Gloucestershire Hospitals
NHS Foundation Trust

Research Development 02 – Application to the Trust for Sponsorship of a CTIMP

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All staff should regularly check the Research & Development Webpage for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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http://www.gloshospitals.nhs.uk/en/About-Us/Research--Development/

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Author:	Janet Forkes	signature
Reviewed by Associate Director of R&D	Julie Hapeshi 27/03/2018	signature
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The Gloucestershire Hospitals NHS Foundation Trust wishes to acknowledge York Hospitals NHS Foundation Trust and University Hospitals Bristol NHS Foundation Trust who gave permission to use their templates in the development of these SOPs.

Version History Log

This area will be updated with details of all changes made to the SOP whether due for full review or not.

Version	Details of Change	Date Implemented
1.0	Original SOP 03	
2.0	Review and update along with reorganisation into the Gloucestershire R&D Consortium suite of SOPs	13/01/2017
3.0	Rebranding to GHNHSFT, updating of contact details and reference documents	31/03/2018

This SOP will be reviewed every two years unless changes to any relevant legislation require otherwise

Contents

1. Introduction, Background and Purpose

When an organisation agrees to sponsor a CTIMP it takes on a major responsibility. Because this is such a serious undertaking, considerable time and effort must be devoted to setting up a CTIMP. The protocol, all documentation and procedures associated with it must be developed in detail; monitoring must be arranged and the monitor involved in the trial initiation process; all investigators must be trained; there must be sufficient financial and human resources available for safe and effective conduct of the trial. Investigator teams will need to work with the Trust R&D Department on all these matters.

An application to the Trust to sponsor a CTIMP is, therefore, considered in stages:

1. Feasibility Review
   The proposed Chief Investigator (CI) submits to the Trust R&D Department an outline protocol, a basic funding plan and details of the investigator team – qualifications, experience, research training, other current research projects, proposed responsibilities in the trial and time available to carry them out. The Trust R&D Department will decide whether the proposal has potential scientific merit, is practicable, is likely to be adequately resourced, and whether the investigator team has the capacity to carry it out safely and effectively.

2. Full Trial Development
   If the Trust R&D Department agrees that the basic feasibility requirements have been met the investigator team will work with the Trust R&D Department to produce a detailed CTIMP – appropriate protocol, data collection tools and procedures designed to fit with the sponsor's standard operating procedures, investigational medicinal product handling plans, detailed costings and so on. All this will be submitted for independent peer and statistical review before it is submitted again to the Trust R&D Department for approval of sponsorship "in principle".

3. Final Approval
   If the Trust R&D Department agrees sponsorship in principle, the investigators will apply for the Clinical Trial Authorisation (or 'notification' for certain types of trial) and HRA approval. If plans for the trial are changed as a result of this process the trial documentation will return to the Trust R&D Department for further consideration. If no significant changes are made then upon receipt of written confirmation of approval by the MHRA and HRA, final sponsorship approval will be issued.

4. Funding
   Because funding arrangements vary considerably it is recognised that it may be necessary for some flexibility to make this process work in

conjunction with outline or full applications for grants and conclusion of grant contracts.

The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 states that:

> "A person who is a sponsor of a clinical trial in accordance with this regulation may delegate any or all of his functions under these Regulations to any person but any such arrangement shall not affect the responsibility of the sponsor."

The purpose of this SOP is to outline the delegation of responsibilities for the conduct of a CTIMP Sponsored by Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT).

2. Who should use this SOP?

This SOP will be used by the Chief Investigator and Sponsor for any Clinical Trial of an Investigational Medicinal Product (CTIMP) sponsored by GHNHSFT.

Although this SOP is specifically designed in relation to CTIMPs, the guidance within should be applied, when applicable, to the design of any Trust research project where delegation of responsibilities is considered appropriate.

3. When should this SOP be used?

This SOP should be referred to at the earliest stage of development of a CTIMP study (or other suitable study) and referred to throughout the design, approval, conduct and monitoring of the study.

To find out whether your trial is a CTIMP, seek advice from the Trust R&D Department to help you in using the MHRA algorithm. If, after using the algorithm, you are still unsure whether or not the trial is covered by the Regulations send an e-mail to the MHRA Clinical Trial Helpline (clintrialhelpline@mhra.gsi.gov.uk) marked 'scope-protocol review' in the subject line and request an opinion on the status of the trial.

A copy of the draft protocol should be provided with the request – this will probably not be in its final form but should be sufficiently detailed to enable the MHRA to see what you intend to do. You must ensure that all correspondence with the MHRA is retained. If your study is a CTIMP, confirmation that the Trust will act as sponsor will only be obtained through the following application process.

4. Procedure

4.1 Stage 1: Feasibility Review

4.1.1 Contact the Trust R&D Department

It is important to contact the Trust R&D Department at this early stage if you have not already done so. The Trust R&D Department will issue you with a Trust specific R&D reference number which should always be used in any correspondence regarding the trial or when making a submission.

