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. We recommend that you contact the research team as soon as you have your research idea so we can support you through the process.

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

If your project has been classified as research you can proceed with the guide, if this is an audit please contact clinicalaudit@cntw.nhs.uk or service evaluation please contact serviceevaluation@cntw.nhs.uk. Further information on project definitions can be found on the HRA Website.

The HRA have issued student research guidance for students who are planning on setting-up a research project for the purpose of obtaining an educational qualification.

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 accessed on the HRA Website.

My project is Research

You can complete the Student Research Project Application Form if all the following statements are true:

- Your research project is part of an academic qualification
- Your research project will only recruit CNTW staff as participants
- Your research project will only recruit in CNTW

If your project does not fit the above criteria, please continue to read the guide for all other student research as your project will be subject to regulatory approval. Any research project that is towards an educational qualification e.g. your dissertation involving patients, carers or other NHS trusts must go through the HRA, Research Ethics Committee (REC) and other applicable regulatory bodies.

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.

Prepare your Project Documents

Prepare your project 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).

If your project is CNTW staff, CNTW premises and towards an educational qualification then CNTW sponsorship is **not** required.

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

Once R&D have received a valid sponsorship submission, CNTW have a 3-week timeframe for reviewing the request and providing feedback and comments. CNTW can refuse sponsorship requests if an appropriate timescale is not given.

In order for a sponsorship request to be a valid sponsorship submission, we require the following documents to be submitted by the student copying in the CI to CNTWSponsormanagement@cntw.nhs.uk:

- Evidence that the CI holds contractual status with CNTW Trust
- PDF version of the full trial dataset from the Integrated Research Application System (IRAS)
- Current Protocol or Project Proposal *with version number and date*
- Copy of proposed Participant Information Sheet (PIS) and Informed Consent Form (ICF) – *GDPR compliant with version number and date*
- Copy of the independent scientific peer review (non-funded application)
- Organisational Information Document (OID) *if there is more than 1 participating site*
- Schedule of Events Cost Attribution Tool (SoECAT)/Statement of Activities (SOA) *if there is more than 1 participating site*

- Research CV of student and supervisor *signed and dated.* Including information regarding relevant education, training and experience of research or GCP Training

If you require any support, guidance or templates for the above-mentioned documents that are required for a sponsorship request, please email research@cntw.nhs.uk

Sponsorship Review

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

- Appropriateness of CNTW to act as research sponsor
- Project feasibility within CNTW
- CI and 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 or delegate 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 or delegate 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
- Involves staff from more than one participating site

HRA Approval

The IRAS process 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 need to have your authorised IRAS Form from sponsor in place. In IRAS you make one online electronic submission along

with all of your project documents. In order to do this you will be required to create an 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. If your project has been issued with REC Favourable Opinion, or any additional regulatory approvals, these will also need to be submitted to research@cntw.nhs.uk

The Research Coordinator will ask you to complete the capacity and capability form and obtain service manager approval (email confirmation of this is sufficient). Once this has been completed, CNTW will be in a position to issue you the green light to start recruitment.

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

If your research project involves more than one participating site a formal Local Information Pack (LIP) is to be submitted to participating sites so they can review, arrange and assess capacity and capability. You cannot approach other participating organisations until you have formal greenlight email confirmation 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 audit your Trial Master File (TMF) at the point of first participant consented. We also need this for our records.
- Send in monthly recruitment spreadsheets to research@cntw.nhs.uk
- Inform us of any amendments made to the project. All amendments are made using the Amendment Tool.
- Inform us when the research project is closed and send the Declaration of the end of Study form (if the project had REC Approval in place). If the project only has HRA Approval please provide us with email confirmation to the HRA of the project closure. More information on closing the project can be accessed here

To Recap

Student process using CNTW Staff, CNTW premises towards an educational qualification

Before you can recruit a participant, you need the following:

- R&D Approval if using the student form

All other student research projects:

Before you can recruit a participant, you need the following:

- A Sponsor
- HRA Approval
- REC if you are recruiting service users and carers
- Green light from R&D to start recruitment
- Capacity and Capability email confirmation from participating sites

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