Setting up a Research Study in Newcastle Hospitals

Student Guide

Contents

1. Introduction

This guide is aimed at students looking to set up a research study in Newcastle upon Tyne Hospitals (NuTH) with a focus on studies where NuTH will be approached to act as Sponsor. It may also be a useful guide for novice researchers who may not necessarily be undertaking research as part of their studies. All research falling under the remit of the Secretary of State for Health must have a formal Sponsor. This includes all research in health and social care that involve NHS patients, their tissue or information. The Sponsor takes on responsibility for the initiation, management and financing (where relevant) of the research. Further details are in Section 5.

In most cases, it will be appropriate for NuTH to sponsor your research, otherwise it will be your academic institution (or other organisation). You should speak to your supervisor who should be able to advise. Generally speaking, NuTH will sponsor projects which involve Trust patients (including their tissue and data), Trust staff and in cases where your research takes place on Trust premises or involves Trust services or facilities.

NuTH Sponsored Research

If you are looking for NuTH to sponsor your study, you should approach the Research and Development (R&D) Department as early as possible (nuth.genericqueries@nhs.net) to discuss the requirements of the study.

There are two key processes that you need to follow –

- Sponsorship Review – the purpose of this is to confirm that NuTH agrees to sponsor your study which then enables you to apply for the relevant national approvals
- Confirmation of Capacity and Capability – this is a separate process to the sponsorship review and begins once you have obtained all the relevant approvals. Essentially, the purpose of this is to confirm that the Trust have the capacity and capability to support your research and act as a site.

Hosted Studies (NuTH not acting as Sponsor)

If your academic institution or another organisation will be acting as Sponsor, you will need to follow their process regarding the sponsorship review. To enable you to undertake your research at NuTH, you will still need to go through the Confirmation of Capacity and Capability process as outlined above. You should follow the steps in Section 10 of this document which detail the arrangements for hosted studies.

2. Is my Project Research?

When setting up a study the first thing to establish is whether your project is classified as 'Research' as this will determine which approvals you need. The Health Research Authority (HRA) was set up to protect and promote the interests of patients and the public in health and social care research. They have developed a Decision Tool to help researchers establish whether their study is research, an audit or a service evaluation.

- Research is designed and conducted to generate new knowledge and should follow the systems for approval of NHS Research.
- Audit is designed to answer the question "Does this service reach a predetermined standard?"
- Service Evaluation is designed to answer the question "What standard does this service achieve?"

If your project is classed as research, then you will need to apply for approval from the HRA. Research projects which involve contact with NHS patients, their records or collection of their tissue will require an independent ethical opinion by a Research Ethics Committee (REC). This is covered in more detail in section 7. The HRA have produced a bite-sized learning module aimed at students undertaking research in Health and Social Care.

If your project is considered to be either an audit or service evaluation, then you do not need HRA and REC approvals. You should however, contact the R&D Department at the site where you plan to undertake your project for advice on any local review arrangements.

3. Develop your Research Idea

You now need to turn your research idea into a protocol. A protocol acts as an instruction manual for your particular study. 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. Your academic supervisor is responsible for providing advice and support in developing your research methodology. The Research Design Service is part of the National Institute for Health Research (NIHR) can also provide support with research design and research methods.

There is guidance on how to develop a protocol, together with protocol templates available on the HRA website. We would strongly advise you to use one of these templates. In most cases, this will be the protocol template for use in qualitative research.

4. Consider Research Costs and Funding

You should consider whether there are any costs associated with your study and whether you will require funding. There are various opportunities to apply for funding from various

non-commercial organisation including charities, the National Institute for Healthcare Research and Research Councils. Each funder has specific themes they are keen to support, so it is important you identify an appropriate funder to apply to.

Example of costs that can be incurred as part of a research study are; any interaction with patients, analysis, transport or storage of samples, consumables or equipment, travel/ conference attendance, sponsorship fees, and academic elements such as transcription charges, access to journals and publication fees.

