Standard Operating Procedure R&D/SOP008
Un-blinding Subjects in an Emergency Situation

1. **Scope**

For use by Chief Investigators and other research active staff undertaking Trust sponsored EU Clinical Trials, staff of the R&D Department and the Cambridge Clinical Trials Unit (CCTU)

2. **Purpose**

The purpose of this SOP is to describe the procedure to un-blind subjects in an emergency situation.

This SOP should be referred to whenever a situation arises whereby it becomes necessary to unblind subjects in an emergency situation.

3. **Definitions and Abbreviations**

The headings below contain the definitions of terms and meaning of abbreviations used within the document.

Common abbreviations and definitions can be found in CCTU/INF001 Common Abbreviations and Definitions.

3.1. **Definitions**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Trust-Sponsored</td>
<td>Sponsored by Cambridge University Hospitals NHS Foundation Trust (CUH) or sponsored by CUH jointly with The University of Cambridge</td>
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<tr>
<td>Blinded</td>
<td>One or more parties are kept unaware of the treatment assignments</td>
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<td>Un-blinding</td>
<td>Reveal the participants treatment assignment in a double-blind trial</td>
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<tr>
<td>EPIC/e-hospital</td>
<td>CUH Electronic Patient Record system provided by EPIC</td>
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3.2. **Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
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<tr>
<td>CI</td>
<td>Chief Investigator</td>
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4. **Undertaken by**

CI/Research team
Holder of the code break information
5. **Items Required**

None

6. **Summary of Significant Changes**

General review and addition of references to EPIC

7. **Method**

The following sections provide a description of the processes to be followed when implementing this document’s procedures.

*Please note that this SOP should be read in conjunction with the research protocol which should explain in detail the agreed process for un-blinding.*

7.1. **Circumstances**

- The study code should only be broken for valid medical or safety reasons e.g. in the case of a severe adverse event where it is necessary for the CI or treating health care professional to know which treatment the patient is receiving before the participant can be treated
- If the person requiring the un-blinding is the CI then they should promptly contact the holder of the code break envelope/list, or their delegate
- If the person requiring the un-blinding is not the CI then that health care professional should notify the CI/research team (see alert sheet at the front of medical notes or the research tab within the e-hospital patient record) that an un-blinding is required for that patient
- An assessment to un-blind should be made in consultation with the clinical team and research team
- Subject to clinical need, where possible members of the research team should remain blinded

7.2. **Code Break**

- The holder of the code break envelope/list or their delegate informs the CI or treating health care professional with the information as requested
- On receipt of the treatment allocation details the CI or treating health care professional deals with the participant’s medical emergency as appropriate
- If the treating health care professional is not the CI, the treating health care professional must inform the CI (see alert sheet at the front of medical notes or the research tab within the e-hospital patient record) of the code break and the reasons for the actions taken as soon as possible
- The CI documents the breaking of the code and the reasons for doing so on the case report form, in the site file and medical notes and according to the clinical trial protocol. It must also be documented at the end of the study in any final study report and/or statistical report
- The holder of the code break envelope/list or their delegate documents the breaking of the code and the reasons for doing so on the code list within the TMF
• The CI notifies the Clinical Trials Unit (who act on behalf of the Sponsor) in writing as soon as possible following the code break detailing the necessity of the code break
• The CI notifies the relevant Research Ethics Committee

8. Monitoring Compliance with and the Effectiveness of this Document

a. Process for Monitoring Compliance and Effectiveness
As part of routine monitoring visits, audit and inspection

b. Standards/Key Performance Indicators
This process forms part of a quality management system. Documents are reviewed every two years

9. References
The Institute of Clinical Research, 2008, Abbreviations used in Clinical Trials.

10. Associated Documents
NA

11. Equality and Diversity Statement
This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

12. Disclaimer
It is the user’s responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

<table>
<thead>
<tr>
<th>Review date</th>
<th>2 years (or earlier in light of new evidence) from approval date</th>
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<tbody>
<tr>
<td>Owning department:</td>
<td>CCTU QA on behalf of R&amp;D</td>
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<td>Supersedes:</td>
<td>R&amp;D/SOP008 V1</td>
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<td>Local reference:</td>
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