STANDARD OPERATING PROCEDURE FOR:

OSAC Trial Emergency Unblinding

SOP Details:

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Contents

1 Document History

Revision	Date	Author	Changes
1.0	26 Mar 2013	Harriet Downing, Sue Harris, Amy Holloway	None, this is the first version

2 Background

The OSAC trial is sponsored by the University of Bristol. OSAC trial emergency unblinding requests are handled by UH Bristol Pharmacy staff at all times.

Unblinding is the process by which the randomisation code is broken so that clinical staff, the trial Data Monitoring Committee and/or the Trial Steering Committee become aware of the intervention for a person participating in a trial.

Unblinding must be undertaken by a pre-determined process to ensure that researchers and participants are not unblinded unnecessarily and the study results are not compromised. Equally, unblinding should occur in a responsive manner when it is clinically indicated.

3 Purpose

This document describes the conditions under which a request may arise to unblind a randomised patient from the OSAC trial and the steps that must be taken by the research team in all circumstances to ensure the correct unblinding procedures are followed both before and after UH Bristol Pharmacy carries out the specific act of unblinding according to its SOP (CT 5 02). It also describes the additional actions required of UH Bristol Pharmacy staff, in the event of unblinding for OSAC, before and after following the standard Pharmacy procedures (CT 5 02).

4 Scope

The document refers to emergency unblinding for the OSAC trial only.

5 Definitions & Abbreviations

5.1 Abbreviations

SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SSAR	Serious Suspected Adverse Reaction
SUSAR	Serious Unexpected Adverse Reaction
BRTC	Bristol Randomised Trials Collaboration
CI	Chief Investigator
DMC	Data Monitoring Committee
IMP	Investigational Medicinal Product
MHRA	Medicines and Healthcare products Regulatory Agency
MID	Medicine Identification Number
PI	Principal Investigator
PID	Patient Identification Number
SOP	Standard Operating Procedure
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee
TSF	Trial Site File
UH Bristol	University Hospitals Bristol NHS Foundation Trust
UoB	University of Bristol

5.2 Definitions

Unblinding can occur in two contexts in the OSAC trial:

- when clinically indicated (emergency unblinding)
- for data analysis purposes.

5.2.1. Clinical indications/emergency unblinding circumstances:

- there is a medical emergency and unblinding will influence the patient's treatment;

- the patient has suffered an Unexpected Serious Adverse Event or Suspected Unexpected Serious Adverse Reaction (see UH Bristol Pharmacy Emergency Code Break Procedure CT 5 02, Appendix 1) and the intervention must be made known.

Requests for emergency unblinding can only be made by a healthcare professional with clinical responsibility for the patient's care and these requests are handled by UH Bristol Pharmacy at all times.

Other than in exceptional circumstances, requests to unblind should not be accepted from patients and relatives, but referred instead to the patient's GP.

5.2.2 Data analysis purposes:-

- Unblinding can also occur at the request of the Data Monitoring Committee (DMC), and at the conclusion of the trial to determine the effect of the intervention.
- Unblinding requests for data analysis purposes, e.g. as may be requested by the DMC, are handled by the Bristol Randomised Trials Collaboration. See section 8.2.4.

6 Pre-Requisites

6.1 Pre-Requisite Knowledge & Training

- Certified training in ICH-GCP (Good Clinical Practice)
- OSAC Trial recruitment training

6.2 Pre-Requisite Equipment & Systems

None.

