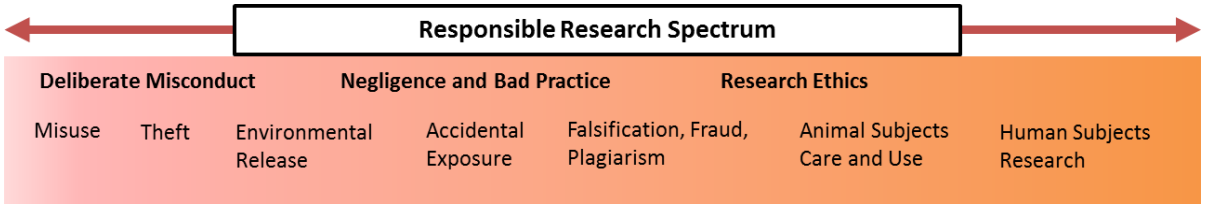
PARTICIPANT PACKET

Practical Training Exercise: Analyzing and Managing Risks in Life Sciences Research

Based on the article by Ahmad, H.A. et al. "Emergence of Foot-and-Mouth Disease Virus SAT 2 in Egypt During 2012."

BIORISK GLOSSARY



The definitions used in this exercise are from the World Health Organization's, *Responsible Life Science for Global Health Security: A Guidance Document*. 2010; http://whqlibdoc.who.int/hq/2010/WHO_HSE_GAR_BDP_2010.2_eng.pdf

Subset of Definitions from WHO

"Bioethics: The study of the ethical and moral implications of biological discoveries, biomedical advances and their applications, as in the fields of genetic engineering and drug research."

"Biorisk: The risk (risk is a function of likelihood and consequences) that a particular biological event (in the context of this document: naturally occurring diseases, accidents, unexpected discovery, or deliberate misuse of biological agents and toxins), which may affect adversely the health of human populations, may occur. An assessment of these risks can be both quantitative and qualitative."

"Biorisk reduction: The reduction of the occurrence of risks associated with exposure to biological agents and toxins, whatever their origin or source, encompassing the full spectrum of biorisks."

"Laboratory biosafety: The containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents and toxins, or their accidental release."

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

"Dual-use life sciences research: Knowledge and technologies generated by legitimate life sciences research that may be appropriated for illegitimate intentions and applications."

"Research excellence: Research that is of high quality, ethical, rigorous, original and innovative."

Additional Definitions

The definitions below are from the *U.S. National Academy of Sciences (2009) On Being a Scientist: A Guide to Responsible Conduct of Research: Third Edition.*

Research Misconduct: "Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results."

Falsification: "Manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record."

Fabrication: "making up data or results"

Plagiarism: the use "of another person's ideas, processes, results, or works with our giving appropriate credit."

Protection of Human Subjects: "Protect the interest of research Subjects" by ensuring "that risks to human participants are minimized; that risks are reasonable given the expected benefits; that the participants or their authorized representatives provide informed consent; that the investigator has informed participants of key elements of the study protocol; and that the privacy of participants and confidentiality of data are maintained."

Animal Subject Care and Use: "to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, research training, and biological testing." Researchers should consider "reduction in the numbers of animals used, refinement of techniques and procedures to reduce pain and distress, and replacement of conscious living higher animals with insentient material."