4.1.2 Prepare documentation for Feasibility Review

- At this stage the draft protocol should contain a brief literature review and justification for the proposed research, and should describe clearly the essential elements of the trial. This document can be used for preliminary discussions with potential trial partners, the MHRA or the potential sponsor. It may be sufficient for an outline grant funding application.

- CVs for Chief Investigator (CI) and all other investigators in the team – use Health Research Authority (HRA) guidance for this to avoid having to duplicate work later. Include details of GCP training undertaken, with dates.

- Use HRA guidance to provide relevant patient facing documentation such as those below as appropriate:
  - Draft Participant Information Sheet (PIS)
  - Draft consent form – use HRA guidance.
  - Draft GP letter

http://www.hra-decisiontools.org.uk/consent/

4.1.3 Submit documentation for internal review by the Scientific Review Committee (SRC)

The CI should submit documentation to ghn-tr.rdsu@nhs.net marked CTIMP feasibility review in the subject heading. The Trust R&D Department will perform an initial review of the application within 10 working days. (See R&D SOP RDVL 01)

Dependent upon the research being undertaken additional staff with specific expertise besides the Trust R&D Department team may be included in the review.
The CI may be invited to attend the meeting to discuss the proposed study and answer any questions. The Group may decide:

- That the proposed study is not feasible in its current form and will not be sponsored by the Trust concerned;

- That if the CI wishes to do further preliminary work on areas specified by the SRC , the SRC will be prepared to consider a resubmission for Feasibility Review.
- That the proposed study is feasible and should go forward to the Full Study Development stage.

4.1.4 Communication of result

The SRC's decision will be communicated to the CI in writing as soon as possible after the meeting (normally within 2 working days). A copy of this letter will be sent to the Trust Pharmacy and also to any other involved departments for early information.

4.2 Stage 2: Full Trial Development (see Appendix B)

When a trial goes forward to this second stage, a request is made for Sponsorship in Principle. This is important as some funding bodies require that sponsorship be agreed at least in principle prior to accepting a funding application.

The sponsor of a clinical trial must satisfy itself that the trial meets all relevant standards and ensure that arrangements are put and kept in place for adequate management, monitoring and reporting. Investigators are asked to note that it is quite normal to take several weeks or even months to refine the plans and prepare the detailed documentation required at this stage. Arrangements must be made for matters such as randomisation of participants, manufacture, packaging, supply, storage and dispensing of IMP (including placebo substances) and provision of any laboratory services. All this is essential because the proposed sponsor must make a fully-informed decision on whether it is able to meet the requirements of the study sponsor as defined in the Regulations, and detailed contracts will have to be negotiated with all involved parties. Investigators must, therefore, be prepared to spend as much time as is necessary developing the protocol and other documentation in collaboration with the Trust R&D Department, incorporating expert statistics and study design advice, drafting a monitoring plan and developing all the relationships that will be essential for the trial.

At the end of this period, you should have a set of documents that are ready for the "sponsorship in principle" application to the Trust R&D Department .

4.2.1 Submit documentation for 'Sponsorship in principle' application:

1. Protocol using the HRA recommended template adhering to the guidelines within the template;
2. PIS;

3. Consent form;
4. CRF;
5. Other key clinical documents (e.g. diary cards/questionnaires);
6. Drafts of any communication with patients, participants, GPs or recruitment advertisements – use HRA guidance;
7. Clinical Trial Risk Assessment, using sponsor-approved template
8. Draft Schedule of Events
9. Draft Statement of Activities
10. Any relevant draft contracts or confidentiality agreements that investigators have received from other parties;
11. Copy of Summary of Product Characteristics (SmPC), Investigator Brochure (IB) and/or Investigational Medicinal Product Dossier (IMPD);
12. Investigator team CVs (which must document GCP training);

The submission should be sent to ghn-tr.rdsu@nhs.net with the subject heading CTIMP 'Sponsorship in Principle' application.

4.2.2 Internal review of 'Sponsorship in Principle' application

The Trust R&D Department SRC will perform a review of the application and initial comments will be sent to the CI within 10 working days for response/protocol modification as required. The investigator team may respond in writing and/or submit revised documentation for consideration.

The Trust R&D Department will develop a draft monitoring plan for the trial in line with the monitoring SOP (R&D MR 04) and this will be included in the paperwork for consideration.

4.2.3 External review of 'Sponsorship in Principle' application

If after internal review and response from the CI, the SRC is not able to confirm Sponsorship in Principle the CI will be invited to attend a meeting with the the Trust R&D Department to discuss options on getting further input to the application. This may be by accessing external expertise reviewers in one or more of the following areas:

- External peer review
- Statistical review
- Pharmacy review
- Financial review
- Review by any other involved departments (e.g. Laboratory or Radiology)

Copies of the reviews will be sent to the CI as soon as possible after receipt by the Trust R&D Department SRC. The aim is to do this within 4 weeks but investigators will appreciate that requests to external reviewers cannot stipulate they respond to these deadlines and they may be unable to do so. The CI will have the opportunity to respond to the reviewers' comments. Once a response from the CI has been received or

confirmation of no response is given, the complete application will be booked into the next available date for final SRC review.

