Document Title: Maintaining the IMP Blinding for Clinical Trials.

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Summary of Amendments

Version Number	Modification:
1.0	New SOP
2.0	Updated for ICH GCP E6 R3 updates to wording

Key related documents:	TPL022 Site Personnel Delegation Log FRM042 Project Management Delegation Log SOP069 Code Breaking in Clinical Trials SOP081 Destruction of Waste IMP SOP082 Returns of IMP to Pharmacy.

Key Points of this Document

- This document sets out the roles, responsibilities, and procedures to be followed by pharmacy and the unblinded members of the research team when delegated to prepare and administer study IMP.
- It aims to provide clear guidance for the documents and processes that must be followed when completing the unblinded IMP dispensing and preparation at Royal Papworth NHS Foundation Trust.

1 Purpose and Contents

a. The document defines the Trust's and Research & Development's (R&D) procedures for maintaining the IMP blinding within a clinical trial at Royal Papworth NHS Foundation Trust.

b. It documents the purpose of maintaining the blind within a clinical trial that should be considered/undertaken by Pharmacy and unblinded research team to ensure that blinding for a trial is maintained and to prevent inadvertent unblinding of the trial.

c. The document contains the guidance on all trial-specific information that should be recorded in the IMP handling guidelines and study specific worksheet.

d. If you need to complete a code break or unblinding of a clinical trial, please see SOP069 code breaking in clinical trials.

2 Roles & Responsibilities

a. This policy applies to all personnel who are delegated unblinded clinical research tasks, when a separate unblinded, team is required for conducting clinical research at the Trust.

b. The research team are responsible for maintaining a list of the names of the blinded and unblinded personnel on the delegation log which must be stored in the Site file and a copy placed in the Pharmacy Site File.

3 Policy

a. This SOP is mandatory and, non-compliance with it may result in disciplinary procedures.

b. All research active staff should be aware of this SOP at the commencement of the research project. R&D staff and Pharmacy staff should be aware of this SOP at all times.

4 The Purpose of Maintaining the IMP Blinding in Clinical Trials

Blinding is the process that keeps one or more parties involved in a trial (for example, the sponsor, the investigator team and/or the participant) unaware of what treatment arm participants have been randomised to. It is vital that the blind is maintained throughout the trial to ensure no bias is introduced when making safety and efficacy assessments.

4.1 Process Maintaining the Blind

a. Unblinded and blinded Site staff must be delegated by the Principal Investigator and qualified by training and experience for the delegated tasks, this must be documented on TPL022 Site Personnel Delegation Log.

b. The study team must be made aware of any changes of study staff and if they are blinded or unblinded. Blinded and unblinded study staff must not switch roles during the lifetime of the study.

c. *Handling documents that show treatment /randomisations*: These documents should be stored and kept under the control of those personnel un-blinded to treatment allocation only. When Interactive Response Technologies (IRT) systems for randomisation are being used, care must be taken that no information is forwarded to blinded members of the research team or sponsors. Clear instructions on trial-specific details can be found in the Pharmacy Site File (PSF) for the relevant trial.

d. Unblinded documentation must be kept in a secured location accessible only to the unblinded site staff and unblinded monitors.

e. *Communication with the Research Team*: This must be done carefully to ensure the blind is maintained. The IMP should be prescribed in a way that does not unblind any blinded team members. Ensure prescription does not indicate treatment allocation to blinded members of the research team.

f. If required, processes must be in place to ensure no unblinding occurs during dispensing of the study drug. Pharmacy must ensure when dispensing the IMP to an unblinded member of the research team that IMP is in an opaque bag to ensure the contents are not seen by members of the blinded research team.

g. Where un-blinded members of the research team have been delegated to prepare IMP, the trial treatment should be prepared in a quiet area, out of sight from the blinded research team and the participant. A member of the un-blinded research team (who is listed on the delegation log as being responsible for this activity) should prepare the IMP.

h. Ensure that participant treatment allocation is only discussed with those unblinded to the treatment allocation.

i. Returns and disposal must be done by unblinded personnel only in line with standard hospital procedures and in a concealed manner. Consideration should be given to how items will be returned to pharmacy to prevent inadvertent unblinding of the trial. The opaque pharmacy bag should be used to prevent the medication being viewed by blinded members of the research team. For IMP returns please see SOP081 Destruction of waste IMP and SOP082 Returns of IMP to pharmacy.

j. *Invoicing and stock management for Blinded Trials:* For trials involving the use of commercial hospital stock and the use of CMM dispensing system to book out the IMP to a consultant during the process of IMP preparation, the IMP handling guidelines should clearly describe a process that does not unblind the study at a later date, for example, when finance reports are run detailing what was booked out on the dispensing system. Invoicing the sponsor for associated drug costs should be carefully considered in these trials and potentially conducted at the end of the study. This will ensure that the Sponsor and the Trial Management team are not unblinded to the treatment each participant has received.

k. *Training:* All staff working on a blinded study will need to read and acknowledge the trial protocol, pharmacy manual if applicable and preparation worksheet if applicable associated with the study. Training will be recorded on the research team specific training logs stored in Pharmacy and Trial Site files.

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken.

SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	Current approved version date
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (and any subsequent amendments) UK Policy Framework for Health and Social Care Research version 3.3 (07/11/17) and authorised amendments thereafter

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Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							

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