INTEGRATED RESEARCH APPLICATION SYSTEM (IRAS) GUIDANCE AND USER GUIDE

Contents of this guide:

What is IRAS and the Approval process?

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.

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 Decision Tool on this webpage. Please note, this tool is for REC decisions only – you may still require HRA approval.

To summarise, the process is as follows:

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

Useful Links

IRAS Portal

IRAS Guidance webpage

Northumbria University IRAS webpage

Approval Process

Step 1: NU IRAS Internal Approval Form

Staff and PGR students need to complete the Internal Approval Form – you can find a downloadable copy of this form on our IRAS webpage. Please be sure to complete 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.

Colleagues from the Ethics team in Research and Innovation Services (RIS) will review your application and seek advice where appropriate. Please send the following to ethicssupport@northumbria.ac.uk:

- Completed IRAS form in PDF format;
- Northumbria's IRAS Internal Approval form;
- Any other supporting documentation including your Organisation Information Document (OID) and Schedule of Events (SoE or SoECAT).

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*

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.*

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

Once you have completed your application, please send your send the above documentation to ethicssupport@northumbria.ac.uk, and they will contact the University sponsor to sign your application.

Step 2: IRAS System Approval

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.

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

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.

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.

You will then receive confirmation of the eAuthorisation from the IRAS system.

Step 3: NU Ethics Online System Approval

After you have approval from the IRAS, please follow Northumbria University's Ethics Online System Approval Process detailed further below in this document on page 10. You can view the internal IRAS SharePoint pages on this process for additional help.

The form will ask you to provide your level of approval:

- If your project only has HRA approval, a **review** from the NU College of Reviewers will be required on the Ethics Online System.
- If your project has NHS REC approval, it will not need an additional review, but an application should still be **recorded** 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:

- 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.

Submitting to NHS REC

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
- 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 £10,000) **OR** Schedule of Events Cost Attribution Template (required for non-commercial NHS studies -part of a funding application/ study is intended for inclusion on a UK research network portfolio)
- 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.

REGISTERING YOUR IRAS APPROVAL ON THE NORTHUMBRIA UNIVERSITY ETHICS ONLINE SYSTEM – USER GUIDE

This section will detail how to register your IRAS approval with the Northumbria University Online Ethics System (EOS).

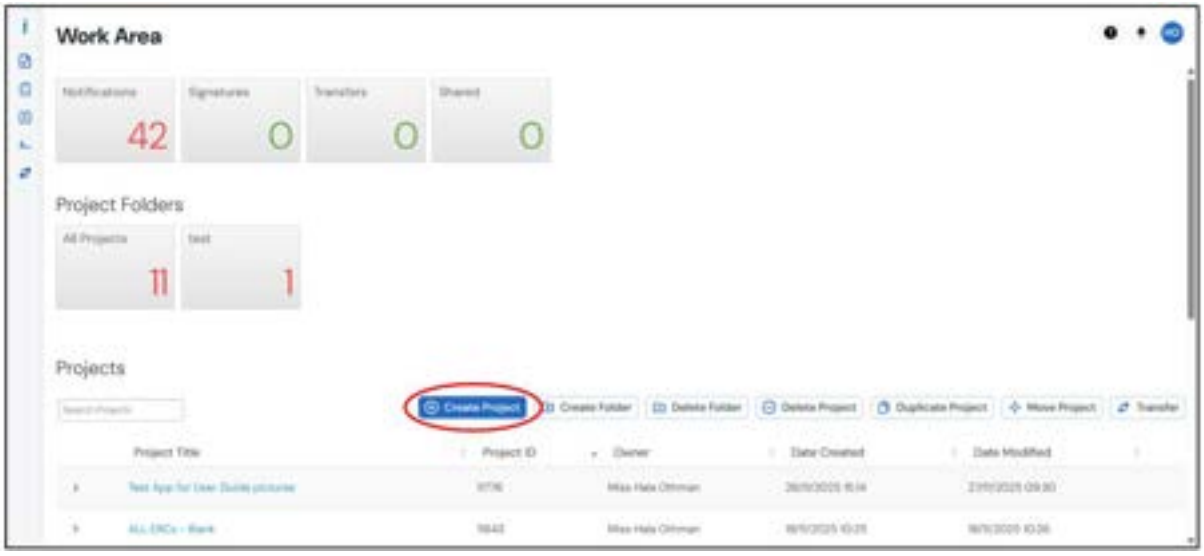
Step 1: Accessing the system

Follow this link to access the Ethics Online System – or navigate to the Application portal from the Ethics and Integrity webpages.

