Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust

CNTW Student Research Guide

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Is your Project Research?

The first thing to establish is whether your project is Research.

The Health Research Authority (HRA) Decision Tool will help you establish whether your project is research, an audit or a service evaluation.

For further information regarding the project definitions please visit the HRA Website and the HRA Defining Research Table.

My project is Research

If your research project is part of an academic qualification and will recruit only staff as participants and will only recruit in Cumbria Northumberland Tyne and Wear NHS Foundation Trust (CNTW), you can complete the **Student Research Project Application Form.**

All other projects **MUST** go through the HRA. This means any project that is towards an educational qualification e.g. your dissertation and any projects involving patients, carers or other trusts must go through the HRA.

Develop your Research Idea

Once you have an idea that is supported by your academic supervisor, you need to turn that research idea into a protocol or project proposal.

A protocol or project proposal acts as an instruction manual for your project. It describes the approach that will be taken and how it will address a specific research question, in a rigorous and consistent manner. It will help ensure results are of high quality, and that data is reproducible as well as ensuring the safety of participants.

Protocol guidance and template can be found on the HRA Website.

The Role of your Academic Supervisor

The role of the Chief Investigator (CI) should be undertaken by the relevant supervisor or course leader, not the student. The roles and responsibilities of the student are outlined in Section **9.3** of The UK Policy framework for Health and Social Care Research.

Exception is made for an experienced care practitioner or manager undertaking an educational qualification for continuing professional development or a doctoral-level project while employed by CNTW. This will need to be discussed and agreed with the R&D Manager by emailing research@cntw.nhs.uk.

A bite-size eLearning module providing guidance on the supervisor's role in supporting student research can be found here.

Prepare your Study Documents

Prepare your study documents with guidance and support from your academic supervisor and in line with Health Research Authority Guidance

Obtaining a Sponsor

The UK Policy Framework for Health and Social Care Research requires all research projects approved by HRA to have an identified Sponsor. (See 9.3 and 9.10 of the framework for further information)

CNTW is willing to consider Sponsorship when the student is employed by CNTW and completing **Doctoral level study and above.** Any student project at Bachelor or Masters Level should be sponsored by the educational institute and **not** CNTW.

You should allow a minimum of 2 weeks' notice when requesting CNTW sponsorship, CNTW can refuse sponsorship requests if an appropriate timescale is not given.

In order for a sponsorship request to be reviewed we require the following documents to be submitted to Research@cntw.nhs.uk:

- PDF version of the full trial dataset from the Integrated Research Application System (IRAS) or your student application form where appropriate
- Organisational Information Document (OID) for each site type
- Current Protocol or Project Proposal *with version and date*
- Copy of proposed Participant Information Sheet (PIS) and Informed Consent Form (ICF) – *GDPR compliant and version controlled*
- Copy of the Independent Scientific Peer Review (where applicable)
- Research CV of student and supervisor *signed and dated.* Including information regarding relevant education, training and experience of research or GCP Training

Sponsorship Review

The R&D Manager will review the project to ensure:

- Appropriateness of CNTW to act as research sponsor
- Study feasibility within CNTW
- Chief Investigator (CI) / Principal Investigator (PI) suitability
- There is no risk to participants or the Trust – you may be asked to complete a Risk Assessment Form

Once the review is complete the R&D Manager will respond to you via email with the review feedback. You will be expected to respond to all queries in a timely manner. The R&D Manager will confirm Sponsorship.

You need confirmation of CNTW Sponsorship before you can submit your project to HRA.

Once Sponsorship has been agreed, the electronic authorisation request can be made via IRAS and the R&D Manager will authorise the IRAS form.

You should allow a minimum of 1 weeks' notice period when requesting authorisation of an IRAS Form – CNTW R&D can refuse requests if an appropriate timescale is not given.

How to Obtain Health Research Authority Approval (HRA Approval)

Will you need HRA Approval?

You will need HRA Approval if your project;

- Involves patients or carers
- Involves more sites than just CNTW

HRA Approval

This brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent ethical opinion by a REC so that you only need to submit one application.

If your project requires HRA Approval you will need to complete and IRAS Form. In order to do this you will be required to create and account with IRAS.

A bite-size eLearning module on HRA Approval can be found here.

IRAS provide an E-Learning Module to gain understanding of IRAS and how IRAS Works.

Any further queries you may have regarding IRAS, your query can be sent to iras.queries@nhs.net who will deal directly with your query.

Gaining Approval from CNTW to start your project

Once you have HRA approval you must send the HRA approval letter and any amendments to research@cntw.nhs.uk. CNTW R&D will then issue a Green Light to start recruitment.

The Research Coordinator will ask you to complete the capacity and capability form. Once this has been completed, CNTW can issue you the green light to start recruitment.

YOU MUST NOT START YOUR PROJECT UNTIL YOU HAVE A GREEN LIGHT EMAIL FROM R&D.

Once you start your project after green light confirmation, you must;

- Inform us when you consent your first participant as we may come and check your Investigator Site File (ISF) at this point and we need this for our records.
- Send in monthly recruitment spreadsheets to research@cntw.nhs.uk
- Inform us of any amendments made to the study. We must also receive an amendment capability form as we must approve these.
- Inform us when the study is closed and send the end of study report

To Recap

Before you can recruit a participant you need the following:

- R&D Approval if using the student form

If you are not using the student project form you need the following:

- A Sponsor
- HRA Approval
- Ethics if you are recruiting service users and carers
- Green light from R&D to start recruitment

Defining 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.

Flowchart for Overall Process