STAFF ETHICS APPLICATION USER GUIDE

This document will walk you through how to create, complete, and submit an ethical approval application in the Ethics Online System. It will also detail how to respond to revision requests and resubmit following revisions.

If you are looking for guidance on how to submit an amendment to an already approved application, please see the Amendment User Guide on the Ethics and Integrity 'Training and Guidance' webpage.

Step 1: Log into the Ethics Online System

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

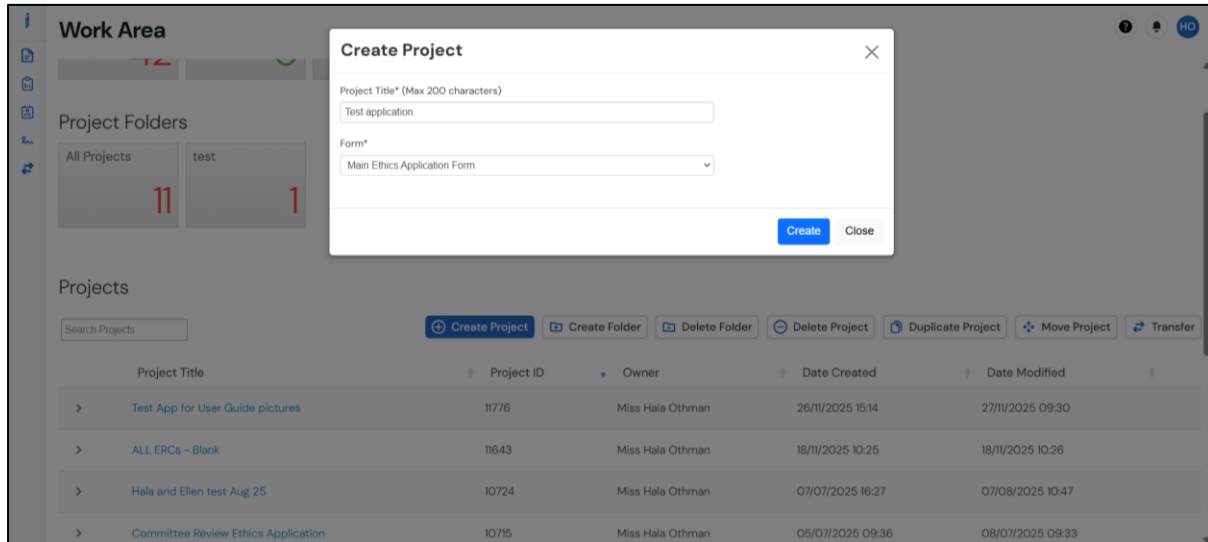This will take you straight into your Work Area as the system uses your university details and single sign on.

Step 2: Creating an application

In your Work Area, click on 'Create Project' in the Actions Bar in the centre of the page.
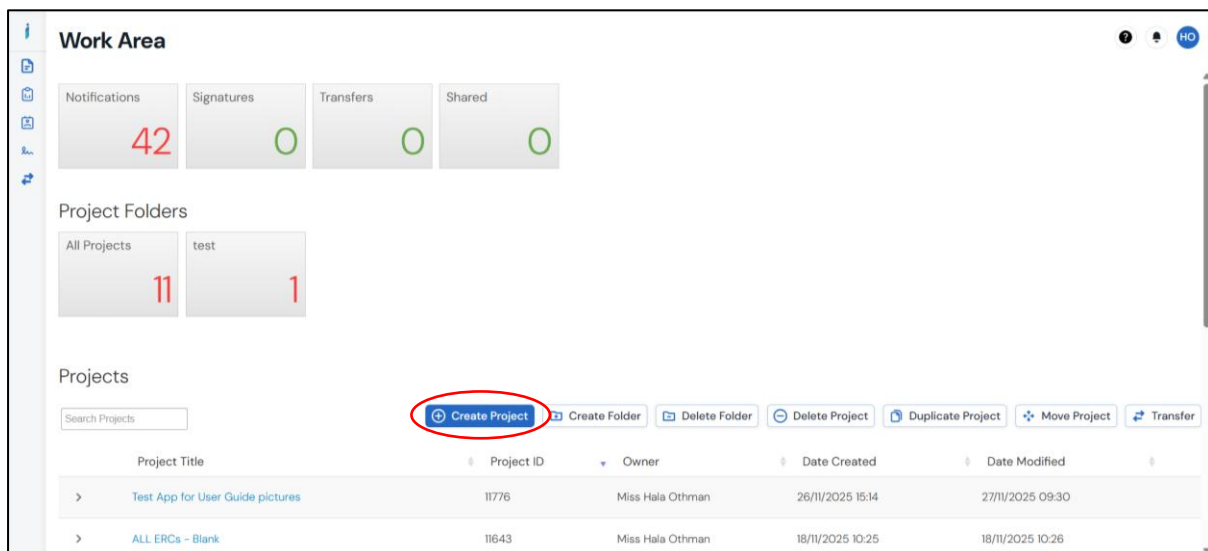
In the pop up, input the title of the project you wish to create.

