Calderdale and Huddersfield NHS Foundation Trust

Obtaining R&D Confirmation of Capacity and Capability
STANDARD OPERATING PROCEDURE (SOP)

SOP Reference:	RDSOP 04	**Effective Date:**	03/05/2019
Version Number:	1.0	**Review Date:**	03/05/2021
Author:	Lesley Thomis	**Title:**	R&D Coordinator
Approved by: Name/Title:	Asifa Ali R&D Lead	**Date:**	14/06/2019
Signature of Approver:			
Approved by (SOP Controller) Name/Title:	Lesley Thomis R&D Coordinator	**Date:**	14/06/2019
Signature of Approver:			
This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise.			

This is a controlled document.

The controlled document can be found on the shared network drive: U:\SOP CONTROLLED Documents\1. SOPS. A printed copy will be classed as uncontrolled.

Researchers and their teams are responsible for checking the shared drive: U:\SOP CONTROLLED Documents\1. SOPS for the most recent version. This document may be printed for training and reference purposes.

This section details the version history for this document. It should summarise the key changes to the document.

VERSION HISTORY		
Version Number:	**Date Implemented**	**Details of significant changes**
V1.0	03/05/2019	New SOP
V1.2	14/06/2019	Updated to incorporate HRA implementation of the Organisation Information Document and Local Information Pack from 1st of June 2019
Enter number	Enter date	Enter details

TABLE OF CONTENTS	PAGE No
1. Introduction and Purpose	4
2. Who Should Use this SOP	4
3. When this SOP Should be Used	4
4. Procedures	5
5. Standards	7
6. Related SOPs and Documents	8
7. Appendices: **Appendix A – Definition of Research** **Appendix B – UK Local Information Pack – Commercial Studies** **Appendix C – UK Local Information Pack – Non-Commercial Studies** **Appendix D – R&D Amendment Checklist**	9

1. Introduction and Purpose

The purpose of this SOP is to describe the process for obtaining confirmation of capability and capacity from Calderdale and Huddersfield NHS Foundation Trust (CHFT) Research and Development Department for research to take place within the Trust.

The R&D Department has delegated authority by the Chief Executive to assess, arrange and confirm capability and capacity for research activity to be conducted on site. This process is referred to as 'R&D Confirmation' and all research projects MUST receive R&D Confirmation before commencing at the Trust (for exceptions, see section 4 of this SOP).

Definition of research

Under the UK Policy Framework for Health and Social Care Research, research is defined as '*the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods*.'

This excludes audits of practice and service evaluations. It includes activities that are carried out in preparation for or as a consequence of the interventional part of the research, such as screening potential participants for eligibility, obtaining participants' consent and publishing results. It also includes non-interventional health and social care research (i.e. projects that do not involve any change in standard treatment, care or other services), projects that aim to generate hypotheses, methodological research and descriptive research. Projects whose primary purpose are educational to the researcher, either in obtaining an educational qualification or in otherwise acquiring research skills, but which also fall into the definition of research are also included (section 3.1; 2017).

This SOP is not for use if the proposed project is *an audit or service evaluation*. For further information about classification of your project please use the HRA, 'Is my study research?' link: www.hra-decisiontools.org.uk/research.

2. Who Should Use This SOP

This SOP should be used by anyone wishing to conduct research activity at CHFT.

3. When this SOP Should be Used

This SOP should be used when applying for R&D Confirmation. In almost all cases R&D Confirmation for research will be required from CHFT.

However, in exceptional cases certain studies may receive HRA approval which states that a study will not require formal confirmation of capacity and capability from each site, but the study sponsor must notify sites of the study. In such instances CHFT will review the HRA confirmation and record the study details within its local management systems.

4. Procedure(s)

4.1. Before requesting R&D Confirmation

Before requesting R&D Confirmation (and approval for any other regulatory bodies) a sponsor for the research must be identified. If you require CHFT to act as a sponsor, please refer to the current SOP on Applying for Research Sponsorship.

The proposed project should be assessed as to whether it is 'research' as defined in the UK Policy Framework for Health and Social Care Research 2017 (see also 1 above). Further information and guidance can be found on the HRA website using the following decision tool: http://www.hra-decisiontools.org.uk/research/

All research studies should be submitted for HRA Approval following the HRA guidance at: www.hra.nhs.uk Application and submission occurs via the Integrated Research Application System (IRAS). For detailed guidance go to https://www.myresearchproject.org.uk/help/hlphraapproval.aspx

CHFT Confirmation cannot be issued without HRA approval in place.