4.2.4 SRC final review of 'Sponsorship in Principle' application

The SRC will consider the complete application incorporating all of the submitted documentation, the peer reviewers comments, risk assessment and monitoring plan, and make a decision as to whether the Trust is, in principle, able to act as sponsor for the trial. The CI will be invited to attend the relevant part of the meeting.

The SRC's decision will be communicated to the CI in writing, usually within 7 working days. A copy of this letter will be sent to the Trust Pharmacy and other involved departments (where appropriate).

The SRC's decision that the Trust is prepared to accept 'Sponsorship in Principle' will allow the CI to proceed with applications to funding bodies, HRA and the MHRA.

It is important to remember that FINAL sponsorship approval and confirmation of Capacity and Capability are both required before the trial can commence.

4.3.1Final Sponsorship Approval (see Appendix C)

Once HRA and MHRA approval has been received (or in the case of Type A trials, acknowledged - The MHRA provides a notification scheme for certain lower-risk trials, defined as 'Type A' trials. These are trials involving medicinal products licensed in any EU Member State if: they relate to the licensed range of indications, dosage and form or, they involve off-label use, such as in paediatrics and oncology, if this off-label use is established practice and supported by sufficient published evidence and/or guidelines - See more at: http://www.hra.nhs.uk/research-community/applying-for-approvals/medicines-and-healthcare-products-regulatory-agency-mhra-medicines-clinical-trial-authorisation-ctimps/#sthash.zlZ4TTH5.dpuf), the CI should forward copies of the approvals (or acknowledgement) and any amended documents to the Trust R&D Department.

If significant changes have been required as a result of the regulatory applications, the SRC will review the application again.

If everything is found to be in order at this stage then FINAL Sponsorship approval will be granted and communicated in writing. At this stage, the Senior Research Manager for Governance (or designated individual) will register the trial on the MHRA's eSUSAR website (http://esusar.mhra.gov.uk/).

4.3.2 Applying for confirmation of Capacity and Capability

It is expected that investigators will have developed strong collaborations with any proposed trial sites during the study development process and that these sites are named on the HRA submission.

Once Sponsorship is confirmed to be in place an investigator (or delegate) must formally submit the necessary local information packs (refer to HRA website for recommended list of documents) to all site R&D Units so that they can consider and confirm their site's capacity and capability. It would be expected that the local Trust would open the study first in order to identify any remaining issues that might be required to be resolved prior to rolling out to other sites.

In addition the following must take place in a timely manner alongside information pack submission:

- Trial Initiation Session(s): The CI should arrange, in liaison with the appointed Trial Monitor, Trial Manager and the Trust R&D Department , one or more trial initiation sessions at each site. All investigators should previously have received training in the running of trials to GCP standards. The aim of the initiation session is to provide trial-specific training in the protocol, data recording methods and standard operating procedures, to go through the contents of the TMF/ISF, to answer queries and address any inconsistencies. It should also give the Monitor an opportunity to clarify the expectations that will underlie monitoring and to highlight any potential pitfalls s/he may identify. Following the trial initiation the Monitor or Trial Manager will submit a brief written report to the Sponsor confirming whether the Site has been successfully initiated. In the event that the Sponsor does not consider a site to have been successfully initiated then recruitment will be suspended at that site until the issue is resolved.
- Trial master File/Investigator Site File: The CI (or delegate) should compile the Trial Master File (TMF), advice and assistance can be sought from the Trust R&D Department; and, in addition, an Investigator Site File (ISF) for each Investigator Site (NHS Trust) participating in the trial.
- Final preparations by involved departments: The CI (or PI at other sites) should liaise with all other departments involved in the trial to ensure that everything is in place for commencement of the study. This will include final arrangements for matters such as randomisation, shipping of IMP to site(s), unblinding arrangements, laboratory services.

4.3.3 Receiving confirmation of Capacity and Capability

When the Trust R&D Department is satisfied that all is in order then capacity and capability will be confirmed in writing for the CI site. For other

sites the respective R&D offices will assess Capacity and Capability and send onto the Trust R&D Department when complete.

