





## 1. Purpose

The purpose of this operating procedure is to clearly outline the algorithm for unblinding the study participant treatment code and ensure proper documentation of the circumstances surrounding the unblinding process.

## 2. Responsibilities

**Qualified Investigator (QI):** The QI at the research site is responsible for ensuring the safety of all study participants. It is the responsibility of the QI to contact the MC to discuss the need for unblinding a study participant's treatment code.

**Methods Centre (MC):** The MC is responsible for documenting the process and outcome of unblinding discussions with the QI.

## 3. Procedures

- 3.1 Code breaking (or unblinding) procedures must be clearly established by the MC and relayed to the research sites prior to the initiation of treatment in study patients.
- 3.2 Randomization procedures must be followed to ensure that the treatment code is only able to be broken in the event of any of the following occurrences (unless otherwise specified):
  - 3.2.1 Adverse event or medical emergency where the treatment of the patient is dependent on knowledge of the study treatment code
  - 3.2.2 Accidental administration of the investigational product to a patient not participating in the research.
  - 3.2.3 Any other instance as specified in the study protocol.
- 3.3 The study treatment codes may be stored at the research sites, the MC or both.
- 3.4 Treatment codes stored at the research site will be stored in a secure area where only research staff delegated the responsibility to break a patient treatment code has access.
- 3.5 Treatment codes stored at the MC will be stored in a secure location where only staff not involved in study design, execution and analysis are permitted access.
- 3.6 Whenever possible research sites must notify the MC of their intention to unblind a participant treatment code prior to doing so. If time does not permit the notification of the MC prior to unblinding, the MC should be notified as soon as possible following the unblinding of the patient.
- 3.7 When the research site contacts the MC, the MC will discuss the need to unblind with the site to ensure the treatment code is not broken unnecessarily.
- 3.8 Any discussions between the research site and the MC will be documented.
- 3.9 If the treatment code is broken, the following must be documented:
  - 3.9.1 Patient ID
  - 3.9.2 Date and time the treatment code was broken
  - 3.9.3 Individual who revealed the treatment code
  - 3.9.4 Reason for breaking the treatment code



Study Treatment Code Unblinding  
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3.9.5 Study treatment allocation

3.10 The local REB must be notified of any situation where it was necessary to reveal the patient's treatment allocation.

3.11 At the end of the study, the QI must return all unbroken codes to the MC to prove that the study was blinded throughout.

**4. References**

4.1 ICH GCP Section 4.7: Randomization Procedures and Unblinding

4.2 ICH GCP Section 5.13.4: Manufacturing, Packaging, Labeling, and Coding of Investigational Products