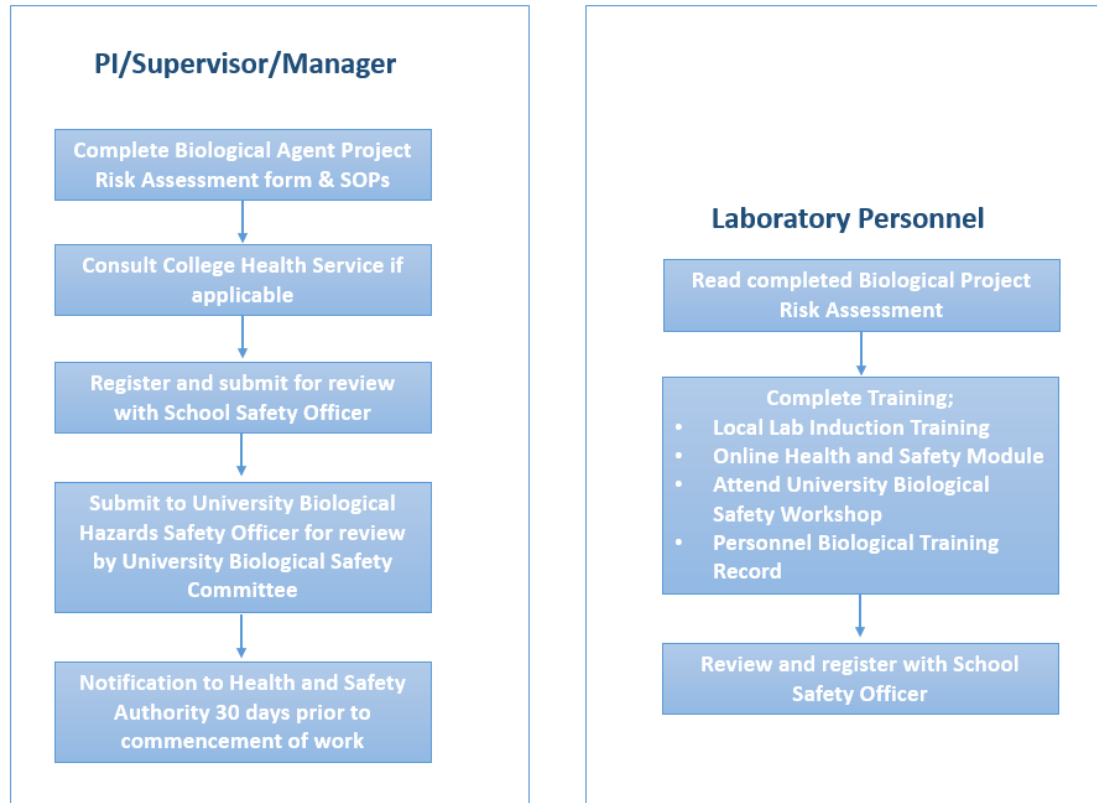


Biological Agent - Local Rules

1. Complete a Risk Assessment

A key requirement of the legislation is to assess the risks associated with projects involving the use of biological agents.

TCD Biological Agents Risk Assessment Process



Principal Investigator Duties

The [Project Risk Assessment template](#) must be used to assess the hazards and risks from an activity involving deliberate work with a biological agent. The aim of the Project Risk Assessment is to identify those at risk from infection or other harm and the measures required to eliminate or control the risks to human health and safety and the environment. It is the responsibility of the PI to ensure that the Project Risk Assessment remains valid and that all personnel undertaking this research have read and understood the risk assessment and are appropriately trained. [Biological Safety Personnel Training Record](#) have been formulated to facilitate the latter.

One Project Risk Assessment is generally sufficient to cover all research projects. However, if the research projects differ drastically, then corresponding Project Risk Assessments may be required.

Completed Project Risk Assessments must be reviewed by the [local Safety Officer](#) and relevant members of the University Biosafety Committee - with respect to the latter, submit to the University Safety Officer for Biological Hazards for distribution to the committee.

