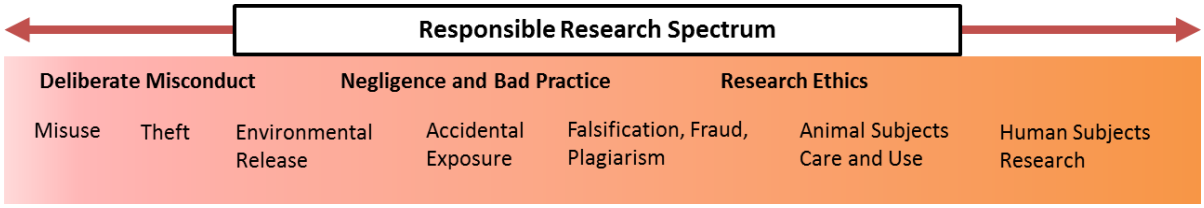
PARTICIPANT PACKET

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

Based on the article by Afifi, S Et al. "Hospital-Based Surveillance for Acute Febrile Illness in Egypt: A Focus on Community-Acquired Bloodstream Infections"

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."

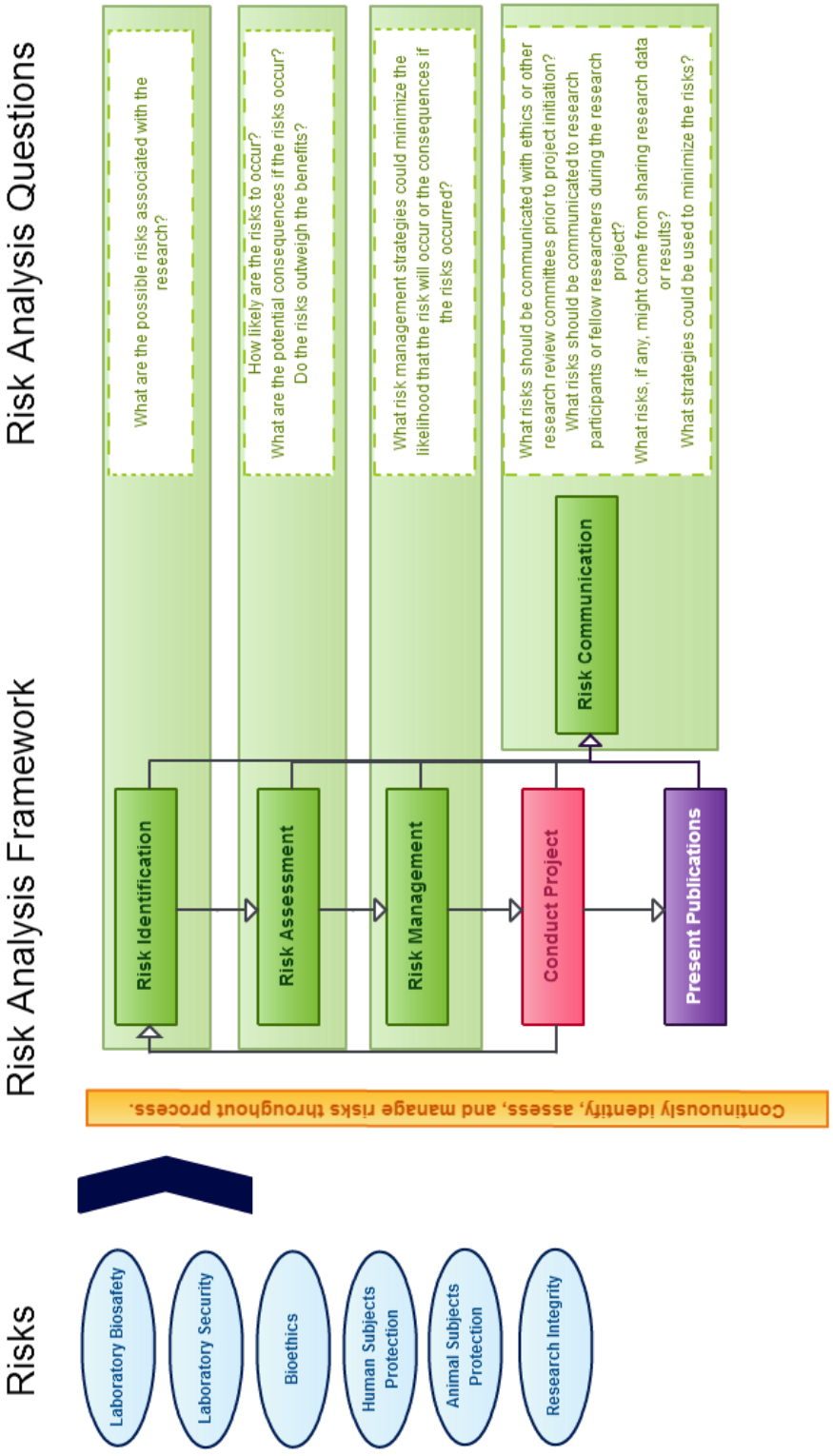
Negligence: "Haste, carelessness, inattention – any of a number of faults can lead to work that does not meet scientific standards or the practices of a discipline."

