

**FORM 52.013C GMO trials**

**To be used when patients are being followed up, samples taken, analysed or transported and when the GMO is not prepared or administered on an NHS Greater Glasgow and Clyde site.**

**RISK ASSESSMENTS OF PROPOSED ACTIVITIES INVOLVING**

**GENETICALLY MODIFIED ORGANISMS**

**Background Information**

Studies involving Genetically Modified Organisms (GMO) come under one of two types of legislation. The NHS GG&C Genetically Modified organism Safety Committee (NHS GG&C GMS Committee) will review studies, taking place within NHS Greater Glasgow and Clyde Board, that come under these regulations to ensure safeguards are in place to ensure patient, staff, public and environmental safety.

This form should only be completed when the GMO is not prepared or administered on a NHS GG&C site. If the GMO is prepared and/or administered at one of the sites FORM 52.013A or Form 52.013B should be completed. This form applies to studies that come under either The Genetically Modified Organisms (Contained Use) Regulations, 2014 or The Genetically Modified Organisms (Deliberate Release) Regulations, 2002.The key aspects to consider when completing this form include:

(a) identification of any potentially harmful effects;

(b) characteristics of the proposed activity;

(c) the severity of any potentially harmful effects; and

(d) the likelihood of them occurring.

In addition to completing the FORM please include a copy of the protocol and the environmental risk assessment for the trial.

**Form 52.013C**

**Research conducted using a GMO that is neither prepared nor administered on a NHS GG&C site but when patients are being monitored, followed up or when samples are taken to be analysed or transported.**

**risk assessment for Clinical Research Involving Genetically modified organisms**

**THE INFORMATION IN THIS BOX MUST BE READ BEFORE COMPLETING THE RISK ASSESSMENT FORM**

**Work must not commence** until all relevant parts of this form have been reviewed and approved by the Board Genetically Modified Safety (GMS) committee.

It is the responsibility of the person directing the research (i.e. the Principal Investigator) to ensure that all these requirements are complied with and any changes to the risk assessment or accidents involving the Genetically Modified Organism are reported to the GMS committee. All SUSARS identified at an NHS GG&C site should also be reported to the GMS committee.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| *Person responsible for this clinical trial (the Principal Investigator)* | | | | |
| Name: | Position: | Site(s) where GMO will be administered to patients (external to NHS GG&C): | | |
| Department: | Contact details: |  | | |
| Site(s) study will take place in Glasgow : | NHS GG&C R&D Ref. no.: |  | | |
| *Person conducting this study (if different from above)* | | | | |
| Name: | Position: |  | | |
| Department: |  |  | | |
| *The project- Title, EudraCT, GTAC ref. CTA No. and Sponsor details* | | | | |
| Title:  EUDRACT No.:  GTAC Ref:  CTA No:  Status of MHRA approval:  Sponsor:  Sponsor contact details:  Has the study been approved through DEFRA/SEERAD/or HSE (the sponsor will be able to provide details): Explain: | | | | |
|  | | | |  |
| *Notification of premises to be used for contained use (refer to Regulation 9 of 2014 Regulations* | | | | |
| Has the site where the patient/patients are being followed up been approved by the HSE through a notification? Yes/No  Explain:  Note – a site only needs to be notified to the HSE once and will allow the site to carry out multiple trials in multiple disciplines. | | |  | |

# Summary of proposed investigation including goals and objectives.

The goals of the trial should be explained and justified. The trial aims, endpoints, inclusion and exclusion criteria and potential benefits should be detailed. This should also include a paragraph on the activity at the Glasgow site, number of patients and numbers of samples collected, analysed or transported.

|  |
| --- |
|  |

# An Overview of the Different Genetically Modified Organisms (GMOs) that will be used.

**2.1** Describe the different types of GMO that will be used describing their characteristics, donor(s), recipient vector (s) and construction. Outline the scope of the project. All individual GMOs must be listed. Indicate whether the GMOs are micro organisms or larger organisms.

|  |
| --- |
|  |

* 1. **Names and functional properties of all inserted gene(s)**

Describe the listed genes in such a way that an outside reviewer will have a general idea of their function i.e. providing an abbreviation may not be sufficient. Provide details of any known homologues if the function of a gene is unknown.

|  |
| --- |
|  |

## Indicate the most hazardous GMO

Identify the most hazardous GMO to be used in this work giving consideration to both human health and the environment. This will be the most hazardous combination of recipient strain, vector or virus and inserted material from the lists made above. With some projects it will not be clear that one GMO will be more hazardous than any of the others (e.g. if all the work is Class 1 for studies that come under the Contained Use Regulations). If this is the case, this should be stated.

