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| **Biological Risk Assessment** |
| This form allows for assessment of the hazards and risks associated with projects involving the use of **biological agents, genetically modified microorganisms**, or of materials such as **cells and tissues** that may be contaminated with these agents. It also identifies those at risk from the work and the measures necessary for preventing or controlling these risks.  The work described within this risk assessment **must not** start until final approval has been given on [RADAR](https://www.imperial.ac.uk/safety/safety-by-topic/laboratory-safety/biological-safety/risk-assessment-database-and-register-radar/).  Any changes to the work must be notified on RADAR by uploading an amended version of this form to the existing RADAR entry. You must list all changes to this form in the Notes section of the RADAR entry or in a separate document uploaded alongside this form. Changes to the people registered on this project should also be recorded on RADAR.  If you are planning to work with invertebrates only (no other biological material), please complete a CC1 form. |

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| **Guidance on the colour scheme for this form:** | | | | | |
| Blue fill: complete for all work, as indicated | Pink fill: tissues, cells, body fluids and excreta | Green fill: complete for all biological agents | Orange fill: specific to creation of genetically modified microorganisms | Purple fill: work with laboratory animals | Yellow fill: record of review and consent |

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| **Project Details** |
| Activity title: |

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| --- | --- | --- |
| **Principal Investigator** |  | **Person completing risk assessment (if not PI)** |
| Name: |  | Name: |
| CID: |  | CID: |
| Faculty: |  | Faculty: |
| Department/Section: |  | Department/Section: |

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| **1** | **Background and regulatory requirements** | |
| 1.1 | Background and aims of the project:  *Please provide a brief introduction to the project which summarises the key aims and scope of your work* | |
|  | |
| 1.2 | Description of the experimental procedures:  *Include details on the use of specialised equipment such as bioreactors, shared equipment/facilities, novel techniques etc.* | |
|  | |
| 1.3 | Where will this work be carried out?  *Please include campuses, buildings, and room numbers. If the project is conducted at more than one location, indicate which part(s) of the project will be conducted at each of the locations.* | |
|  | |
|  | Will this project involve fieldwork, or hosted work in another institution?  *If* ***yes****, please upload a risk assessment for this aspect of the work to RADAR.* | |
|  |  | No |
| 1.4 | Does the work involve the use of any biological toxins?  *If the answer is yes, list the material, including quantities and concentrations.* | |
|  |  | No |
| 1.5 | Does any of the material in this project (including toxins) appear on [Schedule 5](https://www.imperial.ac.uk/safety/safety-by-topic/laboratory-safety/biological-safety/biosecurity/) of the Anti-terrorism, Crime, and Security Act?  *If the answer is yes, list the material and describe the security arrangements in place.* | |
|  |  | No |
| 1.6 | Is any of the material in this project covered by the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)?  *If the answer is yes, list the material. There is more information on* [*gov.uk*](https://www.gov.uk/guidance/cites-imports-and-exports)*.* | |
|  |  | No |
| 1.7 | Are any of the biological agents in this project listed in the Specified Animal Pathogens Order (SAPO)? If yes, list these agents, including the specific strains you plan to use and their SAPO hazard group, here:  *Refer to* [*HSG280*](https://www.hse.gov.uk/pubns/priced/hsg280.pdf) *(Appendix 1, page 56) for this information.* | |
|  |  | No |
|  | Describe the type and severity of the disease that can be caused to animals by these agents: | |
|  |  | |
| 1.8 | Are any of the biological agents in this project classified as plant pathogens? If yes, list these agents, including specific strains, here:  *If your work includes the use of plant pests, please complete a* [*plant health risk assessment*](https://www.imperial.ac.uk/media/imperial-college/administration-and-support-services/safety/internal/biosafety/F005-Plant-Risk-Assessment--Including-regulated-and-prohibited-material.docx)*.* | |
|  |  | No |

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| **2** | **Tissues, cells, body fluids and excreta** | | | | | |
| *Complete this section if you are using human or animal tissues, cells, body fluids or excreta. Otherwise, proceed to section 3.* | | | | | | |
| 2.1 | List all tissues, cells (including cell lines), body fluid and excreta, and the source of the samples: | | | | | |
| Description of material | Source/cohort | GM? | Proposed GM Class? | | |
|  |  | Yes  No |  | | |
