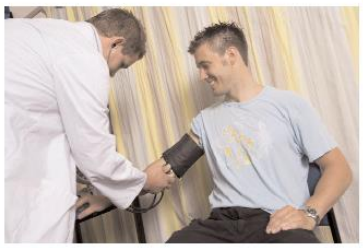
The University Of Sheffield.

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Clinical Research Office, Sheffield

information for staff

Process Map for conducting non-commercial research


Introduction

The Clinical Research Office provides comprehensive assistance to researchers conducting clinical research in Sheffield Teaching Hospitals NHS Foundation Trust and the University of Sheffield.

By working closely with our colleagues in the NIHR Research Design Service for Yorkshire and the Humber, the University of Sheffield Clinical Trials Research Unit and the Clinical Research Facility, we provide a streamlined service to support the stimulation, development, set-up, costing and management of clinical research in Sheffield.

We have outlined below the key steps of the process map for conducting non-commercial research which has been broken down into 9 stages, for commercial research separate comments are made throughout this map.

The map shows you who can help you at each stage of the process and an electronic version of this map can be found on our webpage.

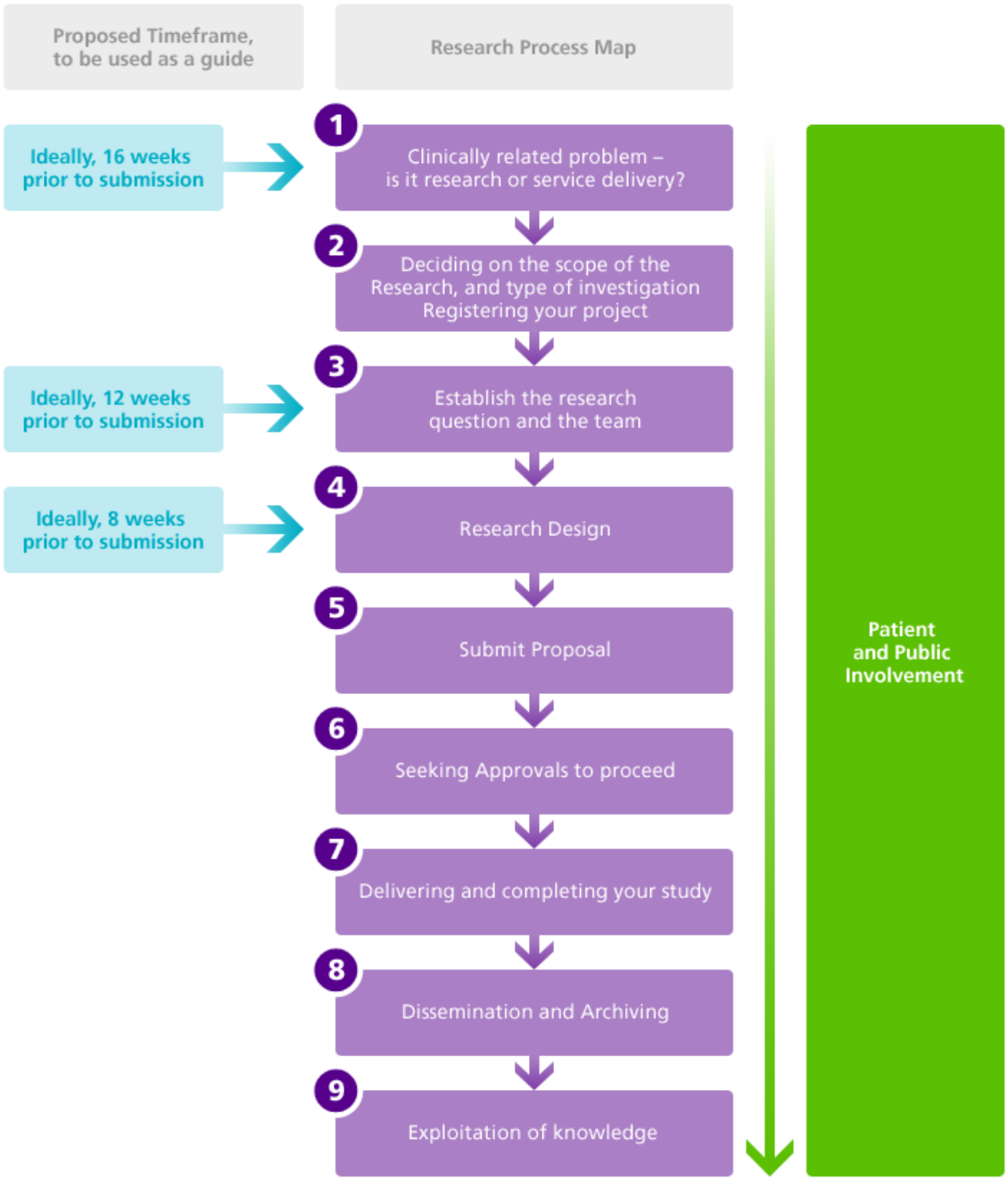
http://www.sheffieldclinicalresearch.org/for-researchers/

