

OSAC TRIAL EMERGENCY UNBLINDING INSTRUCTIONS FOR RECRUITING SITES (SEE EMERGENCY UNBLINDING STANDARD OPERATING PROCEDURE, v1.0, 26/03/2013)

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 OSAC SOP Appendix 1 - UH Bristol Pharmacy Emergency Code Break Procedure) 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.

1. UH Bristol Pharmacy should be the first point of contact for clinicians:-

- When it is clinically necessary for the unblinding of a OSAC patient, the clinician **must put the request directly to UH Bristol Pharmacy**;
- In a medical emergency, please access the 24-hour unblinding service provided by UH Bristol Pharmacy;
- Contact details are found in the Trial Site File, on the Trial Participation Card carried by the patient and on the OSAC trial website:-

- i) In normal working hours (Monday to Friday, 9:00am to 5:00pm), please call UH Bristol Pharmacy Clinical Trials Unit: **0117 342 4175** and quote the PID and 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**.

- The Trial Participation Card should be carried by all trial participants for the duration of their involvement in the trial;
- All OSAC recruiting sites will receive training on using the trial unblinding service before recruitment starts;
- If the patient **is not** carrying their Trial Participation Card in an emergency situation, it will be possible to unblind the patient using their name and date of birth (or name only).

2. Clinicians contacting trial team in the first instance

- If the clinician contacts the trial team with an unblinding request before contacting UH Bristol Pharmacy, the Trial Manager will:
 - Record the clinician's name and relevant PID on the **OSAC Unblinding Accountability Log**;
 - Ensure the clinician has the 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.