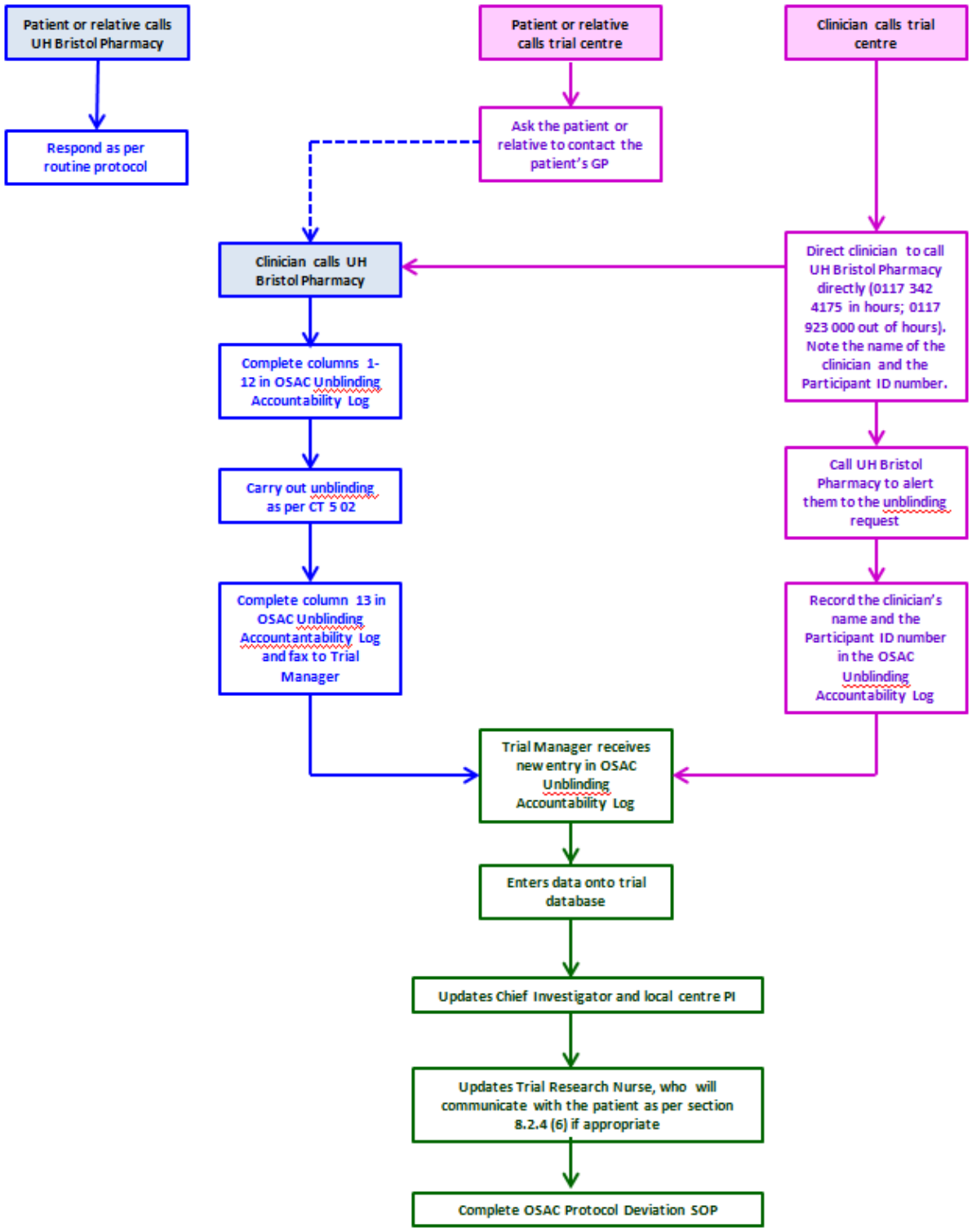
7 Roles & Responsibilities (Actors)

Who	What & Why
Chief Investigator	• Authorises this SOP jointly with the trial sponsor.
Principal Investigator	• Ensures SOP is adhered to in all local sites.
Bristol Randomised Trials Collaboration	• Has access to the unblinded data; provides 'unblinding' function for trial data analysis for review by DMC for safety monitoring purposes but not to OSAC TMG unless previously authorised by the TSC. • Does not provide a role in clinically indicated (emergency) unblinding.
UH Bristol Pharmacy	• Responsible for actioning all emergency unblinding requests from healthcare professionals according to the UH Bristol unblinding SOP CT 5 02. • Reports all unblinding incidents (but not outcomes) to the Trial Manager / CI as per SOP CT 5 02. • Has access to the unblinded data.
Trial Sponsor (UoB)	• Authorises this SOP jointly with the CI.
Trial Manager	• Acts in a manner so as to maintain blinding of whole trial research team. • Maintains Unblinding Accountability Log (which does not include the outcome of unblinding, i.e. the treatment allocation, so that blinding of the research team is