A list of the web links that appear in this document is below

- Clinical Research Office
  - http://www.sheffieldclinicalresearch.org/for-researchers/
- Research Design Service
  - https://www.rds-yh.nihr.ac.uk/
- Clinical Trials Research Unit
  - https://www.shef.ac.uk/scharr/sections/dts/ctru
- Research & Innovation Services
  - http://www.sheffield.ac.uk/ris
- University of Sheffield Library
  - http://www.sheffield.ac.uk/library
- Simple Rules Toolkit
  - http://clahrc-cp.nihr.ac.uk/wp-content/uploads/2012/07/Simple-Rules-Toolkit_2.pdf
- Cancer Clinical Trials Centre
  - https://www.sheffield.ac.uk/oncology/units/co/research/crc
- Sheffield Clinical Research Facility
  - http://www.sheffield.crf.nihr.ac.uk/
- Medipex
  - http://www.medipex.co.uk/
- Sheffield Healthcare Gateway
  - http://shg.sheffield.ac.uk/
- The Sheffield Microsytems Coaching Academy
  - http://www.sheffieldmca.org.uk/

Overview of the Entire Map

Over the coming pages we will show you the details under each of the nine steps, so you can see what you need to do at every stage of your research and who can assist you.



Step 1 – Clinical related problem- is it research or service delivery?

Ideally, this should occur 16 weeks prior to submission

If you have a substantive contract with Sheffield Teaching Hospitals please liaise with the Clinical Research Office (CRO) on how to get started. The Clinical Research Office can also assist you in identifying funding opportunities and collaborators to take your research idea forward.

If you have a substantive contract with The University of Sheffield please liaise with Research & Innovation Services, who can also assist you in identifying funding opportunities and collaborators to take your research idea forward.

Additional support can also be found at Research Design Services, Clinical Trials Research Unit and the Cancer Clinical Trials Centre

A brief outline of the abovementioned support services can be found on our partners page -

http://www.sheffieldclinicalresearch.org/about/our-partners

Involve Clinical Directorate management

You should liaise with all clinical teams within the hospital directorates that you are conducting your research in, so that all staff and managers are aware of your work, and what facilities and infrastructure support you may require.

Step 2 – Deciding on the scope of the Research, and type of investigation.

Registering your project

Scope of Research

To assist with performing a literature review please liaise with The University of Sheffield Library and our local Research and Design Services can offer advice on literature review and publication database searches, embracing systematic review, determining what research has already been done on a topic to avoid duplication and how new research may be able to add to existing knowledge.

Type of Investigation

Talk to the Clinical Research Office or Research & Innovation Services staff to determine the type of research. You can also use the Simple Rules toolkit and our local Research and Design Services who can offer advice on the correct research design to help you answer your research question.

Register Project

If you are going to use Sheffield Teaching Hospitals (STH) Facilities, staff, data or patients please register your project with the Clinical Research Office. Registration is the first step towards authorisation by the Director of R&D, without which no study on the hospital premises, involving STH patients, staff or their data may begin.

Step 3 – Establish the research question and the team

Ideally, this should occur 12 weeks prior to submission

Establishing the right team to both prepare and deliver your research is key, both The Clinical Research Office and Research & Innovation Services can advise you as to who to approach in this respect.

Additional support can also be found at Research Design Services, Clinical Trials Research Unit and Cancer Clinical Trials Centre.

