti Putra Malaysia
- Universiti Teknologi Malaysia
- Universiti Malaysia Sabah
- Universiti Malaysia Sarawak
- Universiti Teknologi Mara
- Universiti Sains Islam Malaysia
- Universiti Malaysia Kelantan
- National Defence University of Malaysia
- Universiti Kuala Lumpur
- Management and Science University
- Monash University Malaysia
- Universiti Tun Abdul Rahman
- International Medical University
- Perdana University
- Quest International University Perak

ANNEX D: BIOGRAPHIES

SPEAKER & FACILITATORS BIOGRAPHIES

Dr Mohana Anita Anthonysamy (co-facilitator)
Dr Anita Anthonysamy joined the Ministry of Natural Resources and Environment (NRE) in the year 2007 and is a Research Officer with the Department of Biosafety. She has been providing support to the NRE in implementation of the Malaysian Biosafety Act 2007. She has been actively involved in developing the related regulations and biosafety policies and implementation mechanisms for the Biosafety Act in addition to participating in consultations with stakeholders and biosafety experts. She also does initial technical assessment and research support to process applications received for activities related to genetically modified organisms (GMO).

Dr Anita has played an active role in raising awareness on the Biosafety Act through development of public awareness materials such as newsletters and write-ups, guidance documents, content development for the biosafety website and also represented DOB/NRE in giving talks about the Biosafety Act in events. In addition, Dr Anita has helped DOB/NRE to organise capacity-building activities on biosafety for local stakeholders. She also provides technical assistance to DOB/NRE in responding to queries from the public or interested parties regarding the Biosafety Act. Dr Anita acquired a

degree in BSc Horticulture and a PhD in Agriculture from University Putra Malaysia.

Professor Datin Dr Azizan binti Baharuddin

Professor Azizan Baharuddin received her Bsc (Hons) in Biology from the University of Tasmania, Australia in 1978, Msc (University College London) in 1979 and PhD in Philosophy of Science (Science & Islam) University of Lancaster, UK, in 1989. She specialises in areas such as ISLAM AND SCIENCE, environmental ethics and bioethics; science, religion and sustainable development; interfaith and intercivilisational dialogue. She has published widely in all these areas (more than 120 books, book chapters, monographs and articles).

She is also active in several NGOs that are connected with youth, gender, development, Islam and the environment as well as being a member of various advisory and consultative committees for ministries such as the Ministry of Science, Technology and Innovation; the Department of Unity and National Integration, Prime Minister's Department, the Ministry for Women, Family and Community Development; Ministry of Higher Education; National Commission for UNESCO Malaysia, Ministry of Education; Ministry of Culture, Heritage and Ministry of Youth and Sports. From 2011 – 2014, she has been appointed by the Prime Minister, as a member of the National Committee of Science and Research (MSPK, MOSTI). In 2011 – 2014, she was appointed by the Prime Minister as the Chairman of the Jawatankuasa Mempromosikan Persefahaman dan Keharmonian Di

Antara Penganut Agama (JKMPKA) 2014 – 2015; appointed by the Minister of Science, Technology and Innovation as a member (2009 – current) and Chairman of the National Bioethics Committee (NBC) (2014 – 2015). In 2014 she was appointed by the Director General of UNESCO to be a Member of the International Bioethics Committee (2014 – 2016). She was instrumental in establishing the first UNESCO Club (UM) in Malaysia in 2010.

Since 2009 she has been appointed a member of the UNESCO Network of Women Philosophers and she has received an award from the Centre for Theology & Natural Sciences (2001) for her work on Science & Religion. Besides annually giving papers at various conferences locally and abroad she is also regularly invited to give inputs through the local media (TV, radio) regarding issues that are of relevance to society in her areas of specialisation. She was Director at the Centre for Civilisational Dialogue, University of Malaya (2000-2011). Currently she is Deputy Director-General of the Institute of Islamic Understanding Malaysia/Institut Kefahaman Islam Malaysia (IKIM) as well as Professor at the University of Malaya.

