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| **An electronic copy of the original application (saved as a PDF) is to be submitted to the relevant Faculty Biosafety Committee as per the details below:****ENQUIRIES AND SUBMISSIONS TO:****Faculty of Health Sciences**Olivia Langenhoven; Telephone: 021 650 5677Fhs.fbc@uct.ac.za**Faculty of Science**Dr Thomas Oelgeschläger; Telephone: 021 650 4115 thomas.oelgeschlager@uct.ac.za **Faculty of Engineering and the Built Environment**Please submit to the Faculty of Science (see above) | ***For office use only*** |
| Application Number |  |
| Request for expedited review? (YES/NO)*(Note: Expedited Review will only be granted in exceptional circumstances, and will require strong motivation; please attach separate motivation letter;* ***late/delayed submission of F/IBC application does not constitute valid grounds for expedited review****)* |  |
| Request for F/IBC waiver? (YES/NO)*(Note: If “Yes”, please attach separate motivation letter)* |  |
| Risk Assessment:(guidance categories) |  |
| Highest Containment level required(BSL1, BSL2, BSL3) |  |
| Date complete application received by FBC |  |
| Date FBC approved |  |
| Date IBC approved |  |
| If F/IBC waiver granted, date of waiver |  |

# When to complete this form

* When conducting laboratory or clinical work, based at the University of Cape Town[[1]](#footnote-2), which requires BSL1 or higher containment. Containment levels are described in table 2, below.
* Do not need to complete this form if your work falls into the “Exempt Experiments” as defined in the [IBC Policy](https://uct.ac.za/sites/default/files/content_migration/uct_ac_za/87/files/IBC%2520POLICY%2520for%2520REVIEW%2520OF%2520RESEARCH%2520INVOLVING%2520RECOMBINANT.pdf), page 3.

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| **Table 2. Description of activity classes for GMMs** |
| Class | Description |
| 1 | Activities of **no or negligible risk**, for which **Containment Level 1** is appropriate to protect human health and the environment. |
| 2 | Activities of **low risk**, for which **Containment Level 2** is appropriate to protect human health and the environment. |
| 3 | Activities of **moderate risk**, for which **Containment Level 3** is appropriate to protect human health and the environment. |
| 4 | Activities of **high risk**, for which **Containment Level 4** is appropriate to protect human health and the environment |

# Guide to completing this form

1. The **Principal Investigator is responsible for the content** of this form **and is required to sign it off**.
2. The **F/IBC will not consider retrospective applications** for work which has already started. Please plan for this process to take approximately 3 months.
3. Please provide only the requested information. **DO NOT** copy and paste your study brochure, nor research project/ funding proposal, into the form.
4. **Incomplete or inappropriately completed application forms will be returned** to the applicant for revisions, before any review takes place.
5. You may **expand/reduce the text response boxes** to suit the length of your answers.
6. The **following table must be used when assessing the risks involved in your proposed research** in F/IBC supplementary forms.

## **Table 1. Basis for the Classification of Biohazardous Agents by Risk Group (RG)**

(Table taken from[NIH guidelines](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) – refer to page 39 of document).

|  |  |
| --- | --- |
| Risk Group 1 (RG1) | Agents that are not associated with disease in healthy adult humans |
| Risk Group 2 (RG2) | Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available |
| Risk Group 3 (RG3) | Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk) |
| Risk Group 4 (RG4) | Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk) |

# Which parts of the form should you complete?

|  |  |
| --- | --- |
| Form section | Applicable to |
| Key information | ALL APPLICANTS |
| Reg.Work1. | ALL APPLICANTS |
| GMM 1 | 1. Work with/ use of (i) recombinant nucleic acid molecules, (ii) synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and (iii) cells, organisms, and viruses containing such molecules.
2. Culturing of organisms used for GMO work where more than 10 litres in volume are required.

C1. The release of genetically modified organisms into the environment. C2. The deliberate transfer of recombinant nucleic acids (DNA, RNA, *etc*.) into Humans. |
| GMO1 | F2. Work with genetically modified plants or animals requiring BSL2 containment. For experiments involving whole animals or plants: will these experiments utilize an animal(s) or plant(s) whose genome(s) has been altered (transgenic animals or plants) or the testing of viable, rDNA-modified microorganisms on whole animals or plants (where minimum requirement is biosafety level 2 and higher).1. If completing Biol.Agent.1, as per (G), *carry out a risk assessment for each procedure using form GMO1 to provide guidance.*
 |
| Biol.Agent.1 | 1. Plant or animal pathogens.
2. **[When not covered by risk assessments in GMM1 or GMO1]** Biological Agents (human pathogens or potential pathogens, such as bacteria, trypanosomes, viruses, or material potentially containing pathogens, such as blood, body fluids, tissue samples and human and mammalian cell cultures) requiring biosafety level 2 containment and higher.
3. The use of cultured human, animal or insect cell lines, primary or commercial.
 |
| An.1 | F1. Work with animals (*e.g*., amphibians, birds, fish, invertebrates, non-human mammals, reptiles). |

# Key Information

This section of the form must be completed by all applicants.

