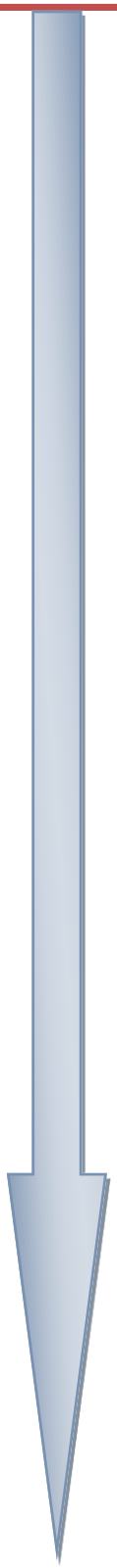
ICH student guidance for Research Governance

All ICH student projects need to be registered with us here in the R&D office, the student registration form needs to be completed and forwarded to research.registration@gosh.nhs.uk. A governance review is undertaken and the R&D office will advise on what is necessary for R&D approval to be issued so that the project can commence. Just to note this guidance is not an exhaustive list.



Health Research Authority approval

If your project involves NHS patients and/or their relatives/carers (including tissue/data) then you will need to apply for HRA approval. This incorporates a NHS ethical review.
https://www.hra.nhs.uk/approvals-amendments/

Timelines: NHS ethics review (up to 60 days full meeting, 21 days proportionate review); HRA approval should be issued shortly after.

UCL Data Protection Registration

If you are collecting and storing personal data at UCL then you will need to register this project with UCL data protection. Forms can be found at https://www.ucl.ac.uk/legal-services/research.
More details on the use of the UCL Data Safe Haven can be found here: https://www.ucl.ac.uk/isd/services/file-storage-sharing/data-safe-haven-dsh

ICH risk assessment approval

If you are using ICH facilities then you need to submit an appropriate risk assessment on riskNET https://www.ucl.ac.uk/safety-services/risknet.

UCL ethics approval

All non-NHS research proposals involving Human Participants (including collection and/or analysis of data) undertaken by university staff or students on university premises or elsewhere (including overseas research) require UCL ethics review.
https://ethics.grad.ucl.ac.uk/

Please note the UCL Data Protection registration and ICH risk assessment needs to be completed (please see below) and documented in the UCL ethics application before it is submitted.

Timelines for approval: Full meeting (decision within a week of the meeting), 21 days for proportionate review

R&D approval

Frequently asked questions- General Queries:

Is my study research?

The UK Policy Framework for Health and Social Care Research defines research as an "attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods."

Some projects may not be classed as research, and therefore would not require review by the R&D Office. To determine whether your study is research, you can complete the Health Research Authority online decision tool kit. If you are still unsure, you can contact the governance team for further advice. Please provide as much information as possible regarding the project.

A handy guide for defining research projects at GOSH/ICH and the relevant contact details can be found here.

Do I need R&D approval before I can access my grant funding?

Yes, you will need R&D approval from the R&D Office to access funding from the grant linked to the study.

I am a student based in UCL outside of ICH and my study does not involve GOSH or ICH. Do I need R&D approval from your Office?

No, the study does not need registering with the GOSH/ICH R&D Office if there is no GOSH or ICH involvement. However, you may need to register your study with UCLH/UCL Joint Research Office for review and approval.

My research project does not involve GOSH or the NHS. Do I still need NHS ethics, Health Research Authority (HRA) and R&D approval?

If your study does not involve NHS patients and/or their relatives/carers (including tissue/data) then you do not need NHS ethics or HRA approval. However, your study may require UCL Ethics approval.

Your study will still need to be registered with the R&D Office if you plan to undertake any research procedures at ICH. You will need to liaise with the governance team for R&D approval prior to carrying out any research procedures at ICH.

What is the Data Protection Act 2018 and how is this related to research?

The Data Protection Act 2018 is the UK's implementation of the General Data Protection Regulation (GDPR). Everyone responsible for using personal data has to follow strict rules called 'data protection principles'. They must make sure the information is:

- used fairly, lawfully and transparently
- used for specified, explicit purposes
- used in a way that is adequate, relevant and limited to only what is necessary
- accurate and, where necessary, kept up to date
- kept for no longer than is necessary
- handled in a way that ensures appropriate security, including protection against unlawful or unauthorised processing, access, loss, destruction or damage

The Health Research Authority (HRA) provides guidance on how the DPA 2018 affects NHS research. Information provided to participants in NHS research requires the inclusion of transparency information, more guidance can be found here.

UCL provides guidance on the DPA 2018 here. This includes information on privacy notices and training courses.

Frequently asked questions- Project Specific:

My study is being conducted abroad. Do I need ethics approval?

Studies conducted abroad would normally require UCL ethics review and local approvals abroad. If any personal data is being sent to ICH then UCL Data Protection Registration may be required. If relevant material defined under the Human Tissue Act is received and stored at ICH then this may need to be stored under the ICH HTA licence. You will also need to submit an appropriate risk assessment on riskNET https://www.ucl.ac.uk/safety-services/risknet.

More guidance on HTA relevant material can be found here.

My research project is purely laboratory based at UCL ICH. There is no GOSH/NHS involvement; does this still need to be registered with the R&D Office?

Yes, we are a joint R&D Office and review studies for both for GOSH & ICH. A member of the governance team will liaise with you regarding any study queries they may have. This will include checking to see if any contracts are needed for the study. If you are using Human Tissue then the R&D office would need confirmation of the NHS (or UCL) ethical approval in place to use the tissue in the research.

More information on Human Tissue use in research can be found on the Human Tissue Authority (HTA) website.

For laboratory-based studies, you will also need to submit an appropriate risk assessment on riskNET https://www.ucl.ac.uk/safety-services/risknet.

