ECTU Central Office SOP ECTU_IT_07: Unblinding Procedure

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Authorship and Approval			
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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	14 Mar 2012	New document
2.0	10 Jun 2016	Updated the description of the process to focus on the dataset to be collected
3.0	10 Jun 2024	Moved to new template (v3.0). Major updates to reflect current procedures.
4.0	11 Nov 2026	Minor changes to section 2.0. Updates to sections 4.1, 4.2 and 4.4.2. Major formatting changes made to 4.0 overall. QMS template updated to v4.0.

1.0 PURPOSE

The purpose of this SOP is to describe the process of performing a treatment allocation unblinding prior to the end of the study.

2.0 SCOPE

2.1 This SOP applies to all the bespoke research support systems developed in-house by Edinburgh Clinical Trials Unit (ECTU), where a blinded treatment allocation is provided.

3.0 RESPONSIBILITIES

The ECTU Software Developer or designee is responsible for setting up an unblinding facility or manually unblinding a participant on request.

4.0 PROCEDURE

4.1 The specifications for an emergency unblinding will be provided by the trial manager and will be risk assessed by the Sponsor at the beginning of the trial.

4.2 The following details will be recorded in the study database if ECTU systems or personnel are involved with performing the unblinding.

- Unique participant identifier.
- When the unblinding occurred.
- Reason for unblinding which can include the details of the requester.
- Which role and/or individuals requested the unblinding, if applicable.

4.3 Inbuilt unblinding in databases

4.3.1 If the need for unblinding of a participant's allocated treatment has been determined, and where unblinding facility has been built into the eCRF, the PI or designee can complete the action.

4.4 Manual unblinding

4.4.1 In non-critical situations, if the unblinding facility has not been built into the eCRF, the site PI or clinician on the delegation log will then contact the trial management team via the trial inbox, who in turn will inform the Software Developer, that a manual unblinding is required.

4.4.2 If manual unblinding has been performed, the Software Developer will inform the Trial Manager once completed by emailing the trial inbox, without revealing patient identifiable information.

5.0 RELEVANT DOCUMENTS AND REFERENCES

ECTU_SOP_IT_07, IT_14 and IT001

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