



ECTU Central Office SOP ECTU_IT_07: Unblinding Procedure

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1. PURPOSE

To describe the process of performing a treatment allocation unblinding prior to the end of the study.

2. SCOPE

- 2.1. This SOP applies to all the research support systems developed in-house by Edinburgh Clinical Trials Unit.
- 2.2. This SOP applies to those systems where Edinburgh Clinical Trials Unit provide a blinded treatment allocation.

3. Record an unblinding occurred

Once the need for an unblinding of a participant's allocated treatment has been determined the following details will be recorded in the study database if Edinburgh Clinical Trials Unit systems or personnel are involved with performing the unblinding.

- 3.1. Unique participant identifier.
- 3.2. When the unblinding occurred.
- 3.3. Reason for unblinding.
- 3.4. Which role and/or individuals were unblinded.

4. RELEVANT DOCUMENTS

5. DOCUMENT HISTORY

Version Number:	Effective Date:	Reason(s) for change(s):
1.0	14-Mar-2012	New document
2.0	10 th June 2016	Updated the description of the process to focus on the dataset to be collected