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| **1. PROJECT DETAILS** |
| Project title |  |
| Start and end dates of project\**\*make sure start date is minimum of 3 months after the relevant F/IBC submission date\** |  |
| Indicate the level of review that this application requires and justify the selection. *For guidance on determining the level of review required, please consult “When to complete this form” (above) and the* [*IBC policy*](https://uct.ac.za/sites/default/files/content_migration/uct_ac_za/87/files/IBC%2520POLICY%2520for%2520REVIEW%2520OF%2520RESEARCH%2520INVOLVING%2520RECOMBINANT.pdf) |  |

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| **2. DESCRIPTION OF RESEARCH AND/OR SCIENTIFIC GOALS**Please provide a brief synopsis of the proposed research which addresses all of the following key questions:1. What is the aim of your study?
2. What is the nature of the samples?
3. How and/or where will samples be obtained?
4. What will be done to the samples (experimental manipulations, storage, transport, *etc*.) and where will these activities take place (can be more than one location; *e.g*., where samples are acquired in a clinical setting and moved to the laboratory for experimental analysis)?
5. What are the major biosafety risks and why is biosafety approval required?
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| **3. DETAILS OF PRINCIPAL INVESTIGATOR (person responsible for the project)** |
| Title (*e.g*., Prof, Dr, Mr, Ms, *etc*.) |  |
| Name & Surname |  |
| Position or appointment |  |
| UCT Staff number |  |
| Faculty/ Department/ Division |  |
| Address for correspondence |  |
| Telephone number, extension |  |
| Cell phone number |  |
| E-mail address |  |

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| **4. CONTACT DETAILS (ADDITIONAL CONTACT PERSON) (*e.g*., senior lab member, scientist, student, lab manager, or the person who compiled the form)** |
| Title (*e.g*., Prof, Dr, Mr, Ms, *etc*.) |  |
| Name & Surname |  |
| Position or appointment |  |
| UCT Staff number |  |
| Faculty/ Department/ Division |  |
| Telephone number, extension |  |
| Cell phone number |  |
| E-mail address |  |

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| **5. RESEARCH TEAM** |
| *For example: Collaborators, students and any other persons working on the project who will be involved in sample collection, sample handling, or other clinical or laboratory procedures which may expose them to biosafety risk.***NB. Any UCT postgraduate students involved in this project must be listed here; failure to do so may impact submission of their dissertation or thesis.**  |
| Name and surname | Staff/Student number | Email address | Worker registration form attached(Yes/No/Not applicable) | Required vaccinations received(Yes/No/Not applicable) |
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| **6. LOCATION OF RESEARCH:**List laboratory and rooms where research carrying potential biosafety risk will be conducted and/or samples stored. |
| **CAMPUS** | **BUILDING** | **ROOM NO** | **CLINICAL SITE** | **BIOSAFETY LEVEL** |
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| **7. RISK ASSESSMENT*****To identify which assessments will be required for the project, please answer YES/NO to all of the questions below. Does or will this project include:*** |
| 1. Work with/ use of (i) recombinant nucleic acid molecules, (ii) synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, and (iii) cells, organisms, and viruses containing such molecules?

***If yes****, please note that* ***work can only be carried out in a DALRRD-approved GMO laboratory****.* ***Please append proof of DALRRD GMO facility registration.******If yes****, carry out a risk assessment for each procedure using form* ***GMM1*** *to provide guidance* | YES | NO |
| 1. Culturing of organisms used for GMO work where more than 10 litres in volume are required?

