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The IRAS system is an online system for preparing regulatory and governance applications for health and social or community care research. It is a UK-wide system which is provided by the NHS HRA (NHS Health Research Authority) which captures the information needed for the review bodies listed on this IRAS webpage.

IRAS contains several different authorisations (e.g. resources, sponsorship, Organisation Information Document (OID), and insurance which require high-level authorisation within the university.

You will need to complete your submission to the Integrated Research Approval System. You can access the IRAS Online Guide here. Follow this link for the appropriate form and guidance. The HRA Approval Process can be accessed via this link.

Information surrounding amendments to a project and guidance on how to submit this to the IRAS system can be found on their website.

After you have approval from the IRAS, complete Northumbria's IRAS Internal Approval process.

Guidance

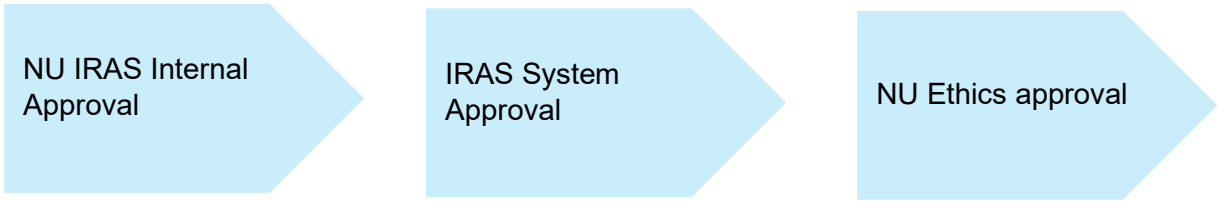
The IRAS system is the single system for applying for HRA permissions and approvals for health and social or community care research in the UK. The system enables you to enter the information about your project once instead of duplicating information in separate application forms, and it uses filters to ensure that the data you collect and collate is appropriate to the type of study, and consequently, helps you to apply for all the relevant permissions and approvals required.

If you are unsure if you need to complete and IRAS application:

- If you are a Postgraduate Research Student – check with your supervisor first, and then consult your Associate Head of School for Research and Knowledge Exchange (AHoS RKE) or School Ethics Lead (contact details can be found on this webpage) if you are still unsure
- If you are a member of staff, consult your AHoS RKE/ Ethics Lead (contact details can be found on this webpage)

If you are unsure if your project needs NHS REC (Research Ethics Committee) Ethics Approval, you can use the HRA Decision Tool on this webpage. You can find supporting guidance on the Applications and Reviews webpage.

To summarise, the process is as follows:



Step 1: NU IRAS Approval

A. Staff and PGR students need to complete Northumbria's Internal Approval Form including all of Declaration C (except the signature). Northumbria's Insurance information can be found on the Insurance Hub. If you cannot find what you need, or if you have any Insurance-related questions, you can email the Insurance team at fi.insurance@northumbria.ac.uk.

Please note, clinical trials may require additional insurance mitigations.

B. Send a PDF copy of your IRAS application, NU IRAS Internal Approval form, Organisation Information Document (OID), and any supporting documentation to ethicssupport@northumbria.ac.uk.
C. Ethics colleagues from Research and Innovation Services (RIS) will review your application and seek advice where appropriate.

   Common errors include:
   - Getting the official name of the university wrong - it should be *'University of Northumbria at Newcastle'*
   - Not knowing which address to include - it should be *'Sutherland Building, College Street, Newcastle Upon Tyne, NE1 8ST'*
   - Not including a version number and a version date - all documents should include a version number (e.g. *'Version 1'* or *'v.1'*) and a full version date

(dd/mm/yyyy) within the documents themselves (including the research protocol, interview schedule, invitation letter, etc.)
    - If not supplied, the HRA will return the submission as, should they need to request amendments, they need to be able to see which is the most up to date version
- Not addressing GDPR considerations on any participant information documents
- Not including an Organisation Information Document (OID)
- Inaccurate or missing sponsor details (please see step 3)
- *You can also read the **FAQs** at the end of this document*

D. Following review, the NU Internal Approval form is sent to the Chief/Principal Investigator (C/PI) for any amendments.
Please note, staff are encouraged to check with colleagues who have recently submitted to NHS REC to ensure their paperwork meets the requirements.
E. Once the NU Internal Approval form is complete, the C/PI must download a PDF copy of the full data set for university approval.

