SOP

MONITORING & OVERSIGHT OF RESEARCH ACTIVITY

SETTING Trust wide

FOR STAFF All staff involved in research

QUERIES Contact Jess Bisset, Research Operations Manager x20227

Guidance

1. Introduction

In accordance with the Department of Health's Research Governance Framework for Health and Social Care (RGF) and the Medicines for Human Use (Clinical Trials) Regulations, the Research & Innovation Department has a responsibility to monitor research studies conducted within UH Bristol or where UH Bristol is acting as a research sponsor respectively.

The Sponsor is defined in 2 ways:

RGF: Sponsor: "Individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study"
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/139565/dh_4122427.pdf

Clinical Trials Regulations: "sponsor" means, in relation to a clinical trial, the person who takes responsibility for the initiation, management and financing (or arranging the financing) or that trial.
http://www.legislation.gov.uk/uksi/2004/1031/regulation/3/made

The purpose for monitoring is to ensure:

- The dignity, rights, safety and wellbeing of the subjects participating in the study are protected
- The conduct of the study is in compliance with the current approved protocol/protocol amendment(s), with Good Clinical Practice (GCP) and with the applicable regulatory requirements
- The reported trial data are accurate, complete and verifiable from the source

2. Purpose and Scope

The purpose of this document is to describe the risk based procedures that will be used by UH Bristol Research & Innovation Department (R&I) to monitor and provide oversight for research studies conducted on Trust premises or which fall under a Service Level Agreement with other organisations.

3. Risk Assessment and Risk Management

All studies reviewed by UH Bristol R&I will be subject to a risk assessment which will be completed before NHS permission for the study to start is granted by UH Bristol. The areas reviewed for risk include, but are not limited to, the following:

- Regulatory and contractual requirements
- Essential documents
- Consent
- Study type
- Data and tissue
- Research team
- Recruitment and retention
- Sponsorship arrangements
- Financial arrangements
- Resource use
- Organisational responsibilities

A copy of the risk assessment template can be found on the R&I website.

4. Sponsor Set up and Management and Green Light Processes

For CTIMPs, as soon as the sponsorship letter is issued the Research Management Facilitator (RMF) allocated to that study will organise a Study Set Up and Management meeting with the Chief Investigator (CI), Point of Contact (PoC), support service signatories (or delegates) and any other relevant personnel. This meeting and associated documentation (provided as annex 2) is intended to evidence the management plan following agreement by UH Bristol to sponsor the study. The tasks for the management of the study are outlined and cover the period from the initial set-up to the close down of the study. Each task is assigned to the appropriate personnel. It is then their responsibility to undertake the task within the target time frame specified. It is also an opportunity to ensure that all parties are aware of their responsibilities before the study can start recruitment. UH Bristol, as Sponsor, will delegate some of its responsibilities to the CI at the point of sponsorship. A separate document entitled 'Statement of CI responsibilities' will be completed and signed by the CI to evidence this. As part of the setup and monitoring process for each study the RMF will periodically review progress of each item with the CI and/or PoC. This also forms part of the approval process and when all necessary approval specific checks have been completed, NHS permission will be issued. Any conditions of NHS permission and tasks from the Study Set Up and Management plan requiring completion before trial commencement will then be followed up by the RMF in liaison with the research team and support departments. When all conditions have been met and all required tasks completed, the RMF will issue Sponsor green light for UH Bristol as a site. For multi-centre trials with sites outside Bristol a separate site initiation checklist will be completed (provided as annex 3) by the UH Bristol research team with input from R&I as required, for each site. When completed this will be sent to the allocated RMF who will issue green light for the site to open to recruitment.

5. Monitoring Plan

The risks identified using the Risk Assessment Template will be used to develop a monitoring plan for each study granted NHS Permission by UH Bristol R&I. The monitoring plan will document the methods that will be used for monitoring (e.g. site visits, telephone monitoring, self-monitoring) and the schedule and frequency of planned visits/self-monitoring. More information can be found in Annex 1; Monitoring Plan Completion Guidance Notes.

