University of Essex

Biological Safety Policy

University of Essex

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Table of Contents

1.	**Policy Statement**	**4**
2.	**Responsibilities**	**4**
2.1	University Strategic Responsibilities	4
2.2	Head of Department (HoD)	4
2.3	University Biological Safety Adviser (UBSA)	5
2.4	Departmental Biological Safety Officer (DBSO)	5
2.5	Biological Hazards and Genetic Modification Sub-Group (BHGMSG)	6
2.6	Principal Investigator (PI)	6
3.	**Definitions**	**8**
3.1	Hazard Groupings of Biological Agents	8
3.2	Containment Levels	8
3.3	Genetically Modified Organisms (GMOs)	9
4.	**Arrangements**	**10**
4.1	Appointment of a DBSO	10
4.2	Department Local Rules	10
4.3	Risk Assessment	11
4.4	Workers Lists	11
4.5	Notification to the HSE	11
4.6	Approval Process	11
4.7	Ethical Approval	11
4.8	Risks from Blood-Borne Infections	12

5. Risk Assessment and Approval 14

5.1 Scheme of Work 14

5.2 Approval Process for Work with Biological Agents 14

6. Record keeping 15

6.1 Documentation 15

6.2 Risk Assessments 15

7. Training and supervision 16

8. Review 16

Appendix 1 - Abbreviations 17

Appendix 2 – Sources and further information 18

1. Policy Statement

The University of Essex recognises its responsibility to comply with current legislation and appropriate guidelines in the management of hazardous biological agents. This document and the departmental local rules for biological agents form part of the University requirements to comply with the Control of Substances Hazardous to Health (COSHH) Regulations.

This policy applies to all intentional work which involves the handling, storage, transport, and waste disposal of biological agents at the University. Work placements in external health care facilities are not covered by this policy. This also does not include contact with blood/bodily fluid through first aid/cleaning activities.

The use of Genetically Modified Organisms (GMOs) is not covered in detail in this policy. This work is only carried out in the School of Life Sciences and is therefore covered by departmental local rules.

The policy will be reviewed and updated by Workplace Health, Safety and Wellbeing (WHSW) every 5 years.

2. Responsibilities

Full details of health and safety responsibilities of all employees can be found in the University's Health and Safety Policy. The additional responsibilities for biological safety are as follows:

2.1 University Strategic Responsibilities

- Full strategic responsibilities for health and safety are in the University's Health and Safety Policy.
- The University Steering Group (USG) has delegated authority from Council for the effective implementation of the University's Health and Safety Policy. All members of USG are collectively and individually responsible for the overall health and safety management of the University.

2.2 Head of Department (HoD)

- Overall responsibility for ensuring that there are effective arrangements in place and that there are adequate resources allocated to the control of biological safety within their department.
- Appointment of a Departmental Biological Safety Officer (DBSO).
- Approval of all biological schemes of work/risk assessments.

2.3 University Biological Safety Adviser (UBSA)

- Advises on technical requirements and procedures to enable the University to meet statutory requirements, relevant industry/sector guidance and Approved Codes of Practice.
- Ensures recording systems meet requirements of statutory bodies.
- Advises on the technical implications of new and revised legislation and codes of practice.
- Chairs the Biological Hazards and Genetic Modification Sub-Group (BHGMSG) and gives final signature for schemes of work on behalf of the committee.
- Oversees the content of relevant Local Rules and the University Biological Safety Policy.
- In conjunction with the BHGMSG Secretary, maintains a list of current schemes of work/workers lists.
- Submits documentation as required to the Health and Safety Executive (HSE), including notification of first use of a substance (refer to section 4.5)
- May obtain expert competent technical advice where appropriate.

Some responsibilities of the USBA may be allocated to members of Workplace Health, Safety and Wellbeing (WHSW) where appropriate.

