ECTU Central Office WPD ECTU_ST_W6: Randomisation System Description and Confirmation

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Authorship and Approval			
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Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	6th Nov 2018	Initial creation/New document
2.0	11 Feb 2021	Minor edits, clarification of 2.1, addition of emergency randomisation
3.0	04 Dec 2024	Minor edits to bring into line with other documents. Transfer to new ECTU template

1. INTRODUCTION

This Working Practice Document provides guidance on the procedure for confirming that a computerised randomisation system that has been built by Software Developers or REDCap Developers has been built to the specification provided by the Trial Statistician. Procedures for designing a randomisation system can be found in ECTU Central Office SOP ECTU_ST_02 Considerations for Randomisation and Blinding Procedures.

2. INSTRUCTIONS and GUIDANCE

2.1 The Trial Statistician or designee will be responsible for confirming that the randomisation system has been built correctly. Simple block randomisation, or block stratification, can be checked by requesting a sample of the training randomisation list to check for balance. More complex randomisations (minimisation etc) should be checked by the developers to ensure the systems are performing correctly. The randomisation programming code must be checked by the Trial Statistician or designee to ensure all minimisation variables are present and correct. If the confirmation process has the potential to unblind the Trial Statistician, this must be carried out by the Unblinded Statistician.

2.2 The Trial Statistician or designee will be responsible for ensuring that the Randomisation System Description is generated and documented. This will be completed on the Randomisation System Description and Confirmation Document (see section 3).

2.3 Part 1 of the document will be completed from the details agreed for the study protocol. Further information may be required from the Chief Investigator, Software Developer or REDCap Developer and Trial Manager to complete this.

2.4 Once part 1 is complete, this will be submitted to the Software Developer or REDCap Developer who will build the computerised randomisation system.

2.5 Once the system build is complete, the Software Developer or REDCap Developer will provide access to the build code and training randomisation list (if available) to the Confirming Statistician (the Trial Statistician or designee). At no time should the unblinding key be included in the documentation.

2.6 The Confirming Statistician will complete part 2 detailing the checks made to confirm the system meets the requirements. Suggested checks include a sense check of the build code to see if it agrees with the detail provided in part 1, confirm the correct number of stratification/minimisation factors (if any), the block sizes and random element, and the allocation ratio are present in the training randomisation list and any other suitable checks. If discrepancies are found, this will be discussed with the Software Developer or REDCap Developer, with necessary amendments made to the code until both parties agree.

2.7 Once the confirmation has been completed and passed, part 3 will be completed and signed by both the Confirming Statistician and the Software Developer or REDCap Developer.

2.8 The authorised form will be returned to the Software Developer or REDCap Developer and a copy filed in the Statistics Master File (SMF).

2.9 The randomisation system will not be made live until the Randomisation System Description and Confirmation Document has been fully authorised.

2.10 Randomisation System Description and Confirmation Document Guidance

2.10.1 The Randomisation System Description and Confirmation Document will be completed for the design and build of the randomisation system.

2.10.2 Each version of the document will refer to the applicable version number and effective date of the study protocol.

2.10.3 Current and superseded versions of the document will be retained in the SMF and clearly labelled. Ensure the current version of the document is used for any changes.

2.10.4 Completion guidance for part 1 of the document:

- **Treatment**
  Specify the treatment arms as defined in the study protocol and include the treatment allocation ratio. Do not include the key to the treatments.
- **Randomisation Method**
  The protocol may state the randomisation method but additional information from the Chief Investigator may be required.
- **Stratification**
  Specify the stratification variables, including details of categorisation of continuous or multi-category variables that will be used to define strata. (if applicable).
- **Minimisation**
  Specify the minimisation variables including details of categorisation of continuous or multi-category variables that will be used to define cut-off values (if applicable).
- **Random Element**
  The Software Developer or REDCap Developer will provide details of the random element used (e.g. block size, ratios)
- **Notifications**
  Specify how the researcher will be notified of the treatment arm the participant has been randomised to. The Chief Investigator and/or Trial Manager may provide this detail.
- **Accessibility and storage of randomisation list**
  Specify as stated. The Software Developer or REDCap Developer will advise where the randomisation lists used for the live randomisation system will be stored and who will have access to them.

- **Emergency randomisation**
  Details of procedures where electronic randomisation may fail during time critical randomisations
- **Other Comments**
  Specify any additional information as applicable.

2.11. Confirmation of the randomisation after recruitment has begun

Checks of the balance of randomisation should be performed at regular intervals, such as for DMC reports (closed). Where there is no DMC, these checks should still be performed by the unblinded statistician. See ECTU Central Office WPD_ST_W3: Data Monitoring Committee Reporting and ECTU Central Office WPD ECTU_ST_W5: Statistical Analysis and Reporting for details.

3. RELEVANT DOCUMENTS AND REFERENCES

ECTU Website

- ECTU_SOP_ST_02: Randomisation and Blinding Procedures
- ECTU_WPD_ST_W3: Data Monitoring Committee Reporting
- ECTU_WPD_ST_W5: Statistical Analysis and Reporting

ECTU Shared Drive

- ST002 - Randomisation System Description and Confirmation Document Template

SOP_ST_02, WPD_ST_W6 and ST002 Template

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