|  |
| --- |
|  |

# Identification of the hazard to human health

### In which hazard group is each host organism placed by the Advisory Committee on Dangerous Pathogens?

**Hazard Group:**

### Hazards associated with each host organism (e.g. viral vector)

|  |
| --- |
|  |

### What are the hazards associated directly from the inserted gene product?

|  |
| --- |
|  |

### If the function of the inserted gene is unknown, describe the function of any known homologues

|  |
| --- |
|  |

### 3.1.4 Hazards arising from the alteration of existing traits of the host

|  |
| --- |
|  |

### Hazards arising from the sequences within the GMO being transferred to related microorganisms

|  |
| --- |
|  |

# Identification of the hazard to the environment.

### Hazards associated with the recipient microorganism (e.g. viral vector). Indicate bio-safety level, if relevant and whether shedding occurs

|  |
| --- |
|  |

### Hazards arising directly from the inserted gene product

|  |
| --- |
|  |

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

|  |
| --- |
| . |

### The potential hazards of sequences within the GMM being transferred to related microorganisms

|  |
| --- |
|  |

# Risks, likelihood & Control Measures

### Managing risks within the clinical trial environment

Describe the patient pathway and the GMO pathway. Identify the risks associated with each of the procedures and the likely effect if it did go wrong. Describe control measures in place to reduce/minimise risk.

|  |
| --- |
| ***For example***  *Step 1-10 patients will receive GMO at hospital X, external to NHS GG&C-*  *Step 2-Patients monitored for 24 hours and then discharged from hospital X.*  *Step 3- Week 1 – Patients attend CRF at QEUH where they are monitored, vitals taken and a number of bloods, some bloods analysed on site and others transported*  *Assessment of risk for step 3*  *Monitoring of patients undertaken by staff trained in the study protocol, named on the delegation log and aware of the risks associated with the GMO. This training is logged in the training files. All staff have been made aware that immuno suppressed or groups of staff such as pregnant or lactating staff members should not come into contact with the GMO. The staff have been informed if they have concerns they should contact occupational health or discuss with the PI.*  *Samples-The study team have discussed the study with local labs involved. The labs been provided with a manual, the protocol and a file to keep information relating to the study in. Processes in escalating non-compliances to the protocol and any issues with non-conformity in samples and results have been provided to the labs.*  *Sample transport- the sponsor has arranged an external courier to collect samples every 6 months. The samples are being stored within the Biorepository according to the conditions of the lab manual until transport. The samples are tagged and logged and their transit followed until completion by the sponsor.*  **Please complete section 5.2. If these details are included within section 5.1 please insert N/A under section 5.2** |

**5.2 Detail of activity within NHS GG&C site(s)**

**Please complete if this is not detailed within section 5.1.**

5.2.1 What samples are required to be taken from the patients following administration of the gene therapy product? Will standard NHS procedures for handling samples suffice? Have you contacted the lab(s) and provided the protocol/lab manual?

|  |
| --- |
|  |

5.2.2 How will these samples be removed from the patient? Will sharps be used? How and where will these sharps be disposed of?

|  |
| --- |
|  |

5.2.3 Who will take these samples?

|  |
| --- |
|  |

5.2.4 What Personal Protective Equipment will they be required to use?

|  |
| --- |
|  |

5.2.5 5.2.5 red or administered on anWhere will these samples be taken to for analysis? How will the samples be transported? Is there a sample tracking system in place?

|  |
| --- |
|  |

5.2.6 Who will analyse these samples? How and where will this waste be disposed of?

|  |
| --- |
|  |

For decontamination and laundering.

|  |
| --- |
|  |

b) b)No 5.12 sectionWill gloves be worn? If yes, what type are these and where will they be stored?

|  |
| --- |
|  |

c) Is any other type of personal protective equipment to be used?

|  |
| --- |
|  |

## 5.3 Controls

### Delegation log (Please include a Health and safety section within the delegation log)

Have available for audit purposes the delegation log for the trial containing the names of individuals who are delegated Health and Safety responsibilities e.g. training of staff in handling of samples, disposing and cleaning, dealing with concerns and issues from staff exposed to activities involving the GMO

### 5.4 Information, Instruction and Training

a) Describe the training of all staff identified as being at risk of exposure. Include details on record keeping.

|  |
| --- |
|  |

b) Has a Local Code of Practice been prepared? If yes, is this available to all those at risk of exposure? Consider members of the public who may come into contact with the patient.

|  |
| --- |
|  |

## 5.5 Medical issues (for staff involved in this GT/GM Clinical Trial)

**Who is the contact if any trial staff or personnel who may be exposed to the GMO have concerns or issues.**

### Name and Contact Details

|  |
| --- |
|  |

### How will staff be informed of this individual

|  |
| --- |
|  |

## Specify any health surveillance requirements for staff involved in the work

|  |
| --- |
|  |

## 5.6 Specify any health issues or conditions that will exclude staff from working with the GMO? What is the process to inform staff of this and for staff to indicate they may be excluded from working on the trial?

|  |
| --- |
|  |

### 5.7 Routine Decontamination

### 5.7.1 Waste handling

All waste potentially contaminated with GMO culture material must be rendered non-viable (inactivated by a validated means) prior to leaving the site for final disposal. Only include details of waste within NHS GG&C and the home environment (if appropriate).

