|  |  |
| --- | --- |
|  |  |
| PROJECT PROPOSAL AND RISK ASSESSMENT **FOR THE CONTAINED USE OF GENETICALLY MODIFIED ORGANISMS** | |

# Section 1: General information

|  |  |
| --- | --- |
| 1.1 Project Supervisor | |
| Surname: |  |
| Forename: |  |
| Email address: |  |
| College/Department/Other: |  |
| 1.2 Title of Project | |
|  | |
| 1.3 GM project number (SCBHGM to allocate) | |
|  | |

|  |  |
| --- | --- |
| **1.4 Is this proposal is an extension of a previously-approved project?**  *If so please tick box and enter previous reference number.* | |
| Previously-approved project | Yes  No |
| Previous reference number |  |

**Please complete the form, emphasising the connection between the original project and this application.**

|  |
| --- |
| **1.5 Project lay summary**  *Please describe the project, detailing aims and objectives, significance and outcomes, indicating how the GMMs will help to achieve the objectives of the project. This description should contain enough detail to help a non-specialist to understand the project.* |
|  |

|  |
| --- |
| 1.6 Is this GM activity going to form part of an undergraduate practical class?  *If yes please provide details:* |
|  |

# Section 2: Details of genetic modification

Please complete:

* Part A for Genetically modified microorganisms and/or
* Part B for Genetically modified higher organisms.

## Part A: Projects involving the contained use of genetically modified microorganisms (GMMs).

|  |
| --- |
| 2A.1 The identity, source organism and function of each sequence of genetic material to be inserted/modified. |
|  |
| 2A.2 Is the donor organism pathogenic?  *If so what harm does it cause.* |
|  |
| 2A.3 If the donor organisms has pathological or harmful characteristics, are the donated sequences implicated in them.  *If yes please give details.* |
|  |
| 2A.4 Will the sequences cause harm if expressed in humans after accidental transfer?  *If yes, what harm would occur and how severe would it be?* |
|  |
| 2A.5 Will the sequences cause harm if transferred to species in the environment  *If yes, what harm would occur and how severe would it be?* |
|  |
| 2A.6 Identity of the vector(s), and nature of any potential harmful properties(to humans and/or the environment).  *Include in your description their ability to mobilise and the presence of active promoters of expression.*  *Note: disables viruses used as a vector should be treated as recipient organisms.* |
|  |
| 2A.6 If using a disabled viral vector, state its origin and the mechanisms of attenuation. |
|  |
| 2A.7 State identity [Species, strain(s)] and ACDP/SAPO hazard category of all recipient microorganisms. |
|  |
| 2A.8 Are the intended recipient organisms pathogenic to humans?  *If yes what harm will they do and how severe is the harm?* |
|  |
| 2A.9 Are the intended recipient organisms capable of independent survival in the environment, or will infect or transfer to other hosts?  *If yes please give details* |
|  |
| 2A.10 Natural host *(if any)* of recipient organism(s)and routes of transmission/infection (*if known)*. |
|  |

|  |
| --- |
| 2A.11 Characteristics of the genetically modified microorganisms. What effect will the modification have on the intended recipient organisms?  *Include in your description any changes to pathogenicity or toxicity to humans* |
|  |
| 2A.12 Will the modification alter the recipient organisms ability to survive in the environment, compete with other organisms or transfer to them the inserted sequences?  *If yes please give details.* |
|  |

## Part B: Projects involving the contained use of larger genetically modified organisms.

|  |  |  |  |
| --- | --- | --- | --- |
| 2B.1 List the identify of all recipient organism(s)  *Give common and scientific names and where relevant strain, cultivar or subspecies designations* | | | |
|  | | | |
| 2B.2 Identity of the host/vector system or the method used for genetic modification | | | |
|  | | | |
| 2B.3 Nature and identity of any toxic, allergenic or other potentially harmful effects attributed to the recipient organism, or its metabolic products | | | |
|  | | | |
| 2B.4 Origin and intended function of inserted genetic material. Identify any harmful effects attributable to the inserted sequences | | | |
|  | | | |
| 2B.5 Do these LGMO pose greater risk to humans than the unmodified parental organism | | | |
| Yes |  | No |  |
| *Please summarise the justification for this statement* | | | |
|  | | | |

# Section 3: Risk Assessment

Please complete:

* Part A for Genetically modified microorganisms and/or
* Part B for Genetically modified higher organisms.