2.4 Departmental Biological Safety Officer (DBSO)

- Appointed by the HoD in consultation with the UBSA.
- Advises the HoD on all matters relating to biological hazards.
- Represents the department on the BHGMSG.
- Appraises all schemes of work for the department before they are submitted to the BHGMSG for approval.
- Co-ordinates day to day operational activities and pre-screens local issues before they are sent to the UBSA or BHGMSG.
- Advises the HoD on whether Class 1 projects can be approved or should be escalated to the BHGMSG.
- May obtain expert competent technical advice where appropriate.

2.5 Biological Hazards and Genetic Modification Sub-Group (BHGMSG)

- Considers changes in legislation and best practice that significantly affect the management of biological agents at the University and recommend to HSG any changes in policy or practice that might be required.
- Examines risk assessments and other relevant documentation for all projects involving:
  - genetic modification (GM) work
  - use of biological agents
  - any proposed use of specified animal pathogens
  - use of plants, plant products and plant pests requiring a licence or other permission
  - use of pathogens and toxins subject to Schedule 5 of the Anti-terrorism, Crime and Security Act 2001
- Gives final approval for schemes of work for Hazard Group 2 pathogens (refer to section 3.1).
- To monitor and report, as appropriate, to HSG on compliance with statutory and University requirements.
- Provides reports, gives advice, and makes recommendations to and on behalf of HSG on any matter involving biosafety for the possession, use and control/containment of GMOs and other hazardous biological agents/materials, as relates to this Policy.

The Sub-group must be satisfied that:

a) schemes relating to undergraduate practicals are justified academically and there is no viable alternative; and

b) all reasonable measures have been taken to minimise any risk to researchers and students.

2.6 Principal Investigator (PI)

- Ensure that the risks associated with their work are fully assessed as required by current legislation.
- Maintains an up-to-date copy of the scheme of work for their project and provide copies of these to the UBSA/BHGMSG Secretary.

- Maintain a list of all researchers (staff, postgraduates, undergraduates and visiting workers) who are currently working (or have worked on) their projects that include biological agents and provide a copy for the UBSA and BHGMSG Secretary.
- Regularly review the risks and worker's lists.
- Where there is no approved classification for a biological agent, provisionally classify the agent according to its nature and properties.
- Ensure that workers understand and comply with departmental local rules and work to the correct containment level.
- Ensure that adequate training is given and that changes are notified.
- Provide safety information for Permits to Work, which are required by maintenance staff and contractors before they may enter any area where work with biological agents is taking place.
- Inform the UBSA of any new schemes of work which may need notification to the HSE (refer to section 4.5).

3. Definitions

3.1 Hazard Groupings of Biological Agents

The term biological agent is defined under the Control of Substances Hazardous to Work (COSHH) Regulations as “a microorganism, 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 include bacteria, viruses, fungi, agents which cause Transmissible Spongiform Encephalopathies (TSEs), microscopic endoparasites and microscopic forms of larger endoparasites.

Biological agents are classified into four Hazard Groups (HG), based on their ability to infect healthy humans:

Hazard Group	Description
HG1	Unlikely to cause human disease
HG2	Can cause human disease and may be a hazard to employees; it is unlikely to spread to the community and there is usually effective prophylaxis or treatment available.
HG3	Can cause severe human disease and may be a serious hazard to employees; it may spread to the community, but there is usually effective prophylaxis or treatment available.
HG4	Causes severe human disease and is a serious hazard to employees; it is likely to spread to the community and there is usually no effective prophylaxis or treatment available.

Source: ACDP Approved List of Biological Agents, p9

The Advisory Committee on Dangerous Pathogens (ACDP) categorises biological agents that are human pathogens and publishes these in the Approved List of Biological Agents.

Only agents in HG 2, 3 and 4 are listed in this publication. Those not listed in these groups are not necessarily classified in Group 1. If there is no approved classification for an agent, the Principal Investigator must provisionally classify the agent in accordance with its nature and properties (refer to Schedule 3 Part 1 of the COSHH Regulations). A risk assessment should be carried out to determine the containment level required for working with any organisms. The risks of allergenicity and toxicity should also be considered.