For studies identified for monitoring where a detailed monitoring plan is not already in place, the R&I monitors will contact the Principal Investigator(PI)/PoC after approval to discuss monitoring requirements.

6. Types of Monitoring

Self-monitoring

R&I monitors will email self-monitoring forms to the PI and PoC to check recruitment, safety and overall study progress. The forms also request information about changes to the research team, whether training needs have been met as well as any updates to the study documentation to ensure that the R&I department have been notified of them. The form should be returned to the monitor within two weeks and will be chased if no response is received. This form of monitoring is an opportunity for the research team to identify any issues with the study which need addressing. If any are identified follow up via telephone calls or emails will be made by the R&I monitors until the issues are resolved. If the self-monitoring raises any concerns for the R&I monitors a site visit may be arranged.

Site File Review

A site file review may be conducted at a setup visit to ensure everything is in place before the study starts. A site file review will not be completed at every site visit and when this type of review is carried out, will be determined by the risks identified during approval of the study and if issues raised at a first site visit have not been adequately addressed. To conduct a site file review, a checklist based on the UH Bristol Investigator Site File templates is used. This checklist reflects the essential documentation required to run a study as defined by Good Clinical Practice.

Protocol Compliance

Protocol compliance review will be carried out for most studies identified as requiring a monitoring visit. The risks identified during approval of a study will be used to guide the protocol compliance review.

The key aspects to be assessed during this type of monitoring visit include, but are not limited to the following:

- Verifying, for Investigational Medicinal Product(s) (IMPs):
    - That storage temperature and conditions are acceptable, and that sufficient supplies are in place throughout the study
    - That the IMP(s) are supplied only to the participants who are eligible to receive it and at the protocol specified dose(s)
    - That participants are provided with necessary instruction on properly using, handling, storing, and returning the IMP(s)
    - That the receipt, use, and return of the IMP(s) is controlled and documented
    - That the destruction of unused IMP(s) complies with applicable regulatory requirements and is in accordance with the protocol
- Verifying that the investigator follows the approved protocol and all approved amendments
- Verifying that the investigator is enrolling only eligible participants and that consent has been given by participants in accordance with ethical approval
- Checking the accuracy and completeness of the Case Report Form (CRF) entries, source documents and other study related records against each other, i.e. that:
    - The data required by the protocol is reported accurately on the CRFs and is consistent with the source documents
    - Any dose and/or therapy modifications are well documented for each of the study participants
    - Adverse Events (AEs), concomitant medications and illnesses are reported in accordance with the protocol
    - Visits that the participants fail to make, tests that are not conducted, and examinations that are not performed are clearly reported as such on the CRFs
    - All withdrawals of enrolled participants from the study are reported and explained on the CRFs
- Reviewing CRF entry error, omission or illegibility and the method by which this has been

recorded
- Ensuring changes are made, explained (if necessary), and initialled by the investigator or member of the research team authorised to do so
- Determining whether all AEs are appropriately reported within the timelines specified by the applicable regulatory requirements and the sponsor
- Checking archiving arrangements
- Checking systems are in place to ensure compliance with data protection
- Checking the transportation and storage arrangements for any samples taken as part of the protocol

Recruitment and study progress
- Monitoring research management database records for accuracy
- Oversight of recruitment issues and study progress

7. Research Sponsored by UH Bristol

Research sponsored by UH Bristol can be split into three main categories:

a) Clinical Trials of Investigational Medicinal Products (CTIMP) or Clinical Investigations of Devices (CID)
b) Non CTIMP interventional trials, defined in this document as Randomised Controlled Trials (RCTs) and surgical trials
c) Non CTIMP non-interventional trials

Monitoring responsibilities may be delegated to a Clinical Trials Unit if appropriate.

