| SOP number | **17.035** | Version | **2.0** |
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| Title | **Administration of a Vaccine** | | |

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| SOP category | 17 NHS GG&C Clinical Research Facility – Clinical | | | | |
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| Staff category | **Staff Category** | **R** | **A** | **C** | **I** |
| | Nursing | X | | | |
| | GCRF Manager | | X | | |
| | Site Clinical Trials Pharmacy | | | | X |
| | GCRF Associate Director | | | | X |
| | Senior R&I Manager | | | | X |

## 1. Scope

This procedure applies to Glasgow Clinical Research Facility clinical staff.

## 2. Purpose

The purpose of this procedure is to describe the procedure for administration of a vaccine within a clinical study.

## 3. Procedures

### 3.1 Before vaccination

Receipt, storage and release of study vaccines will be managed either by Clinical Trial Pharmacy or through arrangement with Health Protection Scotland (HPS). For vaccination programs with HPS, follow the Guidance on Vaccine Storage and Handling from National Services Scotland. This guidance includes how to manage the Cold Chain (system of transportation and storage essential to maintain an unbroken cold chain from point of vaccine manufacture, through transportation to pharmacy, and clinical settings).

Where a clinical drug fridge is used as part of the Cold Chain, follow advice in HPS guidance for storage and distribution of vaccine within the fridge, and SOP 17.034 Storage and Management of Medication.

If the vaccine is a Genetically Modified Organism (GMO) additional approvals and steps must be followed as per SOP 17.013. Appropriate spillage kits must be available prior to vaccine handling.

Administration of a vaccine requires one of three types of instruction in place:
i) A signed prescription
ii) A signed Patient Specific Direction (PSD)
iii) A patient Group Direction (PGD)

Clinical Research Nurses are required to ensure their mandatory Learnpro modules for infection control, handling of sharps and hazardous waste are up-to-date in addition to Immediate Life Support (ILS) and Management of Anaphylaxis (SOP 17.029).

**3.2 Vaccine preparation:**
Personal Protective Equipment should be worn as per NHS GGC hospital policy or as per GMO risk assessment (FORM 52.013A). Anaphylaxis kits should be available at the location.

Receipt or removal from the vaccine store (e.g. from Clinical Trials Pharmacy or from the Cold Chain) should be recorded including:

- Date and time of removal/receipt
- Trial Number
- Product name
- Batch
- Vial number (where available)
- Expiry date
- Log to be signed by both members of staff at the time of checking

For frozen vaccines hold the unopened vial in the gloved hand to encourage thawing of the frozen vaccine.

Once defrosted, remove the cap and swab the septum (bung) using an alcohol wipe, allow to dry.

Prior to inserting the needle into the vial, ensure all possible air is expelled from the syringe; air being forced into the vial may cause a build-up of pressure and result in ejection of its content when withdrawing the needle. Using standard universal precautions draw up the vaccine to the required volume as specified in the protocol.

Where very small volumes are being used it is likely that air bubbles will appear in the syringe. By keeping the vial on the needle it will be possible to remove these by tapping the syringe and drawing back and forth, **AT NO TIME SHOULD THE NEEDLE BE REMOVED FROM THE VIAL AND "FLICKED" AS THIS MAY LEAD TO ENVIROMENTAL CONTAMINATION WITH A GMO.** If air bubbles are a problem hold the vial between the thumb and forefinger and syringe with the other fingers and gently flick the barrel of the syringe with the other hand.

Once the required volume is drawn, recheck the vaccine label (two members of the clinical team) against the vaccination administration instructions. A new needle of a size appropriate to the individual patient should be used to inject the vaccine.

For pre-filled vaccines check the vaccine label (two members of the clinical team) against the vaccination administration instructions. The pre-filled syringe will have an integral needle for injection to the patient.

For multi-dose vials, follow the instructions in the protocol for storage of the vial before the subsequent dose is drawn up: ensure the maximum period for storage is not exceeded.

**3.3 Vaccine Administration**

- If the skin is clean, no further cleaning is necessary. Only visibly dirty skin needs to be washed with soap and water. It is not necessary to disinfect the skin.

- Administer the vaccine as prescribed by the protocol. For guidance for injection technique please refer to Chapter 4 of the Green Book (www.gov.uk). Once administered, apply an occlusive dressing for the length of time specified in the protocol. An occlusive dressing is only required for a GMO vaccine.
- Once the vaccine has been administered, record the time and site/location of injection.
- Where appropriate remove the flag label from the vial, annotate with the participant's ID number and stick to the vaccination administration record.
- Reconstituted vaccine must be used within the recommended period and according to the manufacturer's instructions. Once opened, vials must not be re-used unless designated for multiple dosing.
- Place all equipment used in the administration of GMO products, including the dressing, gloves and apron in the appropriate waste receptacles.
- At the end of the session clean all surfaces that have possibly come into contact with the vaccine.

## 4. Referenced documents

SOP 17.013 Study Site Coordination and Delivery of an ATIMP Study
SOP 17.029 Management of Anaphylaxis in Adults and Paediatrics
FORM 52.013A GMO Contained Use Regulations
Health Protection Scotland: Guidance on vaccine storage and handling
SOP 17.034 Storage and management of medication
The Green Book: Immunisation procedures: the green book, chapter 4 - GOV.UK (www.gov.uk)

## 5. Related documents

NHS GGC Guideline: Immunisation and Best Practice
Learnpro mandatory modules

## 6. Document history

| Version | Date | Description |
|---|---|---|
| 1.0 | 26/05/2020 | First Release |
| 2.0 | 25/10/2024 | Update to SOP template v2.0<br>Addition of RACI matrix<br>Change of all signatories<br>Clarification on dressing usage and details to be recorded |