

Biological Risk Assessment Resource

Consider the following when performing a risk assessment:

I. Evaluate and classify the biological agent and assign it to a Risk Group.

Primary Resource: [Risk Group Classification of Human Etiologic Agents](#) (Appendix B of the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules)

Risk Group	Risks
RG1	Not associated with disease in healthy human adults.
RG2	Associated with human disease; rarely serious; preventive or therapeutic interventions often available.
RG3	Associated with serious or lethal human disease for which medical interventions may be available; high individual risk but low community risk.
RG4	Likely to cause serious or lethal human disease for which medical interventions are not usually available; high individual AND high community risk.

Additional Resources:

- [Researcher's Planning Tool: Profile Your Infectious Agents](#)
- [Emerging Infectious Agents and Research: Planning for Biosafety](#)
- [Biosafety Guide for Research Cores: Identifying & Minimizing Biomaterials Risk](#)
- [Bloodborne Pathogens Profile](#)
- [Resources for Researchers: Recombinant DNA Molecule Use](#)

II. Further classify biological material features and risks

1. How readily does the biological agent spread and cause disease?
 - a. Has it been genetically modified, and if so, has it become more or less infectious than unmodified (wild type) agent? Is recombination possible?
 - b. Has it been treated (killed, partially inactivated)?
 - c. What are the possible routes of transmission (injection, inhalation, ingestion)?
 - d. What are the risks of transmission & release to the environment?
 - i. Does this agent spread human to human and/or between different species?
 - ii. Does it cause disease in animals that can endanger livestock?
 - e. How long does it remain viable in the environment? For instance, can aerosols remain airborne and viable for a long period (such as COVID-19 or TB)?
 - f. If the biological agent source is clinical, is there a special disease presentation to consider? What are the symptoms?
 - g. If the biological agent source is from an animal, what is the species?
 - i. Does source animal have symptoms?
 - ii. Is source animal domestic or does it come from outside the country?
 - h. Was the agent/material generated in a BSL-3 or 4 facility? If so, is documentation available to support that the material is contaminant-free?
2. Is effective prophylaxis (vaccine) or treatment available for the biological agent? Is it resistant to treatment (antivirals or antibiotics)?

To help answer these questions, complete the [Occupational Health Clinic Biologic Research Risk Assessment](#). This will help you identify if there are pre-exposure measures (vaccination) or specific information about risks and/or exposure follow up for the biological agents you will be using.

III. Identify Equipment, Procedures & Handling Processes

Handling and processing increase exposure risk and spreads contamination. Consider the following:

1. What is the maximum volume and concentration of liquid biological materials used for each step? Will agent amplification be performed?
2. Are solid tissue samples fixed or unfixed?
3. What type of vessels will be used? (Glass?)
4. What type of material transfer tools & equipment will be used?
5. What other physical hazards will be present? Here are a few common hazards:
 - a. Live animals
 - b. Sharps
 - c. Glass
 - d. Pressurized fluids
 - e. Pressurized air
 - f. Pneumatics
 - g. Aerosol-generating equipment (centrifuge, shaker, vortex mixer, pouring, etc.)
 - h. Extreme heat or cold

IV. Reduce and Control Your Risks

Once you have identified the risks, identify steps to improve safety.

Can you eliminate any risky steps, use different equipment or reagents, or modify any procedures to improve safety?

1. Where possible:
 - Eliminate hazards – especially those presenting the greatest risks).
 - Substitute less hazardous materials, equipment, and/or techniques when possible.
2. Identify engineering (equipment) and administrative controls (procedures) that help minimize the exposure risk. Protect personnel performing the procedures **and** anyone else who may be present in the lab.
 - *Engineering controls* are specially designed buildings and safety equipment that help isolate or eliminate hazards.
 - *Administrative controls* are procedures that reduce hazards, such as restricting access to the lab, personnel training & proficiency evaluations, proper disinfection and waste handling, and the use of PPE.
3. Protect people
 - Prevent infection in all staff – including those with special immunity concerns (suppressed immune system, pregnant). Make sure all staff receive appropriate vaccines.
 - Identify special infectious hazards for the biological agents you are using and identify any necessary exposure follow-up procedures.
 - Evaluate & verify knowledge skill of lab processes before any lab worker begins work with biological agents.
4. Evaluate effectiveness of controls
 - Before any new procedure is carried out using “live” hazardous material, perform a “test run” using a non-hazardous simulant
 - Test run outcomes can be used to optimize procedures for both safety & scientific reasons.
 - In addition to performing an initial test run for a new process, test runs should also be carried out following any spill, exposure or near-miss event. A test run should also be performed whenever a major component of the procedure has changed.

Need help with biomaterial risk assessment? Contact [OCCRS Biosafety](#) for assistance.