Researcher Duties

Make arrangements to consult with your local Safety Officer and PI before you commence work or study to ensure that your work complies with local procedures and legislative requirements. Lab personnel must:

1. Be acutely conversant with the safety documentation that applies to your research: e.g. local Safety Statement, Project Risk Assessment, any GMO, Chemical or Radiological risk assessments, local standard operating procedures (SOPs), policies, and lab rules.
2. Undertake training with respect to Point 1 as organised by the PI, and complete the Biosafety Training Record form and obtain the appropriate signatures.
3. Adopt safe practices in activities involving biological material as per [SOPs](#) etc., in particular, carry out work in designated areas, wear appropriate protective equipment and dispose of waste in the specified manner.
4. Report any incident, accident or defect in equipment relating to the handling of biological materials
5. Cooperate with supervisors, local safety officer, or any other person appointed to monitor safety.

Project Risk Assessment Overview

Complete the [Project Risk Assessment form](#)- refer to the following for further advice:

1. Identify biohazardous materials to be used in the research protocol.
2. The identified biological agent must then be classified into one of 4 Risk Groups: Risk Group 1; Risk Group 2; Risk Group 3; Risk Group 4. To aid the process of classification, the Health & Safety Authority has provided a list of biological agents classified into risk group's two to four. If there is a doubt between two hazard groups, then the higher of the two must be chosen. If your biological agent is not on the list do not assume it is Risk Group 1, further research of published material is required. Please select the link '[Biological Agents](#)' to view the list.
3. Identify risk factors for exposure to biological agents within the research protocol's. This includes modes of transmission (inhalation, ingestion, etc.), steps in the protocol that may create an exposure risk (use of sharps, creation of aerosols, injecting animals, etc.), and the possible consequences of an accidental exposure.
4. Review available resources for health hazards, laboratory hazards, handling procedures, and recommended precautions.
5. Considering the aforementioned and revise the classification for the biological agent accordingly.
6. The outcome of risk group classification is then aligned with a suitable containment level, which specifies the minimum operational, technical and physical requirements of a laboratory for manipulating a particular pathogen. [Containment Levels](#) increase in operational, technical and physical complexity from containment level 1 to containment level 4. - Containment Level 1 is suitable for Risk group 1 agents. - Containment level 2 laboratories are designed to maximize safety when working with Risk Group 2 biological agents. - Containment level 3 laboratories are required for Risk Group 3 infectious agents that may cause serious or potentially lethal diseases as a result of exposure. . In certain circumstances Containment Level 3 must be used for large volumes or high concentrations/titers of Risk Group 2 organisms that pose an increased risk of aerosol spread. Similarly, Containment Level 2 may be appropriate for large volumes or high concentrations/titers of Risk Group 1 organisms.

7. Identify specific exposure control measures that will be implemented to reduce each exposure risk as identified in Step 3 & 4. Incorporate these exposure control measures into written Standard Operating Procedures (SOPs).

8. Prior to commencement of any work this form requires:

- sign-off by the PI
- reviewed by the Local Safety Officer (LSO);
- reviewed by the University Biological Safety Committee; and
- subsequent submission to Health and Safety Authority 30 days prior to commencement of work with respect to the following:
 - - First time use of a group 2 biological agent.
 - - First time and subsequent use of a group 3 biological agent.

2. Ensure Facility Compliance

All work with Biological Agents is ultimately approved by the Health and Safety Authority with the proviso that the laboratory meets the Physical Containment conditions defined by S.I. No.572 of 2013 and that work practices comply with the requirements of this standard.

Principal Investigator Duties

The PI must propose the appropriate Containment Level(s) when completing the Project Risk Assessment. The Containment Level determination must consider all aspects of the work, hazards, and controls. The local Safety Officer and TCD Biosafety Committee will review the final Containment Level & submit to the Health and Safety Authority.

Researcher Duties

In the context of facility compliance, use all safety devices and equipment correctly, and undergo training and assessment as required. Report any defects, dangerous practices or situations immediately to the PI and/or local safety officer.

Facility Compliance Overview

The purpose of this outline is to aid Principal Investigators in the design and construction of biosafety containment laboratory.

Containment Level 1

Containment Level 2

Containment Level 3

The Latest guidance from The Advisory Committee on Dangerous Pathogens (ACDP) UK details technical information related to Containment Levels 2 and 3.