3.2 Containment Levels

Working with HG2 biological agents requires a minimum of containment level 2 (CL2).

For laboratory areas, the ACDP publication 'Management and operation of microbiological containment laboratories' describes the requirements for containment levels.

Note: The University of Essex does not have facilities to work at CL3 or 4; therefore research at these levels is not permitted under any circumstances.

If work is being carried out on unscreened blood where the presence of HG 3 or 4 is unlikely, the sample is presumed to be HG2 and therefore requires containment level 2.

3.3 Genetically Modified Organisms (GMOs)

Genetic modification is defined as any alteration of the genetic material (DNA or RNA) of an organism using a method that does not occur naturally by mating and/or natural recombination. As a result of this modification, a novel product will be formed that may have an altered characteristic to that of the original organism. This is known as a genetically modified organism (GMO). GMOs which are plants or animals are called larger GMOs (LGMOs); and genetically modified micro-organisms (such as bacteria, viruses, parasites, or fungi) are called genetically modified micro-organisms (GMMs).

Work with GMOs and GMMs at the University is covered by the Genetically Modified Organisms (Contained Use) Regulations 2014.

"Contained Use" covers any activity in which organisms are genetically modified, or in which GMOs are cultured, stored, transported, destroyed, disposed of, or used in any other way and for which physical, chemical, or biological barriers, or any combination of such barriers, are used to limit their contact with people and the environment. There is a requirement to notify the HSE of GM work under certain circumstances.

Work with genetically modified organisms must have a risk assessment, which is covered by a scheme of work, where appropriate and will need to be approved by the Biological Hazards and Genetic Modification Sub-Group (BHGMSG). Departmental local rules must be in place before any GMO work commences.

The School of Life Sciences is currently the only department permitted to carry out genetic modification research. Any other department considering GMO research MUST contact the UBSA for advice before commencing any work.

4. Arrangements

4.1 Appointment of a DBSO

All departments which handle biological samples must have a DBSO, appointed by the HoD. This should be a member of staff (usually an academic or technician) who is knowledgeable and competent in work with biological agents.

4.2 Department Local Rules

All departments which handle biological samples must have documented Local Rules detailing their arrangements for controlling the risks. This must include:

- The scope of the activities covered in the department.
- Identification and description of the containment levels and areas.
- Local responsibilities (in addition to those in Section 2 of this policy and the University Health and Safety Policy).
- Arrangements for visitors, visiting workers and contractors.
- Risk assessment/scheme of work requirements (such as justification for grouping projects).
- Training and supervision requirements.
- Recordkeeping.
- Equipment procurement, maintenance and inspection regimes (including fumigation if applicable).
- Control measures, such as use of microbiological safety cabinets, designation of work areas, signage and personal protective equipment.
- Disinfection procedures.
- Emergency procedures including identifying how accidental exposures may occur and the appropriate action to take.
- Transport, receipt, labelling and packaging of samples (including action to take if packaging is damaged).
- Storage and inventory management.
- Lone working and out of hours policy.

- Waste disposal arrangements.

Local rules should be reviewed at least every 3 years or following changes to legislation and must be approved by BHGMSG.

4.3 Risk Assessment

All work with biological agents (or material which may contain biological agents, such as human tissue) must have an up-to-date risk assessment, which is covered under a scheme of work. For further details, refer to Section 5.

4.4 Workers Lists

An up-to-date workers list must be kept for every scheme of work involving biological agents or genetically modified organisms. This is maintained by the Principal Investigator and a copy provided to the UBSA and BHGMSG secretary at least once per year.

4.5 Notification to the HSE

The first use (i.e. deliberate work) of a biological agent at a premises must be notified to the HSE prior to the work commencing. This is carried out by the UBSA; therefore they should be informed of all new scheme proposals and the revision of any existing schemes at CL2 before work commences. Allow at least 20 days for the assessment by the HSE before work starts.

