Standard Operating Procedure For The Preparation and Administration of Class I GMO Vaccines Within Research Space, LRI

University Hospitals of Leicester NHS
NHS Trust

Research Space SOP 5011

Trust Reference:C2/2022

1. Introduction and who this Standard Operating Procedure (SOP) applies to

The purpose of this SOP is to provide information on giving Class I Genetically Modified Organisms (GMO) vaccines within Research Space. Genetically modified organisms (GMOs) are organisms whose genes have been artificially altered to somehow modify their characteristics. Activities relating to GMOs are classified into one of four classes, based on the risk that they present to human health and the environment. The risk classification is derived from the outcome of a detailed risk assessment and corresponds to an appropriate containment level. Most activities involving GMO therapies will be class I or II.

This SOP is only applicable to Class I GMO studies where a safety cabinet is not recommended.

This SOP applies to all staff, researchers and research staff working in Research Space involved in the preparation and administration of a Class I GMO vaccine

1.1. Responsibilities

A person performing this procedure must have completed the training specified in the implementation plan, or be under the supervision of a trained person.

All staff members involved in the preparation and/or administration of Class I GMO vaccines are responsible for:

- completing appropriate GMO, vaccine, and Medicines Management training and competency assessments as relevant to their role
- safe handling and management of Class I GMO products in accordance with this SOP, local and national health and safety policy / guidance and study protocols.
- using personal protective equipment (PPE) as per local guidance and UHL B9/2004 Personal Protective Equipment at Work UHL Policy including gloves, plastic apron and visor for eye and mouth protection

The Research Space Senior Management Team (SMT) is responsible for:

- implementing and monitoring compliance with these procedures

2. Guideline Standards and Procedures

2.1. Equipment Required in order to prepare and administer a Class I GMO vaccine

- Metal trolley on which to draw up vaccine,
- Blue plastic tray

- Appropriate sized syringe for vaccination
- Blue needles (23g)
- Alcohol swab
- Clean dressing
- Gloves, plastic apron, visor for eye and mouth protection
- Sharps bin, biohazard bags, tags, biohazard GMO Waste labels
- Biohazard spill kit.

2.2. Preparation

- All staff must be familiar with injection techniques to be used and the study protocol and have received appropriate training – including maintaince of blind of investigational medicinal products (IMP) if the study requires this.
- All vaccinations are to be administered in accordance with study specific protocols and Trust policy/procedures.
- All equipment should be assembled and the trolley prepared as per Trust procedures and protocol.
- Confirm the identity of the study participant and fully explain the procedure, reaffirm consent and eligibility. Proceed and wash your hands thoroughly.
- Those administering the vaccine should wear personal protective equipment as required including gloves, plastic apron and visor for eye and mouth protection.

2.3. Delivery and storage (pharmacy)

- The vaccine is to be delivered to, and stored in a labelled and sealed container in a designated minus 80 degree Celsius freezer or fridge (as applicable to each IMP) that is controlled and monitored by the Clinical Trials pharmacy department.
- The freezer/ fridge must have an incorporated alarm system and a system for recording the temperature so that this information can be made available for the study site file.
- The freezer/fridge in which the material is stored must be in a locked area at all times with restricted access, so that only designated pharmacy personnel will have access.

2.4. Transport of vaccines between pharmacy and the treatment room

- The vaccine will need to be transported to the treatment room located in Research Space. Ensure that blinding is maintained for studies which require this. The vaccine vial must be carried in a rigid, impermeable, sealed and appropriately labelled container, taken by way of a route that avoids office areas or highly populated areas as much as possible.

- On arrival of vaccine in Research Space, the accountability record should be completed (details to include date received, batch number, vials received and signatures of personnel receiving vaccine).

2.5. Preparation for administration of vaccines

- Follow specific study protocol which should detail for how long the vial takes to defrost (or reach room temperature) and how long it needs before being administered once out of the freezer/ fridge.

- The person preparing and administering the vaccine must wear disposable gloves, eye and mouth protection and a plastic apron. The vaccine will be prepared for administration in the Treatment Room. The trial physician/nurse must ensure that the room to be used for vaccination is appropriately equipped.

- At each vaccination, the vial which has been removed from the freezer/fridge will be allowed to thaw/reach room temperature for the time specified in the protocol, avoiding shaking or heating of the vial. Reconstituted vaccine must be used within the recommended period, according to the manufacturer's instructions and study protocol. **Once opened, vials must not be re-used**.

- **CAUTION: Check the specific study protocol for how long the vial takes to defrost/reach room temperature and how long before it needs to be administered once out of the fridge/freezer.**

- Reconstitute vaccine**,** draw up vaccine, label syringe and administer vaccine as per protocol and Trust policy on Medicines Management.

- Complete reconstitution and administration log for each vaccinated subject.

- Follow pharmacy guidance and study specific protocol for returning and destroying of any un/used vaccine vials.

2.6. Dressings

Vaccinations using Class I GMO products must be covered with an occlusive dressing for 30 minutes to prevent environmental contamination, which should then be disposed of into the GMO sharps bin unless otherwise stated in the study protocol.

2.7. Post administration of vaccine

- After administration of vaccine, the vial, sharps and syringe should be placed immediately into a GMO waste labelled sharps bin and all PPE should be removed and disposed in a biohazard bag labelled as GMO waste.

- All biohazard GMO bags should be swan necked tied with a tag and double bagged.

- All Class I GMO waste will be collected and disposed as directed by the Logistics team using an outside contractor (currently Stericycle). The Logistics team may provide details of disposal in a designated area.

- Decontaminate workbenches and surfaces with the disinfectant solution after any spills as outlined in: SOP 5010 Actions in Case of Class I GMO Splash or Spillage Within Research Space when work is completed.

3. Education and Training

- CAUTION: pregnant, breastfeeding, and/or immunocompromised staff are NOT permitted to be involved in the preparation, administration, disposal, or cleaning of any Class I GMO product or spillage at UHL.
- Supervised or unsupervised handling or storage of Class I GMO products within Research Space must only be undertaken by staff who have:
  - Undertaken relevant GMO, vaccination, Medicines Management, and/or study specific training, as applicable to their role in the study
  - approval to work in Research Space managed facilities
  - completed a Research Space orientation

Supporting Documents and Key References

- SOP 5010 Standard Operating Procedure For The Actions in Case of Class I GMO Splash or Spillage Within Research Space
- UHL B9/2004 - Personal Protective Equipment at Work Policy
- Relevant PPE risk assessments

4. Key Words

Research Space, Genetically Modified Organisms, GMO, Preparation, Administration, Class I

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