Who	What & Why
	preserved) • Ensure all requests for unblinding are reported to the CI. • To train recruiting clinicians to explain to patients about the Trial Participation Card. • To train recruiting clinicians in the use of the emergency unblinding service.
Trial Research Nurse	• Acts in a manner so as to maintain blinding of all of the trial research team. • To respond to any unblinding requests from patients as set out in this SOP. • To train recruiting clinicians to explain to patients about the Trial Participation Card. • To train recruiting clinicians in the use of the emergency unblinding service.
Trial Administrator	• Acts in a manner so as to maintain blinding of all of the trial research team.
GP Practices	• To be aware of the OSAC trial emergency unblinding procedure and to take responsibility for making any emergency unblinding requests on behalf of OSAC trial patients where clinically indicated • To teach each recruited patient about the purpose of the Trial Participation Card and that the patient should carry it on their person.
Data Monitoring Committee	• Monitors the safety of the trial by scrutinising the adverse event data. • May request unblinded data from the BRTC for safety monitoring purposes.
Trial Steering Committee	• Makes decisions regarding the safety of the trial and whether the trial should at any time be stopped due to safety concerns.
Trial Management Group	• To be aware of the OSAC trial emergency unblinding procedure and to agree on the management of individual emergency unblinding requests in terms of inclusion in the trial dataset.

8 Procedure

8.1 Procedure Diagram



8.2 Procedure Narrative

Each of the points at which the question of unblinding arises will be described below, with the actions that should be taken.

8.2.1 Emergency unblinding requests received by the trial research team

8.2.1.1 From research participants

1. If a patient or patient's relative contacts the trial team with a request to be unblinded, the research team will ask the caller to contact the patient's GP.

2. If the situation appears to be medically exceptional, e.g. the patient has called an ambulance, the situation must be referred immediately by the trial team to the following sources in order of priority:-

- UH Bristol Pharmacy Clinical Trials Unit;
- OSAC Trial Research Nurse;
- Trial centre PI **or**
- CI (who will liaise with the UH Bristol Pharmacy to resolve the issue).

3. The member of the research team who has received and responded to the request, as above, will complete the OSAC Unblinding Accountability Log, whether the request results in unblinding or not.

8.2.1.2 From clinicians

1. UH Bristol Pharmacy should be the first point of contact:-
   - In a medical emergency, healthcare professionals will have access to the 24-hour unblinding service provided by UH Bristol Pharmacy, the details of which are provided in the Trial Site File, on the Trial Participation Card carried by OSAC trial patients and on the OSAC trial website:-

     i) In normal working hours (Monday to Friday, 9:00am to 5:00pm), the clinician will call UH Bristol Pharmacy Clinical Trials Unit: **0117 342 4175** and quote the PID and the MID numbers from the patient's Trial Participation Card.

     ii) Out-of-hours, the Trust on-call Emergency Duty Pharmacist is available via the Trust switchboard: **0117 923 0000**.

2. Recruiting clinicians will explain the purpose of the Trial Participation Card to all patients recruited into the OSAC trial. The clinician will recommend that the patient carries the Trial Participation Card on their person for the duration of their involvement in the trial.

3. Clinicians participating in the OSAC trial will receive training on how to use the trial unblinding service before recruitment starts at the site.

4. When a clinician decides whether unblinding of the OSAC patient is clinically necessary, they must put the request directly to UH Bristol Pharmacy.

5. The Medicine ID and Participant ID will be the default and preferred combination of data used to unblind OSAC patients where clinically indicated.

6. The OSAC trial will make provision for unblinding in the (unlikely) emergency situation where the clinician does not have access to the Trial Participation Card (and therefore to the Medicine ID and Participant ID numbers) and it is necessary to be able to unblind the patient from the patient's name and date of birth, or from the patient's name only.

7. To enable this, the OSAC trial team will provide the Pharmacy Trials Team with a complete list of Participant ID numbers against patient names and date of birth. This confidential list will be updated by the OSAC trial team on each day that a patient (or patients) are recruited to the trial, and the complete, cumulative list will be faxed to the Pharmacy secure fax number (0117 342 4304) on the same working day that it is updated.

