

## **BIOLOGICAL SAFETY POLICY**

### **1. OVERVIEW AND PURPOSE**

- 1.1 Biological safety refers to the use of safe practices, specialist equipment, and dedicated buildings to ensure that people, animals, and the environment are protected from accidental exposure or unintended release of hazardous biological materials.
- 1.2 This policy sets out the arrangements in place at the University to comply with all legislation concerning biological safety, and applicable codes and standards, to facilitate safe and responsible research practices without unduly limiting academic research.

### **2. SCOPE**

- 2.1 This policy shall apply to all University of Sussex activities, whether regulated or unregulated, involving biological materials of human or non-human origin that pose a hazard to humans, animals or the environment. For the purposes of this policy, activity can refer to procurement, production, handling, use, transport, storage, or disposal.
- 2.3 Third parties who undertake activities involving hazardous biological materials on University premises are required to co-operate and co-ordinate with the University as detailed in the University Health, Safety and Wellbeing Policy.

### **3. RESPONSIBILITIES**

#### **3.1 Vice-Chancellor**

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

#### **3.2 Chief Operating Officer**

- 3.2.1 The Chief Operating Officer (COO) is Chair of the University Health & Safety Committee and is responsible for overseeing the University's health and safety management arrangements. The COO is also responsible for appointing the Biological Safety Sub-Committee (BSSC) Chair.

#### **3.3 University Health and Safety Team & University Biological Safety Officer**

- 3.3.1 The University Health and Safety Team resides within the Human Resources Division and is managed by the University Head of Health and Safety.
- 3.3.2 The University Head of Health and Safety is responsible for appointing the University Biological Safety Officer, who will act as the University's competent advisor on matters relating to biological safety.
- 3.3.3 The **University Biological Safety Officer (USBO)** is responsible for:

- Providing expert advice and support as necessary and appropriate on matters relating to biological safety, including the preparation of specialist policies, Safety Codes of Practice (SCoP), and guidance.
- Liaising with regulatory and enforcement authorities with oversight of biological safety legislation, including the submission of any required notifications or permit/consent applications.
- Coordinating with the other members of the Biological Safety Sub-Committee to ensure a register is maintained of all regulated biological projects and submissions to external authorities.
- Acting as the Secretary of the Biological Safety Sub-Committee.
- Auditing and reviewing biorisk management arrangements at the University on a regular basis against legislative requirements and recognised standards, and making suitable recommendations as required.
- Providing oversight and, where appropriate, leading on investigations involving hazardous biological materials, with support from School Biological Safety Officers (SBSOs) and other health and safety personnel.

### 3.4 **Executive Deans, Head of Schools, and Directors of Professional and Technical Services**

3.4.1 Executive Deans, Heads of Schools, and Directors of Services are responsible for health and safety matters relating to the activities of their Faculty, School, or Division, whether these are undertaken on the institution's premises or elsewhere, and must ensure that:

- All activities involving hazardous biological materials are assessed and managed effectively with suitable local governance and oversight arrangements in place, documented, and reviewed regularly.
- All relevant information on risks associated with hazardous biological materials, including control measures, is documented and communicated clearly and effectively.
- Suitably qualified and experienced individuals are formally appointed to all local safety-critical roles, e.g., School Biological Safety Officers (SBSOs), and they are provided with any training and/or resources and sufficient time required to fulfil their duties.
- Suitable and effective arrangements are in place to deal with emergencies and other untoward occurrences, and these events are reported centrally.
- Appropriate investigations are undertaken following any significant incidents, near misses, or untoward occurrences, and any remedial or improvement actions are implemented.

- Arrangements are in place for effective cooperation and coordination between all relevant parties for the safe management of hazardous biological materials.
- All equipment and facilities are maintained and tested to ensure safe and effective operation, and records are maintained of their performance.

### 3.5 **Head of Technical Services and Head of Technical Facilities**

3.5.1 Where appointed, these individuals are responsible for enacting the delegated duties of the Executive Deans, Heads of Schools, etc., detailed above in Section 3.4.

### 3.6 **Principal Investigators (PIs), Supervisors, and Technical Managers**

3.6.1 PIs, Supervisors, and Technical Managers are responsible for ensuring that all activities under their supervision or control have been risk assessed, and that they have received all required approvals and permissions, **before** issuing final consent to commence.

3.6.2 Additionally, they are responsible for ensuring that: identified control measures are fully implemented and maintained; that all persons under their control are fully aware of any risks and are trained and competent to carry out such activities safely, including emergencies; and for providing appropriate supervision and monitoring compliance with this policy and all local arrangements through accurate record keeping and assurance checks.

