



# **Risk Management of Hazardous Biological Materials**

## **Deliberate work**

## **Procedure for risk assessing and obtaining approval**

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**This information is for you if** you are taking a risk assessment for deliberate work with hazardous biological material through the completion and approval process, or if you just want to know what the process is.

## What do we mean by hazardous biological material?

Hazardous biological material is any biologically-derived material or material which, either by accident or design, contains:

- hazardous biological agents including: bacteria, viruses, micro-organisms, Transmissible Spongiform Encephalopathies (TSEs) etc.
- hazardous multicellular organisms, (including tapeworm, parasitic flukes and nematodes, etc.) which might cause harm (i.e. infection, allergy, toxicity) or otherwise create a hazard to human or animal health or the environment,
- any genetically modified organism.

See the full definition [here](#).

## Step-by-step approach to the biological risk assessment process for deliberate work

See the [flowchart](#) for a visual impression of the whole process.

The process begins when the need for the hazardous biological materials risk assessment is identified. This may be due to an initial idea to start a completely new programme of work, or a need to modify or change an existing programme of work, for example if you want to incorporate different organisms or processes, new locations, or are involving new types of people (such as adapting an existing project for use by undergraduate students) which is outside the scope of the original assessment.

The following steps must be followed if you are deliberately working with hazardous biological material

Speak to your [University Biological Safety Contacts](#) or local Biological Safety Coordinator if you have any questions.

### Step 1 - Confirm that your work involving hazardous biological material is Deliberate

Work with hazardous biological material falls into one of two defined categories; deliberate or incidental. Use the definitions below to confirm which category your work falls into, if you are unsure then speak to the University Biological Safety Contacts or the local Biological Safety Coordinator.

- **Deliberate** – this is work which involves a deliberate intention to handle (isolate, concentrate or propagate) hazardous biological materials or where hazardous biological materials are known to be or are likely to be present; this includes: laboratory work such as in pathology, diagnostics, hospital laboratories; veterinary laboratories; research laboratories; also biotechnology where microorganisms form part of the process. If your work is deliberate then continue to read this procedure.
- **Incidental** – this is work in which contact with hazardous biological material may occur but only incidentally e.g. agriculture, food preparation and production, waste handling, emergency services etc. If you think your work is incidental then speak to your University Biological Safety Contacts to confirm.

### Step 2 - Decide if the work is Contained or Uncontained

Once you have confirmed that your work with hazardous biological materials is deliberate you need to further categorise your work into [contained use or uncontained use](#). The vast majority of work at the University of Leeds is contained, if you are unsure how to categorise your work then speak to your University Biological Safety Manger or local Biological Safety Coordinator.

- **Contained use of hazardous biological materials** – If your work involves any hazardous biological material that is cultured, stored, used, transported, destroyed, disposed of, or used in any other way,

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and for which specific measures (physical barriers, or a combination of physical barriers together with chemical and/or biological barriers) are used to limit their contact with the general population and the environment then it is **contained** (continue to step 3).

- **Uncontained use of hazardous biological materials** – If your work involves any hazardous biological materials (including genetically modified organisms) that are either already in the environment, or are deliberately introduced into the environment (e.g. for experimental purposes). This also includes material placed on the market, for example, as food or medical purposes (e.g. vaccinations).

**If your work comes under the uncontained use category do not proceed further.** Instead speak to the University Biological Safety Contacts as this type of work requires substantial coordination between Line Managers / Academic Tutors, the University Biological Safety Contacts and the relevant authorities (e.g. Health & Safety Executive, Department for Environment Farming and Rural Affairs, Home Office, Police etc.).

### **The remainder of this document only gives the procedure for contained use.**

## **Step 3 - Decide on the hazard group of the biological materials and containment level**

### **Deciding on the hazard group of the biological material**

Legislation has defined that all biological agents (including Genetically Modified Organisms - GMOs) fit within one of [four hazard groups](#).

