

Standard Operating Procedure (SOP) for handling unblinding requests

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The PITCH trial unblinding requests are handled by Pharmacy staff at all times. This SOP is for the use of the PITCH team so that they are aware of how requests to unblind a randomised participant from the PITCH trial (currently recruiting until May 2007) is managed. Pharmacy's procedure for unblinding can be found in the following document, which they have copies of.

Pharmacy's SOP for handling unblinding requests v 2.0 March 07.doc

Located here:

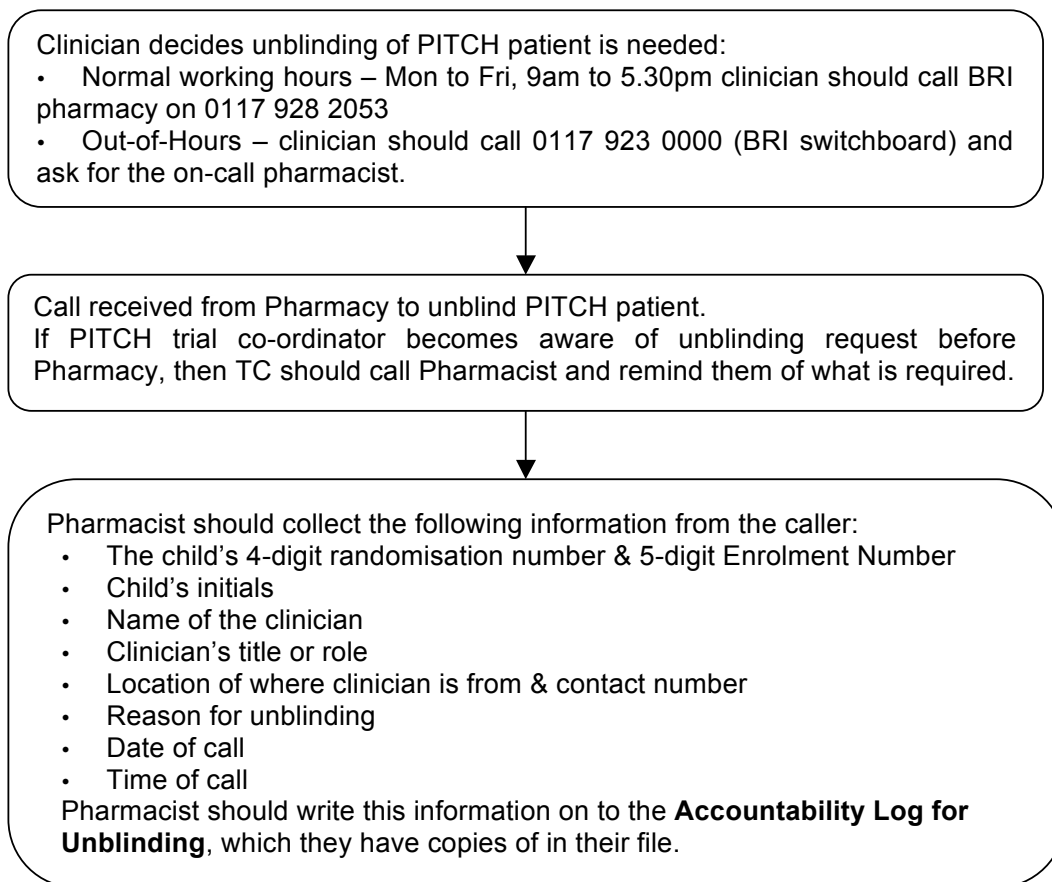
L:\Studies\PITCH\SOPs\Unblinding\current documents

1. Requests to unblind:

Requests for unblinding **should only be accepted from a clinician taking clinical responsibility for the care of the child**. Other than in exceptional circumstances, requests to unblind should not be accepted from parents or relatives, but referred instead to the child's GP.

2. Process to unblind

The flowchart below should be followed:



Pharmacists asks caller to hold whilst unblinding takes place.

To unblind:

- Locate the Unblinding Codes Scratch cards – 1 copy in Pharmacy filing cabinet, 1 copy in On-call pharmacists bag.
- Select the unblinding code with the correct **Randomisation Number**
- Scratch the card to reveal the **Treatment Allocation** and inform the caller of the treatment allocation
- Return the Unblinding Codes back to either the Pharmacy file or the on-call bag.
- **Fax a copy** of the completed **Accountability Log for Unblinding** to: PITCH trial co-ordinator/Dr Alastair Hay on 0117 954 6647
- Keep a copy of the **Accountability Log for Unblinding** in Pharmacy.

PITCH trial co-ordinator receives a faxed copy of **Accountability Log for Unblinding**. On receipt, the TC should:

- Check the Log is completed fully.
- Call Pharmacy to let them know this has been received and query any gaps in the Log.
- Inform the Principal Investigator (AH) of unblinding details.
- Notify the relevant Research Nurse to prevent her being inadvertently unblinded.
- Ensure the RN has informed the parents/guardian of the following:
 - a. That they are still blinded to the medicines
 - b. The importance of continuing with the study
 - c. That they can continue with the study if they wish
 - d. That they can continue to use the study medicines if they wish.
- Update the 'Master accountability log for unblinding- study team (WP, AH).doc' This can be found in L:\Studies\PITCH\SOPs\Unblinding\current documents.
- Complete the 'Operating Procedure or Protocol Deviations.doc'. This can be found under L:\Studies\PITCH\Trial management\Protocol deviations and significant events\Protocol Deviation or Other Significant Events Table.
- Complete the relevant section of the CRF (nurse data collection form).