***If yes****, carry out a risk assessment for each procedure using form* ***GMM1*** *to provide guidance*  | YES | NO |
| C1. The release of genetically modified organisms into the environment? ***If yes****, please* ***provide proof of approval from DALRRD*** *for the application for intentional introduction (conduct a trial release or clinical trial) of genetically modified organisms (GMOs) in the environment of South Africa.****If yes****, carry out a risk assessment for each procedure using form* ***GMM1*** *to provide guidance* | YES | NO |
| C2. The deliberate transfer of recombinant nucleic acids (DNA, RNA, *etc*.) into humans?***If yes****, please* ***provide proof of approval from DALRRD*** *for the application for intentional introduction (conduct a trial release or clinical trial) of genetically modified organisms (GMOs) in the environment of South Africa.****If yes****, carry out a risk assessment for each procedure using form* ***GMM1*** *to provide guidance* | YES | NO |
| D. Plant or animal pathogens?***If yes****, carry out a risk assessment using form* ***Biol.Agent1*** *to provide guidance.****Please note****:**For animal work, you will require a Section 20 permit from DALRRD. For plant work, permits/permissions may be required from DFFE under the NEMBA. In addition, the following may be relevant: For the import of specific plant and plant pathogen species, a permit including phytosanitary regulations and quarantine under the Agricultural Pests Act will be required (introducing pests into SA). The Non-proliferation of weapons of mass destruction Act includes some plant pathogens under Biological controlled goods and registration with the SA Council will be required if research involves those pathogens. Furthermore, GM Plants will be included under the GMO Act and facilities must be registered. If plants are to be be collected from protected areas, permits under the Nature Conservation Ordinance issued by the National Parks (CapeNature) are required.* | YES | NO |
| E. Biological Agents (human pathogens or potential pathogens, such as bacteria, trypanosomes, viruses, or material potentially containing pathogens, such as blood, body fluids, tissue samples and human and mammalian cell cultures) requiring biosafety level 2 containment and higher?***If yes****, and they are NOT covered by assessments carried out under* ***GMM1*** *or* ***GMO1****, carry out a risk assessment using Form* ***Biol.Agent1*** *to provide guidance.* | YES | NO |
| F1. Work with animals (*e.g*., amphibians, birds, fish, invertebrates, non-human mammals, reptiles)?***If yes****, carry out a risk assessment using Form* ***An1*** *to provide guidance.****Please note****:* ***For animal work, you will require a Section 20 permit from DALRRD.***  | YES | NO |
| F2. Work with genetically modified plants or animals requiring BSL2 containment?For experiments involving whole animals or plants: will these experiments utilize an animal(s) or plant(s) whose genome(s) has been altered (transgenic animals or plants) or the testing of viable, rDNA-modified microorganisms on whole animals or plants (where minimum requirement is biosafety level 2 and higher)?***If yes****, carry out a risk assessment using form* ***GMO1*** *to provide guidance.* ***Please note: Work can only be carried out in a DALRRD-approved GMO laboratory. Please append proof of DALRRD GMO facility registration.*** | YESYES | NONO |
| G. The use of cultured human, animal or insect cell lines, primary or commercial? ***If yes***, carry out a risk assessment for each procedure using form **Biol.Agent1** to provide guidance. | YES | NO |
| H. ***If yes in G****, will the work involve genetic modification of the cell lines?* | YES | NO |
| I. ***If yes in G****, carry out a risk assessment for each procedure using form* ***GMO1*** *to provide guidance* | YES | NO |

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| **8. STATUTORY AND OTHER EXTERNAL APPROVALS***You are legally obliged to obtain certain certificates and permits before you may commence with your research; please answer the following questions so that the committee may ascertain the status/need of your**applications.* |
|  | **YES**(If yes, please append a copy of the permit/approval) | **NO** | **NOT APPLICABLE** | **PENDING**(If pending, please append application proof) |
| Department of Agriculture, Land Reform and Rural Development, DALRRD (Animal Diseases Act Section 20 permit) |  |  |  |  |
| Department of Agriculture, Land Reform and Rural Development (GMO Act, GMO Facility registration)*Please note*: When genetically modified Hazard Group 3 or 4 pathogens are produced or handled and a containment level higher than 2 is required, a permit for contained use will also be required (Regulation 2(2) of the GMO Act) |  |  |  |  |
| Department of Agriculture, Land Reform and Rural Development, DALRRD (GMO Act, GMO Trial release permit) |  |  |  |  |
| South African Health Products Regulatory Authority (SAHPRA, Clinical trial approval) |  |  |  |  |
| Department of Health (DOH) National Health Act (Act 61 of 2003) Section 68, Notice R178 (Registration of microbiological laboratories for handling human pathogens) |  |  |  |  |
| Nature Conservation Permits for WildlifeResearch (*e.g*., SANParks, Cape Nature) |  |  |  |  |
| Relevant committee approvals withbiological/biosafety oversight (for example, Human Research Ethics Committee, Animal Ethics Committee) |  |  |  |  |

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| **9. CHECKLIST** |
| **Item** | **Required** | **Submitted** | **Not****applicable** | **If not included, will****be sent to F/IBC when available** |
| Application form complete and signed |  |  |  |  |
| University approvals (Human [HREC] and/or animal [AEC] ethics committee) |  |  |  |  |
| Statutory/External approvals orproof of application |  |  |  |  |
| **PLEASE NOTE: DO NOT ATTACH STANDARD OPERATING PROCEDURES (SOPs).****SOPs SHOULD BE AVAILABLE ON REQUEST.** |

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| **10. DECLARATION BY APPLICANT (Principal Investigator)** |
| Assessments of biological safety have been carried out as required and are attached.All Research Workers on this project will automatically be registered following the approval of the project by the Faculty and Institutional Biological Safety Committee (F/IBC). Copies of all registrations will be sent to the Departmental Health and Safety Representative on request.I understand that work involving Genetically Modified Organisms (GMOs) under parts 1 and 2 and some work involving biological agents/materials that are not genetically modified must await authorisation from the Institutional Biosafety Committee before work can commence.Applicant Signature: Date:  |

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| **11. DECLARATION BY APPLICANT’S HEAD OF DEPARTMENT** |
| **I confirm that I have read and understood the risk assessment relating to this project;** in my opinion, the Principal Investigator is competent to perform and oversee the work described which will be performed in a facility(ies) which complies with all relevant biosafety requirements. I therefore support this application.HoD Signature: Date: Department:  |

