IMP Management Plan

Study title: A Phase 2, randomised, single-blinded, placebo-controlled crossover trial evaluating the safety of Live Attenuated Influenza Vaccine (LAIV) in children aged 12–23 months (FluSNIFF Toddler).

Version: 5.0

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Approved by Chief Investigator: Prof Saul Faust, on 24 /SEPT /2025

1. Purpose

To outline the procedures for the safe and compliant management of the Investigational Medicinal Product (IMP) for the FluSNIFF study, including receipt, storage, dispensing under a Patient Group Direction (PGD), and handling of deviations.

2. IMP Supply & Receipt

2.1 Overview of Products

Product	Type	Source	Regulatory Status	IMP Status
Fluenz (LAIV, also known as LIV)	Live attenuated influenza vaccine	UKHSA via ImmForm	Licensed NHS supply	IMP from point of administration
0.9% Saline (administered via nasal spray)	0.9% saline	Site stock	Routine NHS stock (vials or ampules)	IMP from point of administration

Fluenz (LAIV) is delivered directly from UKHSA to the study site pharmacy.
Normal Saline can be used from on-site NHS stock vials or ampules.

3. Prescribing and Dispensing PSD)

IMP will be supplied and administered under a **Patient Specific Direction (PSD)**

Patient Specific Direction (PSD):

- IMP should be prescribed on an individual basis.
- A PSD requires a prescription or written instruction from an authorised prescriber (doctor, dentist, or non-medical prescriber).
- The prescriber should complete the PSD Proforma provided by the Sponsor.
- The named prescriber must be listed on the Delegation Log and retains responsibility for each authorised administration.
- The PSD covers both Fluenz (LAIV) and placebo, making clear that all participants will receive both products during the trial.
- The PSD will be completed and held on paper at site during the study.
- To maintain parental blinding, the PSD and vaccination entries will be uploaded into the child's electronic health record (EHR) only after Day 60, at the same time as the vaccine administration is recorded.

4. Monitoring & Audit

- All IMP-related records will be available for Sponsor remote monitoring visits and potential audits or inspections.
- Ensure timely and complete documentation of all processes.

5. Distinction in Handling Requirements

Parameter	Fluenz (LAIV)	0.9% Saline Nasal Spray
Source	Standard NHS supply via UKHSA (ImmForm)	Supplied from routine stock vials or ampules
IMP Status	Not classified as IMP until removed from fridge for immediate administration	NA
Storage Requirements	2–8°C, NHS cold chain protocols	Room temperature
Cold Chain Monitoring	Standard NHS refridgerator logs are sufficient until point of use	NA
Accountability Log	Batch/expiry recorded at use; no log required before that	NA
Transport Requirements	Handled via NHS processes	NA
Packaging	Original NHS packaging	Original NHS packaging
Disposal/Return	Record used doses; discard per NHS SOP	As per normal NHS procedures

6. Site Responsibilities Summary:

IMPORTANT NOTE: When planning site vaccine administration workflow, please remember this is a participant-blind trial. The parent must not see whether IMP or placebo is used, and vaccine/drug administration medical records must not be completed until Day 57 or later, once the final remote follow-up visit (Visit 3) has taken place. This ensures consistency across sites and maintains study blinding.

Fluenz (LAIV):
- Ordered via ImmForm and stored in NHS fridges (2–8°C).
- Not classed as an IMP until removed from the cold chain and administered.
- Batch number and expiry date must be recorded in the eCRF at administration. - Recorded in GP Electronic Medical Record (EMR) only at day 57 or after.
- No IMP accountability log required prior to administration.
- Should not be removed from the refrigerator for longer than 20 minutes.

0.9% Saline Placebo Nasal Spray:
- Routine stock of injection or nebuliser-grade 0.9% saline vials or ampules held on site at the GP surgery or hospital site.
- For saline administrations, GP EMR entries must be completed only on/after Day 57 to preserve blinding

- Storage / Handling: Room temperature; retain in original NHS packaging until preparation; verify integrity/expiry prior to use. If any storage concern arises, quarantine and notify Sponsor within 24 hours.
- Disposal: Dispose of used saline, syringes, and atomisers per local NHS clinical waste SOPs; document any quarantined/defective items.
- The saline must be administered using:
    - NHS stock 1 ml syringe
    - NHS stock CE marked nasal atomiser device (to be supplied by sponsor)

Specific site training will be provided to explain how to

- prepare the saline prior to the study visit
- how to administer the saline through the atomiser device
- how to position the parent/carer and child to avoid unblinding of the parent/carer.

See SOP for Fluenz and Saline Placebo Administration v3 dated 25th Sept 2025