There is also a requirement to notify subsequent use of specific agents listed in Part V of Schedule 3 of the COSHH Regulations Approved Code of Practice.

The formal acknowledgement letter from the HSE will be held by the UBSA.

4.6 Approval Process

All work with HG2 agents must be approved by the BHGMSG before the work commences. Refer to Section 5 for further details.

4.7 Ethical Approval

All research with human participants (including work with human tissue and bodily fluids) must follow the University ethical approval process. Any research involving human tissue or bodily fluids which are not immediately rendered acellular may require ethical approval from an NHS Research Ethics Committee flagged to review such research in order to ensure compliance with the Human Tissue Act. In such instances, further advice should be sought from the REO Research Governance team.

A valid risk assessment must accompany the application for ethical approval in the ERAMS.

4.8 Risks from Blood-Borne Infections

Blood-borne viruses (BBVs) are found in blood, semen and vaginal secretions and breast milk. There is minimal risk associated with other body fluids unless contaminated with blood. Carriers of these viruses (including HIV, Hepatitis B and Hepatitis C) may not be ill or have any symptoms. Therefore, all human blood, body fluids and tissue samples should be considered as potentially infectious.

In the laboratory:

- Potential transmission of BBVs is most commonly by accidental puncture injury through the skin, by a contaminated needle or other sharp object.
- BBVs may also be spread by spillage or splashing on to mucous membranes, eyes or open wounds, abrasions/damaged skin.

All work carried out on materials that may contain unidentified biological agents must be carried out at a minimum of CL2. ACDP has advised that all such specimens must be treated as though they are infected with BBVs and allocated to HG2 as a minimum. Processes that generate splashes or aerosols of blood or similar infectious fluids must be carried out in a Class II microbiological safety cabinet.

Hepatitis B Vaccination

Hepatitis B vaccination is recommended for any laboratory staff who handle material that may contain the virus or who may have direct contact with blood, blood-stained body fluids or tissues. This includes any staff who are at risk of injury from blood contaminated sharp instruments.

It is the University policy that staff taking blood samples and laboratory workers working with blood or body fluids must be referred to Occupational Health for a course of Hepatitis B vaccinations. For further advice please contact Occupational Health.

Collection of samples

Only trained phlebotomists may take whole blood samples of up to 100ml for research purposes. A certificate of qualification for phlebotomy must be seen and validated by the supervising academic before blood can be taken. Samples taken using an autolet do not require a qualified phlebotomist. However, those taking samples by this method or with an equivalent medical device must receive training (either by someone competent/experienced in the technique, or a formal course) before commencing their research. The use of manual lancets will only be considered in exceptional circumstances following completion and authorisation of a specific risk assessment.

Donors

Blood may be taken from volunteer donors for research purposes, provided that the informed and written consent of the donor is obtained.

If taking multiple samples from the same donors, the designated person taking blood must maintain a record of the volumes taken from each donor in a blood sample collection record book. In line with NHS Blood and Transplant, the volume of blood donated by any individual should not exceed 470ml within 12-16 weeks. It is the responsibility of the designated person to ensure that this amount is not exceeded and that those donors, who suffer symptoms of ill health, cease participation in the research and consult their medical practitioner. The DBSO must keep a central record of blood donations available for inspection.

Needlestick injuries

Anyone who sustains a needle stick injury or any other direct contact with potentially infectious material is required to seek first aid, submit an incident report, and be assessed by Occupational Health.

5. Risk Assessment and Approval

5.1 Scheme of Work

All work with biological agents (or material which may contain biological agents, such as human tissue) must have an up-to-date scheme of work. Templates are available on the Biological Hazards and Genetic Modification page of the Staff directory.