4.2. The stages for setting up a research study at site

The HRA has defined the different stages that sponsors and participating organisations (e.g. Trust) go through to agreeing that the study can open at that organisation. The stages are Assessing; Arranging and Confirming.

4.2.1 Assessing Capacity and Capability

The R&D Department and local research delivery team work together to identify if the Trust has the capacity and capability to deliver the study – or is able to put the required capacity and capability in place – for example:

- Identify the participant population required
- Have the required equipment/ clinical services/ support services/emergency processes/ adequate space/ safety reporting processes/ IT systems etc. needed to deliver the study
- Have experienced, skilled and trained staff required to deliver the study

For some studies a site selection visit by the sponsor may be part of this assessment activity. Initial discussions with service support departments and finance may also begin.

In most cases the R&D Department may request a partial set of study documentation in order to begin early study assessment to facilitate rapid study set up.

4.2.2 Arranging Capacity and Capability

Once notification has been received that the Trust has been selected as a site and that the site is listed in the initial application to the HRA, or added via a substantial or minor amendment (as appropriate), then the R&D Department will request the study sponsor to submit a full and complete UK Local Information Pack (UK LIP) that should include a localised Organisation Information Document (OID) using the local checklists, See Appendix B and C.

R&D will also facilitate agreement from the relevant service support departments i.e. Pharmacy, Radiology, Pathology etc. The local delivery team will assist in this process to ensure all relevant departments have had the opportunity to assess and agree their participation for delivery. Each service support department will be sent a study synopsis form to complete and return to the R&D Department. In addition any clinical areas or teams likely to be affected by the delivery of the study will be notified. These processes may begin prior to receiving a UK Local Information pack.

The UK Local Information Pack will be requested when the R&D Department are confident that the study will proceed and a full assessment has been undertaken at site by the PI and research delivery team.

On receipt of a UK Local Information pack the R&D Department will aim to issue study confirmation within 10 working days, for contract signing this may require additional time for the receipt of contracts by each party (Trust and sponsor).

All studies will require Divisional approval, usually by the Divisional Director or their deputy. Specialty Leads (Clinical Directors), service area managers will also be notified of the study as deemed appropriate.

Both sponsor and the R&D Department should identify the requirements for any research passport / letters of access or honorary research contracts as soon as is practicable to ensure the timely issue of the required clearance for researchers prior to study commencement.

4.2.3 Confirming Capacity and Capability

Once study assessment and arrangements for delivery have been completed and a UK Local Information pack has been submitted, the R&D Department will proceed to issuing study confirmation.

CHFT accepts the Model Clinical Trials Agreement (mCTA) for contracts. Where a template based on the model agreement is submitted but includes modifications,

the sponsor should explain the rationale. Contracts will be expedited in line with sponsors Site Initiation Visits and 'green light' for study commencement.

4.3. Amendments to research studies hosted at site

All amendments submitted to the HRA are categorised as either category A; B or C amendments. NHS organisations are required to review all category A amendments and category B amendments when applicable to site (change of PI). The process for reviewing amendments at site is outlined in Appendix D. (R&D Amendment checklist)

5. National Standards

Research at CHFT will take regard for all national standards and regulatory requirements.

5.1. UK Framework for Health & Social Care Research 2017

This policy framework sets out principles of good practice in the management and conduct of health and social care research in the UK. These principles protect and promote the interests of patients, service users and the public in health and social care research, by describing ethical conduct and proportionate, assurance-based management of health and social care research, so as to support and facilitate high-quality research in the UK that has the confidence of patients, service users and the public.

It is for organisations and individuals that have responsibilities for health and social care research. This includes funders, sponsors, researchers and their employers, research sites and care providers.

5.2. Good Clinical Practice (GCP)

Good Clinical Practice (GCP) is a set of internationally recognised ethical and scientific quality requirements that must be followed when designing, conducting, recording and reporting clinical trials that involve people.

Guidance on good clinical practice has been produced by the International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use (ICH).
All those undertaking research at CHFT must demonstrate a required and proportionate level of GCP training.