At IKIM one of her major functions is to supervise the research and publication divisions. Her own area of focus is science, religion and sustainable development as well as interfaith dialogue. Besides regularly delivering papers at local and international conferences, through IKIM she contributes regularly to the local newspapers (STAR, Berita Harian etc.) and goes on air live weekly over IKIM fm (IKIM's radio) on Science and Islam/religion. Examples of her recent publications include, Azizan Baharuddin "Guardianship of Nature,

An Islamic Perspective in the Context of Religious Studies, Theology and Sustainable Development" in Michael Ipgrave and David Marshall (eds.), Humanity Texts and Contexts, Georgetown Unversity Press, 2011); Zeeda Fatimah, Norshahzila Idris, Azizan Baharuddin, Amran Mohammed, Nik Meriam Sulaiman, "The Role of Religious Communities in Recycling: Empirical Insights From Malaysia", "Journal of Resources, Conservation and Recycling" 58 (2012) 143-151; Azizan Baharuddin & Y. Shimizu (eds.) 2009. Environmental Ethics Regulation & Economy, Japan Society for the Promotion of Science & University of Kyoto; Simon T.W. and Azizan B. (eds)(2008), Dialogue of Civilisations and the Construction of Peace. Centre for Civilisational Dialogue, University of Malaya, Kuala Lumpur; Islam and Dialogue of Civilisations, (2006), Science & Religion: An Islamic Perspective (2007) and Rediscovering the Resources of Religion in Sharon Harper, The Lab, Temple and the Market: Intersection of Science, Religion and Development, International Development Research Centre (IDRC), Ottawa (2000); Islam and Ecology: a Bestowed Trust; co-edited with Richard Foltz and Azim Najim, University of Harvard Press (2003) and "Dialogue of Civilisations and the Construction of Peace", co-edited with Thomas Simon and A. Gunn, CCD, University of Malaya (2007).

Dr Koos van der Bruggen (co-facilitator)

Dr Koos van der Bruggen (1951) studied political science (International Relations) and wrote his PhD. thesis on criteria for the ethical judgment of nuclear deterrence. He has been working at the Rathenau Institute, the Dutch organisation for parliamentary technology assessment for more than 12 years. He was involved in research and debates on

social and ethical aspects of technological developments (biomedical technology, genetics, and military technology). More recently Van der Bruggen has been working at the Royal Netherlands Academy of Arts and Sciences (developing a Code of Conduct for scientists regarding issues of biosecurity) and Delft University of Technology (research on biosecurity and Dual Use). Furthermore he was the secretary of the Committee of Inquiry into the Dutch involvement in the Iraq War of 2003 (Davids Committee 2009).

Until the end of 2014 Van der Bruggen was the secretary of a Committee on Biosecurity of the Royal Netherlands Academy of Arts and Sciences that –in response to the h5N1 debate - advised government on Dual Use research. Moreover, he is an independent researcher on peace and (bio)security issues. Dr van der Bruggen has also published (in Dutch and English) on issues of war, ethics, technology including biological weaponries.

Dr Julie Fischer (co-facilitator)

Dr Julie E Fischer co-directs a portfolio of research projects in global health security with Dr Rebecca Katz at the George Washington University School of Public Health and Health Services, where she is currently an Associate Research Professor in the Department of Health Policy. From 2007-2012, Dr Fischer directed Stimson's Global Health Security Programme - exploring the tools, policies, and partnerships that strengthen global capacities for disease detection and response. Dr Fischer is a former Council on Foreign Relations

International Affairs Fellow and American Association for the Advancement of Science Congressional Fellow. As professional staff with the Senate Committee on Veterans' Affairs, she worked on issues related to emergency medical preparedness and the consequences of biological, chemical, and radiological exposures during military service. She served as a senior research fellow at the University of Washington and Seattle Biomedical Research Institute, and as a microbiologist with a Thai-USA collaboration aimed at strengthening Thailand's capacities to identify and control emerging infections of regional and global significance. Dr Fischer received a BA from Hollins University and a PhD in microbiology and immunology from Vanderbilt University.

Dr Jo Husbands (co-facilitator)

Dr Jo L. Husbands is a Scholar/Senior Project Director with the Board on Life Sciences of the US National Academy of Sciences (NAS), where she manages studies and projects related to biosecurity, particularly: (1) education and outreach in the broader context of responsible science and (2) the implications of continuing advances in the life sciences for efforts to mitigate the risks of misuse. She represents the NAS on the Biosecurity Working Group of IAP: The Global Network of Science Academies, which also includes the academies of Australia, China, Cuba, Egypt, India, Nigeria, Pakistan, Poland (Chair), Russia, and the United Kingdom. From 1991-2005, she was the Director of the NAS Committee on International Security and Arms Control (CISAC) and its Working Group on Biological Weapons Control.

