
Risk Assessment of the use of Microorganisms & Biological Material

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

# Procedure for assessing biological safety

* The Project Leader completes a draft risk assessment.
* If this project requires the use of Human Pathogen Hazard Groups 2 organisms or above, then part 2 of this form needs to be completed.
* The Project Leader sends the draft assessment via email to the Biological & Genetic Modification Safety Committee (BGMS) Secretary (BGMSC@greenwich.ac.uk).
* The BGMS Secretary circulates copies of the assessment to committee members for comment.
* Comments on the assessment to be sent to the BGMS Secretary and copied to other committee members within two weeks of the date received.
* The BGMS Secretary will collate responses to the assessment and send these to the Project Leader and committee members.
* The Project Leader revises the assessment or justifies clauses where queries have been raised and sends their response back to the BGMSC Secretary and the committee for consideration.
* Once approved by the Committee, a signed hard copy of the assessment should be sent to the relevant Head of Department or (Deputy) Director of Research for approval and signature.
* The Head of Department or (Deputy) Director of Research sends the signed copy of the risk assessment to the BGMS Chair for signature.
* The BGMS Chair sends signed hard copy to the BGMS secretary.
* The BGMS Secretary copies the assessment and sends the original hard copy, signed by the project leader, Head of Department or (Deputy) Director of Research and the BGMS Chair to the Project Leader.
* The project can then commence.
* The project must be reviewed at least annually or sooner if there is an accident or a significant change in the work. Note: There is a five-year cap on risk assessment reviews, therefore all projects will require a complete a new proposal to the BGMS Committee if this is exceeded.
	+ If no revisions are required, the project leader sends a completed “Review of GM/Biological Project Risk Assessment – no Revisions Required” form to the BGMS secretary.
	+ If revisions are required a new project risk assessment form must be completed for BGMS comment as above.

**Note**: If the project proposes work with Human Pathogen Hazard Groups 2, appropriate notification must be made to the HSE Biological Safety Unit by the project leader. Where this has been undertaken, evidence of HSE compliance should be appended to this application.

Local risk assessment will also need to be undertaken.

# PART 1 – to be completed by the project leader

**(a) Scientific goals of the project**

This information provides useful background and puts the work in context.

**(b) An overview of the different types of microorganisms / toxin / animal tissues / material that will be used**

This overview should consist of one or two paragraphs, outlining the scope of the project and a brief description of the planned use of biological agent.

**(c) List of strain / organisms / agents that are/may be present within material**

**(i) Provide the name of the species, or strain, and the extent to which it is disabled. Reference to the applicable HSE Human Pathogen Hazard Group:**

Biological agents requiring containment level 1:

Biological agents requiring containment level 2:

Biological agents requiring containment level 3\*:

Biological agents requiring containment level 3:

Biological agents requiring containment level 4:

For further guidance from the HSE please click [here](https://www.hse.gov.uk/pubns/misc208.pdf)

**(ii) Type of work carried out with the proposed microorganism/biological material**

**(iii) An indication of the most hazardous microorganisms/agents in use (this may be a balance of probability)**

Considering both human health and the environment, the most hazardous / microorganism / animal tissues that will be used in this work should be identified.

**(d) Are you confident that for all of the microorganisms / tissues / agents covered by this assessment there are no harmful properties associated with the material in question (*i.e.,* are human pathogen hazard group 1 or similar)?**

If the answer to this question is YES justification (explanation) must be provided. If the answer to this question is NO or you are in any way unsure, Part 2 of this form must be completed.

**(e) Are you confident that none of the final microorganisms / tissues / toxins / agents could be hazardous to humans or the environment?**

If the answer to this question is YES justification (explanation) must be provided. If the answer to this question is NO or you are in any way unsure, Part 2 of this form must be completed.

**(f) Location(s) of work and containment level required**

List the laboratory(s) and building(s) where this work will be carried out. Include off-campus details where relevant. State arrangements for transportation of materials between locations and the HSE categorisation of biological security level required.

**(g) Method(s) of disposal**

*e.g.. autoclave, incineration, treatment with 1% (w/v) Virkon etc. Please indicate where this will happen.*

If the Genetically Modified Microorganism(s)/Animal Tissue(s), organisms or agents meet the criteria in **BOTH** sections (d) and (e), you may believe that you have sufficient information at this stage to classify the project to Class 1, as defined in the [Genetically Modified Organisms Contained Use regulations 2014](http://www.hse.gov.uk/pubns/priced/l29.pdf). In order to do this you should be confident that even in the event of a total breach of containment the organism would be of no or negligible risk to human health or the environment.

**Note: If the project is classified as 2 or above, appropriate notification shall be made to the HSE Biological Safety Unit by the Project Leader**

If you are assigning the work to Class 1, copy the completed assessment form to the BGMS Secretary for comment by the University Biological & Genetic Modification Safety Committee. Work must not be commenced until this assessment has been commented on by the Committee, and then approved by the Head of Department or (Deputy) Director of Research.

If you have uncertainty as to whether the proposal meets the above criteria, you should complete a Part 2 form and send copies of both forms to the BGMS Secretary for comment by the University Biological & Genetic Modification Safety Committee. Work must not be commenced until both assessment forms have been commented on by the Committee, and then approved by the Head of Department or (Deputy) Director of Research.

The assessment must be reviewed at least annually or sooner if there is an accident or a significant change in the work, procedure(s), location, equipment or materials, personnel or legislation. **Note**: There is a five-year cap on risk assessment reviews, therefore all projects will require a completely new proposal to the BGMS Committee if this is exceeded.

If you are using human cells or tissue / body fluids / excreta, separate governance exists in the form of the Human Tissues Act, as well as local and national ethics board(s). Please speak to your ethics rep if you would like to explore this.

# 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: is HSE notification 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: |  |  |  |  |