List waste types and methods of inactivation and disposal

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Waste type**  **e.g. liquid, blood, syringes, swabs** | **Detail (spillage, disposal of blood)** | **Storage location of waste prior to inactivation** | **Chemical Inactivation specify type of disinfectant, concentration, contact time and conditions of use** | **Validation of treatment (evidence inactivation works)** | **Route of Disposal** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

### If autoclaving is used to inactivate the GMO waste, please provide the following details:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Detail the type of waste** | **Storage location of waste prior to inactivation** | **Autoclave Cycle**  ***Specify temp, and cycle time*** | **Monitoring of treatment**  ***e.g. Chart recorder attached to autoclave*** | **Validation of treatment**  **e.g. Annual 12 point thermocouple testing of autoclave** | **Route of Disposal** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **Location of autoclave** |  | |  | |  | |

# 5.8 Transport

a) Detail the containment measures which will be used to prevent or contain accidental splashes or spillages.

|  |
| --- |
|  |

b) Will viable GT/GM material be transported to or from these labs? If yes, describe the route of transportation and describe in detail the containers to be used. Note that this includes the movement of waste containing viable GT/GM material e.g. to an autoclave elsewhere in the building.

|  |
| --- |
|  |

c) How will specimens be transported around the hospital? Describe the containment measures to be used.

|  |
| --- |
|  |

d) Will any GT/GM material or specimens be transported to other NHS GG&C Board sites or external locations? If yes, please describe the transportation and containment measures to be used.

|  |
| --- |
|  |

# 6 Emergency Procedures

Describe the procedures in place for dealing with the spillages

|  |
| --- |
|  |

Describe the procedures in place for an accidental exposure (if necessary describe different procedures for different types of exposure e.g. eye splash or percutaneous inoculation) Please attach any supporting documentation from the sponsor e.g. drug company exposure guidance.

|  |
| --- |
|  |

c) Describe the specific arrangements required to evacuate a patient in the event of a fire or other emergency e.g. air handling failure

|  |
| --- |
|  |

d) Describe the actions to be taken in the event of death of the patient before the end of the treatment period.

|  |
| --- |
|  |

e) Describe whether any specific procedures are required to be followed in the event of any unexpected clinical events e.g. the patient requiring resuscitation following cardiac arrest or other acute medical emergency. Will other departments be involved e.g. ICU, CCU? Have these departments been fully informed?

|  |
| --- |
|  |

f) Describe the procedures to be followed if the patient suffers from post-operative infection. Would the patient require transfer to another location? Detail the potential for exposure to other personnel and the control measures in place to minimize this.

|  |
| --- |
|  |

## 7 Assignment of Containment Level and Classification – classification determined by sponsor/MHRA for studies that come under the Contained Use Regulations only. Do not complete if the study comes under the Deliberate Release Regulations.

|  |  |  |
| --- | --- | --- |
| Containment Level | Classification | Refer to Part 2 and Schedule 8, Part 2 of the Contained Use Regulations |
| 1 | 1 |  |
| 2 | 2 *HSE notification is required prior to commencement of work* |  |
| 3 | 3 *HSE approval is required prior to commencement of work* |  |

## 8 Personnel

a) Names of all other personnel involved in the handling of the GMO

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Surname | Initials | location | Job title | Employer |
|  |  |  |  |  |

## b) List other people who may be at risk from the activity

For example, other researchers, cleaners or maintenance workers

|  |  |  |
| --- | --- | --- |
| Details ( including their names if known) | Employer | Involvement with this trial and exposure opportunity |
|  |  |  |
|  |  |  |

c) Who will be responsible for managing Health and Safety risks for non-NHS GG&C Board personnel involved in this clinical trial?

|  |
| --- |
|  |

d) Who will be responsible for providing Occupational Health support, where necessary for non-NHS GG&C Board personnel involved in this clinical trial?

|  |
| --- |
|  |

# 9Declarations

***To be completed by the PI responsible for this project****.* By ticking this box I confirm that all information contained in this assessment is correct and up to date. Any changes to the project will be forwarded to the GMO Safety committee.

I also undertake to ensure that no work will be carried out until this assessment has been completed and approved and that all necessary control measures are in place. Also, I accept that a statutory notification period may be required before work can commence.

I confirm that the information detailed on this risk assessment form has been provided to the relevant person with responsibility for the clinical care of patients and also to the person with managerial responsibility for all staff involved in this clinical trial

|  |  |
| --- | --- |
| Local Investigator | |
| Name: |  |
| Signature: | Date: |

|  |  |
| --- | --- |
| GMS COMMITTEE approval | |
| Name: |  |
| Signature: | Date: |

**Data protection**

The information provided on this form will be processed in accordance with the Boards Data Protection Policy.