5.3. UK Clinical Trials Regulations

For the latest update on this regulation see: The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019
http://www.legislation.gov.uk/uksi/2019/744/contents/made

5.4. National Research Ethics Service

Researchers must satisfy a research ethics committee that the research they propose will be ethical and worthwhile. The committee has to be assured that any anticipated risks, burdens or intrusions will be minimised for the people taking part in the research and are justified by the expected benefits for the participants or for science and society.

5.5. Health Research Authority

The Health Research Authority (HRA) protects and promotes the interests of patients and the public in health research. HRA is an executive non-departmental public body, sponsored by the Department of Health and Social Care.

The HRA is an over-arching regulatory body which aims to streamline the research approval process. For more information see https://www.hra.nhs.uk/

6. Related SOPs and Policy Documents

CHFT Research Governance and Procedures Policy
CHFT Research Misconduct Policy
CHFT Distribution of Income for Commercial Research Policy
CHFT Intellectual Property Policy
RSOP03 Application to the Trust for sponsorship of a study.
RSOP06 Set Up, Delivery and Management of Research Studies

Appendix A

Definition of research:

RESEARCH	SERVICE EVALUATION	CLINICAL/ NON-FINANCIAL AUDIT	USUAL PRACTICE (in public health including health protection)
The attempt to derive generalisable or transferable new knowledge to answer questions with scientifically sound methods* including studies that aim to generate hypotheses as well as studies that aim to test them, in addition to simply descriptive studies.	Designed and conducted solely to define or judge current care.	Designed and conducted to produce information to inform delivery of best care.	Designed to investigate the health issues in a population in order to improve population health Designed to investigate an outbreak or incident to help in disease control and prevention
Quantitative research – can be designed to test a hypothesis as in a randomised controlled trial or can simply be descriptive as in a postal survey. Qualitative research – can be used to generate a hypothesis, usually identifies/explores themes.	Designed to answer: "What standard does this service achieve?"	Designed to answer: "Does this service reach a predetermined standard?"	Designed to answer: "What are the health issues in this population and how do we address them?" Designed to answer: "What is the cause of this outbreak or incident and how do we manage it?"
Quantitative research - addresses clearly defined questions, aims and objectives. Qualitative research – usually has clear aims and objectives but may not establish the exact questions to be asked until research is underway.	Measures current service without reference to a standard.	Measures against a standard.	Systematic, quantitative or qualitative methods may be used.
Quantitative research – may involve evaluating or comparing interventions, particularly new ones. However, some quantitative research such as descriptive surveys, do not involve interventions. Qualitative research – seeks to understand better the perceptions and reasoning of people.	Involves an intervention in use only. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/ service user preference.	Involves an intervention in use only. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/service user preference.	Involves an intervention in use only. Any choice of intervention, treatment, care or services is based on best public health evidence or professional consensus.
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care. May involve data collected from interviews, focus groups and/or observation.	Usually involves analysis of existing data but may also include administration of interview(s) or questionnaire(s).	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.	May involve analysis of existing routine data supplied under license/agreement or administration of interview or questionnaire to those in the population of interest. May also require evidence review.
Quantitative research – study design may involve allocating patients/service users/healthy volunteers to an intervention. Qualitative research – does not usually involve allocating participants to an intervention.	No allocation to intervention: the care professional and patient/ service user have chosen intervention before service evaluation.	No allocation to intervention: the care professional and patient/service user have chosen intervention before audit.	No allocation to intervention.
May involve randomisation.	No randomisation.	No randomisation.	May involve randomisation but not for treatment/ care/ intervention.
Normally requires REC review but not always. Refer to http://hra-decisiontools.org.uk/ethics/ for more information.	Does not require REC review.	Does not require REC review.	Does not require REC review.

Appendix B

UK Local Information Pack (UK LIP) – Commercial Studies

Please use the Template Email for Commercial sponsors to share the Local Information Pack with participating NHS organisations in England and Wales found at the following link: https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack-Sharing

UK Local Information Pack for Commercial studies

Please record N/A against any documents which are not applicable. Only attach current versions if any documents have been superseded.