If you need support deciding if your study will need funding or advice on what funding streams are available, please speak to your academic supervisor in the first instance and then the Research and Development (R&D) team in the Newcastle Joint Research Office (NJRO).

One of the other functions of the Research Design Service is to provide advice and guidance regarding developing grant applications and identifying funding sources.

If funding is necessary for your research, please engage with the NJRO as early as possible so you are supported to consider the study logistics and collate accurate costs to request in the grant application.

If you are awarded the grant application for funds, you must provide proof of the funding award before submitting your application for HRA and REC approval. Studies that have been funded and peer reviewed as part of an open national grant call may be eligible for NIHR UK Clinical Research Network (UKCRN) portfolio adoption and if accepted, you may be able to get help with support costs to assist with recruitment.

You can apply to the NIHR UKCRN portfolio at the same time as you submit your application for Approvals via the Integrated Research Application System (IRAS), (see section 8).

5. Identify a Sponsor

The UK Policy Framework for Health and Social Care Research requires all research in health and social care that involve patients, their tissue or their information to have an identified 'Sponsor.' The Sponsor is an institution or organisation which takes on the legal responsibility for the initiation and management of the research study. A Sponsor's responsibilities include ensuring that:

- The resources are adequate to allow the collection, analysis, & protection of high quality research data;
- The project is scientifically sound; and
- Indemnities are in place to cover those who are conducting or participating in research.

You will need to identify an institution or organisation that is willing to take on this role. NuTH will consider accepting the role of Sponsor when the student is employed by NuTH and completing a PhD level study. We will consider PhD sponsorship when the student is not employed by NuTH on a case by case basis. Any student project at Bachelor or Master Level will either be sponsored by the educational institute or NuTH. Generally speaking, if the study involves Trust patients, their staff or takes place on Trust premises, then NuTH should act as sponsor.

There should be a nominated individual identified to take on the role of Chief Investigator (CI) who is responsible for the conduct of the study and be able to supervise the research effectively. For single site studies, this person is also known as the Principle Investigator (PI). In the case of students at Bachelor or Masters Level, this will normally be your academic supervisor. Where an experience care practitioner or manager is undertaking an educational qualification for continuing professional development or doctoral-level study, they may be able to take on the role of CI/PI. Again, the NJRO will be able to provide advice.

6. Apply for Provisional Sponsorship

If you would like NuTH to act as Sponsor for your study, the first step is for you to complete a Project Initiation Form (PIF) which is available online here. The form asks for details such as the project summary, the nature of the research, research activities, timescales, funding and whether there are any staffing or other costs. You should complete and submit this form as early as possible.

Ideally the form should be completed while the protocol is in development, so that the R&D team can provide advice on managing the study. You should allow a minimum of 3 weeks' notice when requesting NuTH sponsorship. NuTH can refuse sponsorship requests if an appropriate timescale is not given. Your application will be considered during an Application Assessment Meeting and may involve further discussions before a decision is made as to whether NuTH provisionally agrees to sponsor your application.

Once NuTH has agreed to provisionally sponsor your application, the R&D team will issue an email outlining the next steps and the email will be copied into one of our Research Delivery Teams who will be your point of contact to help set up your study in the Trust.

7. Prepare Study Documents

Before you can apply for the relevant approvals, you will need to develop and finalise a suite of documents. These need to be submitted with your application and should be all dated and version-controlled. The study documents required are -

- **Research Protocol**

See Section 3

- **Copies of all 'Patient-facing' documents**
  As a minimum, this should include all Patient Information Sheets (PIS) and Informed Consent Forms (ICF). If you are using any questionnaires, invitation letters, diaries, patient cards, advertising material etc. these also need to be submitted. Advice on preparing the Participant Information Sheet and Consent Forms can be found on the HRA Website.