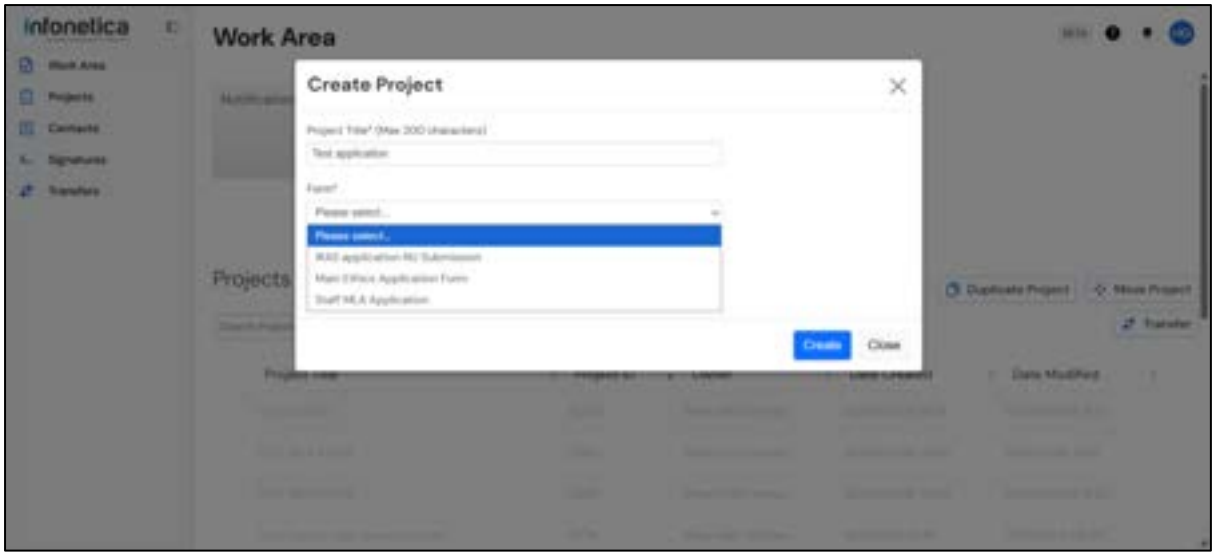
This will take you straight into your Work Area as the system uses your university details and single sign on.

Step 2: Creating your application

In your Work Area, click on ‘Create Project’ in the Actions Bar in the centre of the page.



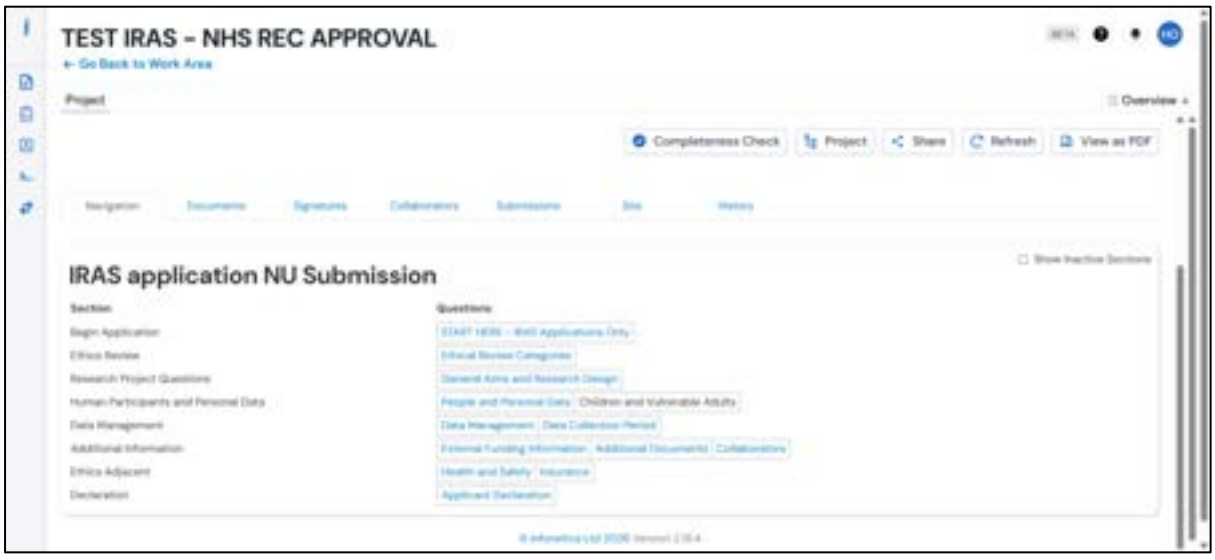
In the pop up, input the title of the project you wish to create. Then select ‘IRAS Application NU Submission’.



