ECTU Central Office SOP ECTU_IT_08: Emergency Randomisation

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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	14th March 2012	Initial creation
2.0	25th Jan 2013	Corrected typo. Changed 'unblinding' to 'randomisation' in the Purpose paragraph.
3.0	10th June 2016	Removed reference to ECTU_IT_04 as this has been withdrawn. Change of name as per naming convention in ECTU_OP_01
4.0	11 Sep 2024	Updated at scheduled review. Document moved to new template. Minor wording changes to section 1 and 2. Minor numbering and format changes throughout the document.

1.0 PURPOSE

This Standard Operating Procedure (SOP) provides a framework for the setting up of project specific emergency randomisation procedures when the computerised or otherwise automated treatment allocation is not available.

2.0 SCOPE

This SOP applies to all University of Edinburgh staff employed within ECTU who are responsible for developing and maintaining a bespoke database for studies with a treatment allocation component. This SOP only applies if there is a requirement for emergency randomisation detailed in the protocol.

This SOP describes the process of adding the data relating to an emergency randomisation manually into the trial dataset once the IT team has been notified that an emergency randomisation has occurred. It does not cover the steps taken by a researcher to perform an emergency randomisation for a particular trial or other research project.

3.0 RESPONSIBILITIES

The study software developer, or designee is responsible for the tasks detailed in this SOP.

4.0 PROCEDURE

4.1 Determine the minimum dataset that will be required from the researcher immediately after an emergency randomisation.

4.2 **Treatment Allocation Algorithm Inputs**
This is the data needed about a research subject before that subject can be allocated a treatment, for example, age and sex.
Identify whether or not any of these data items are already recorded elsewhere in the project database.

4.3 **Treatment Allocation Algorithm Outputs**
This is what the algorithm notifies to the researcher when an automated allocation occurs. This is trial specific but if the trial is unblinded then it's usually the treatment allocation itself, for example: Active or Placebo.
If the trial is a blinded drug trial it's normally a treatment code which the researcher, then delivers to their local pharmacy to receive the research drug.
This will be study specific, but for example could be:

- Treatment A or Treatment B
- The number of the Drug Pack received from the pharmacy
- The serial number of the device retrieved from storage by the researcher performing the emergency manual randomisation

4.4 The date and time of the emergency manual randomisation.

4.5 Create a project-specific Emergency Randomisation Plan (ERP) to follow in the event of an emergency manual randomisation. The ERP should be filed within the Study TMF.

4.6 The ERP should detail step-by-step which data items should be added to the project database.

4.7 Ensure the ERP includes an entry into a Randomisation Issues table. This highlights to the project statistician that a non-standard allocation mechanism occurred for the particular research subject.

5.0 RELEVANT DOCUMENTS AND REFERENCES

ECTU_SOP_IT_08 Emergency Randomisation v4.0

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