5 Delegation of Responsibilities.

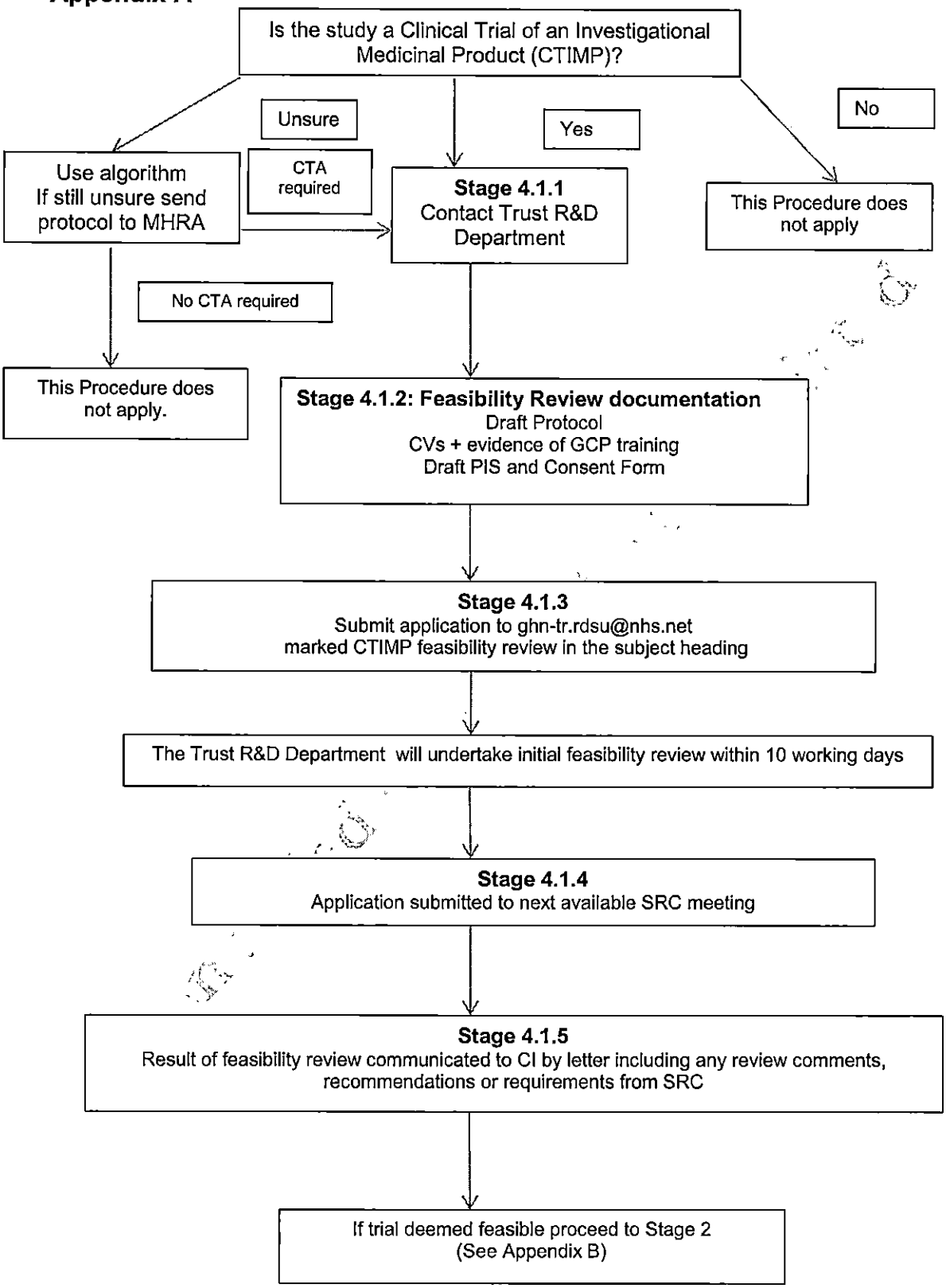
Agreement will be reached on the delegation of responsibilities and a copy of table in Appendix D will be printed and signed by the Chief Investigator and Sponsor. This will be a requirement of Trust Approval.

