**University of St Andrews**

**Notification of Genetic Modification Project**

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| 1.
 | **School/Unit** |  |
| 1.
 | **Workplace(s) if different from Section 1** |  |
| 1.
 | **Name of Project Supervisor** |  |
| 1.
 | **Title of Project** |  |

1. Name(s) and Signatures of ALL worker(s) involved (includes those in other Units who may be affected by the work e.g. SMAU).

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| **Name** | **Signature** | **Date** |
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1. Name and Signature of Project Supervisor

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| **Name** | **Signature** | **Date** |
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1. Approval of the Project by the School/Unit Safety Committee.

Signed on behalf of the School/Unit Safety Committee:

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| **Name** | **Signature** | **Date** |
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1. Approval of the Project by the School/Unit Safety Committee where the work is undertaken if different from Section 7.

Signed on behalf of the School/Unit Safety Committee:

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| **Name** | **Signature** | **Date** |
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1. Ratification of the Project by the Chemical and Biological Hazards Management Group.

Signed on behalf of the Chemical and Biological Hazards Management Group:

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| **Name** | **Signature** | **Date** |
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| **Version number** | **Purpose / Changes** | **Document status** | **Author, role and school / unit** | **Date**  |
| 1 | *New risk assessment* |  |  |  |
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## Guidance for completing the GM1 Form

The *Genetically Modified Organisms (Contained Use) Regulations 2014* requires that all genetic modification projects must be assessed for the risk to human health and the environment.

The GM1 Form should be used to record your project risk assessment.

To perform the risk assessment, you should ensure the following is captured:

* Identify hazards associated with the project procedures.
* Determine the probability that the hazards will cause harm to human health or the environment (i.e. the risks).
* Detail the control measures necessary to minimise the risks to human health and the environment.

All sections should be completed, ensuring as much detail is included as reasonably practicable.

The University GMO Notification & Risk Assessment Course should be completed before commencing the risk assessment.

For additional technical and scientific advice on GMO risk assessment and containment, refer to *Scientific Advisory Committee on Genetic Modification (SACGM) – Compendium of Guidance*.

The SACGM defines a genetic modification procedure as follows:

* Recombinant techniques consisting of the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever the means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism, in which they do not naturally occur but in which they are capable of continued propagation.
* Techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation.
* Cell fusion or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

The University deems other procedures to be classed as GM projects. These include:

* Use of an organism with modified DNA, even if the organism has not been created at the University.
* The generation of transgenic animals/plants using modified DNA as defined by the SACGM (see above).
* Site directed mutagenesis.

Techniques not considered to result in genetic modification include:

* *In vitro* fertilisation.
* Natural processes including conjugation, transduction or transformation.
* Polyploidy induction.

Techniques for which the *Genetically Modified Organisms (Contained Use) Regulations 2014* do not apply are:

* Random mutagenesis (e.g. by chemicals such as methyl nitroso-urea).
* Cell fusion (including protoplast fusion) or prokaryote species which can exchange genetic material through homologous recombination.
* Cell fusion (including protoplast fusion) of cells of any eukaryote species, including production of hybridomas and plant cell fusions.

## Work with Animals

All work with protected animals (including those genetically modified) requires additional Home Office licences under the *Animals (Scientific Procedures) Act 1986 (ASPA)*. The three licences include:

* Personal licence for each person carrying out procedures on protected animals.

**Note:** A **protected animal** is any vertebrate after a certain stage of embryonic development that is dependent on the species, and for any living cephalopod.

* Project licence for the programme of work involving protected animals.
* Establishment licence for the place at which the work involving protected animals is carried out.

All projects using genetically modified animals or infection of animals with genetically modified micro-organisms at the University **MUST BE APPROVED** by the following:

* Chemical and Biological Hazards Management Group
* Management of the animal welfare facilities at the University
* Home Office (contact the University Home Office Liaison Officer email: holo@st-andrews.ac.uk) for animals protected under ASPA.

**Background to Project**

A detailed background to the project should be included here (e.g. using the Abstract from the original grant application). Provide as much detail as reasonably practicable so that the University’s Chemical and Biological Hazards Management Group (acting as the University’s Genetic Modification Safety Committee) can have an informed judgment of the project.

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**Risk Assessment**

Provide as much detail as reasonably practicable so that the Chemical and Biological Hazards Management Group can have an informed judgement about the project, as ratification cannot be given for the project unless enough detail has been provided.

# **Details of the Genetically Modified Constructs**

## Recipient or parental strain(s):

*Include the name of the strain of microorganism(s)/animals/plants, as well as the name of the wild-type organism from which it is derived and the extent to which it is disabled.*

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## If a micro-organism, what other organism(s) (e.g. animals, plants) will the recipient strain infect?