- Identify the hazard group relevant to the material you are working with, using the list of biological materials contained in the “[Advisory Committee on Dangerous Pathogens approved list of biological agents](#)”.
  - This list is updated periodically, so check the latest version each time you go through this process.
  - If you are working with biological materials categorised into more than one hazard group, select the most harmful hazard group.
  - The list does not include organisms for hazard group 1, or some as-yet to be assigned organisms (e.g. new and emergent diseases). When your organism isn't on the list use the hazard group definitions to decide which group your biological material belongs to and include this as a justification in your risk assessment.

### **Deciding on the containment level**

- The hazard group you have identified above then relates directly to the [laboratory containment level](#) you must work at. For example if you are working with hazard group 1 biological material then you will need to work at containment level 1; for hazard group 2 you will need to work at containment level 2 and so on.

Where the work is identified as requiring containment level 2 or 3 measures then discuss with the University Biological Safety Contacts the process for notification to the authorities (usually the Health & Safety Executive). This will help determine if the risk assessment can be included within a previously notified connected programme of work, potentially saving time and money.

Bear these thoughts of your initial estimation of the containment level in mind as you write the biological risk assessment.

## **Step 4 - Complete or modify a risk assessment**

You should use the deliberate risk [assessment form](#) that is attached to this protocol, or you can use your own assessment form as long as it is as good as or better than this one.

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See the [Guidance on how to fill in the deliberate risk assessment form](#) for details of how to fill in the risk assessment.

Once you have completed the risk assessment form double check the control measures identified to make sure that they really do control the hazard of the work, and amend the risk assessment if they don't.

### Step 5 - Gain local approval

- **Gain initial local sign off for your biological risk assessment** – All risk assessments must be agreed to by the Line Manager / Academic Tutor (often the Principal Investigator), to confirm that control measures will be put in place and followed (an email from the Line Manager / Academic Tutor to the chair of the local committee to confirm when submitting your risk assessment will be sufficient).
- **Gain permission to proceed for containment level 3** – Risk assessment for work requiring containment level 3 measures must have approval from the Head of School (email from the Head of School to the chair of the local committee to confirm will be sufficient), before the assessment can be submitted to the committee.
- **For work at containment level 4** – the University currently does not have facilities suitable for this type of work, therefore, approval cannot be granted, speak to the University Biological Safety Contacts for advice.
- Remember to keep a copy of any approvals (e.g. saved emails) received for the work.

### Step 6 - Submit risk assessments to the Local Biological Safety Committee

- Submit your biological risk assessment for approval to the line manager, Local Biological Safety Committee, and if the work is at containment level 3, the Head of School - and copy in the University Biological Safety Contacts. For details about your local committee contact your Health & Safety Manager.
- The committee will either agree that the controls are adequate and approve the project on behalf of the University, or require you to make amendments and resubmit the risk assessment to the committee before work can go ahead (copy in the University Biological Safety Contacts if any changes have been made to the risk assessment).
- **Record your biological risk assessment**
  - Keep copies of your risk assessments for the duration of the work until all the hazardous biological material connected with the work is removed (e.g. disposed of).
  - The University Biological Safety Contacts will keep a copy of the finalised/approved assessment for the statutory period.

### Step 7 - Is external approval necessary?

- **Work at containment level 1** – you do not need approval from external agencies (e.g. HSE, DEFRA) and so work can start as soon as the approval is formally confirmed by the Local Biological Safety Committee and University Biological Safety Contacts.
- **Work at containment level 2 or above** – you must obtain additional approval for these projects from the Health and Safety Executive through the University Biological Safety Contacts before work can begin.

You will need to:

- complete the Health and Safety Executive's form which can be obtained from the University Biological Safety Contacts

- make provision for payment of the Health & Safety Executive fees (speak to the University Biological Safety Contacts to clarify what is needed and coordinate the payment).

Discuss with the University Biological Safety Contacts the feasibility of including your risk assessment within a previously notified connected programme of work, this needs to be agreed by the local Biological Safety Committee.

- **Gaining approval from the Health and Safety Executive**

- The University Biological Safety Contacts will manage the process and send relevant documentation and payment to the Health and Safety Executive on behalf of the Line Manager / Academic Tutor.
- The Health and Safety Executive will either approve or reject a project or request additional information to support the risk assessment and make their decision, via the University Biological Safety Contacts.
- The University Biological Safety Contacts will confirm the Health and Safety Executive's decision with the Line Manager / Academic Tutor and the Local Biological Safety Committee Chair.