6 Related SOPs and Documents

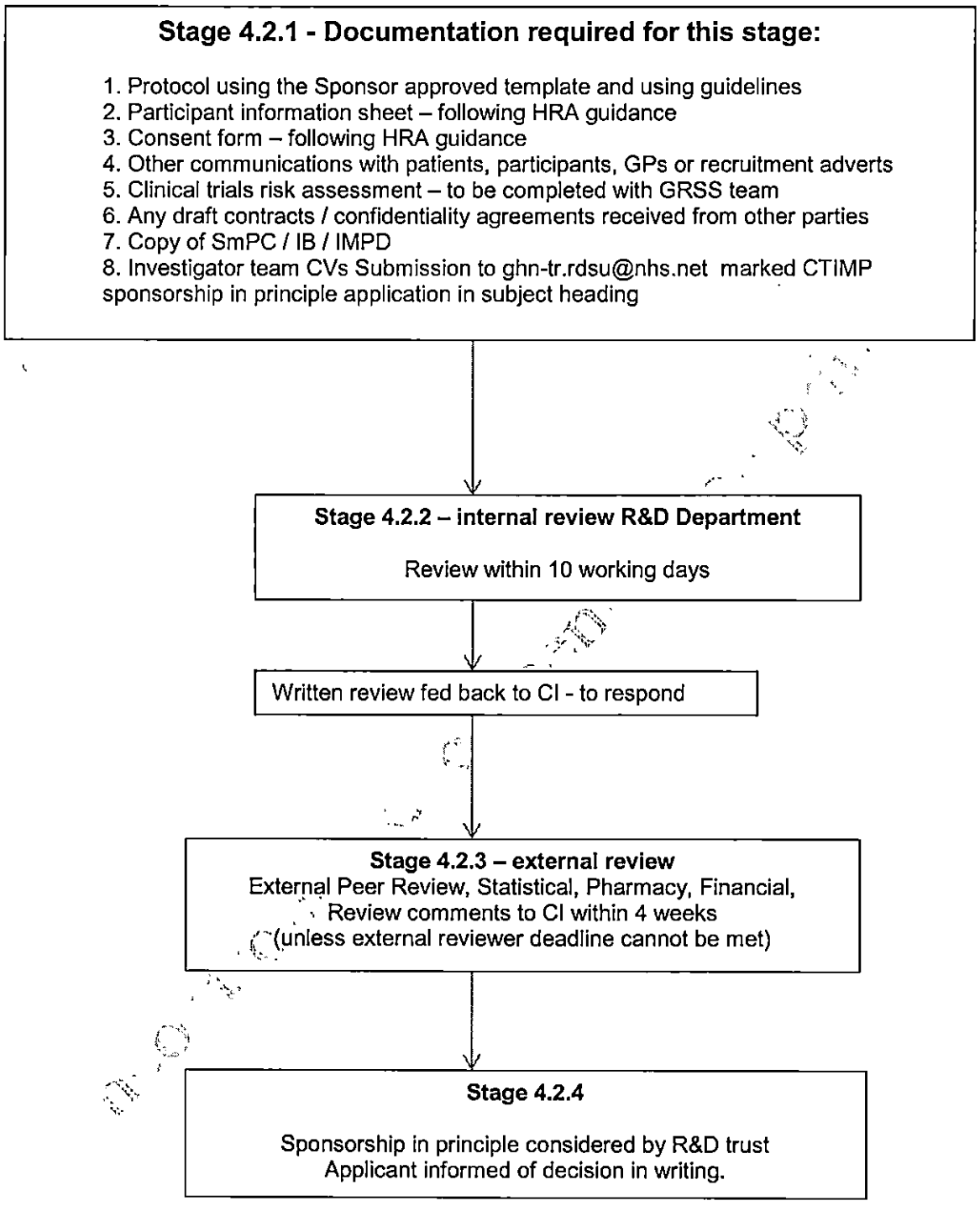
R&D SOP IR 01	Sponsorship
R&D SOP IR 02	Application Process for an Honorary Contract, Letter of Access or Research Passport
R&D SOP IR 03	Writing a protocol
R&D SOP RDVL 01	Scientific Review

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/343677/Risk-adapted_approaches_to_the_management_of_clinical_trials_of_investigational_medicinal_products.pdf

