**Enhancing Biosecurity Oversight in Malaysia with Dual Use Case Studies**

**Participant Packet**

**Introduction and Risk Analysis Overview**

This case study exercise was developed by Gryphon Scientific and the Science and Technology Research Institute For Defence (STRIDE) for the workshop titled “Workshop on Enhancing Biosecurity Oversight in Malaysia with Dual Use Case Studies”

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* International Engagement: Secure Science, Technology, and Research - BMENA Case Studies: <https://www.aaas.org/report/BMENA-risk-analysis-training>
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**Risk Considerations in Life Science Research**

***Range of risk considerations:***

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| **Human participants in research** – risks to well-being, justice and autonomy |
| **Animal subjects in research** – risks to well-being |
| **Research misconduct**: “includes fabrication, falsification, plagiarism and deception” 1 |
| “Haste, negligence, carelessness, and inattention” 1 |
| **Dual-use life sciences research:** “biological research with legitimate scientific purpose, of which the resulting new technologies or information have the potential for both benevolent and malevolent applications.” 2 |
| **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” 2 |
| **Misuse**: “misuse of biological materials describes their inappropriate or illegitimate use, despite existing and subscribed agreements, treaties and conventions”2 |
| 1. National Science Council. (2017) The Malaysian Code of Responsible Conduct in Research.  2. Science & Technology Research Institute for Defence (STRIDE) Ministry of Defence Malaysia. (2015) Workshop on the Development of a National Code of Conduct for BIOSECURITY in the Framework of Biological and Toxin Weapons Convention. Kuala Lumpur: Academy of Sciences Malaysia. |

***Concepts in risk mitigation and responsible science:***

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| --- |
| **Research excellence**: “research that is of high quality, ethical, rigorous, original and innovative” 1 |
| Protection of **human participants** or **animal subjects** in research |
| **Bioethics**: “ethical and moral implications of biological discoveries, biomedical advances and their applications” 1 |
| **Research integrity**: practices include “conscientious avoidance of research misconduct; policies for handling misconduct, conflicts of interests, data management, authorship, peer review and collaborative research” 1 |
| **Biorisk reduction**: “reduction of the occurrence of risks associated with exposure to biological agents and toxins, whatever their origin or source” 1 |
| **Laboratory biosecurity**: “protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release” 1 |
| **Laboratory biosafety**: “containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents and toxins, or their accidental release” 1 |
| 1. World Health Organization (WHO). (2010) Responsible Life Sciences Research for Global Health Security: A Guidance Document. |

**Dual-Use Life Sciences Research**

A report on Malaysia’s Workshop on the Development of a National Code of Conduct for Biosecurity lists several categories of dual-use scientific activities[[1]](#footnote-1):

“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.”

Other scientific activities outside this list may have dual use potential and should be considered in the risk analysis framework.

**Risk Analysis Framework**

*Although risk analysis can be distilled into four steps – risk identification, risk assessment, risk management, and risk communication – the process is continuous and linked with the scientific process.*

**Risk Identification**

**Risk Assessment**

**Risk Management**

**Risk Communication**

Conduct Research

Publish or Present Findings

Plan Project

***Risk Analysis***

***Scientific Activities***

*Continuously identify, assess, manage risks*

The general steps of the risk analysis framework are detailed below with examples. Tailor this approach to a specific analysis by adding to or modifying these questions.

**1. Risk Identification**

* Identify risks to the researchers, human participants or animal subjects, public health, environment, agriculture (including animal and plant health)
* Consider methodologies, materials, and information associated with or resulting from the work
* *Example: Experiment may result in a pathogen with enhanced virulence, which poses risks to human health*
* General question:
  + What are the risks associated with this research?
* Examples of specific questions:
  + What are the risks to researchers from the biological materials used in this study?
  + Could methodologies or results be used for malicious purposes?

**2. Risk Assessment**

* Assess the possible harms that may arise from the risks and the severities of these harms
* Example measures of severity: severity of disease, number of people infected, financial loss
* General questions:
  + What are the harms that may arise from the identified risks? What are the severities of these harms?
  + Does the severity of harms counteract, prevent, or limit the benefits of the study?
* Examples of specific questions:
  + What harms may arise if the identified risks to public health occur? How severe are these harms?
  + What harms may arise if the identified risks to plant health occur? Will these harms be experienced immediately or far in the future?

**3. Risk Management**

* Consider approaches to mitigate or manage risks, without compromising the quality of the scientific work
* Potential approaches include standard operating procedures (SOPs), best practices, safety measures and controls, personnel training, regulations, and alteration of the research methodology
* *Examples of suggestion to manage dual-use and biosecurity risks:*
  + *Require personnel to undergo training with practice materials before working with infectious materials*
  + *Implement access controls, such as locking the laboratory so it is accessible only to authorized persons*
  + *Identify national and/or international regulations for possession or shipment of hazardous materials*

Alter research approach to lower risks, if modified experimental procedures will not compromise research quality; e.g., use non-pathogenic organisms where possible

* General questions:
  + What approaches can mitigate or manage risks?
  + How can risk management approaches be implemented to effectively minimize risk without compromising scientific utility and quality?

**4. Risk Communication**

* Communicate the risks of the research to the appropriate audiences
  + *Example: Communicate human health risks to an Institutional Review Board*
* Communicate risk mitigation strategies to appropriate audiences
* If a risk in sharing the results of the study exists, consider how to communicate findings responsibly
  + *Example: If a study produces a pathogen with enhanced virulence, consider whether/how to communicate methods and results responsibly*
* General questions:
  + To whom should the risks be communicated? How should the risks of the study be communicated to these audiences? What risks must be communicated?
  + To whom should risk mitigation strategies be communicated? How should risk mitigation strategies be communicated to these audiences? What risk mitigation strategies should be shared?
* Examples of specific questions:
  + How should public health risks of the study and containment strategies for pathogen samples be communicated to a biosafety committee?
  + How should the research on pathogen virulence be communicated in published materials to minimize the potential for misuse of information?

1. Science & Technology Research Institute for Defence (STRIDE) Ministry of Defence Malaysia. (2015) Workshop on the Development of a National Code of Conduct for BIOSECURITY in the Framework of Biological and Toxin Weapons Convention. Kuala Lumpur: Academy of Sciences Malaysia. https://issuu.com/asmpub/docs/code\_of\_conduct\_for\_biosecurity\_wor [↑](#footnote-ref-1)