# IRAS Approval Process

The Integrated Research Application System (IRAS) is an online system for preparing regulatory and governance applications for health and social care/community care research. It is a UK-wide system, which is provided by the HRA (NHS Health Research Authority) and which captures the information needed for the review bodies listed [here.](https://www.hra.nhs.uk/about-us/committees-and-services/integrated-research-application-system/)

IRAS now contains a number of different authorisations e.g. resources, sponsorship, Organisation Information Document and insurance which require high level authorisation within the University.

Before submitting to the IRAS system, first complete Northumbria’s IRAS Internal Approval process;

click [here](https://www.northumbria.ac.uk/research/ethics-and-governance/external-approvals/) for the appropriate form and guidance.

Once internally approved, complete your submission to the Integrated Research Approval System [here.](https://www.myresearchproject.org.uk/) Access the IRAS Online Guide [here.](https://www.myresearchproject.org.uk/ELearning/index.html)

The HRA Approval Process can be accessed [here.](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/)

Guidance on Amendments can be accessed [here](https://www.myresearchproject.org.uk/help/hlpamendments.aspx) and [here.](https://www.hra.nhs.uk/approvals-amendments/)

1.

University Ethics Approval (Not applicable for Staff NHS-related projects)

2.

Northumbria's IRAS Internal Approval

3.

IRAS Approval

# Guidance

Integrated Research Application System (IRAS) is a single system for applying for Health Research Authority (HRA) permissions and approvals for health and social care / community care research in the UK. [Here](https://www.myresearchproject.org.uk/) is the link to the IRAS system.

**IRAS** enables you to enter the information about your project once instead of duplicating information in separate application forms and uses filters to ensure that the data collected and collated is appropriate to the type of study, and consequently the permissions and approvals required.

If you are unsure whether you should complete an IRAS form:

If you are a Postgraduate Research Student, check with your Supervisor in the first instance and Department Ethics Lead if you are still unsure

if you are a member of staff, check with your Department Ethics Lead

To find the name of your Department Ethics Lead, or Faculty Research Ethics Director staff can check [here](https://one.northumbria.ac.uk/service/ris/Pages/Ethics-Contacts.aspx)

To help you decide whether or not your project requires NHS ethical approval, access the HRA (NHS Health Research Authority) Decision Tool [here.](http://www.hra-decisiontools.org.uk/ethics/) If your study does not require NHS REC approval you must seek ethical approval via the ethics online system.

## STEP 1

1. **Research by Staff/Postgraduate Research Students Involving NHS Staff**

**Research involving NHS staff means the researcher needs NU ethical approval obtained through Northumbria University’s Ethics Online System:** [**https://ethicsapplication.northumbria.ac.uk/**](https://ethicsapplication.northumbria.ac.uk/)**. And they also need HRA approval, via IRAS this confirms they can access NHS staff.** NB They do *not need to be submitted for ethical review by an NHS Research Ethics Committee.*

1. **Research by Staff/ Postgraduate Research Students Involving NHS Patients: Projects involving NHS patients require NHS REC review, and therefore do not need review via the ethics online system.** Complete IRAS application [here](https://www.myresearchproject.org.uk/) and download a PDF of the completed application, Organisation Information Document (OID) and any other supporting documentation.
2. Please complete your IRAS application as soon as possible to ensure you do not delay the start of your active research. IRAS and NHS HRA (Health Research Authority) have extensive online Help available [here](https://www.myresearchproject.org.uk/help/hlphraapproval.aspx#Which-projects-apply-for-HRA-Approval) and [here.](https://www.hra.nhs.uk/about-us/committees-and-services/integrated-research-application-system/)

NB Where the applicant is a Postgraduate Research Student, their Supervisor must complete Declaration B.

## STEP 2

1. **Staff/Postgraduate Research Students** complete Northumbria’s IRAS Internal Approval Form including all of Declaration C (except the signature). Northumbria’s Insurance information can be found in the Insurance Hub [here](https://livenorthumbriaac.sharepoint.com/sites/InsuranceHub/Pages/Home.aspx?e=1%3A1ae575a165134ed0942860469b6e2f02)[.](https://one.northumbria.ac.uk/service/cs/insurance/Pages/default.aspx) If it is not there, or you have any insurance-related queries, please contact the Insurance Team on fi.insurance@northumbria.ac.uk *Note: Clinical trials may require additional insurance*
2. Send PDF copy of IRAS application, Northumbria IRAS Internal Approval Form, Organisation Information Document (OID) and any other supporting documentation and signed declarations to ethicssupport@northumbria.ac.uk
3. A representative of Research and Innovation Services, detailed in Step 3, reviews applications and seeks advice where necessary.

