**Getting your NHS research project approved: A guide for students**

All student research involving the NHS requires approval before you can begin your study. This summary gives a basic guide as to which approvals are required, what documents you need to prepare, and tips for ensuring a smooth approval process.

**Before you begin – Things to think about**

* Determine what type of study you are proposing to undertake – different studies must go through different channels
* Involve others with the relevant experience at an early stage
* Make an initial enquiry for help from R&D
* What will your research cost and how will you fund it?
* What regulatory approvals are required?
* Is your educational institution prepared to act as study Sponsor?
* Are all support departments on board?

Please follow the link below for further information.

<https://www.research.yorkhospitals.nhs.uk/for-researchers/planning-your-own-research-project/>

**Basic Approval Information**

Depending on the kind of research you wish to conduct, you will need one or more of the following approvals:

* University Ethics Approval
* Ethics Approval
* Health Research Authority (HRA) Approval
* Capacity and Capability

Additional approvals may also be required, depending on the type of study and how you wish to undertake it. This should be discussed with your supervisor and with the R&D team.

1. ***University/Institutional Ethics Approvals***

As a student, you are likely affiliated with a University or Higher Education Institution (HEI) for educational purposes. Your institution will require a Faculty Ethical approval before you can start, whether you plan to work in the NHS or not. Speak to your supervisor to find out the submission and review process for your institution.

1. ***NHS Ethics Approvals***

Most research in the NHS requires an Ethical Approval, provided through the Health Research Authority. Only one ethics approval is required per study, regardless of how many NHS organisations you plan to involve.

*The following types of studies require ethical review:*

* All studies involving contact with NHS service users or carers of service users
* All studies involving identifiable clinical data of service users.
* Any studies involving collecting tissue or samples from participants

*The following studies no longer require ethical review:*

* Studies only involving NHS Staff interviews (unless you are asking sensitive questions).
* Studies only using NHS Facilities without involving service users.
* Studies only using anonymised data which has already been collected as part of standard clinical care.

*There are 2 levels of ethics review:*

* **Proportionate Review:** for studies which are considered to be of low ethical risk to participants
* or **Full Review**, for studies generally involving more intrusive research or research involving vulnerable people or research which could be considered to be higher risk.

*Gaining Ethical Approval*

Your submitted application will be sent to the monthly reviewing committees for approval. If the committees have queries or alterations need to be made, this can mean that your application will take longer to be approved.

1. ***HRA Approval***

All research undertaken with service users, carers, staff, and data or on NHS premises requires HRA Approval. HRA Approval brings together the assessment of governance and compliance (formerly referred to as R&D approval or Research Governance Approval) with the independent ethical opinion of the Research Ethics Committee (REC). This amalgamation has streamlined the approvals process and now only one application is required to be submitted.

***How to apply for HRA Approval***

All applications for approval in the NHS are required to be completed in the Integrated Research Application System, otherwise known as IRAS. This is a web-based application system from which applications for approval are completed within a single integrated dataset. IRAS can be accessed here (free registration required): [www.myresearchproject.org.uk](http://www.myresearchproject.org.uk/)

In addition to completing the application forms, you will need the following documents:

* A well-written protocol
* Patient Information Sheets/Consent Form
* Any other documentation given to prospective participants and/or clinicians i.e. Posters, flyers etc.
* A copy of any questionnaires or interview schedules to be undertaken in the research.
* Researcher CVs.
* Evidence that the clinical area/service that you are involving has been consulted and is happy to take part i.e. email confirmation or signature on the application forms.
* A copy of the Indemnity/Insurance document provided by your University.
* Evidence of funding where required

***Assessing Capacity and Capability***

All research studies that are to be conducted in the NHS must go through an assessment of capacity and capability (CAC). The HRA defines the different stages that sponsors and participating organisations (the Trust) must go through on the way to mutually agreeing that the study can open at that organisation.

The purpose of CAC is to determine whether there is the appropriate patient population and the necessary staff and resources to deliver the study. For student projects this process is usually easier due to the nature of the projects undertaken, because they are often not multi centre studies and local activity is minimal, often not involving members of the Trust research teams or staff as it is the student will be conducting the research with supervision from clinical and academic supervisors.

For further guidance please see R&D/S14 - <https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/sops/>

The R&D Unit is more than happy to meet with you to offer advice and go through the IRAS form with you to check that everything has been completed correctly. Please contact Mia Porteous Trial Manager mia.porteous@york.nhs.uk to arrange an appointment.

**Timelines**

Please be aware that gaining approvals to conduct research in the NHS takes time and is unlikely to happen within a few days. Depending on the complexity of your project and any ethical issues raised, approvals can take weeks to months. It is therefore important to plan your project carefully. Your institution supervisor will be able to advise on this.