Then select 'Main Ethics Application Form' in the drop down, and then select 'Create'.
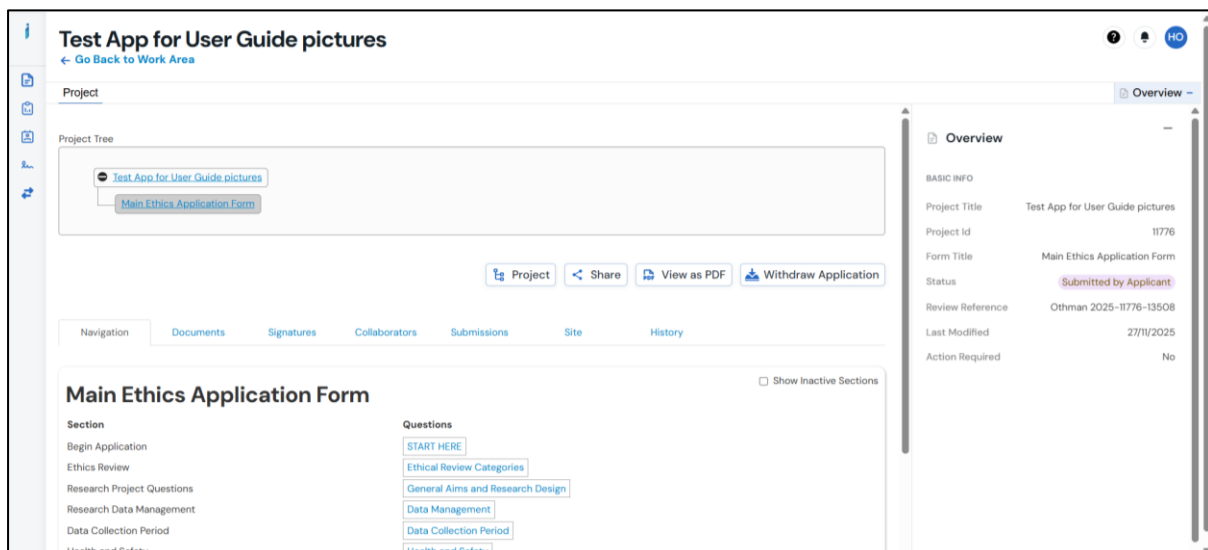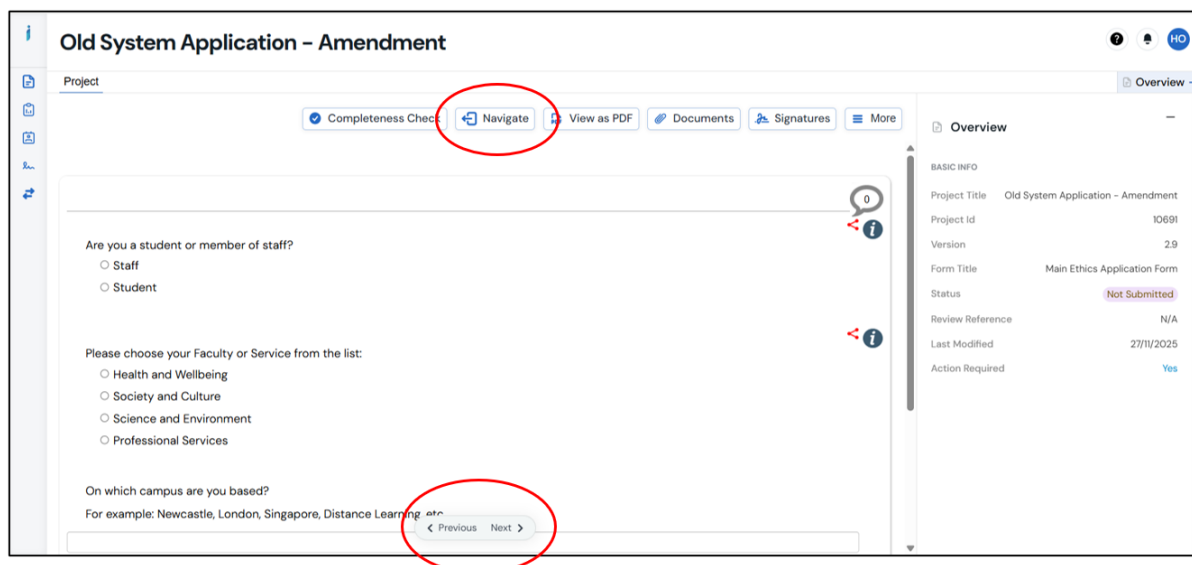
Step 3: Navigating your application