To do this:

1) Click 'Print' (at the top or bottom of the 'Full Set of Project Data' page of your form; or
2) Go to the 'Navigation' page, select the 'Full Set of Project Data' page of your form (from the menu on the left-hand side), and use the 'Save/Print' tab
3) Follow the instructions to produce a PDF file of you 'Full Set of Project Data' page of your form, which you can save electronically

F. Finally, send the completed IRAS form in PDF format, the NU Internal Approval form, Organisational Information Documentation (OID), and any other supporting documentation to ethicssupport@northumbria.ac.uk for check and approval.

Step 2: IRAS System Approval

A. RIS will check the NU Internal Approval form and the OID and then request approval by the Faculty Pro-Vice Chancellor who is the authorised signatory on behalf of the university.
B. RIS confirms approval (with or without any suggested amendments) to the C/PI and provides a copy of the signed NU Internal Approval form, and the name of the eAuthoriser/Sponsor Representative for section A4/A64-1, currently:

Ellen Cole
University of Northumbria at Newcastle
Pandon Building
Camden Street
Newcastle upon Tyne
NE2 1XE

Email: *ellen.s.cole@northumbria.ac.uk*

Tel: 0191 2274257

C. The C/PI then needs to submit the IRAS form for eAuthorisation from Northumbria's sponsor representative from RIS. Once this is completed, the C/PI needs to submit the IRAS to the HRA for review.
D. Regardless of whether your application will need NHS REC review, you now need to book a REC meeting – you can follow the guidance on this webpage to help you set this up.
E. You will then receive confirmation of the eAuthorisation from the IRAS system.

Step 3: NU Ethics Approval

A. After you have approval from the IRAS, please follow Northumbria University's Ethics Approval Process.
    1. If your project only has HRA approval, a review from the NU College of Reviewers will be required on the Ethics Online System.
    2. If your project has NHS REC approval, it will not need an additional review, but an application should still be submitted on the system.

You must not carry out any study-related procedures until you have both NU and IRAS approval.

Electronic Submission Guidance

Are you ready to submit?

Questions to ask yourself:

- Have you read the instructions on how to submit to the relevant review body (under 'Submission' or 'eSubmission')?
- Have you checked that your form is complete?
- Have you completed the online IRAS checklist?
- Are all the appropriate authorisations in place?

If you can answer 'yes' to all the above questions, then you may proceed with your submission. Before submitting, you should ensure that you have read the submission instructions on IRAS for each form – this is available under the 'Submission' or 'eSubmission' tab in the form.

It is important that you establish whether your form will be a Submission or an eSubmission as the process is different for each. You can tell which one your application will be by the tabs on your form (i.e. you will have either a 'Submission' or 'eSubmission' tab). If you can't see these tabs, try scrolling to the right as these tabs may be on the page but just not visible in your current window.

Submission to NHS REC (Research Ethics Committee)

All applications for NHS and Social Care REC review are prepared using IRAS. NHS REC review usually reviews applications in full REC meetings. However, projects that meet certain criteria and are deemed not to raise material ethical issues may not need to go to a full committee review. This proportionate review service is for studies that present minimal risk or burden for the participant and use a proportionate review sub-committee to review applications within shorter time frames on receipt of a valid application.

NHS RECs are geographically located across the UK, but you do not need to choose the nearest one to you as they are often held online. You may be able to request that your application is reviewed at a local NHS REC, depending on the type of research you plan to undertake. Some studies must be reviewed by an NHS REC that is 'flagged' for the type of research which is proposed.