- **GP Letter**
  If you are planning on notifying the participant's GP of their involvement in the study, you will need to draft a letter and submit this also.

8. Obtain Approvals

HRA Approval brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent ethical opinion by a Research Ethics Committee (REC) so that you only need to submit one application. It applies where the NHS organisation has a duty of care to participants, either as patients/service users or NHS staff/volunteers. References to participants include people whose data or tissue is involved in a research project.

The REC reviews applications and gives an opinion about whether the research is ethical. They are independent of those organisations that manage and conduct research and they have a duty to protect the rights, safety, dignity and well-being of research participants. Comprising of up to 15 members, a third of these are 'lay' i.e. they do not have a professional interest in clinical research.

Integrated Research Application System (IRAS)

IRAS is a single system for applying for all the necessary permissions and approvals to conduct health and social care research in the UK. The tool enables researchers to create a core data set and then to create the forms which they will need for applications to R&D, REC and other national bodies/regulators depending on the type of study. You can create your own account and the site includes an E-Learning section for new users together with a Help section which provides useful links. If you have any queries regarding use of the system that cannot be found in the help section, you should contact iras.queries@nhs.net.

The System requires the researcher to complete an online form (Full Trial Dataset) which -

- Creates a core data set which enables you to enter the information about your project once instead of duplicating information in separate application forms

- uses filter questions which then open up relevant additional forms to ensure that the data collected and collated is appropriate to the type of study, and consequently the permissions and approvals required

IRAS uses a system of electronic signatures for authorisations. As such anyone who will need to sign the forms will also need to register with IRAS, including your Academic Supervisors.

After you login to IRAS and create a new project, the first thing you are required to do is complete the project filter questions. It is very important that this is done correctly as it determines the core data required for your submission. Getting it wrong may mean that you answer irrelevant questions or miss out relevant questions and your application may be invalid. You should fill in as much detail as possible and you don't need to complete the form all in one go.

NIHR UKCRN Portfolio

If you want your project to be considered for the NIHR UKCRN portfolio, you will need to answer 'yes' to 5b on the IRAS filter. Selecting this generates a Portfolio Adoption Form which will need completing and submitting, following the instructions in IRAS. The Portfolio Adoption Form can be submitted at the same time as applying to REC and the HRA through IRAS. Further details and web links on the benefits of portfolio adoption and eligibility are in Section 4.

Organisation Information Document and Schedule of Events (multi-site studies only)

New arrangements were introduced on 5 June 2019 to support the set-up of NHS research in the UK to ensure consistency across sites. A UK Local Information Pack has been developed which comprises of an Organisation Information Document and a Schedule of Events or SoECAT for studies which are sponsored by NHS Trusts and other non-commercial companies. The Organisation Information Document replaces the former Statement of Activities is submitted via IRAS. Organisation Information Document templates and associated guidance are available in IRAS Help. The guidance also refers to a Schedule of Events or a SoECAT (see next paragraph).

SoECAT (Single or Multi site studies)

A SoECAT (Schedule of Events Cost Attribution Tool) may be required if your study involves NHS costs and/or your funder has asked for this to be completed. Guidance has been produced on how the NHS attributes costs. Research costs will be discussed as part of your application for provisional sponsorship but if you are unsure, please contact the R&D team for advice.

Obtain Sponsorship 'Sign Off'

Once you have completed the Dataset and before you submit your application via IRAS, you will then need to submit a formal request to R&D via nuth.nuthsponsorship@nhs.net. NuTH will delegate the responsibility for approving the sponsorship request to an individual who will sign the IRAS form on the Trust's behalf. All requests for NuTH sponsorship are reviewed by an appropriate member of the R&D team. In order for a sponsorship to be reviewed the following documents must be provided -