8. The Pharmacy will store this list with the OSAC trial unblinding data in the Pharmacy trial file, and replace outdated lists on receipt of updated faxed lists from the trial team.

9. This information will be filed in the Pharmacy trial file for access during working hours, but will not be transferred to the on-call workspace. Therefore if unblinding is required out of hours and only the patient details are available, the on-call pharmacist will be required to come in to the hospital to find out the treatment allocation.

10. In due course, and prior to the start of multi-centre recruitment in September 2013, the OSAC Trial Management Database (TMD) will enable the Pharmacy trials team to identify OSAC trial participants from patient name via unique password-protected access by the Pharmacist to the TMD.

11. If the Participant ID and Medicine ID number do not correspond, the Pharmacy will refer to the Medicine ID number as the most reliable, based on the master unblinded list from the IMP supplier (Piramal) which is stored in the Pharmacy trial file.

8.2.1.3 If the clinician contacts trial team first

1. If the clinician contacts the trial team first, and the team therefore becomes aware of the unblinding request before UH Bristol Pharmacy, the Trial Manager will:
   - Record the clinician's name and the relevant PID on the **OSAC Unblinding Accountability Log** (Appendix 2).
   - Ensure the clinician has the relevant information to hand (PID and MID numbers).
   - Ask the clinician to contact UH Bristol Pharmacy directly on the above telephone numbers.
   - Call UH Bristol Pharmacy to advise them that the request has been made.
   - All requests for unblinding that are made known to the research team must be recorded on the OSAC Unblinding Accountability Log, whether or not unblinding occurs.

8.2.1.4 Emergency unblinding requests from OSAC trial PIs / CI

1. An OSAC trial team investigator (centre PI or CI) may issue a clinically indicated request for emergency unblinding in response to a reported SAE or SUSAR.

2. In this case, the PI / CI will make the request directly to UH Bristol Pharmacy as a clinician.

3. The request would be handled by UH Bristol Pharmacy as per their SOP (Appendix 1).

8.2.1.5 Emergency unblinding requests from OSAC DMC

1. A request for emergency unblinding by the DMC in response to trial adverse event data will be referred to the BRTC.

8.2.2 Emergency unblinding requests received by UH Bristol Pharmacy

1. Telephone requests for emergency unblinding made directly to UH Bristol Pharmacy by the patient or a relative will be handled as per normal UH Bristol operator and Pharmacy practice.

2. For any OSAC emergency unblinding request received from a clinician taking responsibility for the participant's care, the Pharmacy will respond as follows:
   - Collect the following information from the caller and record on the OSAC Trial Unblinding Accountability Log:
     i) Patient's **6-digit OSAC PID number**
     ii) Patient's **5-digit OSAC MID number**
     iii) Patient's initials
     iv) Tick box to confirm request made by clinician
     v) Name of clinician making request
     vi) Location / site from which request being made
     vii) **Contact number of clinician making request**
     viii) **Reason for unblinding**
     ix) Name of UH Bristol Pharmacy staff member taking the call
     x) Tick box to confirm call is being received at UH Bristol Pharmacy
     xi) Date of call
     xii) Time of call

   - Take the caller's details and tell them that they will be phoned back within a certain period of time, while unblinding is completed in line with UH Bristol SOP CT 5 02 (Appendix 1).

   - Once unblinding is completed, inform the caller of the treatment allocation.

   - Update column 13 of the OSAC Unblinding Accountability Log to confirm whether the unblinding occurred or did not occur. **Do not** write the outcome of the unblinding.

   - Fax the OSAC Unblinding Accountability Log (which does not give the treatment allocation) as soon as possible to the OSAC Trial Manager: 0117 928 7341 (secure fax).

   - Keep a copy of the OSAC Unblinding Accountability Log in the Pharmacy trial file.

   - If unblinding is done out of hours by the On-Call Pharmacist, the preceding three points (updating the OSAC Unblinding Accountability Log, faxing it to the OSAC Trial Manager and filing it in the Pharmacy trial file) will take place on the next

working day, once the On-Call Pharmacist has handed over to the Pharmacy Trials Team.

- Complete the **Emergency Drug Information / Code Break for Clinical Trials Drugs form** (provided at end of SOP CT 5 02; Appendix 1) as soon as possible and give to the Pharmacy trials staff.