A brief outline of the above mentioned support services can be found on our partners page -

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At this stage it may also be appropriate to liaise with the Clinical Research Facility and to inform them of your project if you intend to use their facilities to deliver the research.

External researchers - To determine what access levels and rights you'll require at STH for conducting research please go to our dedicated webpage **http://www.sheffieldclinicalresearch.org/for-researchers/conducting-research/step-2/**

Step 4 – Research Design

Ideally, this should occur 8 weeks prior to submission

Scientific review

Establishing the right team to both prepare and deliver your research is key, both The Clinical Research Office and Research & Innovation Services can advise you as to whom to approach in this respect.

Our local Research and Design Services can offer advice on the correct research design to help you answer the question within your research idea. They will also recommend whether you should work with the Clinical Trials Research Unit or the Cancer Clinical Trials Centre.

To liaise with local Patient & Public Panels to ensure your research will benefit patient please contact getinvolved@sth.nhs.uk. To see a full list of all patient panels based in this hospital, please go to our dedicated webpage http://www.sheffieldclinicalresearch.org/for-patients-public/how-to-get-involved/

Financial planning

Costing your grant application is fundamental, so if you are planning to submit a grant application that involves this hospital please contact your R&D Coordinator **at the earliest opportunity, at least six to eight weeks before the application deadline**. This early contact is essential to ensure that we can collect the NHS costs you need and your application can be signed off by the appropriate representative from STH.

For all staff and non-staff costs going through the University, a University Research Management System (URMS) costing must also be completed and authorised by Research and Innovation Services.

For your Coordinator's contact details please click here or contact Aneeza Lone in the Clinical Research Office on 0114 226 5938 or aneeza.lone@sth.nhs.uk

Step 5 – Submit Proposal

Before submitting you proposal you will need to obtain NHS and University sponsorship, finance sign off and NHS facilities sign off. Your R&D Coordinator will work with you and a research finance accountant to cost your study and put in place the appropriate contracts.

All contracts and agreements should be reviewed, negotiated and signed off by The Clinical Research Office, not the researcher. This applies to all kinds of contracts, including Confidentiality Disclosure Agreements. If you are asked to sign a contract as a Principal Investigator, please refer to your R&D Coordinator for help and advice.

Please inform The Clinical Research Office and (if applicable) Research & innovation Services that you have submitted your application to the Funder.

Step 6 – Seeking Approvals to Proceed

Complete research governance with CRO

If you have a substantive contract with Sheffield Teaching Hospital or involves Sheffield Teaching Hospitals, please liaise with the Clinical Research Office (CRO) on what research governance is required to perform your research.

Depending on the type of research you are undertaking, you may need to obtain approval from a Research Ethics Committee and the Health Research Authority. Drug or device studies may require approval from the Medicines & Healthcare Products Regulatory Agency (MHRA). All studies involving STH staff, patients or facilities will require approval via the STH Clinical Research Office

If you have a substantive contract with The University of Sheffield please liaise with Research & Innovation Services on what research governance is required to perform your research.

Work with CRO/R&IS to establish/set up appropriate funder agreement and contracts and also partner agreements etc.

Please liaise with your Clinical Research Office and Research & Innovation Services contact who will work with the other stakeholders to ensure that the necessary agreements are in place dependent on the funder, nature of your study, the stakeholders involved, and the sites participating.

You should also ensure that the Directorate in which the research is taking place are made aware of the study before it starts.

Ensure recruitment and consent training performed if required

It's important that all staff involved with delivering your research have all the relevant training in place to conduct the research. Key training they should have is Good Clinical Practice and Informed Consent training

It is mandatory at STH that if you are a member of a research team conducting a Clinical Trial of Investigational Medicinal Product (CTIMP) or a device trial that you have up-to-date GCP training. The NIHR provides access to GCP training for researchers and other staff supporting Portfolio research projects. If you have any questions about these courses, please contact Angela Hemingway (angela.hemingway@nihr.ac.uk).

The NIHR Clinical Research Network: Yorkshire and Humber also run a Yorkshire and Humber Informed Consent Workhop. This study day will be of interest to anyone currently working on, or with experience of working on, clinical trials with an interest in informed consent. Informed consent courses are available throughout Yorkshire. For 2015 course dates and information, please contact Angela Hemingway (angela.hemingway@nihr.ac.uk)

Step 7 – Delivering and completing your Study

Involve Clinical Directorate management

You should liaise with all clinical teams within the hospital Directorates that you are conducting your research in, so that all staff and managers are aware of your work, and what facilities and infrastructure support you may require.