|  |  | Yes  No |  | | |
|  |  | Yes  No |  | | |
| 2.2 | Will any biological agents be present in the material listed in 2.1?  *Provide information on any biological agent which you reasonably expect to be present in your samples and the control measures proposed to prevent exposure. If you believe that there are no biological agents present in the material, give details on the sample screening which has been carried out.* | | | | | |
|  | | | | | |
| 2.3 | Do you plan to isolate/purify these biological agents?  *If yes, then section 3 of this form should also be completed.* | | | | | Yes  No |
| 2.4 | Will material be manipulated in any way that could result in the inadvertent concentration of an adventitious biological agent? | | | | | |
|  | | | | | |
| 2.5 | Could cells permissive to bloodborne viruses be present? | | | | | |
|  | | | | | |
| 2.6 | Will any culturing of the material described in 2.1 take place?  *If yes, describe which cells will be cultured and under what conditions.* | | | | | |
|  | | | | | No |
| What is the maximum volume of culture which will be grown?  *Provide information on the volume per flask/culture vessel, and the maximum number.* | | | | | |
|  | | | | | |
| 2.7 | Will any of the material described in this section be donated by you or your colleagues? If so, provide justification for not using material from another safer source e.g. NHS Blood and Transplant. | | | | | |
|  | | | | | |
| Detail who will donate the material and explain any special risks associated with the donation: | | | | | |
|  | | | | | |
| 2.8 | Is any of the material listed in 2.1 genetically modified? If yes, please describe the nature of the genetic modification for each type of sample: | | | | | |
|  | | | | No | |
| Is there a possibility of exposure to the genetically modified material?  *E.g., will aerosols be generated, are sharps being used?* | | | | | |
|  | | | | | |
| Could exposure to the genetically modified material be a health hazard?  *E.g., exposure to cells overexpressing oncogenes or downregulating tumour suppressor genes.* | | | | | |
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| **3** | **Biological agents – Wild-type and genetically modified** | | | | | | | |
| *Complete this section if your project will involve work with wild-type or genetically modified biological agents. Otherwise, proceed to section 4.* | | | | | | | | |
| 3.1 | List **all** biological agents, wild type and genetically modified, which will be used as part of this project. Enter additional rows as required.  *Please refer to the* [*ACDP Approved List*](https://www.hse.gov.uk/pubns/misc208.pdf) *for further information.* | | | | | | | |
| Name of microorganism | Strain(s) | Hazard group/Class | Will it be (further) genetically modified (Y/N) | Route of Infection *(other than for HG1/Class 1)* | Minimum infectious dose | Will it be cultured? (Y/N) | Source *(commercial, collaborator, generated on site)* |
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| 3.2 | Describe the type and severity of the disease that can be caused to humans or the environment by these agents: | | | | | | | |
|  | | | | | | | |
| 3.3 | Describe any known drug resistance in the agents and strains listed, and the drugs that the agents remain susceptible to: | | | | | | | |
|  | | | | | | | |
| 3.4 | If any forms of the agent(s) confer particular resistance to disinfectants, or allow increased stability on dry surfaces, provide details and include any specific controls or methods required to inactivate these strains:  *For example, spore forming bacteria.* | | | | | | | |
|  | | | | | | | |
| 3.5 | What is the highest concentration and volume of biological agent, GM and wild type, to be cultured?  *Provide information per flask, and per experiment. Where numbers vary between agents, specify for each agent.* | | | | | | | |
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| *Complete the rest of this section if you will create genetically modified microorganisms (GMM), or if you are using a system based on lentivirus or adenovirus (or similar). Otherwise, proceed to section 4.* | | | | |
| 3.6 | List the vector system(s) to be used, and their functional properties:  *For multicomponent vector systems, include the generation of the system and if any of the components have been attenuated.* | | | |
| Name of vector | Source e.g., name of supplier | | Functional properties |
|  |  | |  |
| 3.7 | Describe the hazards to human health and to the environment associated directly with the vector systems listed above:  *E.g., use of mobilisable vectors, use of viral post-transcriptional regulatory elements such as WPRE (if these have been mutated or truncated, include details).* | | | |
|  | | | |
| 3.8 | List the names of all altered or inserted genes, or groups of genes, and their functional properties:  *Include information on known or suspected oncogenes.*  *Where a library of mutations is being used, please upload the library to RADAR and add a reference here rather than listing all genes.* | | | |