**NOTE: Only complete and submit the sub-forms which are required for your application, as per the risk assessment in section 7 of this form.**

# GMM 1: Risk Assessment of a Project Involving Genetic Modification of Micro-organisms.

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| Name of applicant |  |
| Project Title |  |

**Instructions**

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| Divide the work with Genetically Modified Micro-organisms (GMMs) in this project into a minimal number of procedures with related risks. Assess each procedure using this form (GMM1) to classify the procedure into [Class 1, 2, 3 or 4 as defined by the NIH guidelines.](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) (Refer to [Table 1: Basis for the Classification of Biohazardous Agents by Risk Group (RG)](#_Table_1._Basis))The process involves assessing each procedure as follows:* Identification of potential risks to humans or the environment (including animals and plants), resulting from the recipient microorganism, insert, vector and final GMM.
* Consideration of relevant [Scientific Advisory Committee on Genetic Manipulation](https://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/) (SACGM) classification schemes, giving provisional classification.
* Identification of risk (in terms of consequence and likelihood)
* Assign final classification to ACGM Class 1,2,3 or 4.

*Note: If you have already submitted a GMO Facility registration form, you may attached that form here provided it contains all information relevant to this F/IBC project application.*  |

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| 1. **DESCRIBE THE EXPERIMENTAL PROCEDURES DETAILING AIMS AND TECHNIQUES INVOLVED**
 |
| *Expand block as needed.* |

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| 1. **RECIPIENT MICRO-ORGANISMS**

Give details of ***all*** recipient micro-organisms specifying the hazard group. |
| *Expand block as needed.* |

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| 1. **INSERTED GENES**

Give details of ***all*** genes or classes of genes (with the organism of origin) to be manipulated.* **If the work involves human genes, this must be specified.**
* If the genes to be manipulated are from indigenous plants/animals/invertebrates/microbes, you must obtain the relevant national or local government permits required before you collect any material.
 |
| *Expand block as needed.* |

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| 1. **CLONING VECTORS**

Give details of all cloning vectors to be used, e.g., viral vectors or plasmid vectors: |
| *Expand block as needed.* |

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| 1. **FINAL GMM**

Give details of all final GMMs that will be created. |
| *Expand block as needed.* |

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| 1. **HAZARD IDENTIFICATION**

To determine the hazard level for all the GMMs identified in Section 5 1. **Consider the properties of the recipient micro-organism (*e.g*., bacterial host or viral vector).**

For example:* Is it listed in [Advisory Committee on Dangerous Pathogens](https://www.hse.gov.uk/pubns/misc208.pdf) (ACDP) hazard groups 2, 3 or 4?
* Which animals can be infected by the recipient micro-organism? Does it infect domestic or wild animals?
* Is it a pathogen that is controlled by the Department of Forestry, Fisheries & the Environment (DFFE) or DALRRD?
* If it is a disabled micro-organism, is there any possibility of complementation or reversion of the disabling mutations?
* Is it a plant pathogen?
 |
| *Expand block as needed.* |
| 1. ***Consider whether the product of the inserted gene has a biological activity which can act directly to cause harmful effects. If appropriate, read the*** [***SACGM guidance notes***](https://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/index.htm) ***on the generation of recombinants containing potentially oncogenic nucleic acid sequences.***

For example* Does the inserted DNA encode a toxin, an oncogenic protein, an allergen, a modulator of growth or differentiation (hormone or cytokine) or any other protein with a potentially harmful biological activity?
* When constructing a cDNA or genomic library, consider the properties of the donor organism - might certain clones encode toxins or oncogenes?
* What is the known or suspected biological activity and the levels and nature of the product required to elicit this activity, *e.g*., activity, toxicity, allergenic or pathogenic effects? The full biological activity may be dependent on post-translational modification, glycosylation or renaturation which may, in some cases, only be achieved in certain host organisms. Is the protein to be synthesised as an inactive or active fusion?
 |
| *Expand block as needed.* |
| 1. ***Consider whether the inserted gene encodes a product that might act alongside the existing characteristics of the recipient micro-organism, so as to endow the GMM with altered pathogenic properties towards humans, or other organisms in the wider environment.***

For example* Does the inserted gene encode a pathogenicity determinant, such as an adhesion, a penetration factor or a surface component providing resistance to host defence mechanisms?
* Is it possible that expression of the inserted gene could alter the tissue tropism, host range or infectivity as compared to the recipient micro-organism?
* Does the inserted DNA encode resistance to an antibiotic, other than the commonly used selection antibiotics, that might be used for the treatment of infections acquired either in the laboratory or outside?
 |
| *Expand block as needed.* |
| 1. ***Consider whether an inserted sequence, that does not give rise to a harmful phenotype in the recipient micro-organism, could give rise to harm as a result of natural gene transfer to another, possibly related, organism.***

For example* In the event of a breach of laboratory containment, could the recipient organism survive in the environment, either
* as a “free living” organism (*e.g*. in soil or sewage), or by infection of some other host?
* Is the vector mobilizable?
* Is the nature of the inserted gene such that its widespread dissemination in the environment would present environmental concerns; *e.g*., a drug resistance or antibiotic resistance gene, or an intact provirus?
 |
| *Expand block as needed.* |
| 1. ***Does this procedure involve work with GMMs in animal models? If so, will this give rise to any additional hazards?***

