SOP 835 Clinical Data Management System – EMERGENCY UNBLINDING

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
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Name of document author:	Martin Pond
Job title of document author:	Head of Data Management, Norwich Clinical Trials Unit, UEA
Name of document author's Line Manager:	Prof Ann Marie Swart
Job title of author's Line Manager:	Director of Norwich Clinical Trials Unit
Supported by:	Julie Dawson NNUH Sarah Ruthven UEA
Assessed and approved by:	Julie Dawson: Research Services Manager NNUH Sarah Ruthven: Research Manager UEA
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This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

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1. Contents

2. Definitions of Terms Used / Glossary

CDMS	Clinical Data Management System
CI	Chief Investigator
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
ICH	International Conference for Harmonisation
NNUH	Norfolk and Norwich University Hospital
PI	Principal Investigator
R&D	Research and Development
SM	Study Manager
SOP	Standard Operating Procedure
SVP	System Validation Plan
UEA	University of East Anglia
TT	Tools and Templates

3. Objectives

Clinical Trials may be 'blinded' to avoid bias.

Double blind trials are those whereby neither the researcher nor the participant knows which treatment the participant is receiving.

The breaking of a code (unblinding) usually occurs when a trial subject has suffered an adverse reaction or a circumstance occurs whereby the Chief Investigator / Sponsor considers unblinding the trial is justified in order to treat the condition, or for example if a participant's child took the medication

4. Scope

Unblinding may not always involve the Data Management Team. For example, others such as Pharmacists or Therapists may also have the details, or the blinding may have been undertaken through a process separate to the Data Management Teams at NNUH or UEA.

5. Purpose

This SOP was written to describe the procedures for unblinding in blinded clinical trials managed by Norwich CTU if such a request is made to the Data Management team. The principles contained in this SOP should be followed for all other requests for unblinding.

6. Rules

Each randomised study must include details about its unblinding procedures in the protocol or in a Trial Specific SOP.

- The study protocol should also specify in detail the agreed process for unblinding in an out of hours emergency (**SOP 320 Developing a Research Protocol**).

7. Procedures

7.1 Authorisation to Unblind a Participant

- Requests for unblinding should only be accepted from the CI/PI or SM unless other specific arrangements have been made for the Trial.

- Where the circumstance demands urgency, the request may be made either by telephone or personal approach to a Data Management Team member
- Or by following the detailed out of hours emergency unblinding process specified in the study protocol and saved in the TMF (**SOP 305 Creating and Maintaining a Trial Master File**).

- If the request to unblind is made face-to-face, precautions should be taken by the Data Management Team member to ensure that the allocation of other subjects is not revealed to the requestor

- Where possible the CI/PI or SM should notify the Sponsor before the code is broken but in the event this is not possible (e.g. an out of hours emergency), the Sponsor should be notified as soon as possible after the event.

7.2 The Unblinding Process

- On receipt of a request for unblinding, the Data Management Team member will find the necessary information from the database and reveal the randomisation details to the requester.
- The Data Management Team member who unblinds the participant should complete an Emergency Unblinding Form (based on an agreed template)
- Store the completed form in the Data Management team's Study Folder as a record of the unblinding.
- A copy of the form must be sent to the unblinded trial statistician

7.3 Online Emergency Unblinding

- Where possible, for blinded trials, the CDMS should include an Emergency Unblinding facility, where specially authorized users can log in and reveal the allocation of a single participant.
- The system would log any attempts at unblinding in the study database. The details of this software would be covered in the Functional Specification.
- Use of this system should be logged, either by the system sending an email to the DBM and to the Study Statistician warning that the Participant's allocation has been revealed,
- **or** by running a regular report from the appropriate section of the database and disseminating the results.

8. References and Related SOP's

SOP No.	SOP Title
SOP 305	Creating and Maintaining a Trial Master File
SOP 320	Developing a Research Protocol

9. Approval

Author	Martin Pond
Role	Head of Data Manager NCTU UEA
Signature	Martin Pond
Date	23/07/2020
Approved & Authorised NNUH	Julie Dawson
Role	Research Services Manager
Signature	Julie Dawson
Date	27/05/2020
Approved & Authorised UEA	Sarah Ruthven
Role	Research Manager
Signature	Sarah Ruthven
Date	28/05/2020

10. Reason for new version and Training Implication

This SOP replaces the previous version number V2.2

Changes made	What changes have been made to the contents of the document
Reason	• New layout • Full Review
Training Implication	No
Actions required	• n/a