Document	Version (where applicable)	Date (where applicable)
Localised Organisation Information Document *(replaces the Statement of Activities)*		
HRA and HRCW Initial Assessment Letter (or HRA and HCRW Approval letter if application is already approved by the HRA and HCRW)		
IRAS Form		
Protocol and any amendments		
Participant information and consent documents (without local logos/ headers)		
Relevant model agreement		
NIHR Industry Costing Template or confirmation that the NIHR Industry Costing Tool has been accepted		
Delegation log if applicable to this study type – or indication of when the delegation log will be shared. When sharing the delegation log list any known members of the research team. Delegation logs are completed and signed during study set up.		
Any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study		

Appendix C

UK Local Information Pack (UK LIP) – Non-Commercial Studies

Please use the Template Email for Non-Commercial sponsors to share the Local Information Pack with participating NHS organisations in England and Wales found at the following link: https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack-Sharing

UK Local Information Pack for Non-Commercial studies

Please record N/A against any documents which are not applicable. Only attach current versions if any documents have been superseded.

Document	Version (where applicable)	Date (where applicable)
Localised Organisation Information Document *(replaces Statement of Activities)*		
HRA and HRCW Initial Assessment Letter (or HRA and HCRW Approval letter if application is already approved by the HRA and HCRW)		
IRAS Form		
Protocol and any amendments		
Participant information and consent documents (without local logos/ headers)		
Relevant model agreement		
Schedule of events or SoECAT		
Delegation log if applicable to this study type – or indication of when the delegation log will be shared. When sharing the delegation log list any known members of the research team. Delegation logs are completed and signed during study set up.		
Any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study		

Appendix D

R&D Amendment Checklist

Receipt of Amendments:

1. Amendments can be received directly from;
    a. Research nurses
    b. CTA's
    c. PI's
    d. Sponsor
    e. R&D colleague
2. Amendments are also received indirectly into the local R&D inbox from the same sources as above. As such it is important to check the local R&D inbox on a regular basis for email notifications of amendments.

Amendment Categories:

1. **Category A**: Implications for, or affects, all participating NHS/HSC organisations hosting the research project. – **All category A amendments will need R&D confirmation of review.**
2. **Category B**: Implications for, or affects, specific participating NHS/HSC organisations hosting the research project. – **E.g. a change of PI at site will need R&D confirmation of review.**
3. **Category C:** No implications that require management or oversight by the participating NHS/HSC organisations hosting the research project. These DO NOT require R&D confirmation of review; however please acknowledge receipt of the amendment by return of email. Add the details to the local R&D database and save the notification and associated documents in the relevant expedited study folder on the shared local network drive V for information.

Notifying Teams:

Once you have received an email notification of an amendment please check whether the team (PI/Research nurse/CTA) are aware of the amendment and whether there are any issues that may impact upon providing R&D confirmation of review. **Request confirmation from the team that R&D can review the amendment before doing so.**

Processing the Amendment:

1. Create a sub-folder in the relevant **expedited study folder on the local shared network V Drive** and save the email notification along with all attached documents in this folder.

2. In addition log the amendment on the local **R&D Database** following local process. If there is no implementation date on the HRA categorisation email then insert a date at 35 days from receipt of the amendment. Please note whether all regulatory documents have been received or are pending. If an implementation date is approaching and the regulatory approvals have not been received – issue a reminder email to the sponsor requesting an update.

Reviewing the Amendment (All category A and B when applicable to our site):

1. Once an amendment has received its regulatory approvals – HRA; REC or MHRA (if a CTIMP) the amendment should be reviewed.
2. Use the local template letter located in the active amendment folder on the **local shared network *V Drive.***
3. Address the local template letter to the Principle Investigator (PI) and other relevant details as required.
4. Review each document received for the amendment and enter the document details on the letter including date and version numbers. Ensure that all the regulatory documents are included: HRA approval email; REC Favourable Opinion Letter; MHRA Letter of Acceptance (if applicable – drugs trial)
5. Save a word copy of the template letter in the relevant amendment folder on the local shared network V Drive and in the local format.
6. Save a PDF copy of the template letter in the amendment folder and send it via email to the PI. Also CC the sponsor; the research nurse(s) and CTA into the letter and email prior to sending it.

Updating R&D Database and complete EDGE:

1. Once you have sent a letter of continuing confirmation of capacity and capability the local R&D database should be updated.
2. Add the amendment to the project on **EDGE** at the 'green level' but ensuring it is not published to other organisations. Use the locally created **'Attributes'** ensuring all the fields are completed.

Finally move the completed amendment folder into the corresponding '**Expedited Studies**' folder on the shared local network V Drive.