



ECTU Central Office SOP ECTU_IT_06: Paper-based Treatment Allocation

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1. PURPOSE

To describe the process to follow when designing and implementing a paper-based treatment allocation mechanism

2. SCOPE

This SOP applies to producing a paper-based treatment allocation mechanism

3. PROCEDURE

This describes the steps to follow when producing a paper-based treatment allocation mechanism

3.1. Identify the key features of the randomisation list.

The randomisation list forms the basis for the paper-based treatment allocation and should be built after taking into consideration the following:

- What type of treatment allocation is required?
- If permuted blocks use a dynamic block size that varies between small multiples of the number of treatments
- Identify any stratification and ensure this is incorporated into the list
- Identify whether the list should incorporate treatment allocation codes or show the actual allocated treatment – related to treatment allocation concealment.
- Confirm the details with the project statistician or other responsible person

3.2. Build the list

3.3. Perform a mail merge of the list to both a set of labels and to standard paper

- Confirm with the project statistician or other responsible person the content and layout of these two mail merge items. For example the label would contain the site details and Randomisation Code as a minimum.

3.4. Prepare for distribution

- Pack the paper containing the allocation details into tamper evident envelopes. One envelope per allocation.
- Stick the appropriate label onto the tamper evident envelope.
- Pass the envelopes to the team responsible for distributing envelopes to sites.

3.5. Definitions

3.5.1. Responsible Persons

A responsible person is a key stakeholder who has the authority to request and define the required change.

4. RELEVANT DOCUMENTS

5. DOCUMENT HISTORY

Version Number:	Effective Date:	Reason(s) for change(s):
1.0	13-Mar-2011	New document

2.0	10 th 2016	June	Change to name as per naming convention in ECTU_OP_01. Relevant documents changed as ECTU_IT_04 withdrawn.
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