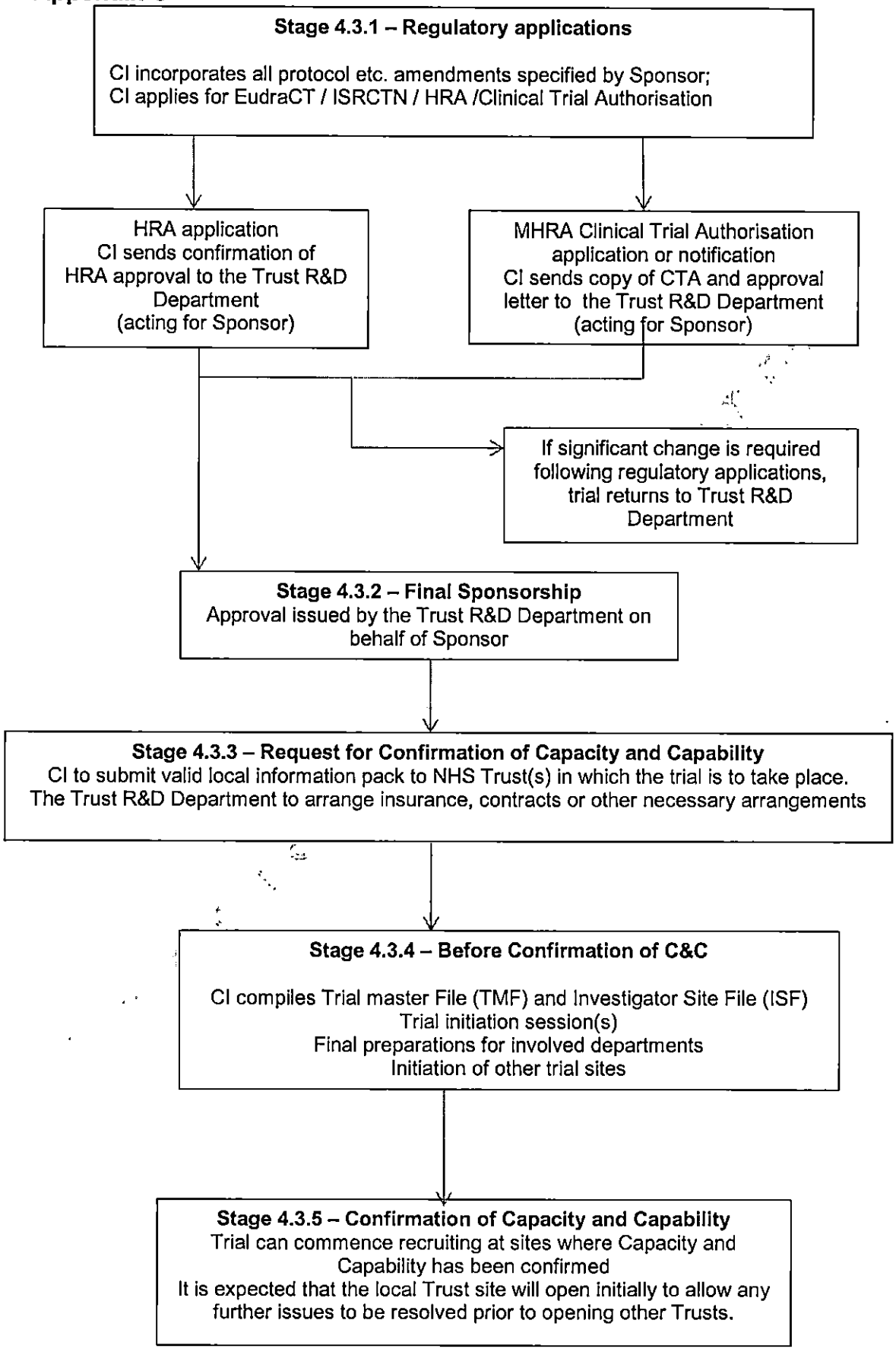
Appendix A


Is the study a Clinical Trial of an Investigational Medicinal Product (CTIMP)?
Unsure
Yes
No
Use algorithm If still unsure send protocol to MHRA
CTA required
Stage 4.1.1 Contact Trust R&D Department
This Procedure does not apply
No CTA required
This Procedure does not apply.
Stage 4.1.2: Feasibility Review documentation
Draft Protocol
CVs + evidence of GCP training
Draft PIS and Consent Form
Stage 4.1.3
Submit application to ghn-tr.rdsu@nhs.net marked CTIMP feasibility review in the subject heading
The Trust R&D Department will undertake initial feasibility review within 10 working days
Stage 4.1.4
Application submitted to next available SRC meeting
Stage 4.1.5
Result of feasibility review communicated to CI by letter including any review comments, recommendations or requirements from SRC
If trial deemed feasible proceed to Stage 2 (See Appendix B)

Appendix B


Stage 4.2.1 - Documentation required for this stage:
1. Protocol using the Sponsor approved template and using guidelines
2. Participant information sheet – following HRA guidance
3. Consent form – following HRA guidance
4. Other communications with patients, participants, GPs or recruitment adverts
5. Clinical trials risk assessment – to be completed with GRSS team
6. Any draft contracts / confidentiality agreements received from other parties
7. Copy of SmPC / IB / IMPD
8. Investigator team CVs Submission to ghn-tr.rdsu@nhs.net marked CTIMP sponsorship in principle application in subject heading
Stage 4.2.2 – internal review R&D Department
Review within 10 working days
Written review fed back to CI - to respond
Stage 4.2.3 – external review
External Peer Review, Statistical, Pharmacy, Financial,
Review comments to CI within 4 weeks
(unless external reviewer deadline cannot be met)
Stage 4.2.4
Sponsorship in principle considered by R&D trust
Applicant informed of decision in writing.

Appendix C


Stage 4.3.1 – Regulatory applications
CI incorporates all protocol etc. amendments specified by Sponsor;
CI applies for EudraCT / ISRCTN / HRA /Clinical Trial Authorisation
HRA application
CI sends confirmation of
HRA approval to the Trust R&D
Department
(acting for Sponsor)
MHRA Clinical Trial Authorisation
application or notification
CI sends copy of CTA and approval
letter to the Trust R&D Department
(acting for Sponsor)
If significant change is required
following regulatory applications,
trial returns to Trust R&D
Department
Stage 4.3.2 – Final Sponsorship
Approval issued by the Trust R&D Department on
behalf of Sponsor
Stage 4.3.3 – Request for Confirmation of Capacity and Capability
CI to submit valid local information pack to NHS Trust(s) in which the trial is to take place.
The Trust R&D Department to arrange insurance, contracts or other necessary arrangements
Stage 4.3.4 – Before Confirmation of C&C
CI compiles Trial master File (TMF) and Investigator Site File (ISF)
Trial initiation session(s)
Final preparations for involved departments
Initiation of other trial sites
Stage 4.3.5 – Confirmation of Capacity and Capability
Trial can commence recruiting at sites where Capacity and
Capability has been confirmed
It is expected that the local Trust site will open initially to allow any
further issues to be resolved prior to opening other Trusts.