| Name of gene or group of genes | | Functional properties | |
|  | |  | |
| 3.9 | Describe the known or potential hazards associated with all the GMMs to be created: | | | |
|  | | | |
| 3.10 | Identify the most hazardous GMM(s) to be created, giving consideration both to human health and the environment:  *Confirm if any of the GMM(s) to be constructed are expected to be more hazardous than the recipient microorganism (is gain of function expected?) e.g., is there an expected change in tropism or pathogenicity.* | | | |
|  | | | |
| Detail the mechanisms in place to identify inadvertent increase in tropism or pathogenicity and any actions that would be taken to address this.  *This should include a description of the triggers that would alert the researcher to increased tropism or pathogenicity.* | | | |
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| 3.11 | Explain the likelihood and consequences of any modifications being accidentally transferred to related microorganisms: | | | |
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| **4** | **Research laboratory animals** | | |
| *Complete this section if your project will involve laboratory animals. If your work involves invertebrates, please complete the CC1 form instead. If no animals or invertebrates will be used, proceed to section 5.* | | | |
| 4.1 | Provide a brief overview of the work involving laboratory animals, including any known phenotypes: | | |
|  | | |
| 4.2 | If you are planning to infect animals with any biological agents described in this risk assessment please provide details, including the method used to infect the animal, here.  *If you* ***will not*** *be infecting the animals, please proceed to Q4.3.* | | |
|  | | |
| If shedding of biological agents by the infected animal is possible, by what route(s) could this occur and how long after infection could shedding take place? | | |
|  | | |
| Could the biological agent be transmitted to other animals in the facility?  *Explain any likely routes of transmission* | | |
|  | | |
| 4.3 | Will the work take place in CBS, or in an external designated room?  *Please contact the CBS Safety and Compliance Manager (CBS) or your Faculty Safety Advisor (Designated room) for more information and access to the risk assessment forms for these areas.* | CBS  Designated room | |
| 4.4 | Are the animals GM?  *If* ***no****, please proceed to Q4.5.* | | Yes  No |
| Are the GM animals any more hazardous to human health or the environment than the non-GM animal?  *If yes, please provide details about the additional controls that are in place to mitigate the risks from these animals.* | | |
|  | | No |
| 4.5 | List any additional controls required for work with animals, including those used to prevent escape:  *E.g., additional PPE (respiratory protection, gauntlets), sticky mats, door barriers, netting, IVC’s, biocontainment cages. If you have considered additional control measures but decided not to use them, justify this decision here.* | | |
|  | | |
| **All those authorised to work with laboratory animals as part of this project must enrol with OH for LAA** [**health surveillance**](https://www.imperial.ac.uk/occupational-health/health-surveillance/)**.** | | | |

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| **5** | **Project related hazards and controls** | | | |
| **Complete this section for all projects.** | | | | |
| 5.1 | Could the work create hazardous droplets or aerosols, either deliberately or by accident? If yes, describe the controls in place to prevent exposure:  *E.g., use of a microbiological safety cabinet, use of safety glasses* | | | |
|  | | | No ☐ |
| 5.2 | Will material be centrifuged? If yes, describe the controls in place to prevent exposure to aerosols.  *E.g., use of sealed rotors or buckets, only opening buckets in a safety cabinet.* | | | |
|  | | | No |
| 5.3 | Will any sharps be used in the project? If yes, justify why there is no suitable alternative, and describe the controls in place to prevent injuries or exposure.  *If cut/puncture resistant gloves will not be used, justify the reasons why. If you have considered any additional control measures but decided not to use them, justify this decision here.* | | | |
|  | | | No |
| 5.4 | Provide details of disinfectants to be used. If the work involves HG2/Class 2 or above, provide a validation plan, or reference to relevant literature.  *Include the concentration, minimum contact time, and final concentration required when added to liquid waste.* | | | |
|  | | | |
| 5.5 | Will material be cultured in an incubator?  *If* ***yes****, provide details of the vessel(s) to be used, and (in the case of shaking incubators) how they are fixed securely.* | | | |
|  | | | No |
| 5.6 | Are you planning to inactivate any of the samples?  *If* ***yes****, describe how, and how this has been validated.* | | | |
|  | | | No |
| 5.7 | Will flow cytometry analysis or cell sorting be carried out? If yes, provide the location and confirm that all those conducting this work have received or will receive training on the use of the instrument(s). | | | |