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## Host/vector system(s):

*Include names and any disabling mutations.*

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## List of genes to be inserted, including their function:

*Include detailed nomenclature for the genes to be inserted (i.e. provide more than 3 letter name). If function of a gene is unknown, provide details of any known homologues if available.*

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# **Hazards to Human Health**

## Hazards associated with the recipient organism (e.g. bacterial host, viral vector, animal, plant):

*Factors to consider include whether the recipient microorganism is listed in ACDP hazard groups 2, 3 or 4. Other relevant factors may be the microorganisms’ mode of transmission, disease symptoms, host range, and tissue tropism, as well as indication as to whether vaccines or chemotherapeutic agents are available. Information should also be provided on any disabling mutations and whether there is any possibility of any disabling mutations being complemented or reverted.*

*If an animal/plant, detail if these organisms are inherently dangerous (e.g. toxic plants, production of allergens).*

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## Hazards arising directly from the inserted gene product (e.g. cloning of a toxin gene or oncogene):

*Consideration should be given to whether the inserted DNA encodes a toxin, an oncogenic protein, an allergen, a modulator of growth or differentiation (hormone or cytokine), or any other protein which may result in potentially harmful biological activity. If function of the inserted gene is unknown, describe the function of any known homologues.*

*Note: Even a normal human gene may be harmful if overexpressed, especially if the overexpression is in tissues that do not normally express the protein.*

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## Hazards arising from the alteration of existing traits (e.g. pathogenicity, host range, tissue tropism, mode of transmission, or host immune response):

*One factor to consider is whether the inserted gene sequence encodes a pathogenicity determinant (e.g. adhesin), a penetration factor or a surface component providing resistance to host defence mechanisms.*

*Another important consideration is whether the inserted gene encodes a surface component, envelope protein or capsid protein that might bind to a different receptor to that used by the recipient microorganism.*

*Consideration should also be given to whether the inserted DNA (or plasmid sequence) encodes resistance to a drug or antibiotic that might be used for treatment of a laboratory-acquired infection.*

*If an animal/plant, will the inserted gene affect the tropism of human pathogens, i.e. will the modified organism act as a new ‘reservoir’ for a human pathogen?*

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## The potential hazards of sequences within the genetically modified organism being transferred to related organisms:

*Factors to consider include whether widespread dissemination of the inserted gene will result from either gene transfer or recombination of the genetically modified microorganism with a wild-type microorganism. If this is the case, in the event of a breach of containment, will the modified organism survive in the environment long enough for gene transfer to take place?*

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## Any other relevant information:

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# **Assignment of Provisional Containment Level that is adequate to protect against hazards to human health**

*This step will involve considering the containment level necessary to control the risk of the recipient organism (e.g. the ACDP Hazard group of the recipient microorganism) and making a judgment about whether the modification will result in the genetically modified organism being more or less hazardous, or the same.*

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# **Hazards to Environment**

## Hazards associated with the recipient organism (e.g. bacterial host, viral vector, animal, plant):

*Factors to consider include whether the recipient microorganism is capable of infecting any plants, animals or insects in the environment, and whether there is any possibility of any disabling mutations being complimented or reverted. In particular it should be ascertained whether the recipient microorganism is a pathogen controlled by DEFRA.*

*If an animal/plant, are these organisms inherently hazardous to any population in the environment? List such groups even if they do not exist in the UK.*

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## Hazards arising directly from the inserted gene product:

*Consideration should be given to whether the inserted DNA encodes a toxin, an oncogenic protein, an allergen, a modulator of growth or differentiation (hormone or cytokine), or any other protein which may result in potentially harmful biological activity. If function of the inserted gene is unknown, describe the function of any known homologues.*

*Note: Even a normal human gene may be harmful if overexpressed, especially if the overexpression is in tissues that do not normally express the protein. Please also indicate if the protein produced by the gene may affect other organisms in the environment (e.g. expression of antibiotics).*

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## Hazards arising from the alteration of existing traits (e.g. pathogenicity, host range, or tissue tropism):

*One factor to consider is whether the inserted gene sequence encodes a pathogenicity determinant (e.g. adhesin), a penetration factor or a surface component providing resistance to host defence mechanisms.*

*Another important consideration is whether the inserted gene encodes a surface component, envelope protein or capsid protein that might bind to a different receptor to that used by the recipient microorganism.*

*If an animal/plant, will the modified organism act as a ‘reservoir’ for an organism that would not have been present in that species before?*