### 3.7 **Biological Safety Sub-Committee**

3.7.1 The Biological Safety Sub-Committee (BSSC) is a sub-committee of the University Health & Safety Committee and functions as the University's oversight and approval body for all activities involving hazardous biological materials. The BSSC shall be responsible for:

- Approval of all activity with Hazard Group (HG) 2 or above biological agents, Specified Animal Pathogen Order (SAPO) Group 2 or above, Genetic Modification (GM) Class 2 or above, and all 'Schedule 5' materials, including monitoring of delegated approvals.
- Maintaining a register of all approved activities involving hazardous biological materials and associated submissions to external authorities.
- Approval, issuing, and updating all biosafety and/or biosecurity arrangements, including standards, guidance, and procedures.
- Supporting and promoting the development of local operational safety arrangements, including documentation, training, and competency etc.
- Reviewing reports involving hazardous biological materials, including incident and accident reports, and making recommendations for remedial actions.

- Reviewing outcomes of both external and internal inspections and audits, making recommendations as appropriate, and providing oversight to remedial action plans.
- Reviewing compliance with waste and transport regulations as related to biological safety.
- Monitoring and advising on the management of biological containment facilities, equipment, and working practices within the University.

### 3.8 School Biological Safety Officers (SBSOs)

3.8.1 School Biological Safety Officers (SBSOs) are appointed by the Head of School and are responsible for:

- Providing specialist guidance to research and technical staff related to working with hazardous biological materials.
- Reviewing and approving all applications for activity with HG1 biological agents, SAPO Group 1, and GM Class 1, and referring all other activities involving hazardous biological materials to the BSSC.
- Coordinating with the other members of the BSSC to ensure a register is maintained of all regulated biological projects and submissions to external authorities.
- Ensuring all local rules are suitable and sufficient and are kept up to date, and monitoring their application through assurance activities, ensuring information, instruction, and training have been provided.
- Escalating any biological safety issues which cannot be resolved locally on a timescale commensurate with the risk.

### 3.9 Line Managers

3.9.1 Biological materials may pose an increased risk or unique hazard to individuals with specific risk factors, e.g., underlying medical conditions, pregnancy/post-partum status, etc., and so individuals with direct line management are responsible for ensuring that:

- Risk assessments are carried out for those individuals at increased risk of harm from hazardous biological materials, seeking specialist advice where appropriate (Health and Safety Team and/or Occupational Health), and these are reviewed on a regular basis.
- Identified control measures are supported and maintained for as long as required.
- Releasing and supporting individuals who need to engage with Occupational Health Services regarding biological safety, e.g., vaccination, health surveillance, etc.

### 3.10 **Executive Director of Human Resources (HR)**

3.10.1 The Executive Director of HR is responsible for the management and oversight of the Occupational Health Service contract.

### 3.11 **All Staff, Students, Contractors, Third Parties, and Visitors**

3.11.1 Every individual (staff member, student, contractor, third party, and visitor) has a responsibility to:

- Comply with all safety arrangements, including, but not limited to, following all applicable safety procedures and wearing required Personal Protective Equipment (PPE) as identified in local operational documents.
- Co-operate with and follow any safety instructions or directions from supervisors, line managers, or safety personnel.
- Report any incidents, accidents, or defects in equipment through the appropriate local reporting and escalation channels

3.11.2 Staff and students acting in a manner that poses a risk to their safety, or the safety of others, may be subject to improvement programmes and or disciplinary action. Individuals who are not members of the University of Sussex, deemed to be acting in such a manner, may be asked to leave the site.

## 4. **POLICY**

### 4.1 **Definitions**

4.1.1 **ACDP** refers to the Advisory Committee of Dangerous Pathogens. ACDP is an expert committee of the Department of Health and Social Care (DHSC) which provides independent scientific advice on all aspects of hazards and risks to workers and others from exposure to pathogens. One of the functions of the ACDP is to classify biological agents into Hazard Groups (see 4.1.2).

4.1.2 **Biological Agent** means a micro-organism, cell culture, or human endoparasite, whether or not genetically modified, which may cause infection, allergy, toxicity, or otherwise create a hazard to human health. Biological agents are classified by the ACDP into four **Hazard Groups** (HG1-4), based on their ability to infect healthy humans, the severity of any resulting disease, and the effectiveness of available treatments and vaccines.

4.1.3 **Genetic Modification (GM)** is the process of altering the genetic material of an organism, which does not occur naturally (by mating or recombination), and has been achieved through any technique set out within Part 1 of Schedule 2 of the Genetically Modified Organisms (Contained Use) Regulations 2014.

4.1.4 **Genetically Modified Organisms (GMOs)** are organisms in which the genetic material has been altered as detailed above. GMOs may be plants, animals, or (most commonly) micro-organisms (including bacteria, viruses, parasites, and fungi). A GMO that is a plant or an animal can be referred to as a **larger GMO (LGMO)**. Where

the GMO is a micro-organism, it is typically referred to as a **genetically modified micro-organism (GMM)**. Activities involving GMMs are assigned to a **GMM Activity Class** (Class 1-4), based on the potential harm to human health and the environment.

