



# **Risk Management of Hazardous Biological Materials**

## **Deliberate work**

## **Risk Assessment Form**

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# Risk assessment form for deliberate work with hazardous biological material



UNIVERSITY OF LEEDS

Reference No:

Committee to complete.

**Guidance:**

If you need help to complete this form then: speak to your local Biological Safety Coordinator, or the University Biological Safety contacts. Use the Hazardous Biological Material Protocol and in particular the Guidance to fill in the [Deliberate Risk Assessment Form](#). to guide you through the process. Please use references where possible to substantiate statements.

**GUIDANCE**

**SECTIONS – fill in as required**

**SECTION 1) RISK ASSESSMENT DETAILS**

**1.1 Applicant details**

|   |                           |
|---|---------------------------|
| <b>Line Manager / Academic Tutor(s):</b><br>(person managing work)      | Click here to enter text. |
| <b>Name of risk assessor:</b><br>(if not Line Manager / Academic Tutor) | Click here to enter text. |
| <b>Contact details:</b><br>(email, or telephone)                        | Click here to enter text. |
| <b>School or Institute:</b><br>(department that will host the work)     | Click here to enter text. |

|   |                           |
|---|---------------------------|
| <b>1.2 Locations where the work will be carried out:</b><br>(Building name / room No etc) | Click here to enter text. |
|---|---------------------------|

|   |  |                 |
|---|--|-----------------|
| <b>1.3 Names and positions of people carrying out work:</b><br>(Give positions (e.g. PI, Lecturer, PG, PD, technician, visitor) in brackets after name) | <b>Name</b>  | <b>Position</b> |
|   | 1)<br>2)<br>3)<br>4)<br>5)<br>6)<br>7)<br>8)<br>etc. |                 |

|   |                           |   |                             |
|---|---------------------------|---|-----------------------------|
| <b>1.4 Provisional Containment Level of work:</b><br>(Use Hazard Group to determine CL) | Choose Containment Level. | <b>1.5 Date submitted to committee:</b> | Click here to enter a date. |
|---|---------------------------|---|-----------------------------|

|  |                           |
|--|---------------------------|
| <b>1.6 Title:</b><br>(Usually the project title used in the grant application) | Click here to enter text. |
|--|---------------------------|

|   |                           |
|---|---------------------------|
| <b>1.7 Overview of work and methodologies:</b><br>(Give aims of the work; include rationale of technologies used to fulfil those aims). | Click here to enter text. |
|---|---------------------------|

| GUIDANCE  | SECTIONS – fill in as required |
|---|--------------------------------|
| <b>SECTION 2) HAZARD IDENTIFICATION IN RESPECT OF HUMAN HEALTH AND SAFETY FOR BIOLOGICAL MATERIAL (Do not use this section for Genetically Modified Organisms)</b>  |                                |
| <b>2.1 Biological Materials and their Hazards:</b><br>i) Identify source of biological material, e.g. culture collection, research collaborators.<br>ii) Identify health hazards associated with biological material.   | Click here to enter text.      |
| <b>SECTION 3) HAZARD IDENTIFICATION IN RESPECT OF HUMAN HEALTH AND SAFETY FOR GENETICALLY MODIFIED ORGANISMS (Fill in for GM work only)</b>   |                                |
| <b>3.1 Give names, functional properties and origin/source of inserted gene(s) or gene family</b><br>i) Describe the listed genes or gene family in such a way that an outside reviewer will have a general idea of their function i.e. providing abbreviations may not be sufficient. Give details of any known homologues if the function of a gene is unknown.<br>ii) Identify hazards inherent in sequence or from expressed biological properties.<br>iii) Identify where transgenic nucleic acid will be obtained, e.g. culture collections, collaborators, banks.<br>iv) Identify any hazards associated with donor organisms, e.g. diseases, allergenic properties. | Click here to enter text.      |
| <b>3.2 Describe the vector system(s) you are using in relation to your work:</b><br>i) Identify type of vector(s) e.g. bacterial, plasmid, virus, etc.<br>ii) How are genes transferred.<br>iii) How is inappropriate genetic transfer to other organisms guarded against, e.g. vectors are non-mobilisable, mobilisation defective, replication defective etc.<br>iv) are accessory genes involved, e.g. antibiotic resistance markers.  | Click here to enter text.      |
| <b>3.3 Recipient(s):</b><br>i) Identify all recipients of genetic material (microorganisms, cell lines, plants, animals, etc.).<br>ii) Are there any safety features that recipients have (e.g. attenuation, disablement)?<br>iii) Identify hazards associated with microorganisms, cell lines, plants or animals receiving genetic material, e.g. diseases, vector for disease, allergenic properties, toxins etc.   | Click here to enter text.      |
| <b>3.4 Resultant GMO(s):</b><br>Are all resultant GMOs formed less harmful, no more harmful or more harmful than unmodified recipient – give reasoning.   | Click here to enter text.      |