|  | | | No |
| 5.8 | Will this project involve work with any of the following hazards? If **yes**, please provide a risk assessment reference here: | | | |
| Liquid nitrogen |  | | |
| Radiation |  | | |
| Open beam lasers |  | | |
| Carcinogenic, mutagenic, or toxic chemicals |  | | |
| **Complete sections 5.9 – 9.4 if you do not have a Code of Practice, Local Rules or other documents covering use of PPE, waste management, training, and access control.**  **If you have these documents, upload them to RADAR and proceed to section 10.** | | | | |
| 5.9 | How and where will material be stored? | | | |
|  | | | |
| 5.10 | How will material be transported within the laboratory? | | | |
|  | | | |
| 5.11 | Will material be transported on campus or between campuses?  *If yes, provide details here:* | | | |
|  | | | No |
| 5.12 | Will material be shipped to other organisations?  *If yes, provide details here:* | | | |
|  | | | No |
| **6** | **Personal protective equipment and hygiene** | | | |
| 6.1 | Describe when gloves will be worn, their type(s), and where they will be stored: | | | |
|  | | | |
| Describe when lab coats will be worn, their type(s), and where they will be stored: | | | |
|  | | | |
| 6.2 | Describe the arrangements for laundry or disposal of lab coats:  *Include the frequency at which lab coats are changed.* | | | |
|  | | | |
| 6.3 | Describe any other types of personal protective equipment, when it will be used, and where it will be stored:  *E.g., oversleeves, safety glasses.* | | | |
|  | | | |
| 6.4 | Confirm that suitable handwashing facilities are available to lab users:  *If* ***no****, please provide an explanation here.* | | | |
|  | | | |
| **7** | **Waste management** | | | |
| 7.1 | Which laboratory waste routes will be used by this project? | | Clear autoclave bags  Yellow bags/Bio-bins  Orange bags/Bio-bins  Yellow sharps bin  Other | |
| For “other”, please describe here: | | | |
|  | | | |
| 7.2 | If waste is chemically treated prior to disposal, describe how the waste is treated, and how it is disposed of after treatment: | | | |
|  | | | |
| 7.3 | If waste is to be autoclaved, who is responsible for the operation and maintenance of the autoclave, and where is it located? | | | |
|  | | | |
| **8** | **Training and competency** | | | |
| 8.1 | Describe the training staff and students will undertake before being authorised to work in this project; include training on emergency procedures: | | | |
|  | | | |
| 8.2 | Describe how competency and ongoing competency will be assessed: | | | |
|  | | | |
| 8.3 | Confirm that training records will be kept and maintained. Indicate where the training records will be kept. | | | |
|  | | | |
| **9** | **Access and shared areas** | | | |
| 9.1 | Who is responsible for providing access to the lab. How will users obtain access to the labs? | | | |
|  | | | |
| 9.2 | If laboratories are shared with other users, explain the controls in place to reduce the risk to these users from material used in this project: | | | |
|  | | | |
| 9.3 | If cleaners have access to the lab, describe the induction or training which is provided to them:  *Include details on who provides the training, and the frequency.* | | | |
|  | | | |
| 9.4 | Describe the systems in place to allow Estates Operations or external contractors/engineers to safely access the lab:  *Who completes Permits to Work, where are they stored, and who provides supervision where this is required?* | | | |
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| **10** | **Occupational Health Assessment** | | | | |
| If you are using material listed in the Occupational Health [reference spreadsheet](https://www.imperial.ac.uk/occupational-health/health-surveillance/working-with-pathogens/), use this to complete the questions below.  If the work is being carried out at containment level 2 or above, and any of the material does not appear on the reference spreadsheet, this form must be sent to [Occupational Health](mailto:occhealth@imperial.ac.uk) for review, before the document is uploaded to RADAR. **All those authorised to work on this project must register for biological agents** [**health surveillance**](https://www.imperial.ac.uk/occupational-health/health-surveillance/)**.** | | | | | |
| 10.1 | Medical risk assessment | |  | | |
| 10.2 | Pre-activity requirements | |  | | |
| Health clearance | |  | | |
| Vaccine | |  | | |
| Other | |  | | |
| 10.3 | Periodic health surveillance requirements | |  | | |
| 10.4 | Post-exposure action | |  | | |
| 10.5 | Antibiotic treatment or chemoprophylaxis | |  | | |
| 10.6 | Additional notes or comments | |  | | |
| **Occupational Health review and consultation**  *This section must be completed by Occupational Health if the pathogen reference spreadsheet was* ***not*** *used to complete the questions above.* | | | | | |
| Name | | Position | | Date | Notes |
|  | |  | |  |  |

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| **Record of Principal Investigator approval** | | | |