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 after you indicate the type of research you will be doing on the 'Ethical Review Categories' page. From here, you can click on any of the blue page titles to fill out your responses.

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.

Ethical Review Categories

'Start Here' page

On the 'Start Here' page, indicate that you are a member of staff, input your faculty and school, and which campus you're based on.

If your project will undergo external ethical approval elsewhere (e.g. NHS Research Ethics Committee, Social Care Research Ethics Committee, HRA Approval, etc), indicate this on this page, and complete the follow up questions. This does not include other non-ethical approvals such as organisational consent.

If you are applying for Module Level approval – which you can read more about on the 'Documentation and Guidance' webpage – select 'Yes' and input the module code in the indicated format (i.e. AB1234)

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 two boxes, please outline the general aims and research objectives, and then detail the research activity/methodology. The recommended word count is there to ensure you 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.
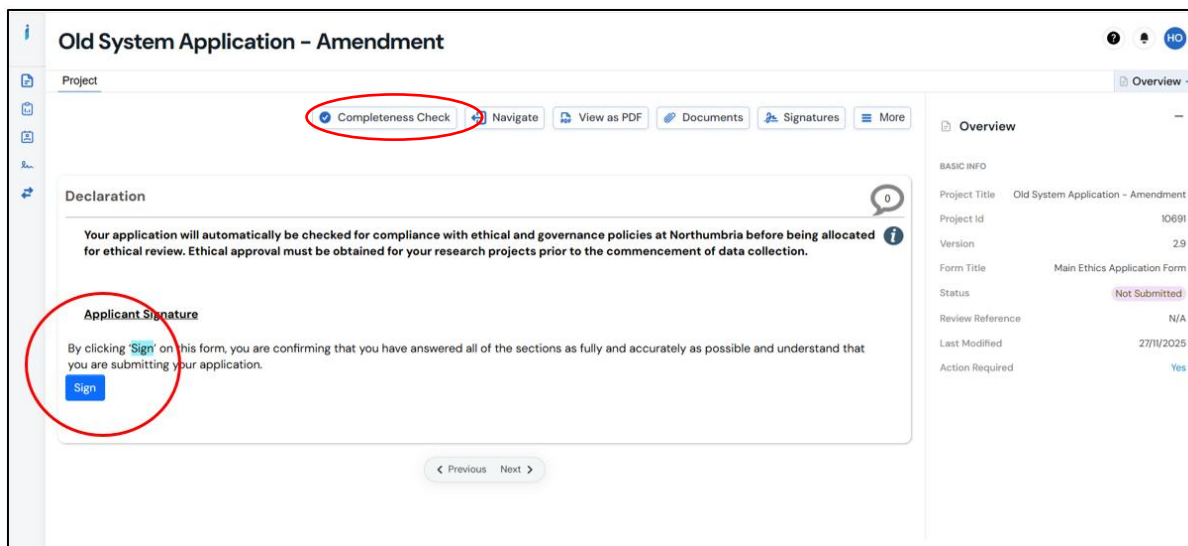
<u>Health and Safety</u>

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, 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.

<u>Collaborators</u>

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.