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## The potential hazards of sequences within the genetically modified organism being transferred to related organisms:

*Factors to consider include whether widespread dissemination of the inserted gene will result from either gene transfer or recombination of the genetically modified microorganism with a wild-type microorganism.*

*If an animal/plant, what would happen if wild-type organisms mated with the genetically modified version (e.g. escape of plant pollen, fish eggs/sperm).*

*If this is the case, in the event of a breach of containment, will the modified organism survive in the environment long enough for gene transfer to take place?*

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## Any other relevant information:

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# **Who is at Risk?**

*All those at risk must be identified. This should include all support services with access to laboratories (e.g. cleaners, maintenance staff). Those at special risk (e.g. pregnant or immunocompromised workers) must also be identified.*

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# **Control Measures required to minimise the risks of the work**

## What level of containment facilities and procedures will be required for the work?

*Refer to the SACGM Compendium of Guidance for details of the physical and procedural requirements for different levels of containment.*

*All workers should be informed on how to obtain these details of the containment requirements.*

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## Are any of the work procedures likely to generate aerosols?

*Identify if the work should be undertaken in a microbiological safety cabinet or isolator.*

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## How will the waste materials be disposed of?

*Describe the waste management measures which will be applied for solid and liquid laboratory waste and waste from experiments with infected animals (including type and form, treatment, degree of kill, proposed process for testing/monitoring the inactivation process).*

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## Will it be necessary to use sharps?

*Does the work involve glass Pasteur pipettes? How will the sharps be disposed of?*

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## If the work involves the experimental infection of animals, is it known whether the animal will shed the genetically modified microorganism?

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## If the work involves the experimental infection of plants, which is known about the likely route of transmission of the genetically modified microorganism?

*E.g. is the microorganism insect-borne or carrier in run-off water? This will have important implications for the type of glasshouse used.*

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## In the case of organisms whose multiplication involves a complex life cycle, will the work involve the propagation of organisms that are in stages in that life cycle that are particularly hazardous?

*E.g. propagation of the infective stages of parasites or the release of spores from fungi. Consideration should be given to all potential routes of transmission including those that might not be used naturally.*

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## Have any disinfectants been validated under the actual conditions of use?

*Chemical disinfection procedure must be shown to be validated against your specific biological agents/genetic microorganisms present. There must be at least a 105 reduction in viable organisms before waste can be disposed. There are also other factors to consider for disinfectants e.g. if disinfectant is being used for treatment of virus in tissue culture medium, is it known that the disinfectant is effective in the presence of high levels of protein?*

*Note: Waste treatment procedure (disinfection and/or autoclaving) must be shown to be validated against biological agents and/or genetically modified organisms/microorganisms you are using. Autoclaving is the preferred method for waste treatment. The HSE will no longer accept the manufacturer’s validations as only evidence of effectiveness; additional evidence either through internal validations or published papers must be provided.*

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## Does the nature of the work impede it being undertaken by any workers who have a serious skin condition (e.g. eczema) or other health problems that might make them more susceptible to infection (e.g. some kind of immunological defect)?

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## Will workers require any vaccinations or health surveillance?

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# Consideration of need to assign additional measures over and above provisional containment level

*Additional measures may be necessary in any of the following circumstances:*

* *To take full account of any properties of the genetically modified microorganism that may be hazardous to human health.*
* *To protect the environment.*
* *To provide additional safeguards for particular work procedures.*

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# Final Assignment of Containment Measures and Risk Class

The following aspects of this project are assigned to Class 1.

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The following aspects of this project are assigned to Class 2.

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The following aspects of this project are assigned to Class 3.

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The following aspects of this project are assigned to Class 4.

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**Risk Assessment Review**

Under Regulation 7 of the *Genetically Modified Organisms (Contained Use) Regulations 2014*, the risk assessment (the University GM1 Form) must be reviewed immediately in the event of the following:

* There is a reason to suspect that the risk assessment is no longer valid.
* There has been a significant change in the contained use to which the risk assessment relates, e.g.:
	+ Changes to containment and control measures;
	+ Use of different organisms or strains of organisms with different inherent characteristics;
	+ Use of different vectors, recipient organisms or genetic inserts;
	+ Change in nature of the work;
	+ Changes to any consent conditions;
	+ New information emerges that changes consequence of exposure.

The GM1 Form will require to be re-submitted to the Chemical and Biological Hazard Management Group in the event of any significant changes to the GM work, as outlined above.

The risk assessment will also be reviewed periodically as per level of risk, nature of the work and likelihood of changes occurring. This review should be performed annually.