For exampleIn the case of infected animals will there be an increased risk of infection due to bites or sharps injuries? Will the GMM be excreted from the infected animal? |
| *Expand block as needed.* |
| 1. ***Evaluate the severity or consequence of any harmful effect not only for humans but also for the environment.***
 |
| *Expand block as needed.* |

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| 1. **Provisional classification**

Based on the risks identified and the Biological Agent Hazard Group listed above, assign your provisional classification level (1, 2, 3, 4) for the project. Risk groups are described in [table 1](#_Table_1._Basis).  |
| *Expand block as needed.* |

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| 1. **RISK IDENTIFICATION AND BIOLOGICAL SAFETY LEVEL REQUIRED**

This is the estimation of the likelihood that the risks will be realized. Assess the risk of access and expression, which together give an overall indication of which biosafety level should be used. Remember to consider not only the risks to humans, but also the risks to the environment, should there be a breakdown in containment or a failure of killing-off.**The ACGM recommend that the risk assessment and the assignment of containment and control measures follows six basic stages for activities using GMMs. This forms a guide as to the procedure to follow and the factors to consider. The six basic stages are:**1. **Stage I: *Consideration of the predicted properties of the GMM to determine if there are any potential mechanisms by which it could represent a hazard to human health and how severe the consequence might be.***

Please indicate, with clear explanation/rationale, how the GMM might present a hazard to humans and/or the environment. |
| *Expand block as needed.* |
| 1. **Stage II: *Consideration of the likelihood that, in the event of exposure, the GMM could actually cause harm to human health***

Please indicate, with clear explanation/rationale, the likelihood that harm might be caused to a person or the environment by exposure to the GMM. |
| *Expand block as needed.* |
| **What is the scale of the proposed experiments?** For example: volume of cell cultures. |
| *Expand block as needed.* |
| 1. **Stage III: Provisional assignment of containment level**

Based on your responses to 8.i to 8.iii, define the containment level required to control the risk (*i.e*., level 1/2/3/4). |
| *Expand block as needed.* |
| 1. **Stage IV: *Consideration of the nature of the work and a detailed review of controls necessary to safeguard human health***
 |
| *Expand block as needed.* |
| 1. **Stage V: *Identification of any hazards to the environment and the assignment of any additional containment measures***
 |
| *Expand block as needed.* |
| 1. ***Stage VI: Assignment of activity Class (1,2,3 or 4)***

The activity classes are based largely on the Advisory Committee on Dangerous Pathogens (ACDP) levels of control. Although no definitions are given, Table 2 below describes activity classes 1-4, as adapted from the ACDP categorisation of human pathogens. |
| *Expand block as needed.* |

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| **Table 2. Description of activity classes for GMMs** |
| Class | Description |
| 1 | Activities of **no or negligible risk**, for which **Containment Level 1** is appropriate to protect human health and the environment. |
| 2 | Activities of **low risk**, for which **Containment Level 2** is appropriate to protect human health and the environment. |
| 3 | Activities of **moderate risk**, for which **Containment Level 3** is appropriate to protect human health and the environment. |
| 4 | Activities of **high risk**, for which **Containment Level 4** is appropriate to protect human health and the environment |

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| 1. **WASTE INACTIVATION AND DISPOSAL, DISINFECTION AND SPILLAGE**
2. **How will you dispose of waste materials (both solid and liquid laboratory waste and waste from animal experiments)? Please provide details.**

For example:* + - All solid waste generated is autoclaved using a program of 15 minutes pulsed free steaming and 30 minutes at 132ºC.
		- Liquid-based waste material is treated by soaking in 1% final concentration of Biocide for a minimum of 12 hours before disposal via liquid waste drums.
		- Solid/liquid biological material is securely packaged and disposed of by incineration *via* a registered contractor.
 |
| *Expand block as needed.* |
| 1. **How has each method for inactivation of GM waste been validated, what is the 'Degree of Kill' and what monitoring is carried out to ensure this?**

For example:* + Autoclaving: Effectively 100% kill at this programme as shown by microbiological testing. Certificated testing of all autoclaves is carried out annually and records are held by the Department. Printed readouts from each run are retained to ensure temperatures within the autoclave were maintained during the cycle.
	+ Incineration: Effectively 100% kill
	+ Liquid waste: Biocide is a total spectrum disinfectant prepared and used as per the manufacturer's instructions. Effectively 100% kill as shown by the results of validation experiments carried out in-house using microbiological testing. (Results may be requested.
 |
| *Expand block as needed.* |
| 1. **What procedures will be used to deal with spills? Consider all likely cases of accidental spillage; *e.g*., spills in a safety cabinet, spills on the floor, spills in an orbital shaker (or an incubator) and spills in a centrifuge due to bottles breaking or leaking. Name the disinfectants to be used in each case. It is strongly recommended that the SOP for spillages be displayed in the laboratory.**
 |
| *Expand block as needed.*ROUTINE DISINFECTIONSPILLAGE |
| 1. **Has the effectiveness of each disinfectant used for routine disinfection and spillage control been validated? Please cite appropriate literature and/or precedent from other laboratories and/or describe internal evidence supporting the proposed use.**
 |
| *Expand block as needed.* |
| 1. **What monitoring procedures are used on a routine basis to confirm inactivation of waste and effectiveness of disinfection procedures?**