Here are some hints & tips to get your research through the process smoothly ☺

1. **Review!!** Ask for your project to be peer-reviewed before you submit. Your supervisor and/or the R&D Unit will gladly review your study in the pre-submission stage. This will give you early feedback about the ethics and feasibility of your study and the standard of your documentation. It will also raise queries that will give you guidance about what you might need to clarify or change before you submit for final approval.
2. **Answer queries promptly!** One of the biggest hold-ups of approvals is applicants not responding to queries promptly. When you receive feedback from the R&D Unit or the outcome from the REC, be prepared to answer queries or make revisions to paperwork quickly. We also advise that you attend the REC meetings if possible, as this gives an opportunity to answer queries on the day so avoiding possible delays.
3. **Communicate early!** Speak to your institution supervisor, involve the R&D Unit from the outset and communicate with both the REC and Faculty Ethics early to find out about timelines and submission deadlines for your review. That way, you can plan ahead and have a realistic expectation of when your study should be approved.
4. **What makes a good application?** You can avoid some of the usual pitfalls of review outcomes by thinking about these factors in your protocol and application:
* Detail – you can never have too much information in your application. The more practical detail, the fewer queries that committees will likely have!
* Help - Have someone experienced in using IRAS to review your application and supporting documents. An extra pair of eyes is invaluable!
* Some key areas to think about - Participant recruitment strategy and numbers required, confidentiality and protection of participant data, quality and clarity of participant information sheets and consent forms.
* Justifying the importance and potential impact of your study on patient care – why is this study important? Justify the reason for doing the study.

**Approvals Submission Process:**

All projects are submitted online through IRAS. At the time of electronic submission of your IRAS form and associated documents, the IRAS website will automatically direct you to the Online Booking Service which will ask you some basic questions about your project (found in the Project Filter Section of IRAS).

You will then be prompted to choose from a number of available REC appointment dates to discuss your study. Currently all appointments are still being held by Zoom or equivalent.

<https://www.myresearchproject.org.uk/SignIn.aspx>

**Gaining Access to the YTH to conduct Research**

If you are not an employee of the Trust, but wish to come onto YTH premises to conduct your research, then you will need either an honorary research contract or a research letter of access, depending on your employer and the nature of the work that you plan to do. Please consult and complete the student checklist (downloadable from the student page) to determine what level of access and training you may require and contact Mia Porteous, mia.porteous@york.nhs.uk for further advice and help with completion of application forms.

**Starting Your Research**

You will **only** be able to start your research (i.e. approach or identify participants) once you have the HRA **and** Ethical Approval (if required) letters and confirmation of capacity and capability.

**Research Training**

If your research involves actively recruiting participants from the Trust, then you should have a valid Good Clinical Practice (GCP) certificate. To obtain the certificate, you will need to attend a GCP Training course or complete an online course. GCP training should be refreshed every 36 months to remain valid. If you are consenting participants you will also need to attend Informed Consent training. Course and booking details are available through the R&D Unit website or by contacting the R&D Unit.

**YTH Student Research Approvals Flow-chart**

Write Protocol and prepare supporting documentation.

Complete draft IRAS application forms.

Submit to University Ethics and/or R&D Unit for peer review

for early peer-review and feedback.

Complete submission and submit to

University Ethics Committee.

Revise documentation and application forms based on feedback

Complete submission and submit for approvals through IRAS

Approvals granted!

CAC assessment

**Be aware:**

**Further revisions**

**may be needed**

**during these**

**stages!!**

Undertake

GCP training if not already completed

Contact R&D Unit re obtaining access to YTH premises – mia.porteous@york.nhs.uk

 and sarah.sheath@york.nhs.uk

If you wish YTH R&D Unit to review your documents and IRAS application in addition to your academic and clinical supervisors please contact:

 mia.porteous@york.nhs.uk or deborah.phillips@york.nhs.uk

Begin completing R&D Student Checklist

Start your study!

R&D will give a final IRAS check if required –

Mia.porteous@york.nhs.uk

YTH Research Delivery Facilitators (RDFs) – Contact the R&D Unit – please follow the link to determine which RDF deals with your project specialty:

<https://www.research.yorkhospitals.nhs.uk/about-us1/meet-the-team/>

**Useful Links and Information:**

NHS Health Research Authority – <http://www.hra.nhs.uk/research-community/applying-for-approvals/>

National Guidance and templates for Consent Forms and Information sheets: <http://www.hra.nhs.uk/research-community/before-you-apply/participant-information-sheets-and-informed-consent/>