A monitoring plan will be drawn up for all studies sponsored by UH Bristol. An initial meeting may take place with the Chief Investigator (CI) and Point of Contact (PoC) to discuss the monitoring requirements. At this meeting a schedule of monitoring visits will be agreed, for example:

- Setup visit – setting up Investigator Site File
- Visit after 1st patient recruited – focus on consent process
- Visit(s) during recruitment period – focus on CRF completion, protocol compliance, source document verification and informed consent
- Close-out visit – Investigator Site File check, archiving arrangements, study reporting requirements

As sponsor, UH Bristol will be monitoring the arrangements for IMP, sample management and other provisions of services. In the first instance the R&I RMF allocated to the study will arrange meetings with the relevant members of staff in the relevant support departments (e.g. Pharmacy, Laboratory Medicine etc) to discuss a monitoring plan for these departments, if required.

Although studies will be monitored and managed in different ways according to the type of study and the agreed monitoring plan, all studies will be:

- Managed through their lifetime
- Have a named individual in R&I (an allocated RMF) to be assigned to the study to keep regular track of status and recruitment
- The allocated RMF will be responsible for carrying out sponsorship (if applicable) and approval and will agree a monitoring plan for each study (as required)
- The monitoring plan will be passed to the RMF monitors who will use the risk assessment template to ensure identified risks during approval are taken into consideration during monitoring

- Recruitment of first patient within 70 days of valid application received and time to target to be monitored throughout study lifetime by allocated RMF and Research Information Officer (RIO)

The different requirements of monitoring due to study type have been outlined below

Clinical Trials of Investigational Medicinal Products (CTIMP) or Clinical Investigations of Devices (CID)

- Study Set up and Management Plan to be carried out by allocated RMF, study team and any other appropriate personnel (e.g. support departments)
- Sponsorship initiation checklist (green light) for external sites to be carried out by study team in liaison with allocated RMF
- Setup visit with research team conducted by RMF monitors if required
- A site visit will usually take place after the first patient has been recruited
- SAE/SUSAR reporting to be monitored and managed by RMF monitors
- Close down visit with research team to take place

Non CTIMP Interventional Trials

- Setup visit with research team conducted by RMF monitors if required
- Site visit subject to current monitoring selection process, in accordance with identified risks during approval process (see Annex 1 for further details)SAE/SUSAR reporting to be monitored and managed by RMF monitors

Non CTIMP Non-Interventional Trials

- Subject to current monitoring selection process, in accordance with identified risks during approval process (see Annex 1 for further details)
- End date of each study to be confirmed or amended following contact with study team

8. Research Sponsored by University of Bristol (UoB)

The University of Bristol holds a service level agreement (SLA) with UH Bristol. Under that agreement the trust undertakes to monitor and carry out pharmacovigilance for certain UoB sponsored studies. These activities will be carried out in accordance with the SLA and the study's specific monitoring plan (if carried out by UH Bristol).

9. Research Sponsored by Other Organisations

Monitoring will be carried out according to the monitoring guidance, study-specific monitoring plan and in accordance with any agreement in place with the sponsor. Study end dates and recruitment figures of all research taking place at UH Bristol will be collected annually for Quality Accounts.

ANNEX 1

Monitoring Plan Completion Guidance Notes

	Type of visit – Minimum Requirements						
Monitoring Category	*Sponsor Initiation Checklist (green light)*	*Setup Visit*	*First Patient First Visit call/email*	*First Patient First Visit (site visit)*	*Site Visit (site file review or protocol compliance)*	*Telephone follow-up and/or self-monitoring*	*Close out Visit*
UH Bristol/UoB Sponsored CTIMP/CID	Yes	Yes*	Yes	Yes	Yes	Yes	Yes*
UH Bristol/UoB Sponsored non-CTIMP interventional	Yes	No	Yes	No	Yes	Yes	No
UH Bristol/UoB Sponsored non-interventional	No	No	Yes	No	Yes	Yes	No
External Sponsor (non-commercial)	No	No	Yes	No	No	Yes	No
Commercial	No	No	Yes	No	No	No	No