8.2.3 Recording and reporting OSAC unblinding requests

1. On receipt of a faxed copy of the OSAC Unblinding Accountability Log, the Trial Manager will check that the log is completed fully.

2. Call UH Bristol Pharmacy to let them know that the log has been received, and to query any information gaps in the Log.

3. Inform the CI of the Log contents.

4. Notify the relevant centre PI.

5. Notify the Trial Research Nurse to prevent the Nurse being inadvertently unblinded.

6. Ensure the Research Nurse informs the participant of the following:
   - the Research Nurse is still blinded to the trial medicines;
   - the participant can continue to take part in the trial if they wish;
   - if appropriate, the participant can continue to use the trial medicines if they wish;
   - the importance of continuing with the trial.

7. Update the Trial Management Database with the information on the Unblinding Accountability Log;

8. Complete the OSAC Protocol Deviations SOP (to be drafted).

8.2.4 Other unblinding requests

1. Non-emergency non-clinically indicated unblinding requests may be made by the DMC to the TMG for data analysis purposes. All such requests will be handled by the BRTC as follows:
   - The Bristol trial team will forward the clinical dataset (the OSAC clinical database download as a result of which the DMC data analysis unblinding request has arisen) to the allocated member of staff within the BRTC;

   - The BRTC staff member will identify the patients by treatment group but still blinded to allocation (i.e. Group 1 and Group 2);

   - If the DMC so request, BRTC will provide the DMC with the same information as above, but unblinded (i.e. Group 1 = active; Group 2 = placebo);

   - The BRTC will forward these data directly to the DMC so as to maintain blinding of the trial team.

2. All DMC requests for unblinded data must be channelled through the CI / TMG; the request itself will be handled only by the relevant member of staff within BRTC so as to maintain blinding of the trial team.

3. Non-clinical unblinding requests will be recorded on the same accountability log.

9 Quality Control Measures

A "mock unblinding" will be carried out prior to the start of recruitment (issue of patient packs to GP practices) to ensure that the above processes work. This will be documented and filed.

10 Related Documents

UH Bristol Emergency Code Break Procedure, version CT 5 02 (see Appendix 1)

OSAC Adverse Event Reporting SOP v1.0 (14 Mar 2013)

11 Additional Guidelines

N/A

12 Appendices

12.1 Appendix 1: UH Bristol Emergency Code Break Procedure (CT 5 02, version 4.0)

University Hospitals Bristol NHS
NHS Foundation Trust

Pharmacy - Standard Operating Procedure

Clinical Trials

Emergency Code Break Procedure (CT 5 02).

This procedure has been designed to assist pharmacy staff, including on-call pharmacy staff, to manage requests for unblinding clinical trials or code breaking in an emergency.

Clinical trial investigators or any physician treating a patient may approach pharmacy staff in an emergency and request for a trial to be unblinded.

Q Who can unblind a trial or code break?
A Any Pharmacist or Technician who is authorised to unblind a trial.

Opening Hours

Pharmacy Production, Pharmacy Parenteral Services (PSU), Pharmacy Trials Unit (PTU), Bristol Eye Hospital Dispensary, Bristol Royal Hospital for Children Dispensary and St. Michaels Pharmacy are all **open until 5pm.**

If a patient/doctor or trial monitor telephones (PTU or BEH) and a call is not answered then an answerphone message will direct urgent calls (e.g. requests for unblinding) to the Bristol Royal Infirmary Dispensary.

After 5pm - answerphone messages (PTU and BEH) direct callers to the Bristol Royal Infirmary Dispensary or UH Bristol switchboard.
The staff working in the Bristol Royal Infirmary Dispensary will help if possible, if they unable to help the caller they will direct the caller (via switchboard) to the on-call Pharmacist who has been trained to respond to requests for unblinding.
UH Bristol switchboard will transfer any calls for pharmacy to the on-call pharmacist.

Oncall Pharmacists
A list of the trials that may require unblinding can be found in the clinical trials folder in the "emergency duty service" section of the Pharmacy Workspace on the trust intranet (refer to section entitled "How to access clinical trials information on the Pharmacy Workspace" at the end of the document).
The list specifies what is involved in the unblinding of patient's medication for that trial, eg. code break envelope, information on workspace, contact Investigator etc.

