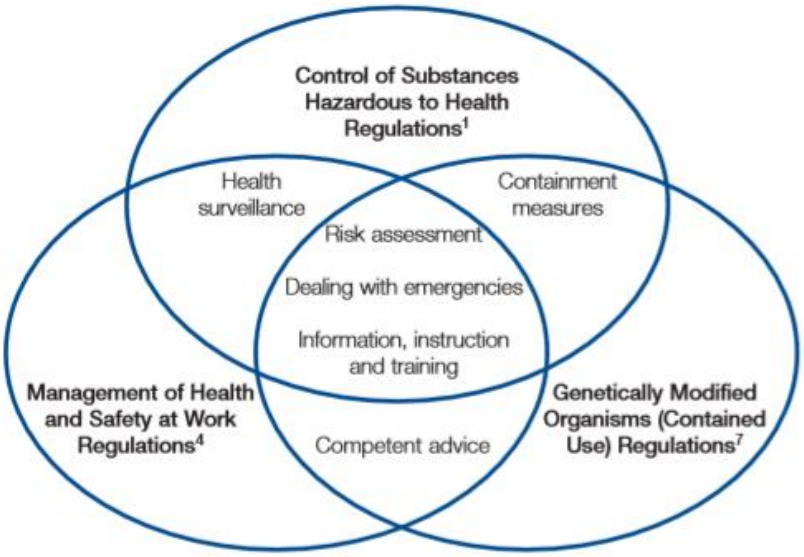
UNIVERSITY OF SUSSEX

[Health and Safety]

BIOLOGICAL SAFETY POLICY



1. OVERVIEW AND PURPOSE

1.1 This policy sets out the arrangements to comply with legislation; principally the Genetically Modified Organisms (Contained Use) Regulations (2014) and the Control of Substances Hazardous to Health Regulations (2002).

2. SCOPE

2.1 This Policy shall apply to all work* involving Genetically Modified Organisms (GMO) and other biological material e.g. micro-organisms, cell cultures, parasites, human or animal tissue (including blood, urine and other body products) or plant material which gives rise to a risk of infection, allergy or toxicity.

** work means handling, use, transportation, storage and disposal of biological material*

3. RESPONSIBILITIES

3.1 Vice Chancellor

The Vice Chancellor will provide leadership and executive oversight of Health & Safety.

3.2 Chief Operating Officer

The Chief Operating Officer is chair of the University Safety Committee and is responsible for overseeing the University's health and safety management arrangements.

3.3 **General Counsel and Director of Governance & Compliance**

The Governance and Compliance office line manages the Head of Safety, coordinates the University's governance, supports and advises the University Executive Group (UEG) on Health and Safety matters.

The Division of the General Counsel, Governance and Compliance includes the University's Health and Safety Team, Business Continuity and Risk Management, Governance Services and Compliance, Legal Counsel, Information Management, and supports the Vice-Chancellor's Office.

The General Counsel and Director of Governance & Compliance will:

- Support and offer advice on Health and Safety: Legislation, University policy and procedures, hazards, incident planning, risk assessment and management;
- Liaise with regulatory authorities who enforce the statutory requirements for Biological Agents.
- Under the COSHH regulations the HSE must be notified in writing using form cba1 whenever biological agents in hazard groups 2 are used:

a) for the first time
b) and, for pathogens and toxins listed in Schedule 5 under Part 7 of the ATSCA
The HSE must be notified in writing at least 20 days in advance of the work commencing.

3.4 **University Health and Safety Office**

The University Head of Safety with support from the University Biological Safety Officer will:

- Act as the University's competent health and safety adviser on behalf of the University;
- Support the University Schools and Directorates by offering advice and guidance in conjunction with legislative requirements and University policies.
- Make notifications to the HSE as required to ensure the public register (GM work) is suitable and up to date.

3.5 **Heads of Schools and Directors of Professional Services**

Heads of Schools and Directors of Services are responsible to the Council, through the Chief Operating Officer, for health and safety matters relating to the activities of their school or service, whether these are undertaken on the institution's premises or elsewhere, and must:

- Make an annual declaration in writing to the Biological Safety Advisory Group (BSAG) of work with biological material in that has not been notified previously.
- Ensure local rules are produced which state the arrangements made within their department to comply with this policy. These arrangements shall identify departmental duty holders and specify the responsibilities placed on each named duty holder. The name of this person shall be forwarded to the University's Biological Safety Officer.
- The local rules are made available to all staff in the department and shall be incorporated in school and unit safety polices
- Risk assessments for work with Biological Agents are carried out **in advance** of work commencing.