*For UoB sponsored studies these visits should be facilitated by UoB

Notes

- The above table relates to the minimum monitoring requirements. More extensive monitoring can be incorporated into the monitoring plan based on study specific needs
- Study setup visits and close out visits can be coordinated by external trials units who have been delegated responsibility of study management e.g. MCRN CTU in Liverpool, however the R&I department should be kept informed of when these take place where UH Bristol is sponsor.
- Frequency of site visits should be dependent on the unit where the study is managed, the experience of the PI and team and whether any other monitoring arrangements are in

place (e.g. monitoring from a central coordinating centre)

- Risks identified during the study approval process should be taken into consideration when completing the monitoring plan
- Frequency of telephone follow-ups/self-monitoring should be dependent on planned rate of recruitment and study duration
- All studies should be monitored for recruitment
- Frequency and extent of monitoring for externally sponsored studies should be dependent on the risks identified during study approval and monitoring responsibilities set out in study agreements
- Frequency and extent of monitoring for all studies can be amended following findings from completed visits or self-monitoring.

ANNEX 2

UH Bristol Sponsor Study Set Up & Management Plan

Full Title of Trial					
Short Title / Acronym					
EudraCT Number (if applicable)		**UH Bristol R&D Number**		**IRAS ID**	
Chief Investigator			**Funder**		

This document is intended to lay out the management plan following agreement by UH Bristol to sponsor the above study.

The tasks for the management of the study are outlined below and cover the period from the initial set-up to the close down of the study. Each task is to be assigned to the appropriate personnel. It is then their responsibility to undertake the task within the target time frame specified.

Where the study has participating sites, the term 'Lead Site' refers to UH Bristol. Where a study involves the set-up of participating sites, this management plan must be used in conjunction with the "Site Initiation Checklist".

1. *Regulatory Approvals*

Tasks	Responsible personnel	Target completion	Status	Comments
Obtain Research Ethics Committee (REC) approval http://www.hra.nhs.uk/research-community/applying-for-approvals/research-ethics-committee/				

Prepare and submit MHRA application for Clinical Trial Authorisation for CTIMP http://www.hra.nhs.uk/research-community/applying-for-approvals/medicines-and-healthcare-products-regulatory-agency				
Prepare and submit MHRA application for a Notice of No Objection for Medical Device Research http://www.hra.nhs.uk/research-community/applying-for-approvals/medicines-and-healthcare-products-regulatory-agency-mhra-notice-of-no-objection-medical-device-research/				
Prepare approval applications from other relevant bodies (e.g. ARSAC, NIGB/CAG, HTA) if applicable				
Register trial with appropriate registration scheme(s) (clinicaltrials.gov, ISRCTN, UKCRN Portfolio)				
Obtain NHS permission at UH Bristol http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/setting-up-and-running-a-clinical-research-study/the-application-process-using-iras/submitting-to-rd/				

2. *Contractual and Financial Arrangements*

Tasks	Responsible personnel	Target completion	Status	Comments
Ensure appropriate contractual agreements in place e.g. Site Agreement(s), Pharmacy Technical Agreements, collaboration agreements				
Arrange sign off of the University of Bristol and UH Bristol Framework Agreement (if study involves UoB staff and there is not a separate collaboration agreement)				
Manage and keep record of trial finances, in liaison with the appropriate Management Accountant, specifically in relation to invoicing arrangement e.g. for support depts.				

3. Support Department approval – Pharmacy *Tick box if N/A* ☐

Tasks	Responsible personnel	Target completion	Status	Comments
Obtain authorisation from the pharmacy department. http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/setting-up-and-running-a-clinical-research-study/the-application-process-using-iras/submitting-to-rd/do-i-need-support-department-authorisation/				
Identify supply of Investigational Medicinal Product(s) (IMPs), in collaboration with the relevant UH Bristol pharmacy departments				
Ensure IMP is provided and labelled in accordance with Medicines for Human Use (Clinical Trials) Regulations 2004, in liaison with pharmacy				
Completion of pharmacy manual (or NIHR template) to record all relevant pharmacy requirements at the lead site.				
Share pharmacy manual with R&I as sponsor and the study team				
Study team to approach all of the pharmacy departments at the participating sites to carry out feasibility (if applicable)				
Annex added to site agreements to document the required activities undertaken by the participating site's pharmacy department (if applicable)				
Set up of pharmacy file (to include associated study SOPs and Protocol)				
Storage arrangements in place for IMP- risk assessment completed for when IMP storage outside of pharmacy.				
Temperature monitoring in place				

