

## PITCH STUDY

### Pharmacy procedure for handling unblinding requests

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

1. Collect the following information from the caller:
  - The child's **4-digit Randomisation Number** and **5-digit Enrolment number**
  - Child's initials
  - Name of the clinician
  - Clinicians position and/or title
  - Contact number of clinician/caller
  - Location or site where the clinician is from
  - **Reason for unblinding**
  - Date of call
  - Time of call

Write this information in the **Accountability Log for Unblinding**, log can be found behind this procedure.

2. Ask the caller to hold while you complete the unblinding.
3. Locate the Unblinding Codes, which are A4 cards with scratch-off sections to reveal the treatment allocated when scratched. There are 2 copies with Pharmacy and these can be found in:
  - The Clinical Pharmacy Office, level 3 in the grey filing cabinet at the far end of the office in the 3<sup>rd</sup> drawer down, marked Clinical Trials Active in the hanging file marked PITCH Study – **for use during office hours**
  - The On-call pharmacist's bag – **for use during out-of-normal hours**
4. Select the Unblinding Code with the appropriate **Randomisation Number**
5. Using a coin, scratch the card to reveal the **Treatment Allocation**
6. Inform the caller of the **Treatment Allocation**
7. Place the Unblinding Codes back in either the hanging file and back in the grey cabinet or back in the on-call bag.
8. Please **fax a copy** of the completed **Accountability Log for Unblinding** to:

**PITCH trial co-ordinator/Dr Alastair Hay on 0117 954 6647**

**NB: Contact details for PITCH study team should you need them:**

Name	Role	Office hours Tel No	Emergency No.	Email address
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The PITCH trial team will try to warn Pharmacy staff of possible unblindings if they become aware of a request prior to Pharmacy staff.