Before joining the National Academies, she worked for several Washington, DC-based nongovernmental organisations focused on international security. From 2001-2012 Dr Husbands was an adjunct professor in the Security Studies Programme at Georgetown University. She is currently a member of the Temporary Working Group on Education and Outreach in Science and Technology of the Organisation for the Prohibition of Chemical Weapons, and is also a Fellow of the International Union of Pure and Applied Chemistry. She holds a PhD in Political Science from the University of Minnesota and a Masters in International Public Policy (International Economics) from the Johns Hopkins University School of Advanced International Studies.

Professor Dato' Dr Jamil Maah (co-facilitator)

Graduated with BSc (Hons) in Chemistry from UM in 1979 and started his academic career as a chemistry tutor at PASUM and later went to University of Sussex, UK to do his MSc in Organometallic Chemistry. This marked the year he worked in collaboration with Professor Sir Harry Kroto, a Nobel Laureate in Chemistry. In 1985 he went again to Sussex University to do his DPhil - continuing on the pioneer work he initiated during MSc on the coordination chemistry of ligands containing P-C multiple bonds under the supervision of Professor John Nixon. Other than research, he is actively involved in chemical education and had been consultants to several ministries and industries in Malaysia. In addition, he has held several academic administrative positions in UM like Head of Department, Director, Dean of several establishments in UM, Deputy Vice Chancellor (Research & Innovation) and Deputy Vice Chancellor (Academic &

International). He is also the Chairman of the Malaysia Chemistry Olympiad Committee. Notably, he also heads several scientific committees involving government ministries and societies. He was recently seconded to the Ministry of Science, Technology and Innovation (MOSTI) as Undersecretary of BIOTEK Division and still serves as Chairman of Management Committee of National Institutes of Biotechnology Malaysia (NIBM). Currently, he is a Professor of Inorganic Chemistry at the Department of Chemistry, University of Malaya.

Dr Piers Millett

Piers D Millett, PhD is Principal of Biosecure Ltd, a company dedicated to safeguarding the bioeconomy. Dr Millett currently consults for the World Health Organisation supporting their R&D efforts on Ebola. Piers also holds a Global Fellowship at the Woodrow Wilson Center for International Scholars in Washington D.C., where he focuses on the implications of, and responses to, the security considerations of modern biology and biotechnology. Until June 2014, Dr Millett was Deputy Head of the Implementation Support Unit for the Biological Weapons Convention (BWC), a treaty for which he worked for over a decade.

Trained originally as a microbiologist, Piers is a Chartered Biologist and works closely with the citizen science movement, synthetic biologists, the biotechnology industry as well as governments. His efforts have seen him collaborate with a range of intergovernmental organisations spanning health (human and animal), humanitarian law,

disarmament, security, border control, law enforcement, and weapons of mass destruction – both inside and out of the United Nations system. Piers is also a founder member of the Safety Committee of the International Genetically Engineered Machines Competition.

Dr Helen Mitin (co-facilitator)

Dr Helen Mitin has been a Research Officer at the Department of Veterinary Services (DVS), Ministry of Agricultural and Agro-based Industries since 2008, holding various posts at different divisions in DVS. Dr Mitin graduated from Universiti Putra Malaysia (UPM) with a Master of Veterinary Science (MVSc) in 1999, followed by a Doctorate in Veterinary Medicine (VDM) in 2013. Her research area of expertise is on animal welfare. She is a committee member of the Institutional Animal Care and Use; in research and scientific experiment for DVS, SIRIM and the Faculty of Veterinary Medicine Graduate Students Association (VGA). She has also been an active advocate of the Animal Welfare Bill from 2011 until now. In 2012, she was appointed as the Secretary to the Malaysian Veterinary Council and Veterinary Association Malaysia (VAM).

