
Risk Assessment for the use of Microorganisms & Biological Material Part 2

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| Project Title:  |  |
| Project Leader:  |  |
| Start Date: |  | Anticipated Duration: |  |

# PART 2 – to be completed by the Project Leader

Part 2 is designed for a detailed assessment of biological safety for material(s) that contain organisms rated as Human Pathogen Hazard Groups 2 and above. For further guidance please click [here](https://www.hse.gov.uk/pubns/misc208.pdf).

**(A) HAZARDS TO HUMAN HEALTH**

**(i) What are the hazards associated with the material?**

Factors to consider include whether the recipient material is listed in the Advisory Committee on Dangerous Pathogens as Hazard Group 2, 3 or 4. Other relevant factors may be the material’s mode of transmission, disease symptoms, host range, and tissue tropism as well as an indication as to whether vaccines or chemotherapeutic agents are available.

**(ii) Potential routes of exposure to humans**

Consider the route of exposure (Inhalation / Ingestion / Injection / Absorption / Other)

**(iii) Who might be at risk?**

Research Staff / Other Staff / Students / Visitors / Public. What are they at risk of?

**(iv) Assignment of a provisional containment level that is adequate to protect against hazards to human health**

This step will involve considering the containment level necessary to control the risk of the recipient material and making a judgement about whether the specific experimental conditions being used impact upon this.

**(B) IDENTIFICATION OF ANY HAZARDS TO THE ENVIRONMENT**

Factors to consider include whether the recipient material is capable of infecting or interacting with people, plants, animals or insects in the environment. It should be ascertained whether the recipient material is controlled by DEFRA, the HSE, Biological or Chemical Weapons Conventions or is a Schedule 5 substance (or organism) controlled by the of the Anti-Terrorism, Crime and Security Act.

**(i) How will containment and control be managed?**

Consideration of the nature of the work to be undertaken and a detailed review of the control measures. Are any of the work procedures likely to generate aerosols? If so, should the work be undertaken in a safety cabinet or isolator?

**(ii) Where will the work take place?**

Will material be transported between rooms locally or between premises outside of the uni?

**(iii) Will sharps be used during or near this work?**

**(iv) What are the potential hazards associated with material being transferred to people, insects, animals or plants**

Would a breach of containment be a matter of concern. If so, an important consideration would be whether, in the event of a breach of containment, the agent could survive in the environment for long enough to create problems.

**(v) How will waste materials (including any sharps) be disposed of?**

Include both solid and liquid laboratory waste, and waste from experiments with infected laboratory animals or plants where relevant.

**(vi) Does the nature of this work preclude it being undertaken by any workers who have a current health condition or are pregnant?**

**(C) STORAGE**

**(i) How will material be stored / contained between experiments?**

What precautions are needed for your specific experiments?

**(ii) Have any disinfectants been validated under the actual conditions of use?**

if disinfectant is being used for the treatment of virus in tissue culture medium, is it known that the disinfectant is effective in the presence of high levels of protein? In the case of material whose multiplication involves a complex life cycle, will the work involve the propagation of materials that are in stages of that life cycle that are particularly hazardous? Examples include the propagation of the infective stages of parasites or the release of spores from fungi. Consideration must be given to all potential routes of transmission including those that might not be used naturally.

**(iii) Are there any known resistances to biocidal materials like antibiotics that could compromise control measures?**

**(iv) Is there is a need to assign additional measures over and above the provisional level of containment?**

**(v) How much material will you be using or producing during the proposed work and with what frequency?**

Please estimate ball-park figures

**(D) CONTAINMENT**

**(i) What measures are in place should containment be breached?**

**(ii) Have you notified Occupational Health of any risk of infection to you, your students, or your colleagues?**

**(iii) Are there any plans for monitoring people who are in the proximity of the people conducting this work (i.e. for infection)?**

This may not be applicable to hazard group 2 work.

**(iv) What are the cleaning arrangements for designated work areas where these materials will be handled?**

**(v) Does the area where this work will be undertaken require restricted access?**

**(vi) Have FM / The current cleaning / security contractors (*i.e.* Sodexo) been notified?**

**(E) SECURITY**

**(i) Is there the potential for the dual use of these agents / organisms?**

**(ii) If there is the potential for dual use, have the counter-terrorism police been notified of this work?** You need to register and any pathogen or toxin on Schedule 5 list of the Anti-Terrorism, Crime and Security Act

**(iii) Is any additional security needed beyond restricting access to the area where this work is being conducted / stored?**

**(iv) Have any national or international regularity bodies been informed?**

These might include the chemical or biological weapons convention regulatory authorities.

**Please append any relevant feedback from the HSE.**

# PART 3 - Final assignment of containment measures and risk class

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| The following aspects of this project are assigned to class 1. |
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| The following aspects of this project are assigned to class 2. |
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| The following aspects of this project are assigned to class 3. |
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| The following aspects of this project are assigned to class 4. |
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**If any aspects of the project are rated as Class 2 or above, appropriate notification must be made to the HSE Biological Safety Unit by the Project Leader.**

# STATEMENT BY PROJECT LEADER

The research stated in this notification/risk assessment will be carried out in accordance with local rules and safety policies. This risk assessment will be kept under review and the Biological & Genetic Modification Safety Committee will be informed if there is an accident or any significant changes in the work, procedure(s), location, equipment or materials, personnel or legislation that might affect risk of harm to humans or the environment.

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| --- | --- | --- | --- |
| **Name (block capitals):** |  | **Date:** |  |
| **Signature:** |  |

# STATEMENT BY HEAD OF DEPARTMENT OR (DEPUTY) DIRECTOR OF RESEARCH

I hereby give approval for the work in this notification/risk assessment to be carried out, subject to any conditions summarised above and the approval of the relevant Committees.

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| --- | --- | --- | --- |
| **Name (block capitals):** |  | **Date:** |  |
| **Signature:** |  |

# COMMENTS OF THE BIOLOGICAL & GENETIC MODIFICATION SAFETY COMMITTEE

Note to Committee: HSE notification is required?

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| **Chair of BGMS (block capitals):** |  | **Date:** |  |
| **Position:** |  |
| **Signature:** |  |

(If ethical issues are involved the Project Leader should also refer project to the Secretary of the Faculty Research Ethics Committee).

# Review of risk assessment:

**Project Title**: ...............................................................................

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| Review Date: |  |  |  |  |
| Reviewer’s Name (Print): |  |  |  |  |
| Signature: |  |  |  |  |