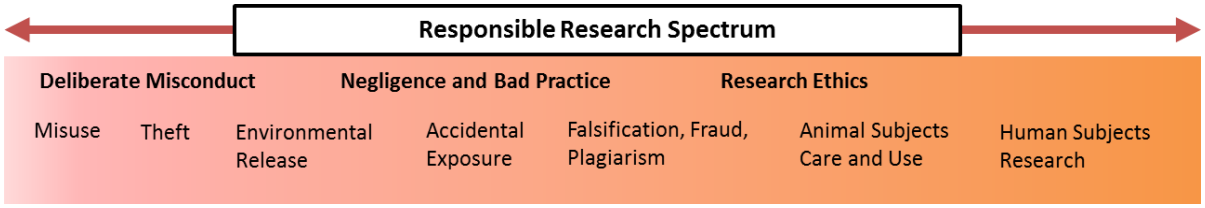
PARTICIPANT PACKET

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

Based on the article "Age-specific Seroprevalence of Hepatitis A Among School Children in Central Tunisia" by Letaief A. et al.

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."

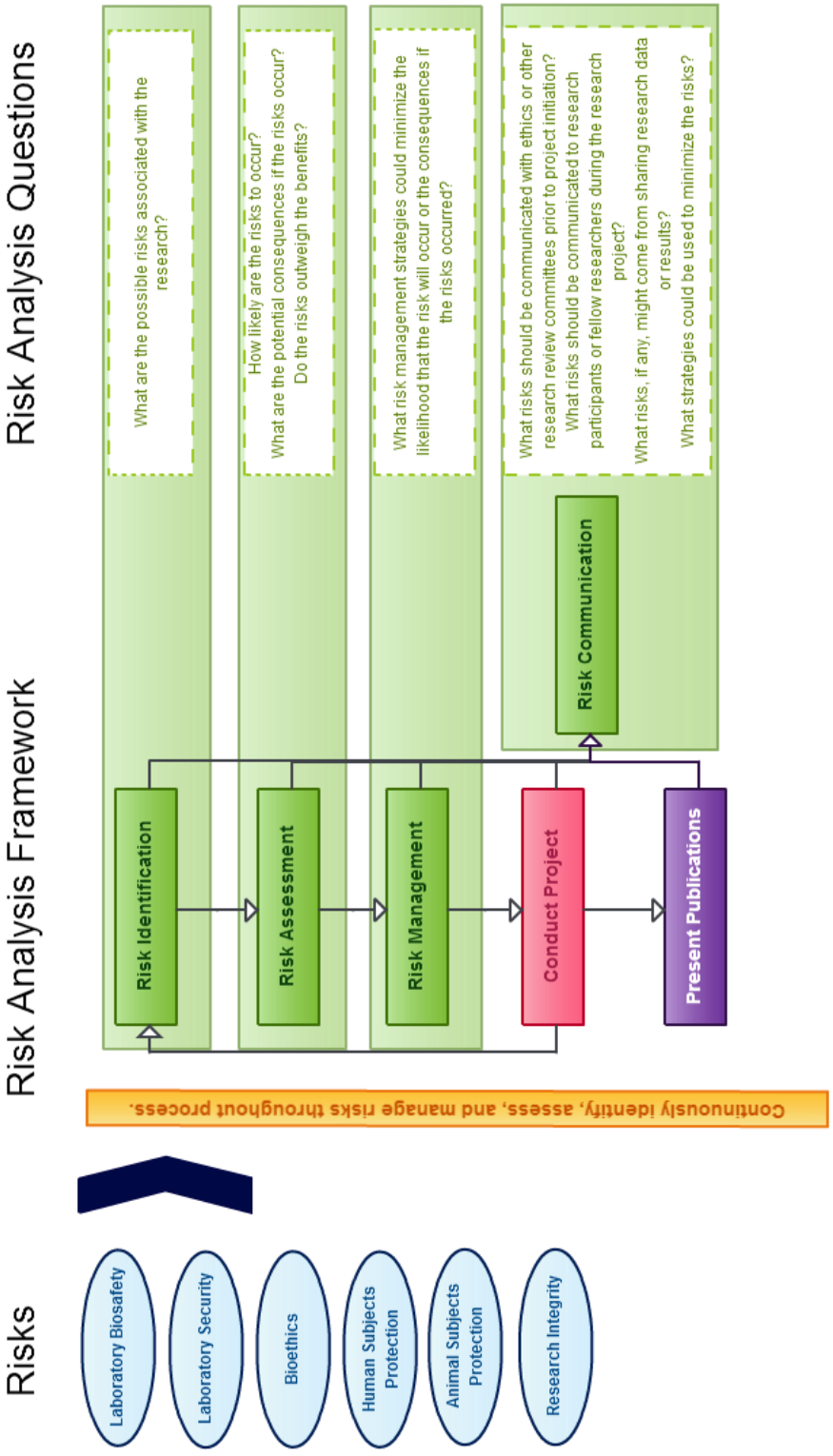
Negligence: "Haste, carelessness, inattention – any of a number of faults can lead to work that does not meet scientific standards or the practices of a discipline."