Procedure

1. If you are approached by a doctor requesting that you un-blind a patient's trial medication you must consider the following:
   - The information you provide to the doctor may disqualify the patient's data from being included in the clinical trial
   - The patient may be permanently withdrawn from the clinical trial
2. This should not stop you finding the identity of a patient's trial medication. If after discussion with the doctor you ascertain that the situation is a medical emergency, unblinding will influence the patient's treatment or the patient has suffered an unexpected serious adverse event, the identity of any trial medication must be ascertained.

3. Please make a record of any information given to the doctors and inform the trials staff at the earliest opportunity as the Investigator and Trial Co-ordinator or Clinical Research Associate will need to be contacted.
4. Please complete all parts of the **Emergency Drug Information/ Code Break for Clinical Trials Drugs Form** overleaf and give to the pharmacy trials staff as soon as possible.

Code Break Envelopes

1. The code break envelopes may be kept with the investigator, research nurses or pharmacy. The details of the location of the code break envelopes can be found in the relevant trial file and/or in the unblinding list found on the "emergency duty service" section of the Pharmacy Workspace on the trust intranet.
2. If pharmacy is holding the code break envelopes they are kept in the top drawer of the black filing cabinet located in the Pharmacy Clinical Trials Unit. Each trial has a separate hanging file that will contain the code break envelopes.
3. Code break envelopes will have the trial details and patients randomisation number clearly marked on the envelope. It is essential that you obtain sufficient information from the physician to ensure you open the correct envelope.
4. Locate the appropriate envelope, open it and pass on the information to the doctors. Please photocopy the envelope and give to the ward for filing in patient notes.
   Ensure the original is kept in the pharmacy file.
5. Place the opened code break into an envelope and seal, then sign and date across the seal. On the front of the envelope write the trial number, patient initials and patient trial number.

Interactive Voice/Web Response Systems (IVRS/IWRS)

IVRS/IWRS are more frequently being used as a method of randomising patients for commercial trials.
If a trial utilises an IVRS/IWRS this will be made clear in the summary sheet in the front of the clinical trial folder.

NOTE: Pharmacy does not always have access via the IVRS/IWRS to unblind a patient's randomisation. In these circumstances it may be necessary to contact the investigator or research nurse who will be able to use the IVRS/IWRS to unblind the patient's randomisation or the drug company directly. Contact details for the investigator, research nurse and drug company can be found on the summary sheet prepared for each clinical trial in the front of the trial folder.

Trial file and code break envelope locations

The clinical trial folders (containing the clinical trial protocol, summary information sheet and dispensing protocol) and unblinding information including location of code-break envelopes (if available) are located in the following locations.

Hospital Site	Location of Clinical Trial files	Location of Code Break envelopes (if available)
Pharmacy Trials Unit (PTU) in Bristol Royal Infirmary (BRI)	Pharmacy Clinical Trials Unit – stored on shelves as you come through the entrance.	Pharmacy Clinical Trials Unit – in the top drawer of the black filing cabinet located in the dispensing area.
Bristol Eye Hospital (BEH)	Stored on shelves, on the left of the front door as you come into the dispensary	In filing cabinet in office. 2nd drawer down in sleeve marked 'clinical trial code breaks'
South Bristol Community Hospital (SBCH)	Currently no clinical trial folders held on site	

Bristol Royal Children's Hospital (BRCH)	Dispensing files are stored on shelves above dispensing bench in out-patient dispensary. Files containing protocols and approvals are stored on shelves behind the storage drawers.	Code-break envelopes if available are stored in BRI. Details of voice activated systems if used will be in trial folders stored in children's hospital dispensary
St. Michaels Hospital	Stored on book shelves. Book shelves located between hatch and office.	Trials currently running at St. Michaels do not require code-breaks
Parental Services Unit (PSU)	Stored on the two shelving units opposite the door in the main PSU office.	Trials currently running in PSU do not require code-breaks. On the (very) rare occasion that an oncology/haematology study involves code break for a cytotoxic drug; the investigator is informed that PSU does not offer code-breaking facilities out-of-hours. If a code break envelope is necessary these should be with the trial investigator / research nurse.
Production (BRI Level 3)	Stored on two top shelves on the right behind door and middle drawer of filing cabinet in Ross's office. This office is second office through first door on right as you enter production	The Production manager specifically informs investigators that pharmacy production does not offer code-breaking facilities out of hours. If a code break envelope is necessary these should be with the trial investigator / research nurse