## Part A: Risk Assessment for Working with Genetically modified microorganisms

|  |  |  |  |
| --- | --- | --- | --- |
| 3A.1 Summarise all potentially hazardous properties of each GMM in relation to human safety.  *Do not forget hazardous properties of the parental organism.*  *Consider ALL properties of the host, vector, insert, and of the final GMM* | | | |
|  | | | |
| *Identify persons who could be exposed to the hazard.* | | | |
| Laboratory workers, co-workers and other staff and students accessing laboratories  Other … | | | |
| 3A.2 Do any of these GMM pose a potential hazard to the environment?  *Consider animals, plants etc.* | | | |
| Yes |  | No |  |
| *Please justify this statement.* | | | |
|  | | | |
| 3A.3 What would be the consequence of these hazards being realised?  *For the purpose of this assessment, assume that there are no barriers to prevent exposure. Please give details of the expected consequences and use the terms “Severe, Medium, Low or negligible”* | | | |
| 1. *On human health* | | | |
|  | | | |
| 1. *On the environment* | | | |
|  | | | |
| 3A.4 Is it possible to substitute these GMM with a safer alternative? | | | |
| Yes |  | **No** |  |
| *Please justify this statement.* | | | |
|  | | | |
| 3A.5Likelihood of hazards associated with GMM being realised*.* | | | |
| *State the maximum culture volume to be used at any one time* | | | |
|  | | | |
| *Identify all types of operation with potential for dispersal (e.g. centrifugation, sonication, aspiration)* | | | |
|  | | | |
| *Do any of these activities generate aerosols of splashes which could pose a risk to the worker? If so please provide details* | | | |
|  | | | |
| *If so is a Microbiological safety cabinet used to control these risks? If yes, please provide details of cabinet and location.* | | | |
|  | | | |
| *Are the GMM’s to be centrifuged?* | | | |
|  | | | |
| *If so will sealed rotors and buckets be used for this and where will these buckets be opened?* | | | |
|  | | | |
| *Please describe the culture conditions for the GMMs. E.g. shacking incubator, static shelves, rotary platforms etc.* | | | |
|  | | | |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 3A.6 Please describe the type of waste generated and its disinfection and disposal route.  *Remember to include liquid waste, sharps, solid waste.* | | | | | | | | | |
|  | | | | | | | | | |
| *What is the expected degree of kill* | | | | | | | | | |
|  | | | | | | | | | |
| *How do you know that this degree of kill will be achieved* | | | | | | | | | |
|  | | | | | | | | | |
| 3A.7 Please describe the emergency procedures for dealing with spills of GMMs | | | | | | | | | |
|  | | | | | | | | | |
| 3A.8 Are animals to be infected with these GMOs?  *If yes please provide details.* | | | | | | | | | |
|  | | | | | | | | | |
| 3A.9 Are the GMM to be transported outside the laboratory to other areas of the university?  *If so please provide details.* | | | | | | | | | |
|  | | | | | | | | | |
| 3A.10 Are the GMM to be transported outside Singleton campus?  *If so please provide details.* | | | | | | | | | |
|  | | | | | | | | | |
| 3A.11 Are any microorganism or nucleic acid derived from a microorganism which is listed under Schedule 5 of the Anti-terrorism crime and security act 2001 as amended? | | | | | | | | | |
| Yes | | |  | | No | |  | | |
| *If yes – please provide details….* | | | | | | | | | |
|  | | | | | | | | | |
| 3A.12 Estimation of risk magnitude – to human health and safety | | | | | | | | | |
| *Based on the likelihood of exposure to GMM (following the procedures described above) and the severity of the consequence of exposure, please select an estimation of risk magnitude from the matrix below.* | | | | | | | | | |
|  | | Likelihood | | | | | | | |
| Consequence | Probable | | | Possible | | Unlikely | | Highly improbable |
| Severe | High | | | High | | Medium | | Effectively 0 |
| Moderate | High | | | Medium | | Medium/low | | Effectively 0 |
| Minor | Medium/Low | | | Low | | Low | | Effectively 0 |
| Negligible | Effectively 0 | | | Effectively 0 | | Effectively 0 | | Effectively 0 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| *If not “effectively 0” please describe the additional measures required to control the risk.* | | | | | |
|  | | | | | |
| 3A.13 Estimation of risk magnitude – to the environment | | | | | |
| *Based on the likelihood of release of GMM (following the procedures described above) and the severity of the consequence of release, please select an estimation of risk magnitude from the matrix below.* | | | | | |
|  | | Likelihood | | | |
| Consequence | Probable | | Possible | Unlikely | Highly improbable |
| Severe | High | | High | Medium | Effectively 0 |
| Moderate | High | | Medium | Medium/low | Effectively 0 |
| Minor | Medium/Low | | Low | Low | Effectively 0 |
| Negligible | Effectively 0 | | Effectively 0 | Effectively 0 | Effectively 0 |

|  |
| --- |
| *If not “effectively 0” please describe the additional measures required to control the risk.* |
|  |

|  |
| --- |
| 3.A.14 Please state the proposed class of GM activity  *(Class 1, 2 or 3)* |
| Class |