Preparing to book your NHS REC appointment

You must ensure that your IRAS application is ready to submit when you book your NHS REC appointment; and you must electronically submit your application on the same day as you book you NHS REC appointment. Therefore, before booking, you must ensure that:

- Your application form is complete
- You have all the necessary supporting documents detailed on the checklist in IRAS
- The declarations in your application forms have been electronically authorised

Booking your NHS REC appointment

Once you're ready to submit, you must book your NHS REC appointment. You can make an appointment on the Online Booking Service.

Social Care REC applications should be booked directly with the Social Care REC. You can read more about this on this NHS HRA webpage.

You must electronically submit your application and supporting documents to the REC on the same day as you book your appointment.

Frequently Asked Questions

What is the university's official name?
University of Northumbria at Newcastle.

What is the university's address?
Sutherland Building, College Street, Newcastle Upon Tyne, NE1 8ST

Is there any external funding for the study and who is providing this?
This should be flagged in the NU Internal Approval form. The university needs to know this as there may be funding terms and conditions that need to be complied with that we must address with the NHS or organisation. It may be that a collaboration agreement is needed with the NHS or organisation. We also need to ensure compliance with these terms.

What should I do if my project involves making payments to participants?
Please flag this in the NU Internal Approval form. The university needs to ensure that there is sufficient budget available for this, and that arrangements for this are appropriate.

If the study involves making payments from Northumbria to an NHS or organisation, what should I do?

- Please flag this in the NU Internal Approval form.
- If, as part of the arrangements, Northumbria are paying the NHS or organisation for either their staff time, use of facilities, recruitment of participants, use of equipment or

data, it is likely that the NHS and the University will require a legal agreement to be put in place to record these arrangements.
- Usually, where a member of staff of the NHS or organisation requires payment for their participation in a research project, a Collaboration Agreement will be put in place.
- For the use of facilities, recruitment of participants' incentive payments, and use of equipment, it is more likely that the NHS or organisation will require a Site Agreement.
- The Legal Services team have templates for these agreements, but early notification that these documents are required will speed up the process
- Please note that sometimes the NHS require a copy of these documents (particularly a Site Agreement) at their R&D Committee considering the approval of this project
- It is recommended that confirmation of the legal documentation required is discussed with your contact at the NHS or organisation as soon as possible

How should I consider what role the NHS or organisation has in the project?
Questions to consider are:
- Is the NHS or organisation allowing the project to be carried out at a particular site/s? If yes, then it may be that the NHS or organisation requires a Non-commercial Site Agreement to be put in place
- If a member of staff from the NHS or organisation has a role in the study, then it may be possible that a Collaboration Agreement is put in place
- These answers are linked to the above question relating to payments to the NHS or organisation

It is recommended that a discussion takes place with the NHS or organisation on whether they require a form of legal contact to be put in place, but you can contact Legal Services for advice on this. Where a legal agreement is required, the agreement will need to be in place before any research can begin. Legal Services can assist with this, but they require at least four weeks notice to get the correct agreements signed off.

Where can I get guidance on the OID and Insurance Indemnity forms?
You can scroll to the bottom of this IRAS webpage for information on the OID, Scheule of Events, and more. Northumbria's Insurance Indemnity forms can be found on the Insurance webpage. If you cannot find it, or if you have any questions regarding Insurance, you can contact the Insurance team at fi.insurance@northumbria.ac.uk.

Who will be the legal sponsor for the study?
For any research involving the NHS or Social Care services in England, it is mandatory that a legal sponsor for the study must be in place. Usually, the sponsor is the organisation who has developed the Study Protocol. A legal sponsor is an organisation that takes responsibility for confirming that there are proper arrangements to initiate, manage, monitor, and finance a study. There can be joint legal sponsor, with one of the organisations taking the lead position as legal sponsor. Discussions should take place with the NHS or organisation regarding this aspect, and the result of this discussion should be provided in the application. Generally, Northumbria would act as the legal sponsor for a student study; however, in all other studies, legal sponsorship could be joint between Northumbria or the NHS, depending on the nature of the study.