The scheme of work forms the risk assessment for the project and must specify the containment level for the work. (Note that there may also be other associated risk assessments required for the project, such as for specific laboratory techniques). It may be appropriate to combine more than one project on the same scheme of work (such as for undergraduate project work) but this must be agreed with the DBSO or UBSA in advance.

Organisms that produce toxins or allergens harmful to humans (e.g. toxin-producing cyanobacteria or toxin-producing corals) must also have a biological scheme of work.

Schemes of work and risk assessments should be reviewed on a three-yearly basis, or when there are significant changes to the project.

No work with HG3 or HG4 agents is permitted at the University of Essex under any circumstances.

5.2 Approval Process for Work with Biological Agents

All new or revised projects involving biological agents must complete section 1 of the scheme of work. HG2 projects will also need to complete section 2. The scheme of work must be approved first by the DBSO, then the HoD.

Once the scheme has been approved within the department, it must then be passed to the BHGMSG secretary for recording and assigning a reference number.

HG1 projects are circulated at BHGMSG meetings for awareness, but do not require approval by BHGMSG and USBA.

All work with HG2 agents must be approved by BHGMSG before the work is carried out. Projects are circulated to BHGMSG for feedback, to be given at meetings and included on the minutes. Following the meeting, the feedback is provided to the scheme author, who must make suggested amendments and return for sign off by the USBA or for further comment by BHGMSG.

Requests for approvals outside of BHGMSG meetings are permitted in special circumstances, at the discretion of the USBA/BHGMSG chair.

6. Record keeping

6.1 Documentation

Workplace Health, Safety and Wellbeing and/or the UBSA holds the following documents:

- Copies of all schemes of work, associated risk assessments and workers lists.
- Correspondence with the HSE.
- Notifications to the HSE.
- Records of approvals and minutes from the BHGMSG meetings.

The DBSO holds donor lists and local records.

6.2 Risk Assessments

The department must keep copies of all relevant documentation for work with biological hazards; this may be electronic or hard copy.

7. Training and supervision

All departments must ensure that personnel are adequately trained in safe handling of biological agents before being allowed to work with them.

They must ensure that relevant staff and students work in accordance with the local rules, risk assessments and procedures for use of laboratory facilities and equipment.

Students must be effectively supervised by senior staff who are competent and experienced in the procedures being supervised.

Specific training and competence requirements for the DBSO and UBSA roles are detailed in the Health and Safety Training Matrix (.docx)

8. Review

Compliance with this policy and local rules is checked annually as part of the routine departmental health and safety inspections. More detailed audits of the system are carried out periodically by the UBSA/DBSO.

Incidents and near misses must be reported to Health and Safety through the normal University procedures and will be followed up by the UBSA/DBSO.

Appendix 1 - Abbreviations

ACDP	Advisory Committee on Dangerous Pathogens
BBV	Blood-borne viruses
BHGMSG	Biological Hazard and Genetic Modification Sub-Group
CL	Containment Level
COSHH	Control of Substances Hazardous to Health
DBSO	Department Biological Safety Officer
GMOs	Genetically modified organisms
HG	Hazard Group
HoD	Head of Department
HSE	Health and Safety Executive
HSG	Health and Safety Group
MSC	Microbiological Safety Cabinet
PI	Principal Investigator
PPE	Personal Protective Equipment
UBSA	University Biological Safety Adviser
USG	University Steering Group
WHSW	Workplace Health, Safety and Wellbeing

Appendix 2 – Sources and further information

University of Essex

- Biological Hazards and Genetic Modification
- Hazardous Substances Safety
- Health and Safety Policy
- Report an incident
- Health and Safety Training Matrix (.docx)
- Ethical approval process

Health and Safety Executive (HSE)

- COSHH Regulations Approved Code of Practice
- Genetically Modified Organisms (Contained Use) Regulations 2014

Advisory Committee on Dangerous Pathogens (ADCP)

- Approved List of Biological Agents
- Management and operation of microbiological containment laboratories

Document Control Panel

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