## Common errors/omissions include:

* + *University’s official name is* **University of Northumbria at Newcastle**
	+ *University’s Address:*

*Sutherland Building, College Street, Newcastle upon Tyne NE1 8ST*

* + *All documents should show 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 and Invitation letter etc). If not supplied, HRA will return the submission as, should they need to request amendments, they need to be able to see which version is current.*
	+ *Include GDPR on any Participant Information documents*
	+ *Include Organisation Information Document (OID)*
	+ *Sponsor details – see Step 3*

Also see **Frequently Asked Questions** below

1. Following review, the Internal Approval Form is sent to Chief/Principal Investigator (CI/PI) for any amendments.

*NB. Staff are encouraged to check with colleagues who have recently submitted to NHS Research Ethics Committee to ensure their paperwork meets the requirements.*

Once Northumbria’s Internal Approval Form is complete, the CI/PI must download a PDF copy of the

full data set for University approval. To do this:

1. Click the ‘Print’ button (at the top or bottom of the Full Set of Project Data or your

form); or

1. Go to the Navigation page, select the Full Set of Project Data or form (from the menu on

the left) and use the ‘Save/print’ tab.

1. Follow the instructions to produce a PDF file of your Full Set of Project Data or your form, which you can save electronically.

Finally, send the completed IRAS form in PDF format, the Northumbria Internal Approval Form, Organisation Information Document (OID) and any other supporting documentation to ethicssupport@northumbria.ac.uk for OID check and University approval.

## STEP 3

1. Research and Innovation Services checks the Organisation Information Document (OID) and then requests the approval by the Faculty Pro-Vice Chancellor who is the authorised signatory on behalf of the University.
2. Research and Innovation Services confirms approval (with or without any suggested amendments) to the CI/PI and provides a copy of the signed Internal Approval Form and the name of the e-Authoriser/Sponsor Representative for section A4/A64-1, currently:

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**Email:** laura.hutchinson2@northumbria.ac.uk

## Tel: 0191 2274257

1. PI submits form in [IRAS online system](https://www.myresearchproject.org.uk/) for e-authorisation from Northumbria University’s

Sponsor representative from Research and Innovation Services as above.

1. Once e-authorisation is completed, CI/PI submits IRAS e-form to HRA for review.
2. Regardless of whether your application will go to an NHS REC for review, you now need to book a Research Ethics Committee using the online system [here](https://www.hra.nhs.uk/about-us/committees-and-services/online-booking-service/)
3. Staff/Student receives confirmation of the e-authorisation from the IRAS system

# Electronic Submission Guidance: Are you ready to submit?

* Have you read the instructions on how to submit to the relevant review body (under the

‘Submission’ or ‘E-submission’ tab)?

* Have you [checked that your form is complete?](https://www.myresearchproject.org.uk/ELearning/submission.html)
* Have you completed the online IRAS system [Checklist?](https://www.myresearchproject.org.uk/ELearning/checklist.html)
* Are all of the appropriate [authorisations](https://www.myresearchproject.org.uk/ELearning/authorisations.html) in place?

If you can answer Yes to all of the above, then you may proceed with your **Submission** or

**e-Submission**. Before submitting your application, you should ensure that you have read the submission instructions available on IRAS for each form. To find this information, click on either the **Submission** or **e-Submission** tab of the relevant form.

It is important that you establish whether your form will be a **Submission** or **e-Submission** as the process is different for each. You can tell which one by the tabs on your form (i.e. you will either have a **Submission** or **e-Submission** tab).

If you can't see a **Submission** or **e-Submission** tab on your navigation page, scroll right as these tabs may be on the page but just not visible in the current window. You will never submit the Full Set of Project Data to a review body.

# Submission to NHS Research Ethics Committee

All applications for NHS and Social Care Research Ethics Committee (REC) review are prepared using IRAS. NHS RECs usually review applications in full REC meetings. However, projects that meet certain criteria deemed not to raise material ethical issues may not need to go to a full committee. This [proportionate review service](http://www.hra.nhs.uk/resources/nhs-rec-proportionate-review-service/) is for studies that present minimal risk or burden for the participant, uses a proportionate review sub-committee to review applications within shorter timeframes on receipt of a valid application.

NHS RECs are geographically located across the UK. You do not have to choose your nearest REC, although that option may be available, depending on the type of research you plan to undertake. Some studies must be reviewed by a REC that is ‘flagged’ for the type of research which is to take place. For other types of research it may be recommended to use a [REC flagged for that type of](http://www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-where-to-book/) [research.](http://www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-where-to-book/)

# Preparing to book

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

* Your application form is complete
* You have all necessary supporting documents to the checklist in IRAS
* The declarations in your application forms have been electronically authorised.

**Booking your REC Review** Once you are ready to submit, you must book your application for review. **For NHS RECs,** bookings are made online [here.](https://www.hra.nhs.uk/about-us/committees-and-services/online-booking-service/)

**Social Care REC applications** should be booked directly with the Social Care REC. Check [here](http://www.hra.nhs.uk/resources/applying-to-recs/) for more information from HRA.

You must electronically submit your application and supporting documents to the REC on the same day as making the booking.

# 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 IRAS Internal Approval Form.

The University needs to know this as there may be funding terms and conditions to be complied with that we must address with the NHS/organisation. It may be that a collaboration agreement is needed with the NHS/organisation. We also need to ensure that the study complies with those terms.

