
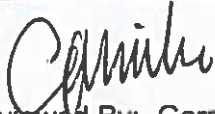


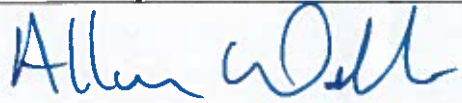




ECTU Central Office SOP ECTU_IT_08: Emergency Randomisation

SOP number:	ECTU_IT_08
Version number:	3
Effective date:	10 th June 2016

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1. PURPOSE

This 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. SCOPE

This SOP applies to computerised systems developed to support research or other projects within the auspices of ECTU. In particular it refers to those projects that have a treatment allocation component.

It covers 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. PROCEDURE

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

- Treatment Allocation Algorithm inputs.
 - Identify whether or not any of these data items are already recorded elsewhere in the project database
- Treatment Allocation Algorithm Outputs. This is the data regarding the emergency manual allocation. This will be project 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
- The date and time of the emergency manual randomisation

3.2. Create a project-specific Working Practice Document to follow in the event of an emergency manual randomisation

- This working practice document should details step by step which data items should be added to the project database.
- Ensure this covers 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

3.3. Definitions

3.3.1. Treatment Allocation Algorithm Inputs

This is the data needed about a research subject before that subject can be allocated a treatment. Things like age, sex and which research site are quite common, for instance.

3.3.2. 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.

4. RELEVANT DOCUMENTS

5. DOCUMENT HISTORY

Version Number:	Effective Date:	Reason(s) for change(s):
1	14-Mar-2012	New document
2	25-Jan-2013	Corrected typo. Changed 'unblinding' to 'randomisation' in the Purpose paragraph.
3	10 th June 2016	Removed reference to ECTU_IT_04 as this has been withdrawn. Change of name as per naming convention in ECTU_OP_01