- Copy of the NuTH One Form
- Copy of the NuTH Costing Tool
- PDF version of the full trial dataset from the Integrated Research Application System (IRAS)
- Copy of the current protocol with version number and date
- Copy of proposed Patient Information Sheet (PIS) and Informed Consent Form (ICF)
- Copies of any Questionnaires, Interview Schedules, Topic Guides, Invite letters, diaries, patient cards, Advertisement material etc. that you are proposing to use as part of your study
- Copy of GP letter if applicable
- Copy of the Independent Scientific Peer Review (if the funder is a charity or NIHR, this is not applicable)
- Research CV (short form) for Chief Investigator and Student
- Details of the proposed funding for the study e.g. Funding Award Letter or confirmation from the Clinical Director this is N/A
- Email confirmation from a member of the NJRO Funding Development Team that all NuTH costs have been identified. Even if the study has no NuTH costs, an email must be provided to confirm this from Funding Development Team.

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

- Appropriateness of NuTH to act as research Sponsor
- Study feasibility within NuTH
- Chief Investigator (CI) / Principal Investigator (PI) suitability
- That there is no undue risk to participants or the Trust

Once the review is complete a member of the team will respond to you via email with relevant feedback. You will be expected to respond to the feedback provided and submit any missing or amended documents.

Submit Application via IRAS

Once all outstanding issues have been addressed, the R&D team member who reviewed your application will request that you submit the electronic IRAS Authorisation. This will enable NuTH to 'sign off' the IRAS Form to confirm that we will act as Sponsor.

If you are applying for Portfolio adoption, you will need to pick the correct LCRN from the drop down menu – North East and North Cumbria (NENC).

Ensure you attach all of the required supporting documentation for your study and that they are all dated and version-controlled. Lack of date and version number is the main reason applications cannot be validated.

If your project is led from England, then when you electronically submit your application it will be submitted for HRA Approval. The application for HRA Approval includes the REC review if applicable. You will need to book a slot for your REC review via a Central Booking Service and we would advise you to make this booking once you have received Sponsor sign off.

Other things to consider -

Confidentiality Advisory Group - If you intend to access confidential patient information without consent in England and Wales you should apply to the Confidentiality Advisory Group (CAG). You will need to apply whether your project is managed as research or non-research.

Departmental Approvals - Many research studies will involve multiple departments throughout the hospital. It is essential when setting up a research study that these additional interventions are discussed with and approved by the department providing the service.

9. Obtain Confirmation of Capacity and Capability – NuTH Sponsored Studies

Once you have had all the relevant approvals (e.g. HRA and REC if appropriate), you need to go through a separate process – Confirmation of Capacity and Capability. **You cannot begin your research study until you have received an email from Trust R&D to confirm Capacity and Capability and have the have the appropriate contracts or access arrangements (see section 11).**

You will receive an email from a member of the R&D team outlining the steps required to submit an application for local R&D approval (Confirmation of Capacity and Capability). This will only come once the study has been signed off for NuTH Sponsorship. Essentially, this involves submitting an email to nuth.nuthsponsorship@nhs.net with the wording '*Request for Confirmation of Capacity and Capability – NuTH sponsored Study*' in the subject title. The documents required are -

- HRA Approval Letter
- REC Favourable Opinion Letter
- NuTH Sponsored Site Study Capability Form fully completed and authorised by all required signatories.

- Support Department Email confirmation
- If there is an Archiving Fee you will require email confirmation from the Head of Newcastle Joint Research Office that they are happy to absorb the costs.
- Caldicott Approval Email

There may be additional documents required depending on the type of study but we will notify you once we receive your submission. See Section 11 regarding final checks before you can start your research at NuTH.

10. Obtain Confirmation of Capacity and Capability – Hosted Studies

If NuTH is not acting as Sponsor (i.e. your academic institution or another organisation has taken on this role) but you would like your research to take place at the Trust (i.e. NuTH to act as a site), you will need to obtain local approval through the Confirmation of Capacity and Capability process. The Trust has a number of Research Delivery Teams, each covering a specified range of clinical areas. You would need to link up with one of these teams who will then guide you through the process to enable NuTH to confirm that we have the Capacity and Capability to host your research.

