STANDARD OPERATING PROCEDURE FOR:

Fax Transmissions of OSAC Trial Related Documents

SOP Details:

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1 Document History

Revision	Date	Author	Changes
1.0	7 Mar 2013	Annie Sadoo	None, this is the first version

2 Background

The Data Protection Act 1998 provides for the regulation of processing information relating to individuals, including the obtaining, holding, use or disclosure of such information. The seventh principle of the Act states that "appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data". The Act also defines processing to include "disclosure of the information or data by transmission, dissemination or otherwise making available".

Therefore, the research team will implement security measures that restrict the transfer and holding of personal data.

3 Purpose

This document outlines the responsibility of all staff working on the OSAC Trial to adhere to data protection regulations and to take every measure to ensure that patient identifiable

information is not made available to unauthorized persons or groups and treated in a manner to risk inappropriate disclosure.

This is the reference document for the trial and should be used by all recruiting site staff, and all members of research and administrative staff working on the trial.

4 Scope

The secure fax medium must be used for the exchange of trial management information including patient identifiable and clinical data between primary care clinical teams at recruiting GP practices, OSAC trial research staff at the four trial centres (Bristol, Oxford, Nottingham and Southampton), the University Hospitals Bristol Pharmacy CTU, and the University Hospitals Bristol Research and Innovation team (acting as the independent trial monitor). This includes the exchange of routine recruitment data and urgent notification of patient safety data.

5 Definitions & Abbreviations

CRF	Case Report Form
CTU	Clinical Trials Unit
IMP	Investigational Medicinal Product
MHRA	Medicines and Healthcare products Regulatory Agency
NOS	Nottingham; Oxford; Southampton (OSAC trial centres)
SAE	Serious Adverse Event
SUSAR	Serious Unsuspected Adverse Reaction
MHRA	Medicines and Healthcare Products Regulatory Agency
N/A	Not Applicable
UH Bristol	University Hospitals Bristol NHS Foundation Trust

6 Pre-Requisites

6.1 Pre-Requisite Knowledge & Training

- Certified training in ICH-GCP (Good Clinical Practice)

7 Roles & Responsibilities

Who	What & Why
Principal Investigator	Ensures SOP is adhered to in all local sites.
Trial Manager	Ensures SOP is adhered to in all local sites
Trial Research Nurse	Adherence to content of this SOP in all trial operations.
Trial Research Administrator (Bristol centre)	Updating of this SOP and adherence to content in all trial operations.
OSAC trial staff at the NOS centres	Adherence to content of this SOP in all trial operations.
GP practices	Adherence to content of this SOP in all recruitment activity.

Who	What & Why
UH Bristol pharmacy	Responsibility to action all urgent notifications from healthcare professionals and OSAC research staff.

8 Procedure

8.1 Procedure Narrative

Urgent Notifications

1. In keeping with trial protocol, MHRA guidelines, EU directive and UK Clinical Trial Regulations key members of staff must be informed in the event an OSAC participant experiences a serious adverse event or serious unexpected adverse event.

2. The following documents relate to urgent notifications to OSAC trial centres and UH Bristol pharmacy. Designated personnel will fax the completed documents in timeframes stipulated on the respective forms to the appropriate named recipient.

3. Documents relating to urgent notifications:
- OSAC Unblinding Accountability Log
- SAE Reporting Forms:
  - OSAC Trial SAE/SUSAR Initial Report Form
  - OSAC Trial SAE/SUSAR Follow-up Report Form

Routine Recruitment Information

1. Trial centres need to know in real time when a patient has consented to participate in the trial along with their contact details to enable patient follow-up.

2. Designated GP practice staff will fax a copy of the consent form and participant registration details on CRF3 before posting to the local trial centre.

3. GP practice staff will be transmitting confidential patient information which contains the following patient identifiable data:
- Surname
- Forename
- Date of birth
- NHS number
- Postcode
- Gender
- Telephone number
- Patient ID number
- Other details (e.g. ethnicity, occupation and employment).