[The Management, Design and Operation of Microbiological Containment Laboratories](#)

3. Health Surveillance.

The University is required to offer immunisations to employees and students who may be exposed to pathogens at work where an effective vaccine is available. Equally, there is a provision to make relevant health surveillance available under section 10.Part 3, Section 12 S.I. No. 572 of 2013

Principal Investigator Duties

Immunisation must be offered to all employees and student groups who are indicated in a project risk assessment to be at risk of an occupationally acquired infection for which a safe and effective vaccine is available. The need for immunisations should be clarified during the recruitment process - pre-employment screening.

Researcher Duties

Any worker on projects involving biological agents is encouraged to discuss concerns with the PI or local Safety Officer, additionally; such individuals may request an appointment with the University Health Centre if they are concerned about their health in the context of an experiment.

Health Surveillance Overview

1. The need for health surveillance will be identified in the Project Risk Assessment
2. Health surveillance should not be necessary for researchers working on projects with biological agents in risk groups 1 and 2.
3. Where the project risk assessment identifies that an effective vaccine exists, such vaccines must be offered unless the researcher is already immune.
4. Principle Investigators and/or Local Safety Officers can assist and clarify any concerns, and refer individuals to the University Health Service for appropriate vaccinations.
5. Those already vaccinated will have to have their titres checked or provide evidence of same.
6. The project risk assessment requires an overview of infection symptoms associated with the biological agent being used, so that staff are made aware of the symptoms, and will therefore, be in a position to monitor their own health.
7. Principle Investigators are required to following up on absence/sickness records and look for anything that could be linked to their research.

4. Undertake Training

Part 3, Section 8 [S.I. No.572 of 2013](#) requires that workers must be trained and be proficient in safe working practices and techniques to ensure the safety of themselves and other persons in the laboratory.

Principal Investigator Duties

Proper training is the most important aspect of biosafety and is the responsibility of the Principal Investigator. A high degree of competence in handling biological agents must be demonstrated prior to allowing an individual to work. Specific, documented training unique to laboratory practices and procedures must be provided and coordinated by the PI.

Researcher Duties

In the context of training; staff must undergo training and assessment and abide by procedures policies and other local rules.

Training Overview

1. To supplement PI training, the University Safety Office organises the [Biological Safety Workshop](#) in May and October of each year. Online training is also available.
2. The PI is ultimately responsible for training researchers and ensuring associated competency before allowing work to proceed, contingent on approval of the Project Risk Assessment.
3. The PI should first identify any gaps in knowledge or experience and then identify and provide appropriate training.
4. In-house documented training ([Biological Safety Personnel Training Record](#)) should reference the local Safety Statement, Risk Assessments, Standard Operating Procedures, Policies and other in-house work protocol documents.
5. Training should also cover:
 - Risk Assessment Process
 - Safe use of Biological Safety Cabinets or other lab equipment
 - Safe use of Personal Protective Equipment.
 - Emergency response to incidents (e.g. spills & exposures)
 - Waste procedures
 - Disinfection procedures
 - SOPs & work protocols
6. It may be necessary to gain experience in techniques and procedures using agents that are in a lower risk group before progressing to a higher Risk Group.
7. There must be some means of demonstrating that the training has achieved the desired level of competency.
8. Training must be documented, and be signed off by both the trainer and the trainee once the desired level of competency has been achieved.
9. Training records should be stored securely and available for inspection when required.

10. Training must be an on-going effort since a person's competence will decline if skills are not utilised regularly.

5. Review and Inspections

Facilities handling hazardous biological agents will be subject to scheduled inspections as organised by the University Biological Safety Committee. Additionally, audits may also be conducted by regulatory agencies such as the HSA on a periodic basis. The inspection process aims to assess the suitability of facilities, practices, working procedures and records.

In addition, the Environmental Protection Agency conduct inspections of facilities licensed for the contained use of GMOs every 3 years.

The inspection template is as follows:

[EPA Site Inspection Template](#)

Additional Resources

[Template Consent Conditions](#)

Sample Signage [CL1](#) & [CL2](#)

[Sample SOPs](#)