There are a number of steps that need to be followed -

i. Contact relevant Research Delivery Team. Identify which Research Delivery Team your study will fall under. Your supervisor may be able to advise or you may already be in contact with someone in that team. If you are still unsure, you can email nuth.genericqueries@nhs.net who will forward on your email to the most appropriate contact.

ii. Seek provisional agreement for NuTH to act as Host Site. You will need to liaise with the Research Delivery Team to ensure that your research can be accommodated at the Trust. Consideration will be given to whether we have the capacity and capability to host your study e.g. do we have the relevant cohort of potential recruits (where applicable), if any support departments are involved, do they have capacity and capability and are there any resource issues or potential costs to the Trust?

iii. Register your Study. The Research Delivery Team will then arrange for your study to be registered with R&D. This will generate a study specific five digit reference number which should be used in all related correspondence with the Trust.

iv. Apply for local approval (Confirmation of Capacity and Capability). Once you have obtained all the relevant approvals (e.g. HRA and REC if appropriate via the IRAS system), the Research Delivery Team will work with you to prepare the necessary documents in order for your study to be submitted for the Confirmation of Capacity and Capability review. They will forward the necessary documentation to R&D on your behalf. Further details of the process are outlined in the Standard Operating

Procedure 'Gaining Confirmation of Capacity and Capability to deliver research at The Newcastle upon Tyne Hospitals NHS Foundation Trust'

v. Confirmation of Capacity and Capability. Once R&D have reviewed your submission and any contracts/agreements have been signed by all parties (if applicable), they will issue an email confirming that the Trust has the Capacity and Capability to host your study. This will be addressed to all relevant parties.

You cannot begin your research study until you have gone through each step in this process, received an email from Trust R&D to confirm Capacity and Capability and have the have the appropriate contracts or access arrangements (see section 11).

11. Commence your research

The study can commence once all the required approvals are obtained and you've received email confirmation from Research & Development that the study can open to recruitment at NuTH. Please note that if you do not have an employment contract with the Trust and your research involves NUTH's facilities, staff or patients, you must have the appropriate contracts or access arrangements before you start your research. Please see Appendix 1 – 'Research Passports' for further information.

To summarise –

Before you can recruit a participant you need the following:

- Funding (if applicable)
- A Sponsor
- HRA Approval (including ethical approval if required) plus any other relevant approvals from regulatory bodies.
- Local R&D 'Confirmation of Capacity and Capability' email
- Appropriate Trust access i.e. Research Passport, Honorary Contract (if applicable – see Appendix A)

Glossary

CI (Chief Investigator)	The lead investigator with overall responsibility for the research. In a multisite study, the CI has coordinating responsibility for research at all sites. The CI may also be the PI at the site in which they work. In the case of a single-site study, the CI and the PI will normally be the same person and are referred to as PI.
Costing Tool	NJRO excel document which sets out all costs (including staffing costs where application) to run a study. This will be provided by the Funding Development Team.
HRA (Health Research Authority)	An executive non-departmental public body of the Department of Health in the United Kingdom. The HRA exists to provide a unified national system for the governance of health research. It serves to protect and promote the interests of patients and the public in health research.
HRA Approval	The process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent REC opinion provided through the UK Health Departments' Research Ethics Service. It replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This allows participating organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study.
ICF (Informed Consent Form)	Informed consent is an ethical and legal requirement for research involving human participants. It is the process where a participant is informed about all aspects of the trial and after studying all aspects of the study, the participant voluntarily confirms his or her willingness to participate in a particular clinical trial
IRAS (Integrated Research Application System)	A single, web-based system for completing applications for the permissions and approvals required for health and social care research in the UK. The various applications can be printed or submitted for this single system
NIHR (National Institute for Health Research)	Established by Department of Health for England in 2006 to provide the framework through which the Department of Health and Social Care will position, manage and maintain the research, research staff and infrastructure of the NHS in England as a virtual national research facility
NJRO (Newcastle Joint Research Office)	A partnership between The Newcastle upon Tyne Hospitals NHS Foundation Trust and Newcastle University. Set up to support researchers in the development, implementation and delivery of world-class experimental, translational and clinical