HRA have asked me to amend one or more of my documents, what should I do?
At HRA review, if you are asked for amendments to be made you must check with the Sponsor whether these are deemed to be substantial or non-substantial amendments. Any

substantial amendments will need to go through the University ethics approval process again before it can be signed off by the Sponsor.

Is there any advice on preparing for an NHS Research Ethics Committee?
You can refer to the HRA Research Planning guidance for support with preparing for an NHS REC. It includes information on setting up your study with advice on protocols and participant information sheets.

Where should I include my IRAS reference ID?
All documents should clearly state the IRAS reference ID.

How should I handle personal identifiable data?
Personal identifiable data should be handled in accordance with the Data Protection Act. You will need to state if personal identifiable data will be transferred to the university at any stage of the project. If this is the case, you will need to explain in the participant information documents what data will be transferred to the university, the purpose of the transfer, how the data will be secured, how long it will be stored, where it will be stored, who will have access to it, and how it will be destroyed.

I want to use quotes from my participants, what should I do?
The participant information documents should state whether you intend to use direct, anonymised quotations from participants.

What is the UK Local Information Pack?
From the 5th of June 2019, the 'Uk Local Information Pack' became the UK-wide mechanism for setting up participating NHS/HSC organisations. It provides a consistent package to support study set-up and delivery across the UK and should be used for all studies with participating NHS/HSC organisations from this date. An exception is where a study is planned as a single centre study with an NHS/HSC sponsor (i.e. there is a single participating NHS/HSC organisation, and it is the same as the NHS/HSC sponsor for the study). In this specific scenario, a UK Local Information Pack and OID is not required.

A key component of the UK Local Information Pack is the 'Organisation Information Document' (OID). This replaces the Statements of Activities. The OID will be used for both commercial and non-commercially sponsored research in the NHS/HSC. Please note, the OID is no designed for use with participating non-NHS organisations – please refer to separate guidance for non-NHS organisations.

Please see this webpage about preparing study documentation relating to your study. This is necessary because the sponsor (Northumbria University and the site) do not operate a joint research office.

Who is the Chief Investigator (CI)?
Students below doctoral level may not be the chief investigator and that it is usually the academic supervisor, although there are some exceptions - detailed on the Student Research webpage.

How do I arrange a Letter of Support from the sponsor, as requested by IRAS?
This would be the sponsor approval (i.e. the signed copy of Northumbria's Internal Approval Form).

What documentation do I need?
When working with NHS Trusts, a minimum set of documents is required which includes:

- IRAS completed form
- Protocol

- Any amendments (as required following REC or HRA review)
- Patient Information Sheets and Consent form
- OID
- Schedule of Events (which can be used in place of a site agreement where the cost to the NHS is less than £10,000)
- Template contract/model agreement
- Costing
- HRA Approval letter

Until the applicant has REC/HRA approval, and all those documents are sent as a complete set in an email to the Trust, they will not commence setting up the study.

What do I need to know about indemnity?

Advice from NUTH Q76 1, 2, and 3: *Northumbria would provide indemnity for the Study Design (unless there had been a major contribution to the design from a clinical partner, then Northumbria and NUTH would negotiate). NUTH would always provide indemnity for the Management of the Study and for the Conduct of the Staff/Research where it was carried out at an NHS site. Where the procedures with the patients were deemed to be 'invasive' that it would be more appropriate for NUTH to act as sponsor in those cases.*

Where can I find templates?

Templates can be found on the HRA website for some of the standard forms such as the Schedule of Events, Informed Consent templates, Participant Information sheets among others. Using these templates makes it easier for the Trusts to process studies as the information is always in the right format.