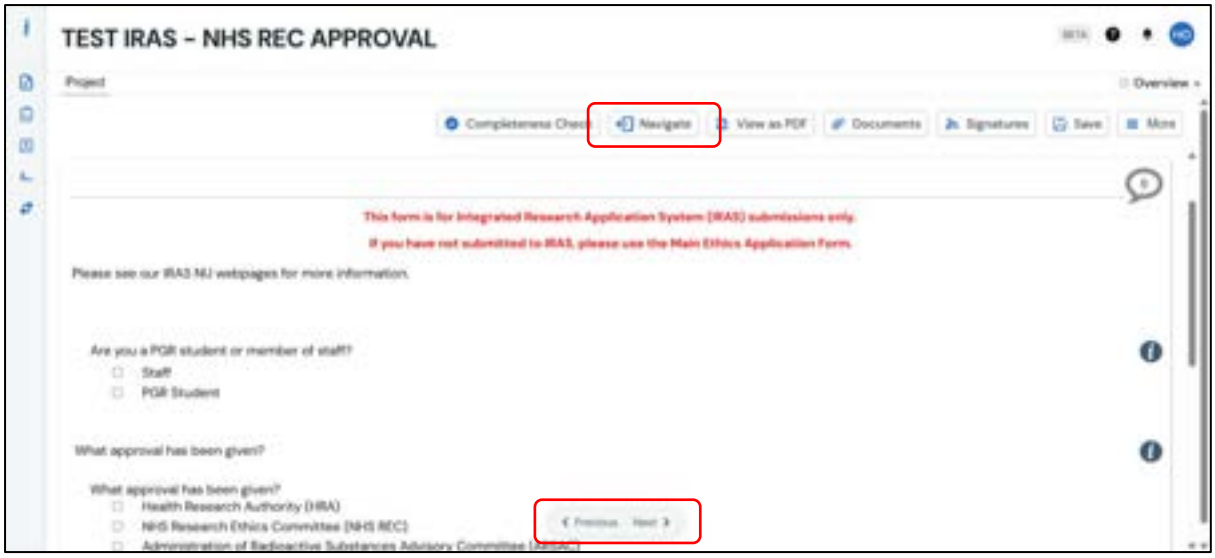
Step 3: Navigating your application

When you create the application, you will start on the ‘Navigation’ page. These are the mandatory pages of the form, but new pages may be added if you are undertaking work that **only** requires HRA approval and not NHS REC approval.

New pages will be based on which research activities and topics you indicate you will be undertaking on the Ethical Review Categories page. Not all applications will see the Ethical Review Categories page, based on the types of approval that are linked to your project.



Once inside the form, you can use the ‘Previous’ and ‘Next’ buttons at the bottom of the page, to flip through the pages. Alternatively, you can click on ‘Navigate’ in the Actions Bar and this will take you back to the list of page titles.



Step 4: Completing your application

This step will detail guidance for just the mandatory pages in the form (except for 'People and Personal Data'). New pages may be added after you indicate the type of research you will be doing on the 'Ethical Review Categories' page.

If you need further guidance on how to answer any of the questions not covered in this guide, please click on the grey 'i' to the right of the questions or consult your AHoS RKE.

'Start Here' page

On the 'Start Here' page, indicate whether you're a member of staff or a postgraduate research student. Select which types of approval are relevant to your project, and then whether external approval has already been given or not.

Please note, if you have not already had your IRAS application approved, you will not be able to submit your NU EOS application.

Ethical Review Categories

On this page, read all the categories in full and tick any of the boxes that are relevant to your project. New pages may be added to your form based on these responses and will populate your form with the relevant questions to your study.