| **Principal Investigator declaration:** | | | |
| I agree that information contained in this form is accurate and truly reflects the scope of the project.  I will ensure that those I authorise to conduct this work remain within the boundaries of this risk assessment.  I understand that this document does not include operating protocols or risk assessments required for specific tasks. Separate written protocols and risk assessments for individual tasks are still required.  I will share information on any equipment which requires a maintenance contract with those responsible for laboratory management.  I will ensure that any individual working at containment level 2 or above, or with laboratory animals, registers with [Occupational Health](https://www.imperial.ac.uk/occupational-health/health-surveillance/) and complies with any pre-activity requirements listed in section 10.  Where applicable, I will ensure that this project complies with the requirements of the [Human Tissue Act](https://www.imperial.ac.uk/imperial-college-healthcare-tissue-bank/research-projects/using-human-samples-in-research/), and that any ethical approval required is obtained prior to the start of work.  I will ensure that any future proposed changes to this work covered by this form are assessed, and the amended risk assessment uploaded to RADAR, before being implemented.  I understand that this risk assessment cannot be closed or transferred to a third party without completion and submission of an [F004 form](https://www.imperial.ac.uk/media/imperial-college/administration-and-support-services/safety/internal/biosafety/F004-Cessation-or-transfer-of-an-activity.docx). | | | |
| Name | Position | Date | Comments |
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| **Record of Departmental review (including CBS review when required)** | | | |
| **Departmental review:**  *All the information included in this form has been reviewed and it is an accurate reflection of the project.* | | | |
| Name | Position | Date | Comments |
|  |  |  |  |
| **Additional review:**  *All the information included in this form has been reviewed and it is an accurate reflection of the project. (Additional reviewers as per local rules, add as many as needed).* | | | |
| Name | Position | Date | Comments |
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| **Record of Faculty review** | | | | | |
| **Faculty Safety review:**  I confirm that, having reviewed the information provided above, the following Containment Level can be assigned to each aspect of this project.  *If different aspects of this work merit different Containment Levels, then all are listed.* | | | | | |
| **Project aspect** | **Location of work** | | **Hazard group** | | |
|  |  | | HG1: | |  |
| Bloodborne HG2: | |  |
| Requires Safety Department approval: | |  |
|  |  | | HG1: | |  |
| Bloodborne HG2: | |  |
| Requires Safety Department approval: | |  |
| Record of all controls evaluated but not implemented (if any), as part of this assessment e.g. safety glasses: | | | | | |
|  | | | | | |
| **Name** | **Position** | **Date** | | **Comments** | |
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| **GM Committee consent** | | |
| **For projects using any GM Class 2 or 3 material:**  This project has been reviewed by GM committee and their decision is documented below.  *If different aspects of this work merit different GM classes, then all are listed.* | | |
| **Project aspect** | **Location of work** | **GM Class** |
|  |  |  |
| This project is: | | |
| A new project requiring notification to the HSE.  A new project where notification to the HSE is not required  A significant change to an existing project, requiring notification to the HSE  A change to an existing project, deemed not significant by the GM committee | | |
| **Name** | **Position** | **Date** |
|  |  |  |

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| **Record of approval by the Safety Department** | | | | | |
| *This section must be completed for all projects involving work with airborne HG2 and any HG3 pathogens, all genetically modified microorganisms, and specified animal pathogens.* | | | | | |
| **Provide a summary of the project below.** | | | | | |
| Class 1 GMMs: |  | Class 2/3 GMMs (requires GM committee approval): | | |  |
| Airborne HG2 pathogens: |  | HG3 pathogens: | | |  |
| SAPO HG2 pathogens: |  | SAPO HG3 pathogens: | | |  |
| f an inspection has been carried out for the labs to be used in this project, record the details, including actions, here. Otherwise explain why no inspection was carried out. | | | | | |
|  | | | | | |
| **Safety Department approval:** | | | | | |
| *I agree with the containment level and (where relevant) GM class assigned to this project. All internal and external consents have been received and recorded on RADAR.* | | | | | |
| **Name** | **Position** | | **Date** | **Comments** | |
|  |  | |  |  | |
| **List all external licence/ reference numbers below:** | | | | | |
|  | | | | | |