

Biosafety and Biosecurity Procedure	
Enabling Policy Statement; Executive Owner; Approval Route:	Our Safety - Chief Operating Officer - Compliance Committee
Associated Policy Statements:	N/A
Authorised Owner:	Director of Health and Safety
Authorised Co-ordinator:	Health and Safety Officer (Hazardous Materials)
Effective date:	9 June 2022
Due date for full review:	8 June 2025
Sub documentation:	Biosafety Manual

Approval History

Version	Reason for review	Approval Route	Date
1.0	Reviewed and updated (including in accordance with new Policy Framework 2022). Replaces Biosafety and Biosecurity Policy (Version 2.0, dated 1 July 2018).	University Biosafety Committee Compliance (Health, Safety and Wellbeing) Committee.	6 April 2022 9 June 2022

1. Purpose

To ensure that all biological agents are appropriately controlled to minimise the risk of infection to humans, animals, or release into the environment, and to avoid a security breach.

Biological agents are:

- Listed in the Advisory Committee for Dangerous Pathogens approved list of biological.
- Listed in the Specified Animal Pathogen Order.
- Listed by the Scientific Advisory Committee on Genetic Modification.
- Pathogens and toxins listed in Schedule 5 under Part 7 of the Antiterrorism, Crime and Security Act.
- Human or animal cell cultures and, bloods and tissue samples.
- Whole animals or specimens from these.
- Plant pathogens.

2. Scope and Exceptions to the Procedure

This procedure applies to staff, students, contractors, and visitors handling listed biological agents.

3. Definitions and Terminology

Listed biological agents are those set out by the competent authorities listed below:

- ACDP - Advisory Committee of Dangerous Pathogens.
- SAPO - Specified Animal Pathogen Order.
- GMO - Genetically Modified Organism.
- COSHH - Control of Substances Hazardous to Health.
- ATSCA - Anti-terrorism Security Crime Act (Schedule 5).
- APHA - Animal and Plant Health Agency.

Competent person – a person who has the skills, knowledge, attitude, training and experience to undertake the role effectively.

Training and briefing – Training is equipping staff, students (and others where the University has a duty-of-care) with relevant skills to deal appropriately with a given health and safety situation.

Briefing is informing such persons of relevant knowledge in relation to health and safety.

Training and briefing will be made available in a range of formats according to the needs of the trainee and different groups of staff, students, and others.

4. Procedural Principles

4.1. Commitment

The University will ensure that:

- All biological agents are handled under appropriate laboratory conditions to minimise; the risk of infection; release to the environment and unauthorised access.
- All biological agents are stored under appropriate conditions to meet the relevant legislative requirements and prevent release to the environment, and unauthorised access.
- All facilities (buildings and equipment) used to handle biological agents are designed to meet legal requirements set by the competent authorities.
- All work with biological agents at the University has been documented via risk assessment and that the control measures are implemented.
- Correct licenses are in place and up to date for the storage and handling of biological agents.
- All staff handling animals infected with pathogens have had appropriate training and briefing and are aware of the legal implications of the transportation of live/dead animals or samples infected with a SAPO, Schedule 5 or ACDP pathogen.

- All biological agents are transported in a contained and secure manner to prevent release or unauthorised access.
- A list of the pathogens is kept (including quantity and form of material).
- Appropriate validation data for the inactivation of all biological agents stored and or used at the University is available as long as required.
- All biological agents are inactivated using validated means to prevent release into the environment or collected by a licensed transporter/waste management company and disposed of at a licensed facility.
- Suitable biosecurity procedures are put in place to prevent the release of biological agents (i.e., disinfection, barriers, foot dips, controlled contact with animals, vehicle, and pedestrian movements).
- All users of biological material are approved for access to relevant listed biological materials.
- All users are adequately trained and briefed to prevent the release or unauthorised access of listed biological material.
- All users handling biological agents undergo health surveillance as detailed in risk assessments.
- All activities with biological agents are notified, as appropriate to the competent authorities.
- All new biological agents being used are notified to the University Biosafety Manager and the University Biosafety Committee.
- No Hazard Group 4 (ACDP and/or SAPO) pathogens or Class 4 GMOs are used within the University.

4.2. Arrangements

All persons using biological agents must comply with the arrangements outlined within the University [Biosafety Manual](#). The Manual will provide details on the following:

- Training required for working at containment level 2 and 3 for staff to be competent to safely handle biological agents.
- Requirement and processes for all equipment used for working with biological agents to be maintained in an effective condition.
- Standard that all laboratories, auxiliary rooms, and biological safety cabinets must attain and maintain so as to prevent release of biological agents.
- Appropriate disinfection procedures required for ensuring that biological agents are not viable after treatment.
- Processes for ensuring that only approved and appropriately licensed waste disposal contractors are used.
- Processes for reporting all incidents involving biological agents using the University reporting system.
- Need for suitable records to be maintained of the above to be able to demonstrate to any competent authority that this procedure is being complied with.

4.3. Roles and Responsibilities

4.3.1. Deans and Directors are ultimately responsible for:

- Implementation of this procedure within their Faculty/Directorate.
- Provision of adequate resources to achieve compliance with this procedure.
- Provision of appropriate facilities and equipment for safe working with biological agents.
- Ensuring compliance with the conditions of any relevant licences issued by a competent authority.

4.3.2. Heads of School/Department are responsible for:

- The safe use of biological agents within their school/department.
- Ensuring compliance with the conditions of any relevant license issued by a competent authority.