This page also determines the level of review that your application will need. Any projects which require proportionate review will be reviewed by one reviewer from your school, and any projects which require committee review (a.k.a. full review) will be reviewed by two reviewers and overseen by a chair from your school.

General Aims and Research Design

In these three boxes, please outline the general aims and research objectives; detail the research activity/methodology; and then outline any ethical issues you're aware

of. Please provide enough information for the Ethics and Integrity team to be able to assign an appropriate reviewer.

People and Personal Data

This is not a mandatory page, but it is a very common page relevant to lots of projects. This page covers different aspects of working ethically with human participants and the questions will prompt you to comprehensively consider different factors and mitigations.

For support on questions relating to consent, remuneration, best practices, and templates for consent documentation, visit the 'Documentation and Guidance' webpage. For information relating to Safeguarding, visit the 'Policies and Procedures' page.

At the bottom of this page in the form, upload copies of your consent documentation: this includes a Participant Information Sheet (PINS), Consent Form/s, and a Debrief Sheet where needed. You can also access copies of the documentation under 'Help' and then 'Templates' in the black menu bar along the top of your screen. These templates have a top sheet with supporting information and boilerplate text to help you fill out these sheets.

Data Management

On this page, please outline the measures you will take to anonymise your data (if relevant) and then outline where your data will be stored.

The university OneDrive is the required location for data storage as it is secure and backed up. If you need to store your data elsewhere – e.g. sharing it with other collaborators or shared on Open Research platforms (such as OSF) – then please tick both boxes and add further details in the relevant box.

Considerations around the collection of special category data are needed to ensure the participant anonymity is upheld, and this data need only be collected when it is relevant to the project. For information relating to Data Management and GDPR (General Data Protection Regulations), visit the 'Policies and Procedures' page.

Data Collection Period

The dates that you need to input here are the dates where you are going to be research active – e.g. if your survey will be open for a month, or your workshop is going to last three days.

You need to ensure that you are proposing a start date far enough in the future to allow for the ethical approval to take place. We recommend allowing at least 25 working days for the review process to be completed.

You are not permitted to begin data collection before ethical approval is granted but, once you receive your confirmation letter, you may begin your research activity even if the date precedes the start date you input on this page.

Collaborators

The ethical review process requires information of both internal and external collaborators. Information about internal collaborators is needed for the assignment of reviewers as, if they are in the college of reviewers, they cannot be assigned to review the application as there is an obvious conflict of interest. External collaborators need to be noted for due diligence reasons and so the Ethics and Integrity team can review who the university is collaborating with.