- Risk assessments are reviewed whenever there are significant changes to the work and annually to ensure that they remain suitable and sufficient.
- All work involving infectious material at a classification of hazard group 2 or above (including unscreened blood) is submitted to the Chair of the BSAG for peer review by the group and approved **before** the work commences.
- All work involving genetically modified organisms is submitted to the Chair of the BSAG for peer review and approved **before** the work commences.
- All work involving plant or animal pathogens that require a DEFRA licence is submitted to the Chair of the BSAG for peer review and approved **before** work commences.
- Persons working with biological material are competent to do so. Professional qualifications must be scrutinised and induction training completed by supervisor.
- The training needs of anyone with duties under this policy are identified and instruction, information and training is provided where appropriate.
- Records of training are retained by supervisors for anyone working with material at containment level 2 and 3.
- Appropriate measures are provided to eliminate or, where this is not reasonably practicable, reduce risks arising from work with biological material.
- Equipment and facilities are maintained and tested to ensure efficient and safe operation.
- Hazard signs are maintained and security arrangements are implemented to prevent unauthorised access in areas identified by biohazard signs.
- All hazardous biological material is stored safely and securely.
- A suitable register is maintained of all biological of hazard group 2 or above kept in storage.

3.6 University Biological Safety Officer

- To give advice to the Heads of School/Department on matters relating to the containment of biological hazards and the safety of staff, with particular reference to the Genetically Modified Organisms Regulations 2002 and other relevant legislation and codes issued by the Advisory Committee on Genetic Modification.
- To work with schools/units to ensure local rules are suitable and sufficient and are kept up to date.
- To maintain a register of projects working with genetically modified organisms and to monitor that workers have suitable training, instruction and supervision.
- To make any required notifications to external agencies such as the HSE.
- To monitor the following safety aspects of genetic modification work within the University:
    - that local rules are followed
    - that appropriate training in good microbiological practice is given
    - that accidents are investigated; remedial actions are taken where necessary and appropriate records are kept
    - that recombinant organisms and pathogenic or potentially pathogenic material are stored in a safe way and that appropriate records are kept
    - that recombinant organisms are transported in a safe way (transfer of organisms constructed at containment level 2 or above must be recorded in the appropriate Risk Assessment).

3.7 Occupational Health Advisor

- Advise on the need for vaccination prior to work commencing.
- Maintain records of immunisation.

- Advise on appropriate prophylactic treatment where personnel have been exposed to a hazardous micro-organism against which they may not have immunity.
- Advise where additional measures may be requirement to protect the health of individuals working with biological material such as LAA, lung function and mask fir testing.

3.8 **Principal Investigators and Supervisors**

- Ensure that the work under their supervision has been risk assessed and approved by the appropriate group as specified in this document **before** work commences.
- Ensure that appropriate control measures are used and that procedures are followed and that persons whom they are supervising are aware of the risks and procedures in the event of accidents or incidents.
- Provide appropriate supervision and monitor compliance with this policy and local rules.
- Assess the competence of persons under their control to work safely and where appropriate conduct or arrange for the necessary training. To retain training records of personnel working with biological agents.

3.9 **Staff and Postgraduate Students**

- Be familiar with the risk assessments that apply to their work.
- Follow instructions from supervisor/line manager.
- Follow safe practices (SOPs) in activities involving biological material, in particular to carry out work in designated areas. Wear appropriate protective equipment and clothing and dispose of waste in the specified manner.
- Report any incident, accident or defect in equipment relating to the handling of biological materials.
- Co-operate with their supervisors, health and safety department, biological safety officer or any other person appointed to monitor safety in the department.

3.10 **Line Managers**

Within this guidance Heads of School and Principal Investigators or their Professional Support equivalent are referred to as line manager.

Line managers are responsible for undertaking a risk assessment in relation to your condition, and if necessary, will discuss with you any steps needed to minimise risk. It is the responsibility of line managers to ensure that:

- Activities carried out within their area of control that may pose a significant risk to women of childbearing age are identified and that action is taken to minimise the potential for harm from these activities where appropriate.
- Information is provided to staff about the preventative and protective control measures implemented to reduce, remove or control risk.
- Assessments are completed and any necessary control measures to work are put in place and monitored.
- The Display Screen Equipment (DSE) workstation checklist has been completed to highlight any significant risks that may be present at the new or expectant mothers DSE workstation and to ensure it is as comfortable as possible.

- The New and Expectant Mothers Risk Assessment is reviewed at regular intervals and on the mother's return to work.

3.11 **Implementation**

The health and safety implications of pregnancy are adequately addressed by normal health and safety management procedures. There are, however, specific health and safety regulations which protect staff while they are pregnant, when they have recently given birth, and while breastfeeding. These relate largely to exposure to chemical and biological substances, and to certain extreme physical conditions.

Other specific risk assessments such as DSE, Control of Substances Hazardous to Health and Manual Handling may have to be reviewed.

3.12 **Key Contacts:**

University Biological Safety Officer: Seimon Barton-Jones (s.barton-jones@sussex.ac.uk)
Head of Safety: Katie Bennett (K.A.Bennett@sussex.ac.uk)
Chair – Biological Safety Advisory Group: Dr Edward Wright (ew323@sussex.ac.uk)

4. **POLICY**

4.1 **Policy Statement**

The University will ensure that all biological agents used by the University of Sussex are controlled, so as to minimise the risk of infection to humans and animals, and are secured to prevent unauthorised access and misappropriation.