4. It is imperative that CRF3 is only sent to the local trial centre via secure fax transmission before being posted. It contains the EQ-5D-5L standardised questionnaire used as a measure of

health outcome. OSAC is registered with permission to use the paper version of this questionnaire only. Thus, we may not collect or store data via digital representations, e.g. the web.

5. Other documents to fax to the local trial centre via secure fax transmission and in timeframes stated on the respective forms or relevant SOPs:

- OSAC Screening Log
- OSAC Trial GP Practice Delegation Log
- OSAC Withdrawal Form
- IMP Handling Documents –
    - OSAC IMP Storage Risk Assessment Form
    - OSAC Trial Patient Pack Requisition, Transfer and Receipt Form
    - OSAC Trial IMP Storage Temperature Monitoring Log
    - Significant Temperature Variations Log
    - OSAC Trial GP Practice Patient Pack Accountability Log

9 Quality Control Measures

1. One of the most common breaches of confidentiality occurs when documents containing patient identifiable information are sent by fax. To minimize this, the fax machine should be placed in a secure location where information cannot easily be seen by unauthorized persons. The research and administrative team will ensure, as far as practicable, that data cannot be intercepted or seen by anyone other than the research team.

2. When a fax is sent the OSAC trial fax cover front sheet (Appendix 1) must be used. This will include the following details:

- Name and contact details of the sender
- Details of the intended recipient
- Number of pages in total
- Confidentiality notice

3. File copies of the transmission verification reports where appropriate:–

- GP sites in your OSAC Site File
- Trial centres in your OSAC Trial Master File.

4. Where possible, the GP practice should put policies and procedures in place for the handling of confidential information received by fax, e.g. ensuring an appropriate person is responsible for collecting and delivering any faxed information to the appropriate person.

10 Related Documents

OSAC Trial Fax Cover Front Sheet (Appendix 1)

11 Additional Guidelines

1. Refrain from sending faxes to the trial centre if they are not going to be seen for some time and whenever possible send transmissions within office opening times.

2. Do not leave information unattended whilst a fax is being transmitted.

3. If it is possible, store the fax number in the fax machine memory or assign to the OSAC trial a speed dial number.

4. Follow-up with an email or telephone call to the named fax recipient stating that the fax has been sent. The named recipient must reply to confirm the fax has been received.

12 Appendix 1 – OSAC Trial Fax Cover Sheet

DATE:

THE INFORMATION CONTAINED IN THIS FAX IS **STRICTLY CONFIDENTIAL** AND INTENDED FOR THE NAMED RECIPIENT ONLY. IF YOU ARE NOT THE NAMED RECIPIENT YOU MUST NOT COPY, DISTRIBUTE OR DISSEMINATE THIS INFORMATION, NOR DISCLOSE ITS CONTENTS TO ANY PERSON. IF YOU HAVE RECEIVED THIS FAX IN ERROR, PLEASE NOTIFY THE SENDER IMMEDIATELY. THANK YOU.

Send to: Bristol Trial Centre* / UH Bristol Monitoring Team – SAEs/SUSARs only* (*delete as necessary)	**From:**
Attention:	**Site Name:**
Phone Number: 0117 342 0233 (UH Bristol Monitoring Team – SAEs/SUSARs only)	**Phone Number:**
Fax Number: 0117 928 7341 (Bristol Trial Centre) * / 0117 324 0239 (UH Bristol Monitoring Team – SAEs/SUSARs only)* (*delete as necessary)	**Number of Pages, Including Cover:**

❑ URGENT ❑ URGENT: SAE/SUSAR REPORT FOR UH BRISTOL MONITOR ❑ REPLY ASAP ❑ PLEAS COMMENT

❑ PLEASE REVIEW ❑ FOR YOUR INFORMATION

COMMENTS:

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