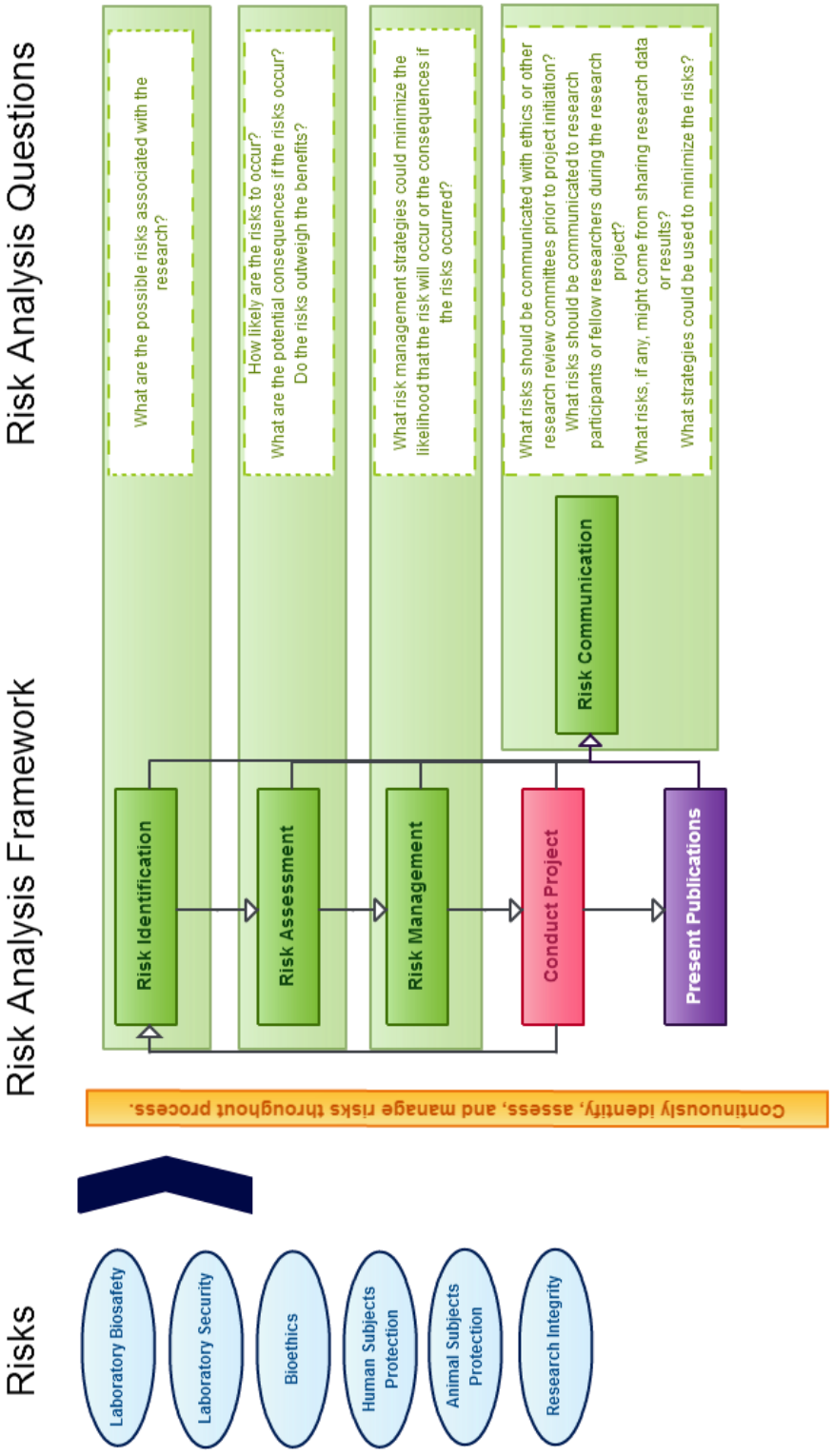
Negligence: "Haste, carelessness, inattention – any of a number of faults can lead to work that does not meet scientific standards or the practices of a discipline."

The definitions below are from the *U.S. National Academy of Sciences (1992) Responsible Science, Volume I: Ensuring the Integrity of the Research Process.*

Research Integrity: "the adherence by scientists and their institutions to honest and verifiable methods in proposing, performing, evaluating, and reporting research activities.

Research Process: "the construction of hypotheses; the development of experimental and theoretical paradigms; the collection, analysis, and handling of data; the generation of new ideas, findings, and theories through experimentation and analysis; timely communication and publication; refinement of results through replication and extension of the original work; peer review; and the training and supervision of associates and students.

RISK ANALYSIS FRAMEWORK



RISK IDENTIFICATION

Questions	Answers
What, if any, are the potential biosafety risks? What, if any, are the potential biosecurity risks?	
Does this research pose any additional risks to FMD-susceptible animal populations or the economy?	
What, if any, are the risks involved in transportation of infected animal samples?	
Could the research activities and/or results be used to cause harm?	

RISK ASSESSMENT

Question	Answers
What, if any, are the potential consequences of the environmental and animal population risks associated with this research? How likely are these risks to occur?	
What, if any, are the potential consequences of the biosafety risks associated with this research project? How likely are these risks to occur?	
What are the resources, expertise, training, and tools that could be useful in assessing the risks identified for this research project?	

RISK MANAGEMENT

Question	Answers
What international, national, or institutional regulations, laws, or best practices could be used to mitigate potential biosafety and biosecurity risks?	
What, if any, specialized competencies, skills, and training are needed to successfully carry out this research project?	
What additional scientific approaches or methodologies, if any, could be used to further minimize the identified biosafety and biosecurity risks?	
What could be done to manage the risks of an unintended result, such as mutation of a FMD viral isolate in the laboratory?	
What policies and protocols should be in place to prevent accidental or intentional release of the FMD viral isolates?	