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 to the researcher and staff? Consider the research steps, including: collection and handling of human blood and serum separation.	
What , if any, are the potential risks to the general population? Is there a biosecurity risk or dual use potential for this research?	
Participants were randomly recruited from public schools in Tunisia. What are the risks or ethical concerns, if any, associated from recruiting children from schools to participate in the research?	
What, if any, are the possible risks (ethical or safety) to the children who participate in this study and to their families? What are the risks or concerns associated with gathering social and economic data from participant families?	

RISK ASSESSMENT

Question	Answers
In your opinion, what are the negative consequences that might result from the identified ethical risks? In your opinion, what are the negative consequences that might result from the identified biosafety risks?	
How likely is this experiment to result in a negative consequence for one of the children participating? How likely is this experiment to result in a negative consequence for the research staff?	
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
Are there any international, domestic, or institutional laws and/or regulations that would help manage risks from this study?	
What standard operating procedures (SOPs) and best practices for sample collection, treatment, and analysis should be used in this experiment to reduce the likelihood of a laboratory accident, such as a needle stick with blood?	
What other experiments, participant recruitment strategies, or data collection methods could be used to minimize the risks identified?	
What, if any, are specialized competencies, skills, and training needed to successfully enroll, interview, collect blood samples from participants, and analyze blood samples?	

RISK COMMUNICATION

Question	Answers
What are the risks that should be communicated during this research? To whom?	
How would you communicate possible risks and reasons to participate to potential research participants and their families?	
What data and information protection measures should be implemented to protect the safety and anonymity of research participants?	
How would you communicate the research results to the public and/or public health officials? What sensitivities, if any, exist with communicating the study's results to the public?	

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

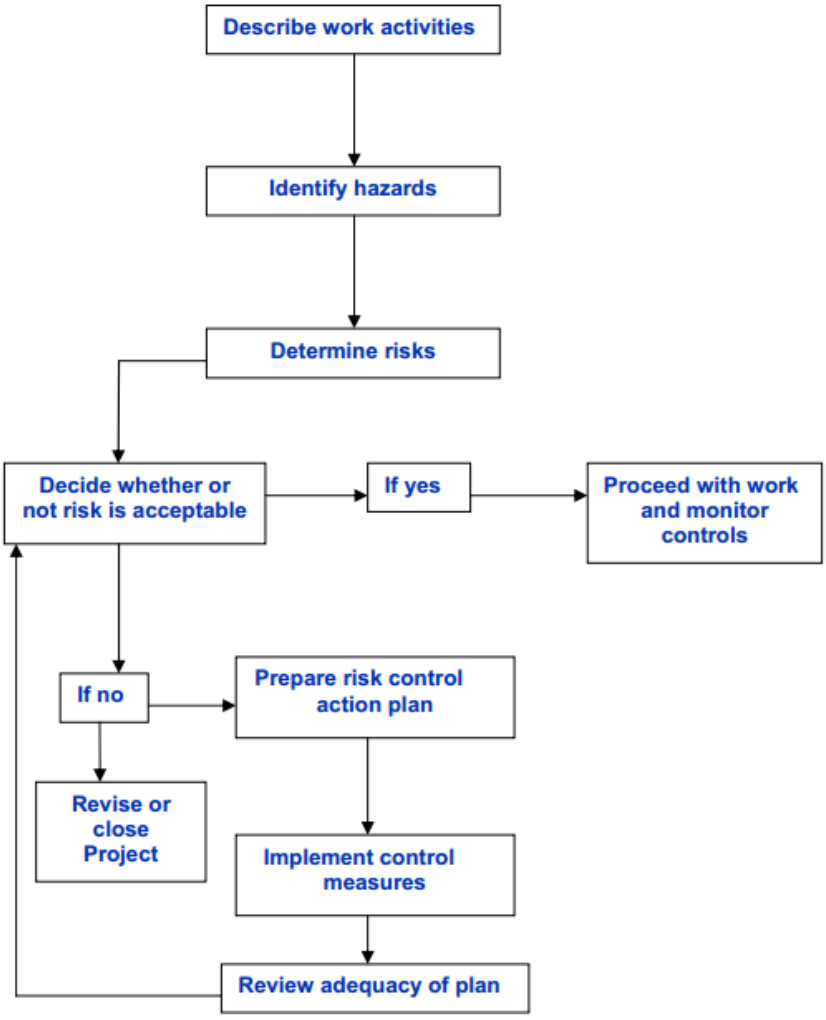


Figure 1 — Risk assessment strategy