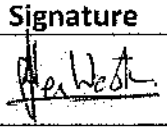
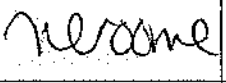
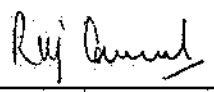
STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_006

SOP Title: Code breaks

Role	Name	Signature	Date
SOP Author	Alex Weston – Principal Pharmacist R&D		02-Mar-2016
SOP Reviewer	Victoria Croome – Clinical Trials Technician		06-Mar-2018
SOP Authoriser	Raj Parekh- Chief Pharmacist		05-APR-2018
SOP Review Date	**June 2020**	Effective date: [illegible]	

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	November 2012	V.1- Initial Version	14-Nov-2012
2	August 2016	V.2 – content reviewed to ensure still current	
3	1-June-2018	Content reviewed to ensure still current	05-Apr-2018

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1. PURPOSE AND CONTEXT

1.1. In an emergency situation where it is in the patient's best interest, it may be necessary to break the code which identifies the treatment a patient taking part in a blinded trial is receiving. This procedure provides information for this situation.

2. DEFINITIONS

- IVRS – Interactive Voice Response System accessed via the telephone
- IWRS – Interactive Web Response System accessed via the internet

3. PROCEDURE and RESPONSIBILITIES

3.1 Location of information

3.1.1. Paper code breaks: these are kept in one of the following locations:

- The main pharmacy site file
- A secure cupboard in pharmacy
- The MARC/R&D manager's office

3.1.2. IVRS/IWRS: for many trials, the code break information is accessed via IVRS or IWRS using the system described in the study protocol. Details of how to access these systems is available in the main pharmacy site file.

3.2 Contact names and numbers

3.2.1 The names and contact numbers of persons to be contacted in order to break the code will be available for each trial. Where possible, the person receiving the request for unblinding should contact the investigator.

3.3 Breaking the code

3.3.1 Requests to break the code should be obtained in writing unless the nature of the emergency dictates otherwise.

3.3.2 Obtain authorisation for breaking the code as directed in the clinical trial protocol.

3.3.3 A summary of code breaking instructions is included in the "clinical trial summary" document of the working documents folders.

3.3.4 For paper code breaks:

- Locate the emergency envelopes and remove the code break for the individual patient involved.
- Open the sealed code break and identify whether the treatment was active or placebo.
- Document on the envelope the date, reason for opening, initial and sign the envelope.

3.3.5 For IVRS/IWRS:

- Follow the procedure in the main pharmacy site file.

3.3.6 Document in the patient's file all details relating to the unblinding including who requested the code break, the reason it was required, the date and time the unblinding occurred and the result of the code break.

3.3.7 Contact the chief investigator and principal investigator to notify them that a patient has been unblinded if this has not already been done.

	Responsibility	Undertaken by	Activity
1	Chief pharmacist	Clinical trials pharmacist	Ensure adequate code break procedures are in place

4. SUPPORTING MATERIAL and ATTACHMENTS

5. TRAINING

- ICH-GCP training
- An understanding of the protocol procedures for unblinding/code breaking
- An understanding of trial legal requirements needed before commencement of trial.

6. REFERENCES