

**STANDARD OPERATING PROCEDURE**

**Unblinding subjects in an emergency situation**

**R&D/S/012/2.0**

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VERSION

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## Unblinding subjects in an emergency situation

### 1. **PURPOSE AND SCOPE**

The purpose of this SOP is to describe the procedure to unblind subjects in an emergency situation and is for all Chief Investigators and other research active staff undertaking Trust sponsored (solely or jointly with the University of Cambridge) EU Clinical Trials, and staff of the R&D Department

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

### 2. **ASSOCIATED DOCUMENTS**

009 Pharmacovigilance SOP  
010 Urgent Safety Measures SOP

### 3. **RESPONSIBILITIES**

CI/Research team – to follow the agreed unblinding procedure as outlined in the research protocol and this SOP and report any unblinding to the Clinical Trials Office (CTO) and Ethics Committee

Holder of code break information – to provide unblinding of subjects in emergency situations.

Clinical Trials Office (CTO) – to record code break

### 4. **PROCEDURES**

#### 4.1 Unblinding Subjects

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

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 unblinding is the CI then they should promptly contact the holder of the code break envelope/list, or their delegate.

If the person requiring the unblinding is not the CI then that health care professional should notify the CI/research team (see alert sheet at the front of medical notes) that an unblinding is required for that patient and an assessment to unblind should be made in consultation with the clinical and research teams.

Subject always to clinical need, where possible members of the research team should remain blinded.

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.

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If the treating health care professional is not the CI, the treating health care professional must inform the CI (see alter sheet at the front of medical notes) 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 CRF, 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 Office (acting 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.

**5. ILLUSTRATIONS/APPENDICES**

*None*

**6. CHANGES SINCE LAST VERSION**

<b>Description of changes</b>	
<i>Section Ref:</i>	<i>Brief description of change</i>
	<i>Updated to new template format.</i>
<i>1</i>	<i>Clarification of scope</i>
<i>4.1</i>	<i>Addition of line to clarify reading the SOP in conjunction with the research protocol</i>