## Step 8 - Determine if any additional notifications or licences are required for the work

Depending on the type of work being carried out, additional U.K. [notifications or licences](#) may be needed. For the majority of deliberate contained work this shouldn't be an issue, however, checks must be made to determine whether or not the work needs notifications or licence (e.g. when importing biological material from outside the European Union). Speak to your Health and Safety Manager or the University Biological Safety Contacts for advice. Below is a brief summary of legislation that may relate to your work.

- **Biological weapons**

- Where there is any plan to use hazardous biological materials covered by [Schedule 5](#) of the Anti-terrorism Crime and Security Act ([part 7](#)) then the local Biological Safety Coordinator must be notified.

- **Non-human pathogens**

- Work with non-human pathogens is likely to be regulated and licensed by any one of a number of statutory authorities including [Department for Environment, Food and Rural Affairs](#); [Food and Environment Research Agency](#); [Centre for Environment, Fisheries and Aquaculture](#); etc. The nature of the work and the type of pathogen being used will determine which authority (if any) needs to be contacted, this should be done via the University Biological Safety Manger.

- **Medical (including veterinary) products**

- The development of medical products is regulated by the Medicines and Healthcare products Regulatory Agency (and the Veterinary Medicines Directorate for animal products). Work that involves development for these products must be licensed by the relevant authority.

- **Human material**

- Before people within your remit plan to work with human tissue (i.e. "[relevant material](#)" such as blood, tissue, bone, urine, faeces, saliva, etc.) then there must be ethical approval for the work in accordance with the [Human Tissue Act](#), and the material must be handled using [best practice](#)– speak to the Human Tissue Act Officer for more [information](#).

- **Import (Export) of biological material**

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- Importation of biological material (including animal by-products) from outside the European Union is covered by national, European, and International regulations and conventions (from C.I.T.E.S. to the “Importation of Animal Products and Poultry Products Order”)
- Export of biological material is unlikely to be regulated by UK authorities other than requiring that the material is packaged so that it is safe for transport. Export of certain biological materials to some countries may be covered by arms control legislation. Countries to which exports are being sent will have their own import control regulations which either you or the intended recipient must comply with.
- **Environmental impact**
  - If the work has an impact on the environment (typically collection or trapping of plants or animals e.g. for laboratory analysis, or introduction of biological material into the environment) then it may well be regulated by conservation regulations. Licensing systems are often in place for these types of activities; seek advice from the University Biological Safety Contacts.

### Step 9 - Implement control measures before work begins.

- The Line Manager / Academic Tutor must ensure that any control measures identified are implemented before work begins, and that the relevant sections (particularly the risks, control measures and any emergency procedures) of the risk assessment are effectively shared with people who may be affected. Key sections (e.g. spill procedure) must be immediately accessible for people working with the materials.
- The level of detail involved in sharing the risk assessment will change depending on your circumstances. For example, if another workgroup shares your laboratory space, you should make them aware of the risks, control measures and emergency procedures.

### Step 10 - Work Starts

Only once the risk assessment has the necessary approvals, and the controls identified in the assessment are in place may work begin.

### Step 11 - Review your biological risk assessment

Add a reminder into your diary to review the biological risk assessment in accordance with the level of risk of the project. For example:

- containment level 3 work should be reviewed 6 monthly to yearly,
- containment level 2 work should be reviewed every year,
- containment level 1 work should be reviewed within at least 3 years.

This is to ensure the control measures are still appropriate and being adhered to.

- **Significant Changes** – If significant changes occur before this time period is up - e.g. new equipment, material, people or processes are introduced, or if there is an accident or near miss - you will need to review the biological risk assessment earlier. In general a significant change is any change to the work which results in the risk assessment no longer being relevant to the work now being done (e.g. the identified controls are no longer effective, or the biological material being used has changed, etc.). Speak to the University Biological Safety Contacts if you are unsure when you need to review.

Discuss any significant findings of a review with your local Biological Safety Coordinator, or the University Biological Safety Contacts to determine if the assessment should be resubmitted to the local Biological Safety Committee for approval.