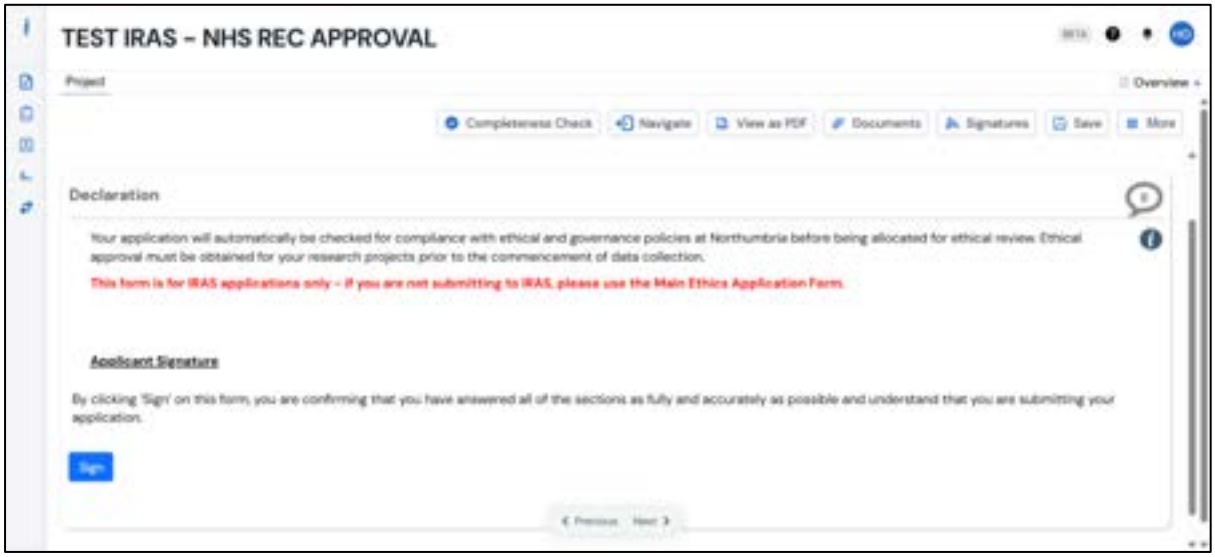
Health and Safety

On this page, confirm that you have read the Health and Safety Policy and have considered if you need a risk assessment for your project. If you are doing research that poses any health or safety risks to yourself, your participants, or others involved in your research; you will need to upload a risk assessment that has been approved by your supervisor, line manager, Head of School, or a technical manager. You can upload this at the bottom of the page after you confirm an RA is needed. You also need to ensure that the RA is no older than one year old as a current assessment of the risk is needed to ensure its viability.

Step 5: Submitting your application

When you have completed the application form and are ready to submit, on the last page, it is good practice to click the 'Completeness Check' button in the Actions Bar. This will check your application for completeness and will flag any questions that you have missed. You can click on the text and jump to the questions to finish your form.

If you are a member of staff, by clicking the blue 'Sign' button, you will be signing off the form and it will automatically be submitted.



If you are a student, you will need to request your supervisor's sign off.

First, click 'Request Signature' and search for your supervisor's name in the pop-up, then request their signature.

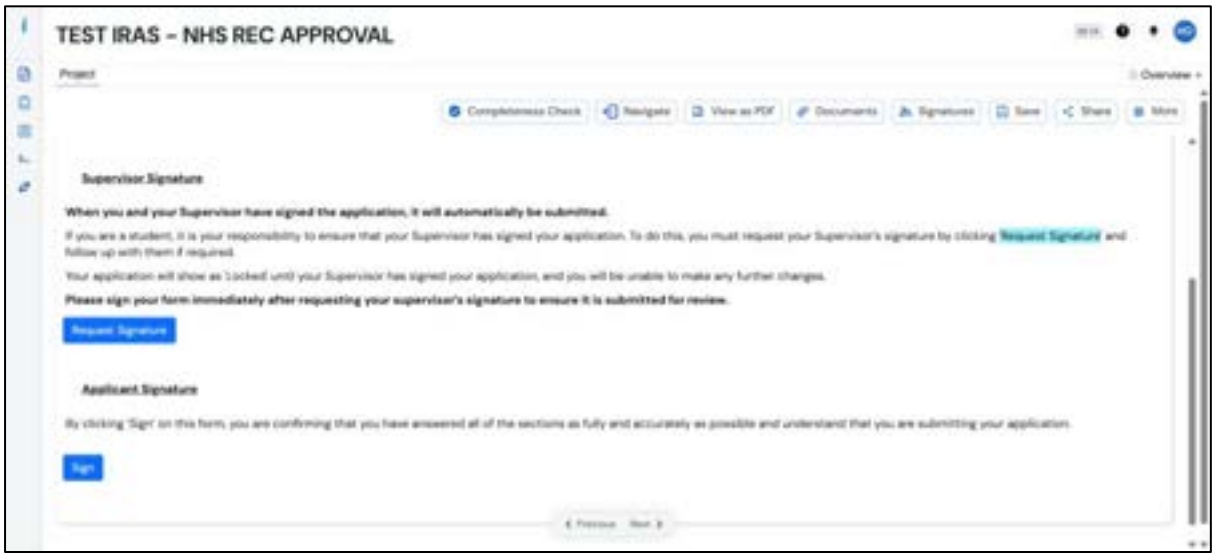
If you cannot find their name in the system, this means they have not been into the Ethics Online System before. Ask them to log in to the Application Portal using the links/instructions in Step 1. Then, you should be able to find them in the 'Request Signature' pop-up.

Then, also sign the form yourself by clicking the blue 'Sign' button.