Registration of Patient Accruals (if appropriate)

For all studies taking place at Sheffield Teaching Hospitals NHS Foundation Trust, it is mandatory that a member of the study team reports patient recruitment for their study into a web based system called EDGE.

It is essential that recruitment is entered into EDGE on a real-time basis to allow accurate monitoring of recruitment. Failure to report recruitment into EDGE may result in loss or delay in funding to the Trust and the Directorate.

Once NHS Permission is issued for your study to commence at STH, please contact the EDGE Local Administrator to obtain a login for EDGE. Once you have been issued with a login, please refer to the training materials below to use the system:

- EDGE Full Training Manual
- EDGE Quick Recruitment Guide

Please note the definition of a recruited participant is an 'eligible patient recruited onto a trial'. Screen failures do not count as recruited participants.

EDGE Local Administrators at STH:
Gaurika Kapoor (gaurika.kapoor@sth.nhs.uk) and Zoe Whiteley (zoe.whiteley@sth.nhs.uk).

Complete annual reports

The funder of your work, the Ethics Committee and any applicable regulatory bodies will make it known to you which reports they expect from you as part of the conditions of their award. If they ask for annual and or final reports please liaise with your study Sponsor and ensure that these are produced in accordance with their requests. Failure to comply with this could result in delay or loss of funding or loss of applicable regulatory approval. A copy of your reports should be sent to your Clinical Research Office (CRO) and Research & Innovation Services (R&IS) contact as applicable.

Project/governance closure with CRO, R&IS and regulatory bodies

Once your study has ended, you must notify your R&D Coordinator and submit an End of Study Notification to the Research Ethics Committee and any other regulatory bodies that are applicable for your study. A year after notifying the Research Ethics Committee that your study has ended, you are required to submit an 'End of study report' summarising your findings to them. Your R&D Coordinator will be able to advise you on the reports required once your study has ended.

Step8 – Dissemination and Archiving

Plan your publications

Your peers will advise you as to which publication will be the best academic publication for you to approach to disseminate your results.

Plan dissemination activities

We would recommend that all researchers don't just limit their dissemination of results to academic publications. Local patient groups can also help you write publications for the lay audience, which can disseminate your work further and to the patient groups most affected by your research.

Guidance from the Health Research Authority now states that participants in clinical trials and other interventional studies should be given information at the end of a study explaining:

- How their care might change
- When they can expect the summary findings to be made available
- How they will be given access to the summary findings

Please go to the dedicated HRA webpage **http://www.hra.nhs.uk/documents/2015/08/hra-guidance-end-study-pis-v4-1_20-august-2015.pdf**

Complete final reports

The funder of your work, the Ethics Committee and any applicable regulatory bodies will make it known to you which reports they expect from you as part of the conditions of their award. If they ask for annual and/or final reports please liaise with your study Sponsor and ensure these are produced in accordance with their requests. Failure to comply with this could result in delay or loss of funding or loss of applicable regulatory approval. A copy of your reports should so be sent to your Clinical Research Office and Research & Innovation Services contact as applicable.

Archive your research in line with Clinical Research Office guidance

The CRO Research Archive Lead can advise on the storage of study documents while the study is running, as well as the archiving of essential documents once the study is complete.

Please contact Natasha Ottley (natasha.ottley@sth.nhs.uk) for further information.

Step 9 – Exploitation of Knowledge

Plan taking study forward to next stage and grant application

The Clinical Research Office and the University's Research & Innovation Services and Research Design Services can advise you on where to go next with any follow on research coming out of your original research.

Intellectual Property opportunities

Research & Innovation Services at The University of Sheffield and Clinical Research Office can advise you on any Intellectual Property opportunities that might arise from your research. They will let you know if you should also liaise with Medipex and/or the Sheffield Healthcare Gateway.

Microsystems improvement

The Sheffield Microsystems Coaching Academy is based within Sheffield Teaching Hospitals and uses action centred learning to carry out improvement work in your own workplace (microsystem). Please contact them if you would wish to find out more on how to become a microsystems coach.