| SECTION 4) HAZARD IDENTIFICATION IN RESPECT OF THE ENVIRONMENT  |   |                           |
|---|---|---------------------------|
| <p><b>What would happen if there is an accidental release of any hazardous biological material, and for GM work, donor(s), recipient(s), vector(s) or final GMO(s) to the environment:</b></p> <p>i) Is it already present in the environment?<br/>           ii) Can they survive in the environment?<br/>           iii) Can they colonise humans, animals, insects, or plants?<br/> <b>If not, say why</b><br/>           iv) Are there any adverse effects upon humans, animals, insects, plants and microorganisms?<br/> <b>If none, say why</b><br/>           v) Are there any economic or ecological consequences of a major escape to environment?</p> | Click here to enter text.   |                           |
| SECTION 5) LIST ANYTHING THAT SHOULD BE EXCLUDED FROM THIS RISK ASSESSMENT:   |   |                           |
| Identify types of hazardous biological material or activities that you want to exclude from your work e.g. toxin genes, pathogenicity determinants, volumes over a certain amount (or write N/A if no exclusions are required).   | Click here to enter text.   |                           |
| SECTION 6) RISK MANAGEMENT  |   |                           |
| <b>6.1 Will you be using all the controls corresponding to the provisional containment level.</b>   | Indicate Yes or No...If No, please state why:<br>Click here to enter text.  |                           |
| <b>6.2 Are there any other additional control measures that need to be considered</b><br>For example, consider containment of aerosols, requirements for safety cabinets and specific requirements for waste disposal if different from standard default procedures, see standard procedure below.<br>Additional controls may include how others access the work area (e.g. maintenance staff) or Biosecurity etc.  | Indicate Yes or No...If Yes, please state what:<br>Click here to enter text.  |                           |
| <b>6.3 Confirm the containment level of your facilities:</b>  | Click here to enter text.   |                           |
| <b>6.4 Describe procedure for</b>   | <b>Liquid waste disposal:</b><br>Indicate if you are using a departmental procedure, and if there are any changes to the procedure?                         | Click here to enter text. |
|   | <b>Solid waste disposal:</b><br>Indicate if you are using a departmental procedure, and if there are any changes to the procedure?                          | Click here to enter text. |
|   | <b>Spills:</b><br>Indicate what the scale of the activity is i.e. maximum volume (If spillage of the maximum volume occurred, how would you deal with it?). | Click here to enter text. |
| <b>6.5 Storage of materials:</b><br>Give details of :<br>i) Location?<br>ii) How stored? (4°C, -20°C, -80°C etc?)<br>iii) Security arrangements?  | Click here to enter text.   |                           |
| <b>6.6 Does the risk assessment indicate emergency procedure are required:</b><br>Do the harmful consequences of an escape from containment present a significant risk to the community or local environment such that a disaster plan is required?   | Indicate Yes or No...If yes, please include emergency plan:<br>Click here to enter text.  |                           |

| SECTION 7) HEALTH & SAFETY CHECKLIST   |   |   |
|--|---|---|
| <b>7.1 Are people registered as necessary:</b><br>A record of all people working with GM must be maintained. People using biological materials or GMOS from hazard group 2 or above must be registered with the Occupational Health Service.   | Indicate Yes or No...If no, please explain:<br>Click here to enter text.  |   |
| <b>7.2 Are all workers enrolled on/or have completed the on-line Bio training:</b><br>Exemption from the training course only for experienced workers and those that have other formal training – exemptions must be approved by the Health and Safety Manager   | Indicate Yes or No...If no, please explain:<br>Click here to enter text.  |   |
| <b>7.3 Are all workers trained in good microbiological practice or to be trained? Give details:</b>  | Click here to enter text.   |   |
| THIS SECTION IS TO BE COMPLETED BY THE LOCAL BIOLOGICAL SAFTY COMMITTEE  |   |   |
| SECTION 8) SIGN OFFS   | Electronic Signatures:  | Approval Dates:   |
| Line Manager's / Academic Tutor's electronic signature to confirm that control measures will be implemented and followed.  | Has Line Manager / Academic Tutor agreed to this risk assessment and the controls identified within (e.g. via email)? <b>Yes/No?</b>                    | Click here to enter a date.                                 |
| For work at <b>Containment Level 3</b> the Head of School/Institute signs to give permission to proceed.   | For Containment Level 3 work has the Head of School / Institute given permission for the work to proceed (e.g. via email)? <b>Yes/No?</b>               | Click here to enter a date.                                 |
| The Biological Safety Committee at The University of Leeds agrees that the above is an accurate assessment of the risks associated with this work and the containment required.  | Has Committee Chair on behalf of the committee agreed to this risk assessment and the controls identified within (e.g. via email)? <b>Yes/No?</b>       | Click here to enter a date.                                 |
|  | Committee Assigned Containment Level <b>Choose Containment Level, 1, 2, or 3?</b>   |   |
| University Biological Safety Manager signature to confirm that assessment has been through approval process  | Has the University Biological Safety Manager confirmed that this risk assessment has been through the approval process (e.g. via email)? <b>Yes/No?</b> | Click here to enter a date.                                 |
| Only to be completed if notification to the Health and Safety Executive is required.   | HSE approval for work <b>Yes/No?</b>  | HSE reference No. GM559/Ref No. Click here to enter a date. |
| Committee Notes  |   |   |
| <b>Additional sources of information</b><br>For work with Biological Agents useful information can be found in the Health & Safety Executive's ' <i>Biological agents: Managing the risks in laboratories and healthcare premises</i> ' ( <a href="http://www.hse.gov.uk/biosafety/biologagents.pdf">http://www.hse.gov.uk/biosafety/biologagents.pdf</a> ).<br>For help with Genetically Modified Organisms work, useful information can be found in the Scientific Advisory Committee on Genetic Modification ' <i>Compendium of Guidance</i> ' ( <a href="http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/">http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/</a> ).<br>For work with Biological Agents, and Genetically Modified Organisms, useful information can also be found in the Health & Safety Executive's ' <i>The management, design and operation of microbiological containment laboratories</i> ' and the HSEs Advisory Committee on Dangerous Biological agents ' <i>Approved List of Biological Agents</i> ' ( <a href="http://www.hse.gov.uk/PUBNS/misc208.pdf">http://www.hse.gov.uk/PUBNS/misc208.pdf</a> ).<br>Advice can also be sought from experts on the Local Biological Safety Committee. |   |   |