	research.
OneForm	NJRO Form which is completed by the researcher and outlines basic details of their proposed study including brief description, timescales, costs etc. A blank version will be provided by the Funding Development Team.
PI (Principle Investigator)	Principal Investigator: The lead person at a single site designated as taking responsibility within the research team for the conduct of the study
PIS (Participant or Patient Information Sheet)	An information leaflet given to those who have been invited to participate in a research study. The sheet is designed to provide the potential participant with sufficient information to allow that person to make an informed decision on whether or not they want to take part
Portfolio (CRN)	A database of high-quality clinical research studies that are eligible for support from NIHR Clinical Research Network in England.
Protocol	A document that describes the objectives, design, methodology, statistical considerations (or other methods of data analysis) and organisation of a research study.
R&D (Research and Development) Team	Team within the Newcastle Joint Research Office who are responsible for ensuring all research projects are conducted in accordance with all applicable principles, standards, regulations and legislation within the Newcastle Upon Tyne NHS Foundation Trust.
RDS (Research Design Service)	Organisation with a number of experts who can help write the protocol/documents for NIHR grant applications
REC (Research Ethics Committee)	Authorised by the National Research Ethics Service to review study documents for research taking place in the NHS, or social services. Some REC specialise in Clinical Trials, or topics such as research in children, Mental Capacity Act etc. All Research in NHS and/or social services involving patients, their information or their tissue must have been reviewed by a UK REC
Research Passport	A system for Higher Education Institution- employed researchers/postgraduate students who need to undertake their research within NHS organisations, which provides evidence of the pre-engagement checks undertaken on that person in line with NHS Employment Check Standards (among them CRB and occupational health checks). See Appendix 1
Site (Research)	The organisation with day-to-day responsibility for the location where a research project is carried out (UK Policy Framework for Health and Social Care Research, paragraph 9.14).
Sponsor	The person or body who takes on ultimate responsibility for the initiation, management and financing (or arranging the financing) of a clinical trial.

Standard Operating Procedure (SOP)	Set of step by step instructions or guidance material to outline key policies and procedures required to perform a specific task or process.
UKCRN (UK Clinical Research Network)	The Clinical Research Network is made up of 15 Local Clinical Research Networks that cover the length and breadth of England. These local networks coordinate and support the delivery of research in the NHS and across the wider health and social care environment, in England. The Local Clinical Research Network in this region is hosted by Newcastle Upon Tyne NHS Foundation Trust and is based at Regent Point, Gosforth, Newcastle. It covers the North East and North Cumbria.

Useful Web links

Attributing the costs of health and social care Research and Development (AcoRD)

Clinical Research Network (North East and North Cumbria)

Health Research Authority

HRA Resource on Student Research (includes a link to a bite-sized Learning Session

Integrated Research Application System

National Institute for Health Research

Newcastle Joint Research Office

Research Ethics Service

UK Policy Framework for Health and Social Care Research

UK Research and Innovation (includes information on Funding from the various Research Councils)