Training of pharmacy personnel undertaken (as appropriate) and ensure familiarity of research team at lead site with appropriate use of IMP as described in protocol and other product information				
Dispensing- study prescriptions in place				
QP release in place (if applicable)				
Accountability records in place (and system set up)				
Destruction/return of IMP – system in place (including participating site arrangements if applicable).				
Unblinding arrangements in place (if on call pharmacists to carry out unblinding)				
Out of hours arrangements (if applicable)				

4. *Support Department approval - MEMO (Medical Equipment Management Organisation)* *Tick box if N/A* ☐

Tasks	Responsible personnel	Target completion	Status	Comments
Obtain authorisation from the MEMO http://www.uhbristol.nhs.uk/for-clinicians/memo/memo-authorisation/				
Type of device – does it need MHRA approval? http://www.mhra.gov.uk/Howweregulate/Devices/index.htm				
Tailored maintenance plan (if needed); any other MEMO conditions				
Arrangements for requesting replacements and/or new supplies				
Storage arrangements in place for equipment and/or consumables				

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5. *Support Department approval – Labs* *Tick box if N/A*

Tasks	Responsible personnel	Target completion	Status	Comments
Obtain authorisation from the labs (may also require histopathology sign off or agreement from external labs if applicable) http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/setting-up-and-running-a-clinical-research-study/the-application-process-using-iras/submitting-to-rd/do-i-need-support-department-authorisation/				
Sample labelling in place				
Sample storage arranged and in compliance with any HTA requirements or temperature monitoring as applicable				
Sample transfer arrangements in place- include transfer from clinics/theatres to labs and MTA if required				
Retrieval of histopathology samples arrangements in place				
Lab manual in place including documentation of local lab reference ranges for participating sites (if applicable)				
Arrangements in place for destruction/storage/transfer of samples on study completion				

6. *Support Department approval - Radiology and Radiotherapy* *Tick box if N/A* ☐

Tasks	Responsible personnel	Target completion	Status	Comments
Obtain authorisations for radiology and radiotherapy requirements for the study including IRMER, Medical Physics and ARSAC. http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/setting-up-and-running-a-clinical-research-study/the-application-process-using-iras/submitting-to-rd/do-i-need-support-				

department-authorisation/				
Obtain assurance that appropriate process in place for requesting imaging/radiotherapy.				
Ensure procedure in place for anonymisation of images if scans are to be sent externally				
Authorisations in place for any external imaging to take place e.g. PET scans				
CRIC Agreement and Project Specification Form are in place (if applicable)				

7. *Support Department approval- any other (e.g. ECG, Medical Imaging, CRIC etc)* *Tick box if N/A* ☐

Tasks	Responsible personnel	Target completion	Status	Comments
Authorisations in place (as required) *Specify:*_____				
Authorisations in place (as required) *Specify:*_____				
Authorisations in place (as required) *Specify:*_____				

8. *Safety*

Tasks	Responsible personnel	Target completion	Status	Comments
Copy of Safety reporting SOP in site file				
Familiarisation of safety reporting procedure by study team http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/setting-up-and-running-a-clinical-research-study/what-to-do-when-approval-is-received/safety-reporting-(adverse-events)/				