RISK COMMUNICATION

Question	Answers
What are the risks that should be communicated during this research? To whom?	
How would you communicate the risks and risk management steps to an institutional review committee, other researchers, or other FAO partners?	
What are some strategies for communicating these particular research risks to the agricultural community? Do the researchers have an ethical obligation to share their findings with farmers and other livestock stakeholders?	
Under what circumstances would the researchers have an ethical, safety, security, or economic obligation to NOT share some aspect their findings with the public? Does such a circumstance exist in this case study?	

FINAL EXERCISE

1. Identification: What are the primary risks you face in your research? Think about the risks to you and other researchers and technicians in the field, clinic, and/or lab, the general public, the environment and economy, your institution, and human and animal subjects.
2. Assessment: What are the consequences of the identified risks if they occur? How likely are they to occur? Based on your assessment of the potential consequences, are there are there any risks that could harm people, animals, crops, or the economy? What resources, capabilities, and skills are needed to mitigate these risks?
3. Management: What strategies could you use or resources you could refer to minimize or mitigate these risks? (These strategies should not decrease the quality of the research.) For ideas of possible strategies and resources, consider those discussed in this practical exercise and from your own experiences. Are there any risks associated with your research that cannot be adequately mitigated?
4. Communication: What risks, if any, are associated with communicating your research during the design or conduct of the research? What risks, if any, are associated with communicating the research results at scientific conferences and in publications? What strategies could you use to mitigate the risks? Are there any stakeholders with whom you must share or should share the risks of your research? Your findings?

CWA LABORATORY RISK MANAGEMENT STRATEGY

“Laboratory risk management.” CWA 15793: 2011

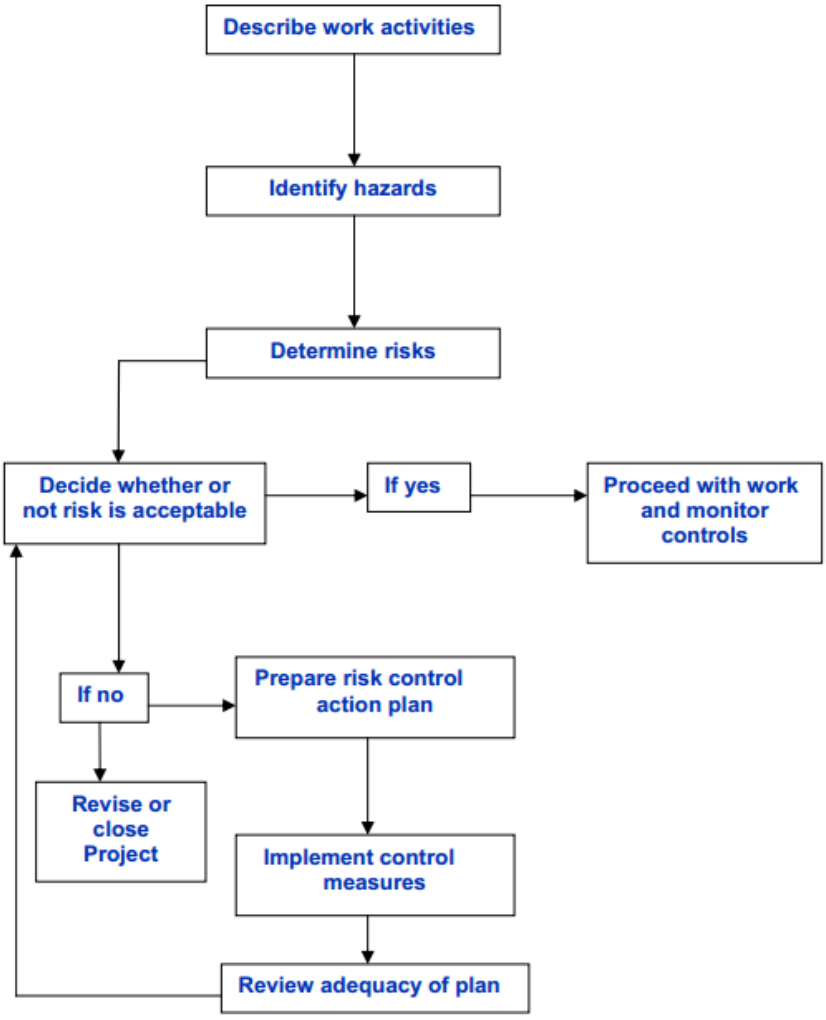


Figure 1 — Risk assessment strategy