## If the study involves making payments to individuals, what should I do?

Please flag this as part of your IRAS Internal Approval application. The University needs to know this to ensure there is sufficient budget available, and appropriate arrangements for payment are in place.

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

* + Please flag these arrangements as part of your internal approval application.
	+ If, as part of the arrangements, Northumbria are paying the NHS/organisation for either their staff time, use of facilities, recruitment of participants and 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/organisation requires payment of their time for a research project a Collaboration Agreement will be put in place.
	+ For the use of facilities, recruitment of participant’s incentive payments and use of

equipment, it is more likely that the NHS will require a Site Agreement to be put in place.

* + Legal Services have templates for these agreements, but early notification that these documents are required will speed up the process. Please note, sometimes the NHS require a copy (particularly of the Site Agreement) at their R&D committee considering the approval of the Study.

It is recommended that confirmation of the legal documentation required is discussed with your contact at the NHS organisation as soon as possible.

## Consider what role the NHS organisation has in the Project?

This question is linked to the above question around payments to the NHS organisation. Questions to consider are:

* + Is the NHS allowing the study to be carried out at a particular site or sites? If yes, then it may be that the NHS organisation require a Non-Commercial Site Agreement to be put in place.
	+ If a member of staff of the NHS organisation has a role in the study, then it may be possible that a Collaboration Agreement is in place.

It is recommended that a discussion takes place with the NHS organisation on whether they require a form of legal contract to be out in place, but you can approach Legal Services for advice around this issue.

Where a legal agreement is required, the agreement will need to be in place before you can start any research with them. Legal Services can assist with this but require at least four weeks’ notice, to get the correct agreements signed off.

## Have you uploaded the Organisation Information Document and Northumbria’s Insurance

**Indemnity forms?**

Scroll down for guidance on the Organisation Information Documentation (OID), Statement of Events (SoECAT) and more on the IRAS website [here.](https://www.myresearchproject.org.uk/help/hlpsitespecific.aspx#UK-Local-Information-Pack-OID)

The current versions of Northumbria’s Insurance Indemnity forms can be found [here](https://www.northumbria.ac.uk/about-us/campus-services/insurance/)[.](https://one.northumbria.ac.uk/service/cs/insurance/Pages/default.aspx) If it is not there, or you have any insurance-related queries, please contact the Insurance Team on 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 research 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 on responsibility for confirming there are proper arrangements to initiate, manage, monitor, and finance a study.
	+ There can be joint Legal Sponsors identified with one of the organisations taking the lead as the Legal Sponsor.
	+ Discussions should take place with the NHS/organisation regarding this aspect and the result of those discussions should be provided in the application.

As a guide Northumbria would act as a Legal Sponsor for a student study. However, in all other studies, **Legal Sponsorship could be joint, could be the NHS or Northumbria, 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.

## Do I need to use version control on my documents?

Always! HRA will expect to see a version control reference on each of your submitted documents. This enables them to track any amendments that they ask you to make during the course of the review and following REC. This includes everything from the Participant Information Sheets to posters advertising your study.

## Is there any advice on preparing for NHS Research Ethics Committee?

You should refer to the HRA standards for preparing for REC [here.](http://www.hra.nhs.uk/research-community/before-you-apply/) This includes information on setting up your study with advice on protocols and participant information sheets for example.

## What do I do with the IRAS reference ID?

All documents should clearly state the IRAS 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 study. If this is the case, will be you need to explain in the PIS documents what data will be transferred to the University, the purpose of this 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 document should state whether you intend to use direct, anonymised, quotations from study participants.

## UK Local Information Pack

From 5 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 Organisation Information Document is not required.

A key component of the UK Local Information Pack is the ‘Organisation Information Document’. This replaces the Statements of Activities. The Organisation Information Document will be used for both commercial and non-commercially sponsored research in the NHS/HSC (note: the Organisation Information Document is not designed for use with participating non-NHS organisations – please refer to separate guidance for non-NHS).

Please see guidance regarding all documents relating to your research study [here.](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/)

This is necessary because the sponsor, University of Northumbria at Newcastle and the site, (NHS Foundation Trust), do not operate a Joint Research Office.

## Who is the Chief Investigator (CI)?

Students below doctoral level may **not** be CI but that although it’s usually the academic Supervisor

although there are [some exceptions.](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/)

## 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 document from Dianne Ford as part of Northumbria’s internal sponsor approval process

## Documentation

When working with NHS Trusts require a minimum set of documents which includes:

* + IRAS completed form
	+ Protocol
	+ any amendments (as required following REC or HRA review)
	+ Patient Information Sheets and Consent Form
	+ Organisation Information Document
	+ Schedule of Events (which can be used in place of a site agreement where the cost to the NHS is less than £10k)
	+ Template contract/model agreement
	+ Costing
	+ HRA Approval Letter

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

## Indemnity

Advice from NUTH - Q76 1,2 &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.*

## Templates

Templates are available [here](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/) 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.