How to access clinical trials information on the Pharmacy Workspace

Using the UH Bristol intranet select the tab for **"Workspaces"** then scroll down until you find the **"Pharmacy"** workspace under the sub-heading "Team Workspaces". Double click on the **"Pharmacy"** workspace.

On the left of the screen you will see a tab called **"Emergency Duty Services".** Click once on this tab.

On the next screen you should select the appropriate information you are looking for. Click once on either 'Production', 'PSU' or 'Clinical Information' if you are looking for Pharmacy Clinical Trials from the Pharmacy Trials Unit.

If you select **'Clinical Information'** on the next page you will need to select **'Clinical Trials'**. If you do this you will then have a list of files to select from depending on which trial you are looking for.

There are lists that detail the blinded studies for BEH, BCH, BHOC and BRI and individual patient lists for studies which we are most likely to be involved in unblinding.

NOTE: The "Pharmacy Workspace" is only accessible for Pharmacy staff.

Emergency Drug Information/ Code Break for Clinical Trials Drugs Form

Date: Time:

Trial Name and Number:

Patient Name: Hospital Number:

Ward: Admitting Doctor:
Contact/Bleep Number:

Patient Trial Number:

Reason for information (reason for admission):

Information requested:

Summary of Information given:

Code Break requested – Yes / No

Code break carried out – Yes / No
(Please attach envelope if opened)

Signed Date

Trials Staff use

Investigator Informed – Yes / No

CRA/ Trial Co-ordinator Informed – Yes / No
Date

Action to be taken:

Document Management System (DMS) and change control information			
Document keywords (for DMS search)	Code break Unblinding Clinical trials		
Version Number:	4.0	Description of Change:	Updated location of trial files.
Major/Minor Change:		Staff Group(s) if applicable:	

Issued by: Sally-Ann Hall Reviewed by (1): Reviewed by (2):
Issue date: 28/05/2012 Review date (1): Review date (2): 28/05/2013
Version Number: 4.0 Page 5 of 5

12.2 Appendix 2: OSAC Unblinding Accountability Log v1.0, 26 March 2013

UH Bristol Pharmacy
Pharmacy staff please complete columns 1-12 of this log, in the event of any unblinding request relating to an OSAC trial participant, and fax to the number below.

OSAC trial staff
If unblinding requests are received by a member of the OSAC trial research team, the researcher should contact UH Bristol Pharmacy immediately to advise them of the request, then complete columns 1-12 of this log and fax to the number below.

Please record all requests to unblind treatment, even those that were subsequently deemed not necessary to unblind (and hence were not unblinded).

FAX ALL ENTRIES TO 0117 928 7341

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Participant ID	**Medicine ID**	**Patient initials**	**Request made by (tick box): Clinician, Patient, or Other (please specify)**	**Name of person making unblinding request**	**Location or OSAC site of person making request**	**Contact number of person making request**	**Reason for unblinding request (please record in full the difference unblinding will make to the patient's management)**	**Name of person taking the call**	**Location of person taking the call**	**Date (dd/mm/yyyy)**	**Time (24 hr 00:00)**	**Action taken, for example:** **Pharmacy actions** Unblinded Not unblinded **Trial centre actions** Reported to Pharmacy Other (pls specify)	**Chief Investigator signature + date**	**Date (dd/mm/yyyy)**
			Clinician ☐ **Other** ☐ **Patient** ☐ **If other, whom:**						**Pharmacy** ☐ **Trial centre** ☐					
			Clinician ☐ **Other** ☐ **Patient** ☐ **If other, whom:**						**Pharmacy** ☐ **Trial centre** ☐					
			Clinician ☐ **Other** ☐ **Patient** ☐ **If other, whom:**						**Pharmacy** ☐ **Trial centre** ☐					