Appendix D – Table of Delegated Responsibilities

This table covers the majority of tasks involved with setting up, running, maintaining and monitoring a CTIMP. However, the list is not designed to be exhaustive and discussions should be held between the CI and the Sponsor at the earliest opportunity to add/adapt the responsibilities in relation to the specific CTIMP being developed.

Once agreed, the table will be appended to the Trust Approval Letter, which must be signed by the Chief Investigator to signify agreement to all conditions of approval and the delegation of responsibilities within the CTIMP.

NB – some guidance is also included for studies involving Medical Devices.

Clinical Trials of Investigational Medicinal Products – Delegation of Responsibility to Sponsor and Chief Investigator/Research Team			
Responsibility	**TASK**	**Person/ Department Responsible**	**Relevant SOPs**
Trial Preparation	Write Protocol	CI	R&D SOP IR03
	Write Information Sheets, GP Letters, Consent forms, CRFs, Data Collection Tools etc. as appropriate	CI	R&D SOP IR03
	Conduct R&D Risk Assessment – initial stage of R&D Approval in Principle	Sponsor (R&D Managers)	
	Decision on Sponsorship	Sponsor	
	Secure Funding for the Trial	CI	
	Assist in preparation of funding application.	Research Design Service where applicable/R&D Office Staff	
	Draft and negotiate contracts with other sites and sub-contractors as required	Sponsor (R&D Managers)	
Applications and Registrations	Apply for Scientific/ Peer Review from Sponsor if applicable	CI	R&D SOP RDVL01
	Apply for Clinical Trial Authorisation (MHRA)	CI	
	Apply for Ethical Opinion	CI	
	Apply for NHS Permission in CT Site	CI	
	Apply for NHS Permissions at Participating Site	PI	
	Register Trial on EUDRACT and ISRCTN	CI	

Clinical Trials of Investigational Medicinal Products – Delegation of Responsibility to Sponsor and Chief Investigator/Research Team			
Responsibility	**TASK**	**Person/ Department Responsible**	**Relevant SOPs**
Trial Conduct	Overall responsibility for work at site – ensure it is done in accordance with the protocol, the Clinical Trial Regulations and the terms of regulatory approvals	CI at CI site and PI at Participating Site	
	Overall responsibility for patient care while in trial	CI at CI site and PI at Participating Site	
	Prepare and maintain Trial Master File	CI	
	Prepare and maintain investigator site files for participating sites	PI at participating site	
	Arrange Site Initiation Visit at CI and all Participating Sites	CI	
	Liaise with all involve support department to ensure readiness at CI and Participating sites	CI and PI at participating sites	
	Ensure GCP training of all Research Staff recruiting to study	CI and PI	
	Ensure all Research staff are trained on the protocol	CI and PI at site	
	Populating, signing and maintaining Delegation Log	CI at CI site and PI at Participating site	
	Ensure consistent definition of source data across all trial sites	CI	
	Develop and manage any trial specific SOPs	CI	
	Control arrangements for handling Investigational Medicinal Products	Pharmacy	Pharmacy SOPs
	Retain responsibility for Randomisation Procedures	CI	
	Responsibility for Code Break Procedures	CI/ Pharmacy	
	Arrange and conduct monitoring	Sponsor (R&D Managers)	
	Notify MHRA of Serious Breach	Sponsor (R&D Managers)	
	Report Serious Breach to SP	All Staff	
	Review Breach and assess whether to report as serious	Trust R&D Department using MHRA Guidance	
	Decide on Need for temporary halt to trial at CI site or Participating Site	CI and Sponsor	
	Prepare and submit to Annual Safety Reports to MHRA and Ethics	CI	
	Prepare and submit Annual progress Reports to the Ethics Committee	CI	

