

**UNIVERSITY HOSPITAL OF SOUTH MANCHESTER**  
**NHS FOUNDATION TRUST**  
**CLINICAL TRIALS MONITORING SELF-ASSESSMENT FORM**

The self-assessment form makes reference to essential documentation. Essential documents **“are those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced”** (ICH Harmonised Tripartite Guideline for Good Clinical Practice). The relevant ICH GCP reference is provided for ease of interpretation, for any category which you are unsure about please refer to the relevant ICH GCP point for clarification (click to access the guidelines: <http://www.ich.org/LOB/media/MEDIA482.pdf>) or contact the Trust Research Governance Manager, email: [sian.hanison@manchester.ac.uk](mailto:sian.hanison@manchester.ac.uk), Phone: ext: 5773.

Depending on the type of study and sponsor, some studies require different regulatory documents. Please tick the relevant box for all the questions within each section and note that for questions that do not apply to your research, you have the option to select “N/A” (not applicable).

This form must be returned to the R&D office by **Friday 3<sup>rd</sup> April 2009** and can be returned in electronic format. Alternatively, a hardcopy can be returned marked for the attention of the Trust’s Research Governance Manager (details at end).

**Please note that any or all of the documents addressed in this self-assessment form may be subject to, and should be made available for audit/monitoring by the Trust and inspection by the Competent Authority.**

**Please insert details from attached spreadsheet**

**Principal Investigator:**

**Study title:**

**R&D Reference Number:**

Please complete the information requested below.

1. Official documents (located in Trial File)	ICH GCP reference	yes	no	Don't know	In process	Not applicable
Signed/dated study protocol and amendments/modifications	8.2.2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Subject Information sheet and informed consent	4.8.1, 4.8.11, 8.2.3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ethic committees written approval(s) and correspondences	4.4.1, 8.2.7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ethics annual/interim and final report(s)	3.4.1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Regulatory Authority Approvals (where required)	8.2.9	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Insurance statement/indemnity (where required)	5.8.1, 8.2.5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Advertisements for subjects/patient recruitment and amendments	8.2.3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Signed Agreement(s) (signed and dated)	5.6.3, 8.2.6	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Financial aspects of the study (signed and dated)	4.9.6, 8.2.4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Authorised signature form	8.3.24	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CVs/biographies of site staff	8.2.10	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Records of research team meetings	3.4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>2. Case Reports forms/source documentation</b>						
Completed CRFs (copies) signed and dated	4.9.1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CRFs are legible, accurate and complete?	4.9.3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CRFs are being properly stored		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Documentation of CRF corrections (copy)	8.3.15	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
All withdrawals and dropouts of enrolled subjects from the trial are reported and explained on the CRFs	4.9.1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<b>3. Record of supplies (This information can be obtained from the Trust pharmacy)</b>	<b>ICH GCP reference</b>	<b>yes</b>	<b>no</b>	<b>Don't know</b>	<b>In process</b>	<b>Not applicable</b>
Investigational Product(s) and other supplies Receipt form(s)	5.13	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Investigational Product(s) and other supplies accountability form(s)	5.13, 8.4.1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Instruction for handling Investigational products (if not included in Protocol/IB)	5.14	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Record of destruction at Investigational Site (if applicable)	8.4.2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Randomisation information/un-blinding Procedures/emergency contacts	4.7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If the drugs are not stored in pharmacy do you have records of drug storage conditions		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>4. Subjects Log</b>						
Signed subject/patient Informed consent forms	4.8.8	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Subject screening log sheet	8.3.20	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Subject identification code list	8.3.21	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Subject enrolment log sheet	8.3.22	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>5. Laboratory</b>						
Normal laboratory values + updates are being documented correctly.	4.3.2, 8.2.11	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Laboratory certification/accreditation + updates are handled correctly	8.3.7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Updates to normal values range(s) for technical procedures/Test(s) are included in the protocol	8.3.6	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Record of retained body fluids/tissue (if any)	8.3.25	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>6. Equipment maintenance</b>						
Calibration and service routines are documented and all records are up to date.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