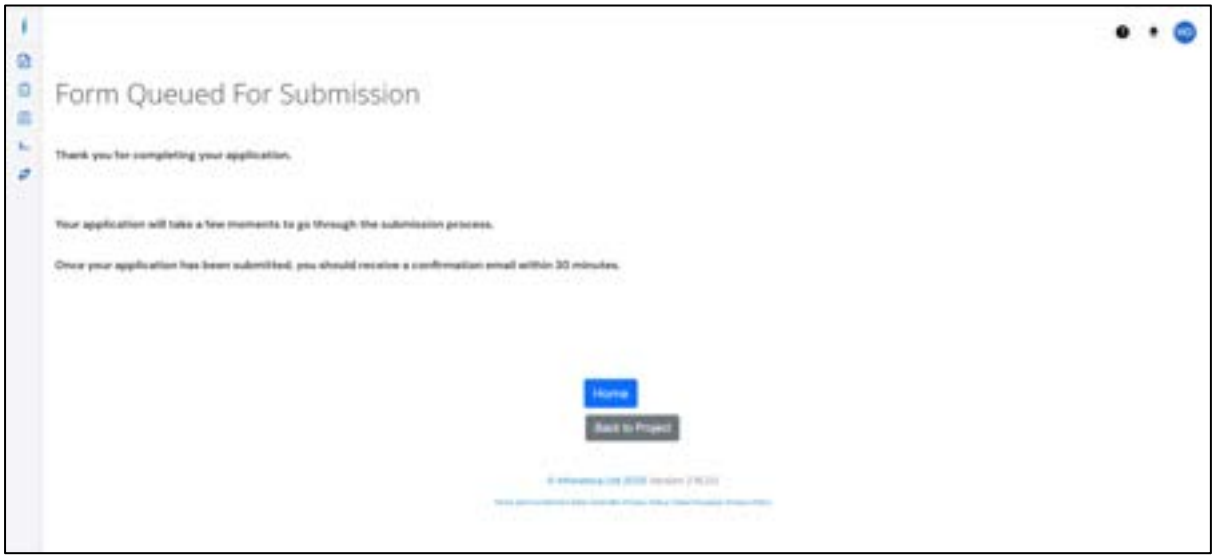
It is important to click both buttons and get both signatures at the same time.

When both signatures are on the form, it will automatically be submitted for review.

It is the responsibility of the student to follow up with the supervisor for their signature.



Once you have successfully completed your application, you should see this page:



Following this:

If you are submitting an NHS REC only application, your application will be reviewed by the Ethics and Integrity team in Research and Innovation Services (RIS), and then approved.

If you are submitting a HRA only application, any projects which require proportionate review will be reviewed by one reviewer from your school, and any projects which require committee review (a.k.a. full review) will be reviewed by two reviewers and overseen by a chair from your school.

Any notifications regarding applications will be emailed to you from Infonetica (the system provider). If you are not receiving these emails, please first check your junk/spam inbox. You can also check the 'Notifications' tile in your Work Area.

Step 6: Revision Requests

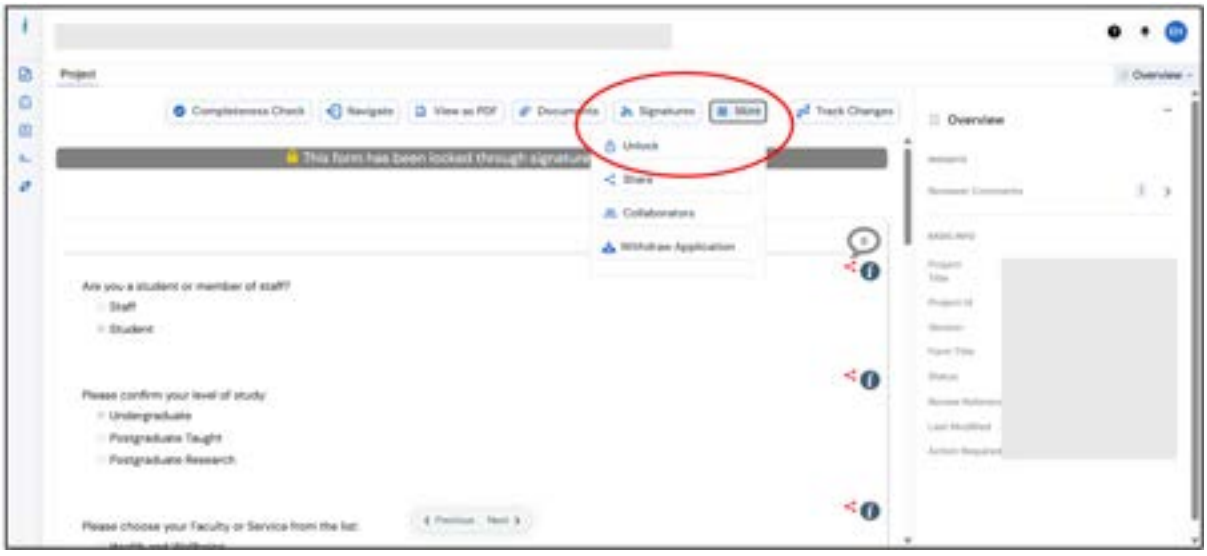
It is a normal, iterative part of the reviewing process to receive revision requests from either the Ethics and Integrity team or the reviewers in your school.