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 risks to researcher and staff during collection, handling, transportation, and laboratory analysis of infected human blood samples? What, if any, are additional or different risks to the health care providers who clinically evaluate and treat infected patients?	
What, if any, are the potential risks of accidental release or exposure might affect the human, animal, or environmental health of the neighboring community?	
Could the research used to deliberately cause harm, through deliberate release of *Salmonella enterica* typhi or *Brucella*?	
What, if any, are the possible risks to the patients who participate in this study?	

RISK ASSESSMENT

Question	Answers
To what extent does this research pose a public health, animal health, or environmental threat?	
What methodological steps in sample collection, transport, and analysis are most likely to result in a biosafety accident or incident? What methodological steps in sample collection, transport, and analysis are most likely to result in a biosecurity accident or incident?	
What are the resources, expertise, training, and tools that could be useful in assessing the risks identified for this research project?	
To what extent does this research pose a public health, animal health, or environmental threat?	

RISK MANAGEMENT

Question	Answers
What international, national, or institutional laws, regulations, policies, or best practices could help mitigate the risks from this research project?	
What standard operating procedures (SOPs) in sample collection, storage, transport, and analysis should be employed in this research project to mitigate any safety or security risks?	
What approaches could be taken to reduce the safety and security risks of the research project?	
What, if any, specialized competencies, skills, and training are needed to successfully carry out this experiment, including identifying and taking samples from patients, transporting whole blood samples, and analyzing samples in the laboratory?	
What approaches could be used to address the ethical considerations associated with the research project?	

RISK COMMUNICATION

Question	Answers
What are the risks that should be communicated during this research? To whom?	
How should researchers communicate the purpose and participant involvement to hospital patients experiencing acute high fever?	
What social and cultural sensitivities should be considered when discussing the research project and results with other scientists, human and animal health officials, clinicians, and policymakers or the public?	
How might the researcher communicate the results while limiting the transfer of sensitive and identifying information? What types of data anonymizing and data security needs to be done to protect collected epidemiological data?	
How can researchers best communicate research results with research participants and relevant stakeholders? Do researchers have an obligation to provide results to any particular individuals, ministries, or organizations?	

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

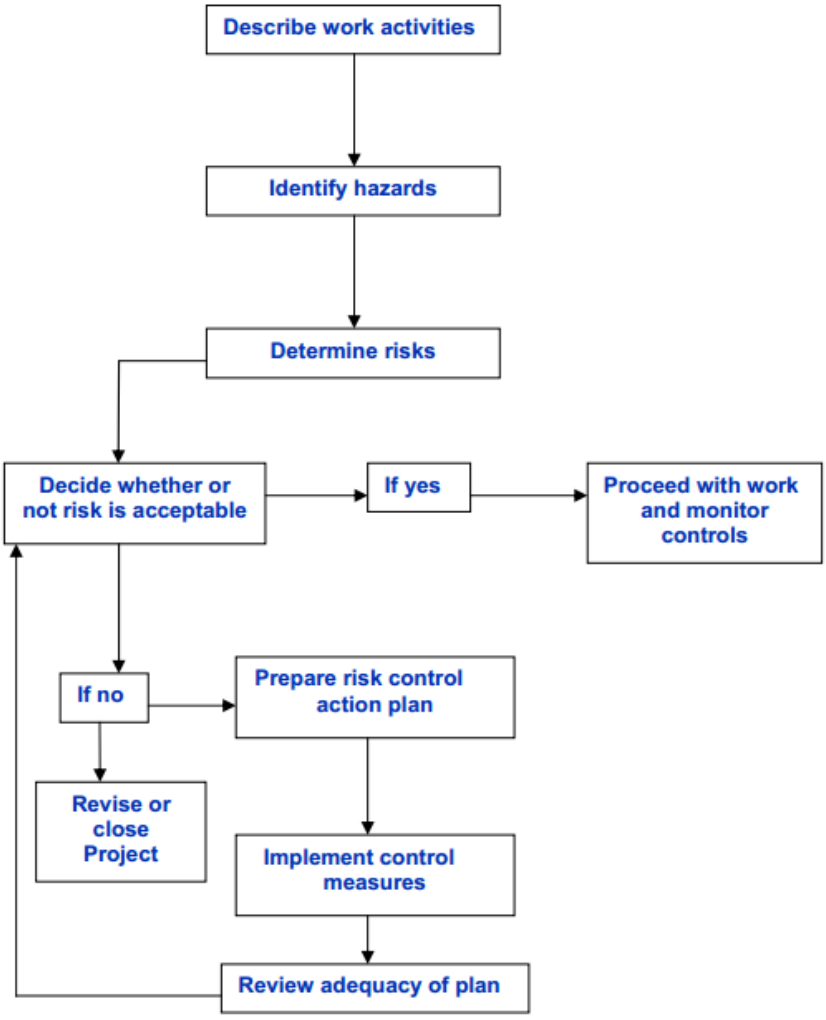


Figure 1 — Risk assessment strategy