For example:* + Regular swab testing of bench areas.
 |
| *Expand block as needed.* |
| 1. **Does your laboratory use sharps? If yes, how are these disposed of?**
 |
| *Expand block as needed.* |

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| 1. **FINAL CLASSIFICATION**

Assign the final class of activity to all aspects of the procedure. This classification is directly related to the biosafety level required to control the risk. It may be necessary to assign the biosafety level above or below that suggested by the hazard assessment. |
| *Expand block as needed.* |

# GMO1: Risk Assessment of a Project Involving Genetic Modification of Plants, Animals, Insects or Cell lines (incl. genome editing).

|  |  |
| --- | --- |
| Name of applicant |  |
| Project Title |  |

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| 1. **GIVE DETAILS OF ALL ORGANISMS TO BE MODIFIED**
 |
| *Expand block as needed.* |

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| 1. **WHAT ARE THE POSSIBLE RISKS FROM THE UN-MODIFIED ORGANISMS?**

Consider all possible consequences of exposure to the hazards; *e.g*., possible allergic responses, bites, transmissible pathogens, *etc*. |
| *Expand block as needed.* |

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| 1. **GIVE DETAILS OF ALL GENES OR CLASSES OF GENES (WITH THE ORGANISM OF ORIGIN) TO BE MODIFIED**
* **If the work involves human genes, this must be specified.**
* If the genes to be modified are from indigenous plants/animals/invertebrates/microbes, you must obtain the relevant national or local government permits required before you collect any material.
 |
| *Expand block as needed.* |

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| 1. **DOES THE GM PLANT, ANIMAL OR INSECT POSE A GREATER RISK TO HUMANS THAN THE UN-MODIFIED ORGANISM? EXPLAIN HOW YOU ARRIVE AT THIS CONCLUSION.**
* Consider all possible consequences of exposure to hazards; *e.g*., allergic responses, bites.
* Consider the severity should any harm be realised.
* Consider the likelihood of any harmful effect occurring.

If a GM plant, animal, or insect poses a greater risk to humans than the un-modified organism, DFFE/DALRRD/DOH (as applicable) must be notified about the work. |
| *Expand block as needed.* |

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| 1. **DOES THE GM PLANT, ANIMAL OR INSECT POSE A GREATER RISK TO ANIMALS, PLANTS AND THE ENVIRONMENT THAN THE UN-MODIFIED ORGANISM? EXPLAIN HOW YOU ARRIVE AT THIS CONCLUSION.**
* Consider the potential capacity of any GM plant (and its seeds) to survive, establish, disseminate, and compete with or displace other plants in the environment.
* Consider the possible adverse effects of any GM animal or insect on animals, plants etc in the environment.
* Consider possible adverse effects resulting from natural transfer of inserted genetic material to wild organisms in the environment.
* Consider the severity of any such harmful effects.
* Consider the likelihood of any harmful effect being realised.

If a GM plant, animal or insect poses a greater risk to humans than the un-modified organism, DFFE/DALRRD/DOH (as applicable) must be notified about the work. |
| *Expand block as needed.* |

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| 1. **WHAT CONTAINMENT LEVEL IS REQUIRED FOR THE WORK? WILL IT BE PLANT CONTAINMENT LEVEL OR ANIMAL CONTAINMENT LEVEL**
 |
| *Expand block as needed.* |

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| 1. **WASTE DISPOSAL**

**How will you dispose of waste materials (both solid and liquid laboratory waste and waste from animal experiments)? Please provide details.**For example:* + - All solid waste generated is autoclaved using a program of 15 minutes pulsed free steaming and 30 minutes at 132ºC.
		- Liquid-based waste material is treated by soaking in 1% final concentration of Biocide for a minimum of 12 hours before disposal via liquid waste drums.
		- Solid/liquid biological material is securely packaged and disposed of by incineration *via* a registered contractor.
 |
| *Expand block as needed.* |

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| 1. **PROVIDE DETAILS OF ANY ADDITIONAL CONTROL MEASURES THAT WILL BE IMPLEMENTED.**
 |
| *Expand block as needed.* |

# Biol.Agent1: Risk Assessment of a Project Involving Biological Agents.

|  |  |
| --- | --- |
| Name of applicant |  |
| Project Title |  |

**Instructions**

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| A hazardous biological agent is “any microorganism, cell of plant, animal or human origin, cell culture, human endoparasite, including those that have been genetically modified, which may cause infection, allergy, inflammation, toxic reaction, malignancy or otherwise create a hazard to human health." [(Hazardous Biological Agents, 2019](https://www.labour.gov.za/DocumentCenter/Regulations%20and%20Notices/Regulations/Occupational%20Health%20and%20Safety/Regulations%20for%20Hazardous%20Bilogical%20Agents.pdf)**PLEASE NOTE**: If all Biological Agents in this project are genetically modified then the assessment of safety carried using form GMM1 will be sufficient for the purposes of Risk Assessment. |