Clinical Trials of Investigational Medicinal Products – Delegation of Responsibility to Sponsor and Chief Investigator/Research Team			
Responsibility	**TASK**	**Person/ Department Responsible**	**Relevant SOPs**
Trial Conduct (continued)	Notify MHRA and Ethics Committee of the end of the Trial	CI	
	Prepare Quarterly Progress Reports to the Sponsor	CI	
	Review quarterly reports and take necessary action	SP and Trial Monitoring Committee/Data Monitoring Committee as appropriate	
Adverse Events	Identify and document all adverse events, adverse reactions, serious adverse events and SUSARs	CI and PI at appropriate sites	R&DSOP PH02
	Assess all adverse events, adverse reactions, serious adverse events and SUSARs	CI and PI at appropriate sites	R&DSOP PH02
	Report all adverse events, adverse reactions, serious adverse events and SUSARs in accordance with the R&D SOP on Adverse Event Reporting	CI and PI at appropriate sites	R&DSOP PH02
	Notify Sponsor of all Serious Adverse Events within required timeframe as specified in R&D SOP on Adverse Event reporting	CI and PI at appropriate sites	R&DSOP PH02
	Follow up Serious Adverse Events at site	CI and PI as appropriate	R&DSOP PH02
	Notify MHRA and Ethics Committee (and competent authority in any other country where trial is conducted) of SUSARs within required Timeframe	SP (R&D Managers)	R&DSOP PH02
	Notify all PIs at Participating Sites of SUSARs	CI	R&DSOP PH02
	Record and notify Sponsor of all pregnancy-related adverse events, including outcome of pregnancy	CI	R&DSOP PH02
	Assess need for unblinding in light of Serious Adverse Events and SUSARs	SP with medical expert/pharmacy	R&DSOP PH02
	Expedited reporting of SUSARs in active IMP to holder of manufacturing authorisation	SP	R&DSOP PH02
	Implement Urgent Safety Measures	CI/PI/SP in conjunction	R&DSOP PH02
	Report Urgent Safety Measures to MHRA, Ethics and SP	CI at CI site, PI at Participating Site	R&DSOP PH02
	Inform CI that an Urgent Safety Measure has been taken at a Participating Site	PI at participating Site	R&DSOP PH02

Clinical Trials of Investigational Medicinal Products – Delegation of Responsibility to Sponsor and Chief Investigator/Research Team			
Responsibility	**TASK**	**Person/ Department Responsible**	**Relevant SOPs**
Adverse events (continued)	Inform SP that an Urgent Safety Measure has been taken at a Participating Site	CI	R&DSOP PH02
Data Management	Manage development of data collection tools/CRFs	CI	
	Develop and maintain data collection databases	CI	
	Overall responsibility for data quality	CI and Research Staff	
Monitoring	Develop monitoring programme for trial	CI and Sponsor	
	Undertake Monitoring of CI Site and Participating Sites	SP	
	Compile Report on Monitoring outcomes	SP	
	Inform CI and PIs of monitoring findings	SP	
	Corrective actions following monitoring activity	CI at CI site and PI at Participating Site	
	Follow-up monitoring to ensure compliance	SP	
	Report suspected research misconduct to the sponsor	All Staff – PIs at Participating sites will report suspected misconduct to the relevant R&D Office	
	Review of suspected misconduct and taking appropriate reaction	Sponsor at CI site. Relevant R&D Office at Participating Site	
Amendments	Identify need for amendments	All	
	Determine whether proposed amendments are "minor" or "substantial"	SP	
	Update documents affected by amendment	CI	
	Ensure version control is consistent and correct	CI	
	Prepare submissions to MHRA and Ethics Committee for all	CI	
	Obtain approval/Notify amendment to MHRA and Ethics Committee as necessary	CI	
	Annual update of Investigator's Brochure (IB)	CI	
	Annual check on status of Summary of Product Characteristics (SmPC) and implement any updates	CI	

Clinical Trials of Investigational Medicinal Products – Delegation of Responsibility to Sponsor and Chief Investigator/Research Team			
Responsibility	**TASK**	**Person/ Department Responsible**	**Relevant SOPs**
Amendments continued	Notify all other staff/sites about amendments, including updates to IB and SmPC	CI	
Archiving	Ensure trial records and data are appropriately archived as per Trust Guidelines and R&D SOPs	SP at CI site Trust R&D at Participating Site	
Publication	Prepare abstracts, posters and publications and submit to R&D Office for review	CI	
	Review dissemination materials prior to external submission for publication/use	SP (R&D Office)	
	External submission of abstracts, posters and publications	CI	
IMPs	Ensure IMP is used only for those purposes detailed in the protocol	CI at CI site and PI at participating sites	Pharmacy SOPs
	Ensure IMP is provided and labelled in accordance with the Medicines for Human Use (Clinical Trials) regulations 2004	CI and Pharmacy	Pharmacy SOPs
	Ensure that IMP is appropriately stored in secure conditions	Pharmacy	Pharmacy SOPs
	Ensure that accurate records are kept relating to storage, dispensing, movement, delivery and destruction/return of IMP as applicable	Pharmacy	Pharmacy SOPs
Devices	Ensure that sufficient product is available for the planned number of participants	CI	
	Ensure that investigational medicinal devices are not used for any purpose other than those described in the protocol	CI	
	Obtain letter of No Objection from MHRA for use of Device for new purpose	CI	
	Ensure appropriate secure storage of medical devices	CI and Sponsor	
	Ensure records are kept relating to storage, movement, return to manufacturer and destruction of medical devices	CI	

Agreed by

Chief Investigator	NAME	POSITION	SIGNATURE	/ /
Sponsor	NAME	POSITION	SIGNATURE	/ /