Newcastle University and NuTH Project Initiation Form

Useful Email Addresses

If you have an R&D Number, please quote this in your email

Subject	Email Address
First approach to NuTH R&D regarding the Trust sponsoring your research or for other queries **which are not covered in either this guide or in the Frequently Asked Questions on the NJRO website.**	nuth.genericqueries@nhs.net Please try to be specific in your subject title as to the nature of the query as this will help us to deal with your email more efficiently.
To register your study with NuTH where NuTH is sponsor (and obtain an R&D number)	nuth.genericqueries@nhs.net In the email title, please include *'Request for R&D Reference Number'*
Request for NuTH to sponsor your research from initial approach through to request for sponsor sign off.	nuth.nuthsponsorship@nhs.net
Queries regarding completing the IRAS form where these are not covered in the help section in IRAS.	iras.queries@nhs.net or nuth.nuthsponsorship@nhs.net
Request for local approval (Confirmation of Capacity and Capability) for studies **where NuTH is the sponsor**	nuth.nuthsponsorship@nhs.net In the email title, please include the R&D reference number and ''*Request for Confirmation of Capacity and Capability – NuTH sponsored Study*'
Research Passport Applications – if you are employed by another NHS organisation or hold an Honorary contract with another NHS org.	Nuth.researchpassports@nhs.net
Research Passports Applications– if you are a Newcastle University student.	Recruitment@newcastle.ac.uk
Research Passport Applications – if you are a student at another HEI other than Newcastle University	Nuth.researchpassports@nhs.net
Extending Letter of Access/Honorary Research Contract where you are a student at Newcastle University	employment.solutions@newcastle.ac.uk

Appendix 1 - Research Passports

A Research Passport is a mechanism for Non-NHS staff to obtain an Honorary Research Contract/Letter of Access to conduct research within the NHS.

An Honorary Research Contract (HRC) is required if your research activities involve interacting with participants in a way that has a direct bearing on the quality of their care.

A Letter of Access (LoA) is required for all other types of access where you may have the opportunity for any form of contact with participants in receipt of healthcare services but are not providing a direct bearing of care or other regulated activities.

Anyone who wants to carry out research involving NUTH's facilities, staff must have the appropriate contracts or access arrangements with the Trust **before they start their research**. Please note that you cannot be issued out a Letter of Access or an Honorary Research Contract for a study that has not yet received formal confirmation of capacity and capability.

As per NuTH Research Passport Policy, Section 8.6, an exemption exists for students conducting research as part of their healthcare placements.

Please see the Standard Operating Procedure for Research Passports for further information if needed.

For Newcastle university students wishing to apply for a research passport please contact: Recruitment@newcastle.ac.uk

If you currently hold a Letter of Access/Honorary Research Contract and you are a student at Newcastle University and you require your access to be extended you must do this at least 4 weeks before the current level of access expires. To apply for this you will need to contact: employment.solutions@newcastle.ac.uk

If you are a student at another Higher Educational Institution other than Newcastle University to gain access to NuTH you will need to submit the following to nuth.researchpassports@nhs.net :

- Research Role Assessment Form
- Research Passport Application Form
- Signed and Dated Research CV (if the CV is not signed your application will not be valid for review)
- Occupational Health fit slip or letter of clearance – this must be signed and dated by Occupational Health
- Proof of Identity – we require 2 scanned copies of photographic ID and 1 scanned copy of a proof of address. These ID Documents require a signature from your Line Manager/HR Department confirming this is a true likeness. If the signature if not there we will not accept these copies of ID Documents.

- Disclosure and Barring Service Clearance Certificate (if required)

If you are from another NHS Organisation or hold an Honorary contract with another NHS Organisation, then you will need to submit the following to nuth.researchpassports@nhs.net:

- NHS-NHS Proforma which needs to be signed off by the HR Department of your substantive employer.
- Research Role Assessment Form which needs to have the local R&D Reference listed on there for the study/studies you are working on and requires your signature and date (you cannot type your name into the document).
- Signed and Dated Research CV (if the CV is not the most up to date version and is not signed your application will not be valid for review).

If you apply for a 3 year Letter of Access/Honorary Research Contract but the study duration is shorter than this you will only be granted the access until the study end date that we have on our system.

Template documents and guidance to help you complete the Research Passport can be found here.

NuTH R&D will check that you have provided a valid submission of your research passport application before this is sent onto NuTH HR for them to issue the HRC or LoA as appropriate.