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| 1. **RISK ASSESSMENT**
2. **Give details of all Biological Agents, and the ACDP group classification (1-4) where relevant.**
* Blood and tissue samples and cell lines may contain Biological Agents. What are the possible agents (*e.g*., latent retroviruses)?
* If the Agent is disabled, the classification may be altered from that given by the ACDP.
* Note that the amendments to the [Regulations for Hazardous Biological Agents (2022)](https://www.labour.gov.za/DocumentCenter/Regulations%20and%20Notices/Regulations/Occupational%20Health%20and%20Safety/Amendments%20to%20the%20Regulations%20for%20Hazardous%20Biological%20Agents%20_October%202022.pdf) also contains a list that the applicant is encouraged to consult.
 |
| *Expand block as needed.* |
| 1. **What are the possible risks of the use of, or exposure to, these Biological Agents?**
* Consider all possible risks; *e.g*., possible allergic responses.
* Consider infection from potential transmissible pathogens; *e.g.*,HIV, Hepatitis B, latent retroviruses.
 |
| *Expand block as needed.* |
| 1. **What risk mitigation or control procedures will be implemented?**
* Are vaccinations required, *e.g.* against Hepatitis B?
 |
| *Expand block as needed.* |

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| 1. **WASTE INACTIVATION AND DISPOSAL, DISINFECTION AND SPILLAGE**
2. **How will you dispose of waste materials (both solid and liquid laboratory waste and waste from animal experiments)? Please provide details.**

For example:* + - All solid waste generated is autoclaved using a program of 15 minutes pulsed free steaming and 30 minutes at 132ºC.
		- Liquid-based waste material is treated by soaking in 1% final concentration of Biocide for a minimum of 12 hours before disposal via liquid waste drums.
		- Solid/liquid biological material is securely packaged and disposed of by incineration *via* a registered contractor.
 |
| *Expand block as needed.* |
| 1. **How has each method for inactivation of waste been validated, what is the 'Degree of Kill' and what monitoring is carried out to ensure this?**

For example:* + Autoclaving: Effectively 100% kill at this programme as shown by microbiological testing. Certificated testing of all autoclaves is carried out annually and records are held by the Department. Printed readouts from each run are retained to ensure temperatures within the autoclave were maintained during the cycle.
	+ Incineration: Effectively 100% kill
	+ Liquid waste: Biocide is a total spectrum disinfectant prepared and used as per the manufacturer's instructions. Effectively 100% kill as shown by the results of validation experiments carried out in-house using microbiological testing. (Results may be requested.
 |
| *Expand block as needed.* |
| 1. **What procedures will be used to deal with spills? Consider all likely cases of accidental spillage; *e.g*., spills in a safety cabinet, spills on the floor, spills in an orbital shaker (or an incubator) and spills in a centrifuge due to bottles breaking or leaking. Name the disinfectants to be used in each case. It is strongly recommended that the SOP for spillages be displayed in the laboratory.**
 |
| *Expand block as needed.*ROUTINE DISINFECTIONSPILLAGE |
| 1. **How has the effectiveness of each disinfectant used for routine disinfection and spillage control been validated?**
 |
| *Expand block as needed.* |
| 1. **What monitoring procedures are used on a routine basis to confirm inactivation of waste and effectiveness of disinfection procedures?**

For example:* + Regular swab testing of bench areas.
 |
| *Expand block as needed.* |

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| 1. **FINAL CLASSIFICATION**

This work will be carried out at Biosafety Level 1/2/3/4 (indicate in box below) with the additional risk mitigation or control measures detailed above. |
| *Expand block as needed.* |

# An1: Risk Assessment of a Project Involving Animals and/or Insects.

|  |  |
| --- | --- |
| Name of applicant |  |
| Project Title |  |

**Instructions**

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| **This assessment must be carried out for all work involving animals unless genetic modification is involved and form GMO1 has been completed.** |

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| 1. **GIVE DETAILS OF ALL ORGANISMS INVOLVED IN THE PROJECT (*e.g*., VERTEBRATES, INSECTS, AMPHIBIA, WORMS):**
 |
| *Expand block as needed.* |

|  |
| --- |
| 1. **WHAT ARE THE POSSIBLE RISKS ASSOCIATED WITH THE USE OF THESE ORGANISMS?**

Consider all possible risks; *e.g*., possible allergic responses, bites, transmissible pathogens. |
| *Expand block as needed.* |

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| 1. **WHAT RISK MITIGATION PROCEDURES WILL BE IMPLEMENTED?**
 |
| *Expand block as needed.* |