Trial Management Group or applicable other set up to maintain oversight of all reported SAEs				
System in place to promptly inform the MHRA, REC, the Research Management Office, the research team at the lead site and the PIs at other sites of any urgent safety measures taken to protect participants				
System set up to ensure investigators at lead site and at participating sites are, at all times, in possession of the current relevant safety information, including SUSARs, for the trial				
Reminders put in place to ensure Annual Safety Reports (ASRs and DSURs) and progress reports are submitted to the MHRA and REC within the required timescales and copies provided to the Research Management Office				
Maintain detailed records of all Adverse Events (AE) as specified in the Protocol and in accordance with the regulatory requirements				
Report adverse events as specified in the Protocol and regulatory requirements				
Ensure all Serious Adverse Events (SAE) at the lead site and all participating sites, other than those specified in Protocol as not requiring immediate reporting, are recorded, assessed and reported in line with the regulatory requirements and Trust policy				
Ensure all SAEs at the lead site and all participating sites are reviewed by an appropriate committee for monitoring trial safety (if applicable)				
Ensure that all Suspected Unexpected Serious Adverse Reactions (SUSAR) are recorded, assessed and reported to the Research Management Office in accordance with the regulatory requirements and Trust policy				
Promptly inform the MHRA, REC, the Research Management Office, the research team at the lead site and the PIs at other sites of any urgent safety measures taken to protect participants				

9. Preparation for additional sites or tick box if N/A ☐

Tasks	Responsible personnel	Target completion	Status	Comments
Identify appropriate participating sites and suitably qualified PIs at these sites				
Obtain sponsor authorisation for the number and location or participating sites				
Obtain NHS Permission from each NHS organisation involved in the research				
Conduct initiation visits at participating sites and issue green light to recruit				

10. Study Team

Tasks	Responsible personnel	Target completion	Status	Comments
Check HR requirements for study team and arrange research passports, contracts or letters of access as required http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/setting-up-and-running-a-clinical-research-study/the-application-process-using-iras/research-passports/				
Train research team in use of trial-specific standard operating procedures				
Ensure members of the research team at UH Bristol are appropriately qualified by education and experience to undertake their role(s)				
Ensure students and new researchers are adequately supervised				
Ensure core research team members have completed ICH GCP training (within previous 3 years)				

11. Study Admin

Tasks	Responsible personnel	Target completion	Status	Comments
Design case report forms and database				
Develop trial-specific standard operating procedures				
Ensure adequate randomization procedures and are in place and documented				
Ensure Trial Master File (TMF) and associated documentation is complete, accurate and legible http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/setting-up-and-running-a-clinical-research-study/what-to-do-when-approval-is-received/site-file-maintenance/				
Maintain a record of patient recruitment and report recruitment to the NIHR (portfolio studies only) and to the R&I Department in line with Trust requirements				
Enter recruitment data to the EDGE database and keep the EDGE study record up to date www.edge.nhs.uk				

12. Research Delivery

Tasks	Responsible personnel	Target completion	Status	Comments
Ensure informed consent is taken for each participant at the lead site, in accordance with Protocol and approved patient-related documentation				
Inform, where practicable, health or social care professionals if their patient is a participant in the trial				
Ensure trial is managed, monitored and reported as agreed in the protocol and main contract with funder and collaboration agreements				
Monitoring arrangements for the lead site				

Monitoring arrangements for participating sites (if applicable)				
Ensure patient confidentiality is maintained in accordance with consent provided and with all study approvals				
Ensure trial is conducted in accordance with ICH GCP and applicable legislation				
Ensure research team at lead site and Principal Investigators at participating sites are aware of dates of approval and version changes for implementation of amendments				
Report suspected breaches of protocol, ICH GCP and research misconduct and fraud, in accordance with relevant policies and guidelines				
Submit progress reports to funder and HRA				

13. Amendments

Tasks	Responsible personnel	Target completion	Status	Comments
Ensure all protocol amendments are agreed and authorised by the sponsor prior to submission for approval and implementation				
Prepare and submit substantial amendments to the MHRA, REC and the Research Management Office http://www.uhbristol.nhs.uk/research-innovation/information-for-researchers/setting-up-and-running-a-clinical-research-study/what-to-do-when-approval-is-received/submitting-amendments/				
Arrange amendments and/or extensions with the funder as necessary following discussion with R&I.				
Update all participating sites				