Dr Helen Nair (co-facilitator)

Professor (Retd) Dr Helen Nair is a Fellow for both Academy of Sciences Malaysia and the Malaysian Scientific Association. She is on the National Biosafety Board and is an Advisor to the Postharvest Biotechnology Laboratory, University of Malaya (UM). She was an academician at UM for over 30 years holding the Professorial Chair

of Plant Physiology from 1994. From 2001-2007 and again from 2011 to 2014, she was inaugural Professor of Biotechnology and Faculty Dean at private universities in Kedah and Perak. She helped develop education programmes, especially in Biotechnology at undergraduate and postgraduate levels. Her major research interests are in postharvest physiology and biotechnology, ethylene genes and cryopreservation for conservation and improvement of crops. She has supervised about 75 graduate and postgraduate students and produced more than 120 publications, the most recent of which is a review on ethylene [Cherian et al. 2014, J Exptal Bot, 65 (17): 4705–22; IF=5.8]. Dr Nair has organised and participated in numerous scientific conferences and served in several professional societies, journal editorial boards, R&D review panels and national advisory councils.

Dr Sohayati Abd Rahman (co-facilitator)

Dr Sohayati Abd Rahman graduated from the University Putra Malaysia, with a degree in Veterinary Medicine in 1994. She joined the Department of Veterinary Services Malaysia as Veterinary Officer in Veterinary Research Institute (VRI) in 2001. In early years, she was attached to the JICA virology expert for 6 years. She finished her PhD in Veterinary Epidemiology, on Nipah virus in Pteropus, from UPM in 2008. She was appointed as Head of Zoonotic Section and was also the officer in charge of the level 3 Biosafety Laboratory in VRI for 5 years from 2008 until October 2012. In November 2012, she was promoted as the Director of South Regional Veterinary Laboratory in Johor Bahru. Currently, she serves at the Veterinary Research

Institute, in the Bacterial vaccine section. At present, her main research currently is related to zoonoses in wildlife and veterinary bacterial vaccine. Dr Sohayati and her team have published over 20 cited papers especially on Epidemiology. She was appointed by Department as the OIE national wildlife focal point from 2008 until now. Her knowledge in Biosafety and Good Laboratory Practice is recognised by the Department, being invited to be a speaker, facilitator and panel at related Workshops and simulation through the country.

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Ms Saraswathy Subramaniam

Ms Saraswathy is the founding member and President of Malaysian Biosafety & Biosecurity Association (MBBA) since 2011. During her term as President she has promoted the association networking with the Biosecurity Engagement Programme (BEP) US Dept of State, the Malaysian Society for Microbiology, Sandia National laboratories and the American Society for Microbiology to organize various biosafety and biosecurity projects and outreach programmes. These include the Malaysian Advanced Biorisk Officers Training (ABOT) courses in 2013/2014 and 2015, the TB biorisk management workshop in 2013 and Ebola BRM in 2014. MBBA now has more than 139 active members. MBBA is affliated with the International Federation of Biosafety Associations (IFBA). Ms Saraswathy is also a committee member of Asia Pacific Biosafety Association (A-PBA).

She is presently serving as a Senior Research Officer and Biosafety Officer at the Institute for Medical Research, Kuala Lumpur. Her research contributions include HIV molecular epidemiology, viral aetiology of acute flaccid paralysis and measles. She has published her research extensively in international scientific journals. Her responsibilities include implementing biorisk management and training in IMR.

Ms Saraswathy has provided her expertise and leadership representing the Ministry of Health in national and international technical expert committees related to the development of biosafety and biosecurity regulatory and guidance documents; policies and standards. Some of these include International guidance, CWA 16393:2012 Laboratory BRM, MOH SOP for Transport of biological

specimens in Malaysia, 2012, Biosafety Guidelines for Contained use activity of LMOs, 2010, Biosafety guidelines, Risk assessment of genetically modified microorganisms and the Malaysian Standards for Biocontainment and Biosafety in microbiology laboratories, published in 2015. She has contributed actively in national biosafety outreach training workshops to raise awareness on biorisk management. She has also represented Malaysia as a technical expert in EU pilot projects on biosafety and biosecurity and the Meeting of Experts (MXP) to the Biological Weapon Convention, Geneva, Switzerland in 2013 and 2014.