Commitment

The University will ensure that:

- all work with biological agents at the University has been documented via risk assessment and that the control measures are implemented.
- all new biological agents being used are notified to the University Biological Safety Officer and the University Biological Safety Advisory Group.
- all activities with biological agents are notified, as appropriate to the competent external authorities e.g. HSE.
- no Hazard Group 4 (ACDP and or SAPO) pathogens or Class 4 GMOs are used within the University.
- correct licences are in place and up to date for the storage and handling of biological agents.
- a list of the pathogens is kept (including quantity and form of material).
- all facilities (buildings and equipment) used to handle biological agents are designed to meet legal requirements set by the competent authorities.
- 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 biological agents are transported in a contained and secure manner so as to prevent release or unauthorised access.
- all biological agents are inactivated using validated means so as to prevent release into the environment or collected by a licensed transporter/ waste management company and disposed of at a licensed facility.
- appropriate validation data for the inactivation of all biological agents stored and or used at the University is available as long as required.
- suitable bio-security procedures are put in place to prevent the release of biological agents (disinfection, barriers, 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 so as to prevent the release or unauthorised access of listed biological material.
- all staff handling animals infected with pathogens have had appropriate training 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 users handling biological agents undergo health surveillance as detailed in their risk assessments.

4.2 Definitions

Genetically Modified Organisms (GMO) are organisms in which 'the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination' using 'recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they
do not naturally occur but in which they are capable of continued propagation'

Genetic Modification (GM) is the process of altering the genetic material of an organism by use of a method that does not occur in nature.

Genetically Modified Organisms (GMOs) may be plants, animals or (most commonly) micro-organisms (including bacteria, viruses, parasites and fungi). Where the GMO is a micro-organism, it is typically referred to as a **genetically modified micro-organism (GMM).** A GMO that is a plant or an animal can be referred to as a **larger GMO (LGMO).**

Micro-organisms are an organism that can be seen only with the aid of a microscope and that typically consists of only a single cell. **Microorganisms** include bacteria, protozoans, viruses, and certain algae and fungi.

Standard Operating Procedure (SOP) is a step-by-step description of the way things are done in a particular setting. Written SOPs help to ensure the quality and consistency of the management of biological agents in each registered facility. They can help to identify and minimise risks and to trace the cause of any errors.

ACDP Advisory Committee of Dangerous Pathogens.

SAPO Specified Animal Pathogen Order.

ATSCA Anti-terrorism Security Crime Act (Schedule 5).

5. LEGISLATION AND GOOD PRACTICE

5.1 The University will comply with all relevant legislation regarding Biological Substances, including:

- Genetically Modified Organisms (Contained Use) Regulations (2014)
- The Control of Substances Hazardous to Health Regulations 2002 Approved Code of Practice and guidance
- Scientific Advisory Committee on Genetic Modification, Compendium of Guidance:
  List of abbreviations
  Part 1: Introduction to the legislation and general health and safety issues
  Part 2: Risk assessment of genetically modified microorganisms (other than those associated with plants)
  Part 3: Containment and control of activities involving genetically modified microorganisms
  Part 4: Genetic modification work that involves plants (including plant-associated genetically modified microorganisms)
  Part 5: Genetic modification of animals
  Part 6: Guidance on the use of Genetically Modified Microorganisms in a clinical setting
- The Approved List of biological agents Advisory Committee on Dangerous Pathogens
- Biological agents: Managing the risk in laboratories and healthcare premises (reference only - no longer in print)
- Safe working and the prevention of infection in clinical laboratories and similar facilities
- Plant Health Guide for Importers (DEFRA)
- Transport: International Air Transport Association/ International Civil Aviation Organization/ European agreement concerning the international carriage of dangerous goods by road IATA/ICAO/ADR
- Waste: Environment and sustainability Health Technical Memorandum 07-01: Safe management of healthcare waste
- UK Biological Security Strategy

Failure to comply with the requirements of this policy and the above legislation could result in University prosecution.

5.2

Review / Contacts / References	
Policy title:	*Biological Safety Policy*
Date approved:	*Feb 2021*
Approving body:	*Health and Safety Committee*
Last review date:	*N/A*
Revision history:	*2.1 - supersedes v 2.0 Feb 2021*
Next review date:	*TBA*
Related internal policies, procedures, guidance:	*http://www.sussex.ac.uk/hso/policies*
Policy owner:	*Health and Safety*
Lead contact / author:	*Senior Safety Advisor (Biological Safety)*

NOTE: SUPPORTING DOCUMENTS *(for example, related procedural or process documents or practical guidance on implementation of/adherence to the policy) should not be included as part of main policy; rather, these should be provided as separate document – also ensure that these are included in the 'related internal policies, procedures, and guidance' portion of the information box at the end of the policy.*