- 4.1.5 **Hazardous biological materials** consist of any substance, whether of biological origin or not, which has the potential to cause harm to living organisms.
- 4.1.6 **Micro-organisms** means a microbiological entity (i.e., can be seen only with the aid of a microscope), cellular or non-cellular, which is capable of replication or of transferring genetic material. They typically consist of only a single cell and include bacteria, protozoans, viruses, and certain algae and fungi.
- 4.1.7 **SAPO** refers to the Specified Animal Pathogen Order, which is the primary legislation that applies to the contained use of specified animal pathogens. Specified animal pathogens are classified (Groups 1-4), based on their ability to produce notifiable disease in animals, whether they are native within animals in this country, and the risk of spread from the laboratory.
- 4.1.8 **Schedule 5 Materials** are materials controlled under the Anti-Terrorism, Crime and Security Act 2001 and include certain pathogens, toxins, and their genetic materials.

## 4.2 Policy Details

- 4.2.1 The University will ensure that all activities involving hazardous biological materials are managed and controlled to minimise the risk of harm to humans and/or the environment, including prevention of their theft, loss, or misuse. To achieve this, the University will ensure that:
  - Arrangements are in place to ensure effective oversight and management of all activities involving hazardous biological materials with clearly defined routes of responsibility and accountability.
  - All activities involving hazardous biological materials will be subject to a robust risk assessment and approval process.
  - All control measures and conditions identified during the risk assessment and approval process are fully implemented prior to activity commencing and are maintained for the duration of the activity.
  - All hazardous biological materials are handled and secured under appropriate conditions to meet the relevant legislative requirements and prevent any unauthorised access or unintended release.
  - No activities involving ACDP Hazard Group 4 biological agents or SAPO Group 4 animal pathogens or Class 4 GMOs are carried out at the University.
  - No activities involving the deliberate release to the environment of GMOs are carried out at the University, as defined by the Genetically Modified Organisms (Deliberate Release) Regulations, e.g., transgenic crops cultivated in open field

- All regulated activities are notified as appropriate to the relevant competent authorities, and that all correct licences, permits, and/or consents are in place.
- All individuals conducting activities involving hazardous biological materials shall receive suitable and sufficient training and be subject to competency assessments at appropriate intervals.
- Arrangements are in place to deal with emergencies and other untoward occurrences for all activities with hazardous biological materials, and these are tested at an appropriate interval.
- Accurate records are maintained of all hazardous biological materials held on site, and all associated documentation pertaining to biological safety, including storage, disposal, training, and assurance activities, is retained in line with all relevant legislative requirements and University policies.
- The central Health and Safety team maintains mechanisms for the effective dissemination of information to all relevant parties following University information governance and record retention processes.
- All facilities (buildings and equipment) used to handle hazardous biological materials are designed and maintained to meet legal requirements set by the competent authorities.
- All hazardous biological materials will be inactivated via a validated method prior to disposal or collected by a licensed waste contractor for disposal at a suitable facility.
- Occupational health services such as pre-employment checks, vaccination, health surveillance, exposure records, etc., where identified as required through risk assessment of any activity involving hazardous biological materials, are provided in accordance with University policies.
- All hazardous biological materials are transported or consigned via a suitably qualified courier in appropriate packaging to ensure compliance and prevent unintentional release or unauthorised access.
- Suitable bio-security procedures are put in place to prevent the release of hazardous biological materials, such as disinfection, barriers, controlled contact with animals, vehicle and pedestrian movements, etc., as identified by risk assessment.

## 5. LEGISLATION AND GOOD PRACTICE

### 5.1 Legislation

5.1.1 Please see below for related key legislation relevant to this policy area:

- Control of Substances Hazardous to Health Regulations 2002
- Genetically Modified Organisms (Contained Use) Regulations 2014

- Anti-Terrorism, Crime and Security Act 2001
- Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009
- Genetically Modified Organisms (Deliberate Release) Regulations 2002
- Specified Animal Pathogens Order (SAPO) 2008

## 5.2 Codes and Standards of Practice

5.2.1 Please see below for related key codes and standards of practice relevant to this policy area:

- [ACDP The Approved List of biological agents](#) (HSE MISC208)
- [ACDP Management and Operation of Microbiological Containment Laboratories](#)
- [HSE The Control of Substances Hazardous to Health Regulations 2002 – Approved Code of Practice and guidance](#) (HSE L5)
- [HSE The Genetically Modified Organisms \(Contained Use\) Regulations 2014 – Guidance on Regulations](#) (HSE L29)
- [HSE Guidance for licence holders on the containment and control of specified animal pathogens](#) (HSG280)
- [HSE Safe working and the prevention of infection in clinical laboratories and similar facilities](#)
- [Scientific Advisory Committee on Genetic Modification \(SACGM\) Compendium of Guidance](#)
- [Carriage of Dangerous Goods Guidance Manual](#)
- [Health Technical Memorandum 07-01: Safe and sustainable management of healthcare waste](#)

### Review / Contacts / References

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Related internal policies, procedures, guidance:	<a href="http://www.sussex.ac.uk/hso/policies">http://www.sussex.ac.uk/hso/policies</a>
Division:	<i>Human Resources Division</i>
Policy owner:	<i>Executive Director of HR</i>
Point of Contact	<i>Senior Science Safety Advisor University Health &amp; Safety Team, HR</i>