14. Study Completion

Tasks	Responsible personnel	Target completion	Status	Comments
Notify regulatory authority(ies) and relevant REC if trial suspended or terminates early				
Notify regulatory authority(ies) of the end of the trial				
Ensure all trial records at each site are archived appropriately on conclusion of the trial and retained in accordance with current regulations and guidelines				
Initiate and coordinate review and submission of abstracts, posters and publications				
Submit final report to all applicable regulatory authorities and RMO				

Date of Initial assessment _____

Name of CI _____

Signed _____ Date _____

Name of Sponsor's Representative _____

Signed _____ Date _____

ANNEX 3

UH BRISTOL SPONSORED STUDIES - SITE INITIATION CHECKLIST

Trial title:

EudraCT:

Site name/address:

PI contact details:

Point of Contact details (if different from PI):

Date of site initiation visit/telephone call:

1. Regulatory Approvals

Items Discussed/Verified	Yes	No	N/A	Actions/Comments
REC approval for addition of site				
R&D approval at site				
Regulatory approval from MHRA				
Any other applicable approvals Please specify_____				

2. Site Personnel

Items Discussed/Verified	Yes	No	N/A	Actions/Comments
Qualification and experience of PI				
CV's for all site study staff stored in site file (*update required every 3 years)				
GCP training record for all consenting study staff stored in site file (*update required every 3 years)				
Training of research team on protocol/study specific procedures				

3. *Pharmacy Procedures*

Items Discussed/Verified	Yes	No	N/A	Actions/Comments
Pharmacy manual provided to site				
SOP/documented process in place for supplying IMP to site				
Process in place at site for QP sign off on receipt of IMP if applicable				
Storage and dispensing arrangements of IMP at site				
Agreed and documented process for return or destruction of unused IMP				
Pharmacy signed agreement documenting compliance to protocol and GCP				
Drug administration procedures				

4. *Device trials*

Items Discussed/Verified	Yes	No	N/A	Actions/Comments
Relevant support department authorisation				
Technical/maintenance manual provided to site				
SOP/documented process in place for supplying consumables to site				
Storage arrangements of equipment and/or consumables at site				
Agreed and documented process for return of equipment and unused consumables				

5. *Other Study Specific Procedures*

Items Discussed/Verified	Yes	No	N/A	Actions/Comments
Sample collection procedures including frequency and exact time points of when samples to be taken				
Sample Logs				
Lab kits provided to/available at site?				

Agreement from site lab staff to undertake the study (if applicable)				
Any other support department procedures specified (enter specific procedures if applicable)				

6. Informed Consent and Enrolment

Items Discussed/Verified	Yes	No	N/A	Actions/Comments
Informed consent procedures				
Randomisation procedures				
Unblinding procedures				
Code break envelopes received at site (if applicable)				
Randomisation log (and specify required location if study team are to be blinded)				
Recruitment monitoring				

7. Safety Reporting

Items Discussed/Verified	Yes	No	N/A	Actions/Comments
AE/SAE reporting process documented and agreed by site				
Toxicity parameters				
Provide emergency contact details of sponsor				
Protocol deviation reporting procedures				

8. Monitoring Arrangements

Please verify with site which of the following monitoring visits will take place

Items Discussed/Verified	Yes	No	Projected Visit Date	Actions/Comments
FPFV Visit/Call				
Protocol compliance site visits				
Self-Monitoring				
Close Out Visit/Call				

9. Investigator Site file

Please check the following documents are stored in the site file

Items Discussed/Verified	Yes	No	N/A	Actions/Comments
UH Bristol site file template provided to site				
Signed Site Agreement with target recruitment included				
Final study protocol, signed and dated by PI				Version:
Financial arrangements (including invoicing procedures)				
Other contractual agreements (please specify)				
Completed delegation log				
PIS *List*				Version:
Informed Consent forms *List*				Version:
GP Letters				Version:
Case Report forms				
Data management procedures (including anonymisation procedures and compliance with data protection act)				
Investigators brochure or SmPCR				Version:

Any outstanding issues which need to be resolved before green light is issued:

Sponsor's representative:

Signature:

Print name:

Date: Signed by e-mail: ☐

Chief Investigator:

Signature:

Print name:

Date: Signed by e-mail: ☐