Professor Dr Herawati Sudoyo

Herawati Sudoyo received an MD from University of Indonesia and obtained her PhD in Biochemistry/Molecular Biology from Monash University, Melbourne, Australia. She is the Deputy Director for Fundamental Research of the Eijkman Institute for Molecular Biology in Jakarta, Indonesia. She is the founding member and former President of Indonesian Biorisk Association whose mission is to raise awareness and build expertise on biosafety and biosecurity in Indonesia. As a member of the Indonesian Academy of Sciences, she is responsible for the development of Indonesian Code of Conduct on Biosecurity, and established a strong collaboration with the US National Academy of Sciences and the Royal Netherlands Academy of Arts and Sciences. She actively participates as member of the Indonesian delegation for UN-BWC Meeting of Experts since 2006, ASEAN Regional Forum Workshops on biosecurity issues, and many other related workshops. She is a member of the National

Commission for the Zoonosis Implementation Team since 2012 and also the Technical Committee of National Standardisation Agency for Laboratory Biosafety Management Standard.

Dr Gerald Walther

Dr Walther has been involved in various research activities that work towards implementing and strengthening the BWC. To illustrate, he has contributed to raising awareness in the potential misuse of neuroscience research by developing educational courses for science students, as well as publishing on this topic in scientific journals. He has also introduced this topic to neuroethicists via his involvement as a section editor of the Springer Reference Handbook of Neuroethics. He has also discussed the need for biosecurity education in UN organized workshops in Africa.

Professor Datin Dr Zahurin Mohamed (co-facilitator)

Professor Zahurin Mohamed graduated from the University of Dundee, Scotland, with a PhD in Pharmacology. She joined the University of Malaya in 1979, and was promoted to Professor of Pharmacology in the year 2000. She was the Head of the Department of Pharmacology for over 19 years from 1994 until August 2014. Her main research currently focusses on pharmacogenomics (PGx). PGx is one of the fastest growing research areas globally. She also supervised over 20 postgraduate students in this field. In 2011, her laboratory was awarded research funding of over USD1 million for over a period of five years, and since then, her team has published

over 65 ISI-cited papers on pharmacogenomics. Professor Zahurin Mohamed represents Malaysia in an international collaborative group on pharmacogenomics, based at the National Institute of Health, USA. Meanwhile, she also represents the country in two regional groups. She is a member of at least 7 committees at the national level - the most significant being the National Committee for Clinical Research (NCCR). Her expertise in Good Clinical Practice (GCP) is recognised, being invited to be a speaker and facilitator at GCP Workshops throughout the country. Her expertise also extends to being a consultant for contract research in the form of Bioequivalence (BE) Studies for various generic drug manufacturers since 1999, and to date, her team has completed over 30 BE studies. Her Bioequivalence Centre has two accreditations, one under SAMM ISO-IEC 17025/2001, and the other under the Ministry of Health, and is one of only three accredited centres in Malaysia. Prof Zahurin Mohamed was appointed by the Minister of Science, Technology and Innovations, to be a member of the National Bioethics Council (NBC) and presented the Keynote Address at its launch. She is currently Vice-Chairman of NBC. She was also recently appointed by the Minister of Education, to represent the University of Malaya's Senate Members in the University's Board of Directors. She is also a member of the Board of Directors of several companies under the University of Malaya including the University of Malaya Specialist Centre. She is actively involved in many NGOs, and in community and student activities.

Dr Zalini Yunus

Dr Zalini graduated with a degree in Microbiology from the University Kebangsaan Malaysia, obtained her M.Sc. degree in Immunology and Allergy from the University of Nottingham, United Kingdom, and received her PhD in Chemical Engineering from the University of Manchester, Institute of Science and Technology (UMIST), UK. She commenced work with the Science and Technology Research Institute for Defence (STRIDE) in 1998 as a Microbiologist. She is currently their Head of Biosurveillance and Biodefence, as well as the facility manager for STRIDE's Biosafety Level 2 and 3 laboratories. She has been involved, both nationally and internationally, in establishing the Biological and Toxin Weapons Convention (BWC). Apart from that, she actively promotes the implementation of biosafety and biosecurity measures in Malaysia in fulfilling national obligations to the Convention. In addition, she is the Chairman for the Technical Committee for Drafting Malaysia's BWC bill and regulations. She is also currently the national contact person/coordinator related to country's collaboration in the Biosecurity and Biorisk Management Programme.

Over the years, she has presented and published numerous papers in national and international conferences and journals. She has been actively involved in organising the national and international conferences related to biosafety and biosecurity, including National Biosecurity Meeting 2005, Asia Biosafety and Biosecurity Conference 2007, International Congress on Biosafety, Biosecurity and Biodefence 2011, Asia Pacific Biosafety Association Conference 2013 and The NCT: CBRNe Asia 2013.

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