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| 1. **WASTE INACTIVATION AND DISPOSAL**
2. **How will you dispose of waste materials (both solid and liquid laboratory waste and waste from animal experiments)? Please provide details.**

For example:* + - All solid waste generated is autoclaved using a program of 15 minutes pulsed free steaming and 30 minutes at 132ºC.
		- Liquid-based waste material is treated by soaking in 1% final concentration of Biocide for a minimum of 12 hours before disposal via liquid waste drums.
		- Solid/liquid biological material is securely packaged and disposed of by incineration *via* a registered contractor.
 |
| *Expand block as needed.* |
| 1. **How has each method for inactivation of waste been validated, what is the 'Degree of Kill' and what monitoring is carried out to ensure this?**

For example:* + Autoclaving: Effectively 100% kill at this programme as shown by microbiological testing. Certificated testing of all autoclaves is carried out annually and records are held by the Department. Printed readouts from each run are retained to ensure temperatures within the autoclave were maintained during the cycle.
	+ Incineration: Effectively 100% kill
	+ Liquid waste: Biocide is a total spectrum disinfectant prepared and used as per the manufacturer's instructions. Effectively 100% kill as shown by the results of validation experiments carried out in-house using microbiological testing. (Results may be requested.
 |
| *Expand block as needed.* |

# Reg.Work1: Registration of Personnel Using Biological Material.

|  |  |
| --- | --- |
| Name of applicant (i.e. the person being registered) |  |
| Status (*delete those which are not applicable*) | Undergraduate student / Postgraduate student / Postdoctoral Fellow Scientific Officer / Researcher (Academic) / Principal Investigator |
| Project Title |  |

|  |  |  |
| --- | --- | --- |
| Does this project involve the use of genetically modified micro-organisms, plants or animals, or cell lines?***If yes****, what are your qualifications and previous experience of using GM material?* | YES | NO |
| *Expand block as needed.* |

|  |  |  |
| --- | --- | --- |
| Does this project involve the use of animals?***If yes****, what are your qualifications and previous experience of working on animals?* | YES | NO |
| *Expand block as needed.* |

|  |  |  |
| --- | --- | --- |
| Does this project involve the handling or manipulation of clinical material and/or potentially harmful biological agents?***If yes****, please specify your qualifications and previous experience with either.* | YES | NO |
| *Expand block as needed.* |

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| **ASSESSMENT OF ADDITIONAL RISKS**Based on the risk assessment, it may be deemed necessary to provide additional control measures over and above the minimum requirements for the biosafety level selected.Additional control measures may take the form of one or more specific measures taken from the list of measures recommended for the biosafety level one level higher than that assigned. Thus, some projects may be assigned to biosafety level 1 with one or two additional measures taken from the requirements of biosafety level 2; *e.g*., the requirement that all work with infectious materials should be undertaken in a safety cabinet.The requirements for biosafety levels can be seen in the WHO, NIH, and CDC manuals.  |
| 1. **ARE ANY OF THE WORK PROCEDURES LIKELY TO GENERATE AEROSOLS? IF SO, WHAT PRECAUTIONS WILL BE TAKEN TO REDUCE THE ASSOCIATED RISKS?**
 |
| *Expand block as needed.* |
| 1. **DOES THE NATURE OF THIS WORK REQUIRE ADDITIONAL CONTROL MEASURES WHEN IT IS BEING UNDERTAKEN BY A RESEARCHER WITH SPECIFIC HEALTH CONDITIONS (*E.G*., ECZEMA, IMMUNOLOGICAL DEFICIENCY)?**
 |
| *Expand block as needed.* |
| 1. **ARE WORKERS REQUIRED TO RECEIVE ANY VACCINATIONS BEFORE COMMENCING WITH THIS PROJECT? IF YES, PLEASE PROVIDE DETAILS**
 |
| *Expand block as needed.* |

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| 1. **WHICH OTHER PRECAUTIONS WILL BE IMPLEMENTED TO MITIGATE RISKS?**
 |
| *Expand block as needed.* |

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| 1. **IT IS IMPORTANT THAT THOSE WORKING NEARBY ARE AWARE OF POTENTIAL HAZARDS.**
* Does the work involve items of communal equipment?
* If so, list the items. Devise a suitable procedure for labelling the equipment when in use and decontaminating it if spillage occurs.
* Identify below the person in charge of each item and obtain their approval for the proposed use.
 |
| *Expand block as needed.* |

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| 1. **RESEARCH WORKER DECLARATION**

I understand that all work with Biological Material must be assessed for safety before work commences. I have read and understood assessments of the project identified above. I will follow appropriate use and disposal procedures. I will keep a copy of this registration document, and when I stop work on an existing project or start work on a new project, I will amend it and send a copy to the Faculty Biological Safety Committee. |
| Signature |  |
| Date |  |

|  |
| --- |
| 1. **PRINCIPAL INVESTIGATOR DECLARATION**

I will ensure sufficient training and supervision is given to ensure safe working practices are upheld. |
| Signature |  |
| Date |  |

1. This includes ‘off-site’ studies, performed by UCT-personnel. [↑](#footnote-ref-2)