<b>7. Serious Adverse Events /incidents</b>	<b>ICH GCP reference</b>	<b>yes</b>	<b>no</b>	<b>Don't know</b>	<b>In process</b>	<b>Not applicable</b>
There is a procedure for reporting of Serious Adverse Events	4.11.1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
There is procedure for the reporting of Suspected Unexpected Serious Adverse Reactions (SUSAR's)	3.3.8, 8.3.17	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have all AE/SAEs been reported to the relevant authorities	8.3.17	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Emergency un-blinding provision - Procedure for the removal of participants from the project which includes a code breaking procedure for blinded trials and informing MHRA/REC/Trust as appropriate.	4.7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Interim or annual reports to the ethics committee and competent authority.	8.3.19	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>8. Relevant communications</b>						
To document any agreements or significant discussions regarding trial administration, protocol violations – letters, meeting notes, notes of telephone calls are retained.	8.3.11	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>9. Consent</b>						
The recruitment process incorporates sufficient time (≥ 24hrs) for potential participants and/or legal representatives to consider fully and rationally the implications of taking part in the study. Unless less time has been agreed with the ethics committee	4.8	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>10. Consent continued</b>						
All researchers taking consent are listed as being eligible to do so in the delegation of duties log	5.7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is there a full record of all research participants written informed consent and or where appropriate written carer assent	4.8	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>11. General/Miscellaneous</b>						
SOPs are available for all project specific procedures e.g. recruitment, archiving, consenting, storage of specimens, reagents, pharmaceutical products and equipment.	1.55	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The title and the study and version number appears on all documentation given to participants.	8.3.3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Based upon CMFT Clinical Trials Monitoring Self-Assessment Form  
Adapted from SCOPE training material and the CMMC Trust GRIP Framework

**Other essential information**

Do you have a copy of the ICH GCP Guidelines in the Trial Master file		Yes    No    N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
EudraCT Number		No:
Is the subject/patient enrolment on target?		Yes    No    N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
If not, has action been taken?		Yes    No    N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
What is your planned enrolment?		No:
How many subjects have been screened?		No:
How many subjects have entered the trial?		No:
How many subjects are active?		No:
How many subjects have dropped?		No:
How many subjects have completed?		No:
Number of Serious Adverse Events (SAEs) at CMMC (if you have not done so already, please attach or post reports and reporting correspondence to the R&D office)		No:
Number of Suspected Unexpected Serious Adverse Reactions (SUSARs) at CMMC (if you have not done so already, please attach or post reports and reporting correspondence to the R&D office)		No:
Does the trial have an independent steering group and/or data monitoring committee?		Yes    No    N/A <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
<b>For trials where the Trust acts as sponsor, please answer these additional questions.</b>		

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List other participating sites (if any) or state if none		
Current protocol version and date		No:
Are you the Chief Investigator for the study?		<p style="text-align: center;">Yes                  No</p> <p style="text-align: center;"><input type="checkbox"/>                      <input type="checkbox"/></p>
Number of Serious Adverse Events (SAEs) <u>in total for the trial (including participating sites)</u> (if you have not done so already, please attach or post reports and reporting correspondence to the R&D office)		No:
Number of Suspected Unexpected Serious Adverse Reactions (SUSARs) <u>in total for the trial (including participating sites)</u> (if you have not done so already, please attach or post reports and reporting correspondence to the R&D office)		No:
Has an annual safety report been submitted to MHRA and the MREC? If so, please attach		<p style="text-align: center;">Yes                  No</p> <p style="text-align: center;"><input type="checkbox"/>                      <input type="checkbox"/></p>
Have there been any changes to the trial, e.g. amendments? If so, please supply documents to R&D		<p style="text-align: center;">Yes                  No</p> <p style="text-align: center;"><input type="checkbox"/>                      <input type="checkbox"/></p>
Has the trial ever been suspended or prematurely terminated? If so, please give details		<p style="text-align: center;">Yes                  No</p> <p style="text-align: center;"><input type="checkbox"/>                      <input type="checkbox"/></p>

**Any comments**

- Do you have any concerns regarding the MHRA inspection in June 2009?
  
- Do you have any significant issues pertaining to the conduct of the clinical trial to report? If yes, please indicate the nature of the issue and provide a short summary.
  
- Do you require R&D assistance in resolving the problem? Yes/No

**Signature page:**

By signing this self-assessment, you are confirming that the information contained within it is a fair and accurate reflection of your Clinical Trial.

<b>Principal Investigator:</b>	
Name:	
Signature:	Date:
<b>Study coordinator:</b>	
Name:	
Signature:	Date:

**Please return completed form to:**

Post: R&D Directorate, University Hospital of South Manchester NHS Foundation Trust,  
Ground Floor ERC, Wythenshawe Hospital, Southmoor Road, Manchester, M23 9LT

Email: [Anne-Marie.Taylor@manchester.ac.uk](mailto:Anne-Marie.Taylor@manchester.ac.uk)

**Any queries on the completion of the form should be directed to the Trust  
Research Governance Manager email: [deepti.sebastian@manchester.ac.uk](mailto:deepti.sebastian@manchester.ac.uk),  
phone 0161 291 5773**

**When complete please return to [Anne-Marie.Taylor@manchester.ac.uk](mailto:Anne-Marie.Taylor@manchester.ac.uk)**