- 4.3.3.** Principal Investigators (that use biological agents) are responsible for:
- Ensuring that personnel who are involved in the use of biological agents receive adequate supervision and information, instruction, and training.
 - Ensuring that all biological agents are adequately controlled and accounted for, undertaking prior risk assessments for all projects involving the use of biological agents.
 - Ensuring that risk assessments are reviewed regularly, and whenever there is reason to suspect they are no longer valid.
 - Completion and maintenance of appropriate records for the use and disposal of biological agents.
- 4.3.4.** Biosafety Manager is responsible for:
- Advising on biological safety matters across the relevant Faculty.
 - Leading on and ensuring the delivery of biological safety audits.
 - Providing specific advice and guidance on Genetically Modified Organisms (Contained Use) Regulations, The Plant Order, The Import of Animal Pathogens Order, Antiterrorism, Crime and Security Act, and Specified Animal Pathogens Order, and clinical waste disposal together with other relevant statutory and University provisions.
 - Managing/advising on the authorising regimes for biological safety at the University and advising where appropriate on required licences/authorisations.
- 4.3.5.** Director of Health and Safety is responsible for:
- Appointing the University Biosafety Manager.
 - Where necessary, liaising with the enforcement authorities, including in relation to incidents reported under RIDDOR.
 - With assistance and advice of the University Biosafety Manager, monitoring compliance with the requirements for this procedure.
 - Overseeing the management of the specialist waste contractor, whose services include the treatment and disposal of biological agents.
- 4.3.6.** Staff, researchers, students, and others working with biological agents are responsible for:
- Undertaking and working in accordance with any training deemed necessary.
 - Working in accordance with the University [Biosafety Manual](#).
 - Exercising reasonable care when working with biological agents.
 - Using any protective equipment provided.
 - Promptly reporting any defects in equipment.
 - Not undertaking any actions which may endanger themselves or other persons.

5. Governance Requirements

5.1. Implementation: Communication Plan

The procedure will be available via the University procedures webpages. The procedure is communicated to all those working with biological agents through relevant training.

The University Biosafety Committee will be informed, and relevant details disseminated through line management. Faculty Health and Safety Committee will also be informed, as required.

This procedure and relevant supporting documentation are also published on the University Health and Safety intranet site.

5.2. Implementation: Training Plan

Staff and others working in containment level 2 and 3 are required to undergo training as detailed in the University [Biosafety Manual](#). Training will enable the university to meet the regulatory requirements listed in Section 5.4.1 of this procedure.

5.3. Review

The University Biosafety Manager and Director of Health and Safety will monitor for required changes and updates. Minor changes will be reviewed by the University Biosafety Committee and approved by the Compliance (Health, Safety and Wellbeing) Committee. Major reviews will also be reviewed by the University Biosafety Committee, prior to submission to Compliance (Health, Safety and Wellbeing) Committee for approval, and if required, noted at Executive Board.

This procedure will be reviewed every three years or in line with relevant changes in legislation, if sooner. The Health and Safety Consultative Committee will be consulted during the review process, as required.

5.4. Legislative Context and Higher Education Sector Guidance or Requirements

5.4.1. Applicable Legislation

This Procedure complies with the requirements of the Health and Safety at Work Act 1974, and biosafety and biosecurity legislation, such as:

- Control of Substances Hazardous to Health Regulations 2002.
- Genetically Modified Organisms (contained use) Regulations 2014.
- Schedule 5, detailed in Part 7 of the Anti-terrorism, Crime and Security Act 2001.
- Specified Animal Pathogen Order 2008.
- The Import of Animal Pathogens Order 1980.

5.4.2. Legislative context

This procedure sets out to comply with the required 'duty of care' placed upon the University. Under Health and Safety Law a 'duty of care' is generated between organisations and individuals when carrying out activities that could foreseeably cause harm.

The primary duty of care is owed through the employer-employee relationship in which the employer owes a duty of care to ensure that work activities that could result in harm to the employee are assessed and controlled. That duty of care is put into practice by the line management responsibilities as set out in the hierarchy of the organisation.

This duty of care cannot be delegated away; instead, the act of delegation must be accompanied by a realistic and workable system of monitoring or supervision to ensure that the delegated task has been adequately implemented (i.e., the responsibility is not met by giving directions; it is met when those directions have been confirmed as carried out). The result is a cascade of delegated accountability that runs through the organisation via the line management network, accompanied by a system of monitoring, supervision, and feedback.

The duty of care extends to assurance that services provided by others (be they another department of the University or contractors) are undertaken safely. The level of assurance required should be commensurate with the risk of the activity. In addition, anyone carrying out an activity owes a duty of care to anyone who may be put at risk by the activity, such as students, staff, and visitors.

5.5. Sustainability

This Procedure has no impact on carbon emissions or on energy consumption.

6. Stakeholder Engagement and Equality Impact Assessment

6.1. An Equality Impact Assessment was completed on **18/05/2022** and is held by the Authorised Co-ordinator.

6.2. Stakeholder Consultation was completed, as follows:

Stakeholder	Nature of Engagement	Date	Name of Contact
Governance	Development and creation of this Procedure v1.0.	May 2022	Ros Allen, Head of Governance Services.
Biosafety Manager	Development and creation of this Procedure v1.0.	Feb/March 2022	Shurene Bishop Simon, FHMS Faculty Health and Safety Manager and Biosafety Manager.
Members of the University Biosafety Committee	Development and creation of this Procedure v1.0.	6 April 2022	Members of this Committee.
Members of the FHMS Health and Safety Committee	Development and creation of this Procedure v1.0.	11 May 2022	Members of this Committee.
Equality, Diversity & Inclusion	Development and creation of this Procedure v1.0.	13 May 2022	Jo McCarthy-Holland, Equality & Diversity Advisor.
Health and Safety Consultative Committee	Development and creation of this Procedure v1.0.	13 May 2022	Members of this Committee.