## Section 3B: Working with Larger Genetically modified organisms

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 3B.1 Identify all potentially hazardous properties of the LGMOs to *human* health and safety  *Take into account any toxic or allergenic effects, new reservoir for pathogens etc.* | | | | |
|  | | | | |
| 3B.2 Identify persons who could be exposed to the hazard. | | | | |
|  | | | | |
| 3B.3 What are the consequences of exposure of humans to these hazards? | | | | |
|  | | | | |
| 3B.4 What are the measures put in place to prevent or control the risk? | | | | |
|  | | | | |
| 3B.5 Identify all potentially hazardous properties of the lGMO’s to the *environment*  *Ability to transfer genes to other organisms, colonise new ecosystems, improved survival etc* | | | | |
|  | | | | |
| 3B.6 What would be the consequence of release of these LHMO’s on the local environment  *Please give details of the expected consequences and use the terms “Severe, Medium, Low or negligible”* | | | | |
|  | | | | |
| 3B.7 Describe the likely routes of release of the GMHO | | | | |
|  | | | | |
| 3B.8 Describe the physical control measures that will be in place to minimise or prevent such release and identify control measures required to manage the risks. | | | | |
|  | | | | |
| 3B.9 Describe the waste routes for GMHO (contaminated) material | | | | |
|  | | | | |
| 3B.10 Estimation of risk magnitude – to human health and safety | | | | |
| *Based on the likelihood of exposure to LGMO (following the procedures described above) and the severity of the consequence of exposure please select an estimation of risk magnitude from the matrix below.* | | | | |
|  | Likelihood | | | |
| Consequence | Probable | Possible | Unlikely | Highly improbable |
| Severe | High | High | Medium | Effectively 0 |
| Moderate | High | Medium | Medium/low | Effectively 0 |
| Minor | Medium/Low | Low | Low | Effectively 0 |
| Negligible | Effectively 0 | Effectively 0 | Effectively 0 | Effectively 0 |
| *If not “effectively 0” please describe the additional measures required to control the risk.* | | | | |
|  | | | | |
| 3B.11 Estimation of risk magnitude – to the environment | | | | |
| *Based on the likelihood of release of LGMO (following the procedures described above) and the severity of the consequence of release please select an estimation of risk magnitude from the matrix below.* | | | | |
|  | Likelihood | | | |
| Consequence | Probable | Possible | Unlikely | Highly improbable |
| Severe | High | High | Medium | Effectively 0 |
| Moderate | High | Medium | Medium/low | Effectively 0 |
| Minor | Medium/Low | Low | Low | Effectively 0 |
| Negligible | Effectively 0 | Effectively 0 | Effectively 0 | Effectively 0 |
| *If not “effectively 0” please describe the additional measures required to control the risk.* | | | | |
|  | | | | |

|  |
| --- |
| 3B.12 Please state the proposed class of GM activity |
| As safe as unmodified parental organism  Harmful - pose additional risk to humans than the unmodified parental organism |

# Section 4: Administration

|  |  |
| --- | --- |
| 3.1 Facility details | |
| Building |  |
| Laboratory number |  |
| Containment level |  |

|  |  |
| --- | --- |
| 3.2 Local contacts *please provide details of your* college | |
| Health and Safety Coordinator |  |
| GM /Biological safety Officer |  |

## Section 5: Declarations

Please print this page, sign and return to Health & Safety Services (either electronically or via internal mail).

**Proposers' Declaration:**

* I am submitting this application for approval at the next meeting of the Biological Hazards and Genetic Modified Organisms Sub-Committee.
* I agree that work will not commence on this project until BHGMO sub committee has given its approval.

|  |  |
| --- | --- |
| Name: |  |
| Signature & date: |  |

**Confidentiality Statement.**

I wish to claim the information given in sections [ ] of this form as “Confidential”.

This information is given on the understanding that it is only received by persons properly authorised by the Biological Hazards and Genetic Modified Organisms Sub-Committee and who have agreed to the non-disclosure of such confidential information.

|  |  |
| --- | --- |
| Signature & date: |  |

**Supporting Declaration**  
*This should be completed by a Head of College or nominated deputy. The College is responsible for ensuring that the facilities and control measures detailed within this risk assessment are in place.*

*The person supporting this proposal must not be involved in the project being proposed.)*I support the presentation of this proposal to the subcommittee.

|  |  |
| --- | --- |
| Name: |  |
| Status in organisation:  Head of College/Department/Section |  |
| Signature & date: |  |