My Research project involves storing identifiable data in the Data Safe Haven- what do I need to do and who can help me with this?

You should speak to the UCL data protection team if your project involves storing data in the Data Safe Haven. The project should be registered by completing the UCL data protection form. The UCL data protection team will be able to provide further guidance regarding Data Safe Haven.

I would like to collect data from GOSH patient medical records and/or use anonymised data at ICH as part of my study. Am I allowed to do this?

Yes, the project would need to be registered with us here in the R&D Office for review.

Research limited to secondary use of information previously collected in the course of normal care (without an intention to use it for research at the time of collection) is generally excluded from REC review, provided that the patients or service users are not identifiable to the research team in carrying out the research. This exception also applies to research undertaken by staff within a care team using information previously collected in the course of care for their own patients or clients, provided that data is anonymised or pseudonymised in conducting the research.

Case note reviews using anonymised NHS clinical data may need to be reviewed by the Health Research Authority, please contact research.governance@gosh.nhs.uk for further advice.

It should be noted that only the Clinical Care team can access identifiable clinical data and anonymise it for the research team.

If you are analysing anonymised data at ICH then your study would still need to be registered with the R&D Office for review.

Research involving the use of the GOSH Digital Research Environment (DRE) should contact DREProjects@gosh.nhs.uk for further guidance. **Please note that currently only anonymised data can be used in the DRE.**

Frequently asked questions- NHS Research:

What is CRAC & when do I need to apply for it?

The GOSH Clinical Research Adoptions Committee (CRAC) is an internal peer review committee that meets monthly to review and endorse any clinical research projects taking place within Great Ormond Street Hospital (GOSH) that are not externally funded ('own-account projects'). The committee aims to ensure the standard and quality of clinical research within GOSH.

You will need to apply to the Clinical Research Adoptions Committee (CRAC) if your project is unfunded, and involves any GOSH resources, GOSH staff or GOSH patients (including patient samples or data). Further information (including future meeting dates) regarding CRAC can be found on the GOSH website.

My project will involves the NHS and requires HRA approval. What are the next steps?

Applications to the HRA should be submitted using the IRAS system. You will need to liaise with a member of the governance team for sponsorship and ensure the documents are ready for HRA/NHS REC submission. If the project is unfunded, you may need to apply to the GOSH Clinical Research Adoptions Committee (CRAC) for approval before you can apply for HRA approval.

Supervisors and students applying to an NHS REC should familiarise themselves with the Health Research Authority (HRA) guidance found here.

Once your project has received an ethical favorable opinion, the HRA will look to issue a HRA approval letter. Once you have HRA approval, you will need to continue liaising with the governance team for confirmation of capacity and capability for GOSH (https://www.hra.nhs.uk/planning-and-improving-research/best-practice/nhs-site-set-up-in-england/)

I need to submit a protocol to the NHS REC for my research project – can the R&D Office help with this?

Protocol templates are available on the HRA website. The R&D Office can provide a protocol template if the study is GOSH/ICH sponsored. Please contact research.governance@gosh.nhs.uk should you need this. You can also find examples of patient information sheets and consent forms on the HRA website.

Do I need HRA approval if my project involves NHS staff only?

Some NHS staff studies require HRA approval to be undertaken within the NHS, please contact research.governance@gosh.nhs.uk for further advice. The study may need to be reviewed by the GOSH Clinical Research Adoptions Committee (CRAC) if there is no funding.

Frequently asked questions- NHS Access Arrangements:

What is a research passport and when do I need one?

A Research Passport is the mechanism which allows researchers affiliated to a University/Higher Education Institution to obtain an Honorary Research Contract (HRC) or Letter of Access (LOA) when they propose to carry out research in an NHS organisation where they do not have contractual arrangements. More information can be found on the IRAS website: https://www.myresearchproject.org.uk/help/hlphrgoodpractice.aspx

As part of the research passport process a DBS check may need to be in place. Research Students who are registered with the UCL GOS Institute of Child Health should consult with their primary supervisor as to whether an enhanced DBS check is necessary based on the student needing to have unsupervised access to patients under the age of 18 years, or require an NHS Research Passport in order to be able to complete their PhD project. Students can also contact research.governance@gosh.nhs.uk for up-to-date advice on access arrangements required for GOSH.

Research students who require an enhanced DBS check should contact the ICH Research Degrees Office to request a DBS clearance form. The form should be completed and then taken to the ICH Research Degrees Office along with the required forms of ID (ie passport, proof of UK address which must be less than 3 months old, proof of National Insurance number (if applicable), UK Driving Licence (if applicable)). The ICH Research Degrees Office will then arrange the DBS check via UCL Registry.

[Please note that the above, DBS checks and Research Passports, only refers to doctoral research students. MSc students who are enrolled with UCL should go directly to the UCL Student Centre to arrange a DBS check and to their Teaching Administrator if they require authorisation on their Research Passport application form.]

What type of contract do I need to carry out research at GOSH?

LOA – A researcher substantively employed or has an honorary clinical contract with an NHS organisation will need to apply for a Letter of Access.

HRC – UK based academic staff/students will need to apply for an Honorary Research Contract.

GOSH HR Honorary Contract – all other persons, e.g. Those from a commercial company, persons from abroad, persons taking part in standard clinical care as well as research, persons who don't hold any contract with an NHS organisation or an academic institution.

Please discuss this with a member of the research governance team (research.governance@gosh.nhs.uk) if you are unsure about what type of contract is needed.

Please note that we cannot issue any access arrangements for researchers coming to GOSH until you have received R & D approval for the project(s) you will be working on at the Trust.

What type of contract do I need?