You will receive an email notification detailing the changes that have been requested. If you receive a blank email, please contact the Ethics and Integrity team at ethicssupport@northumbria.ac.uk and include the 4 or 5 digit project ID number.

You can also view the comments inside the system under the 'Overview' tab on the right of your screen.

To re-enter the system, you can either click on the system link in your notification email or go via the same way as detailed in Step 1.

To make changes to your application form, you may be required to unlock your application. To do this, you need to open the application, navigate to any page, and click 'More' in the centre of the page, and then 'Unlock' (padlock icon).



This will then remove signatures and allow you to make revisions in line with the comments.

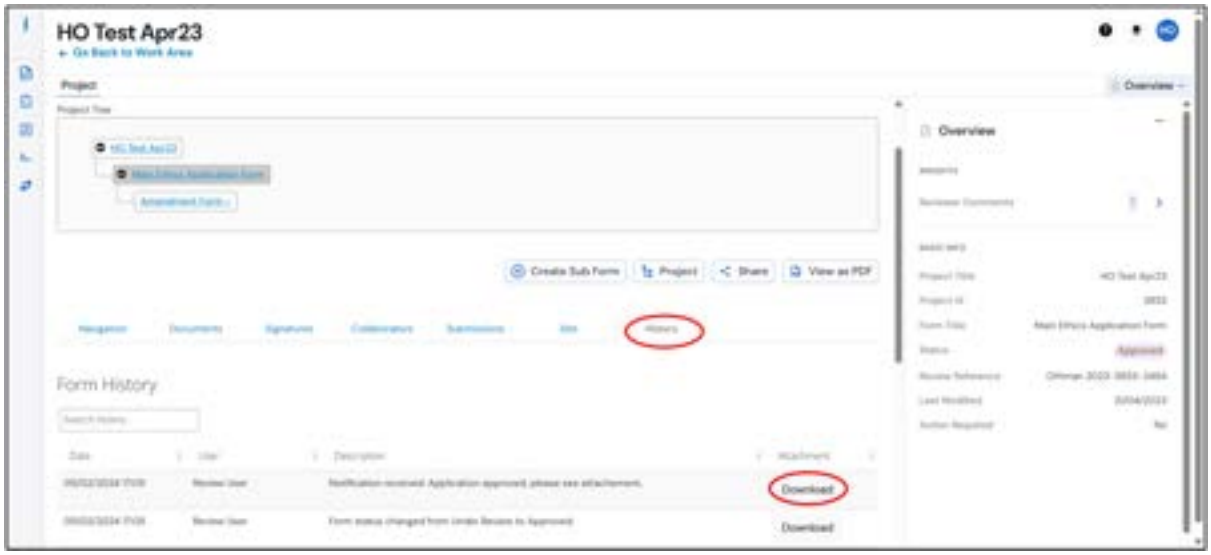
If you need further support with completing the revisions, please consult your supervisor, AHoS RKE, or research mentor. Alternatively, you can contact the Ethics and Integrity team at ethicssupport@northumbria.ac.uk.

To resubmit, sign off the form again (as detailed in step 3) and your application will be resubmitted automatically.

Step 6: Managing your application

Once your application has been approved, you will receive an email with the approval letter attached.

You can also find a copy of your approval letter within the Ethics Online System. If you open your approved application and click the ‘History’ tab, you will see the “Notification received: Application approved, please see attachment” line. The attachment which you can download here is a copy of your approval letter.



For further support, please consult the Ethics and Integrity webpages which include contact information, other user guides, and answers to frequently asked questions.