Step 5: Submitting your application
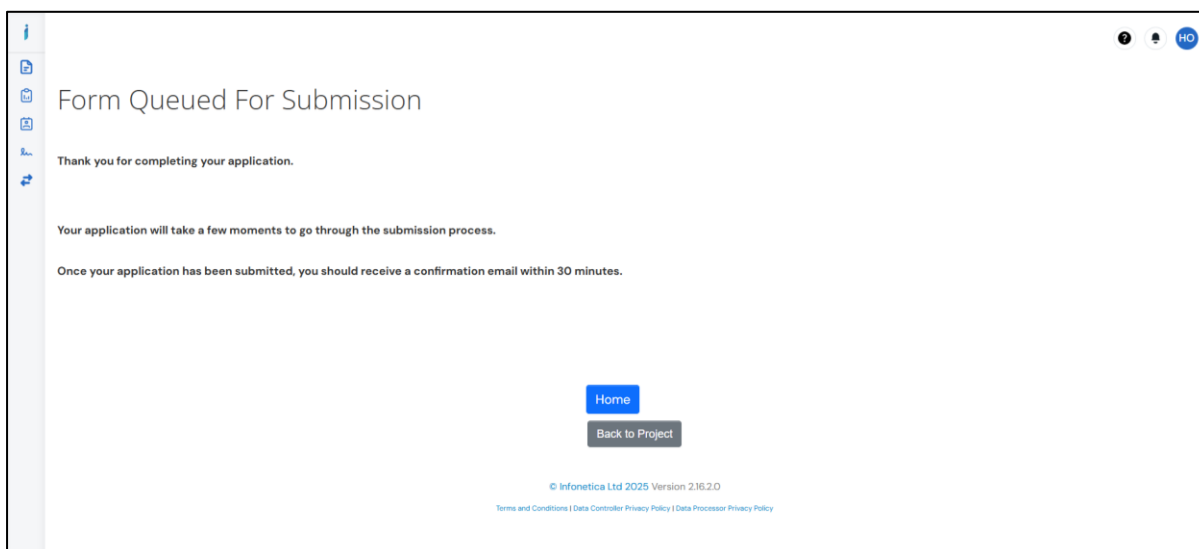
When you have completed the application form and are ready to submit, on the last page, it is good practice to click the 'Completeness Check' button in the Actions Bar. This will check your application for completeness and will flag any questions that you have missed. You can click on the text and jump to the questions to finish your form.

Once you click the blue 'Sign' button, you application will automatically be submitted for a triage review by the Ethics and Integrity team in Research and Innovation Services (RIS), and then by the appropriate reviewers from your School. You should see the below screen after a successful submission.

The Ethics and Integrity team have 3 working days to triage and review your application. If your application needs a DBS (Disclosure and Barring Service) check, this can take up to 5 working days. They then send it on to the reviewers from your School. The reviewers then have 20 working days to review and return a decision to you. If either of them sends you revision requests, this timeline is paused. In total, the review process should take no longer than 25 working days (5 calendar weeks), so please allow enough time for the review process to take place before you would like your research activity to begin.

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.

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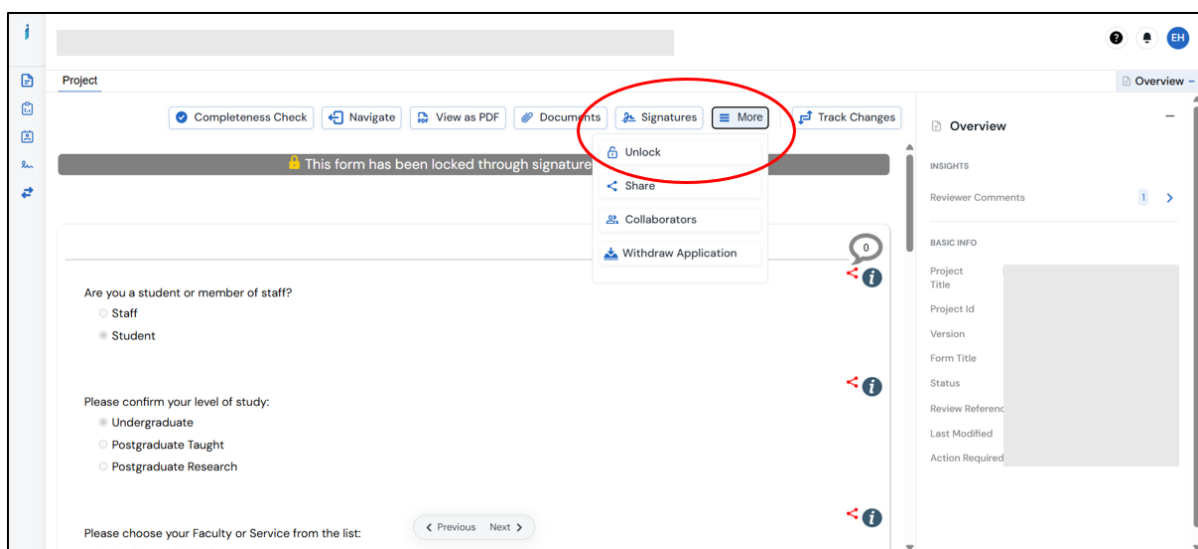
This will then remove signatures and allow you to make revisions in line with the above comments.

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.
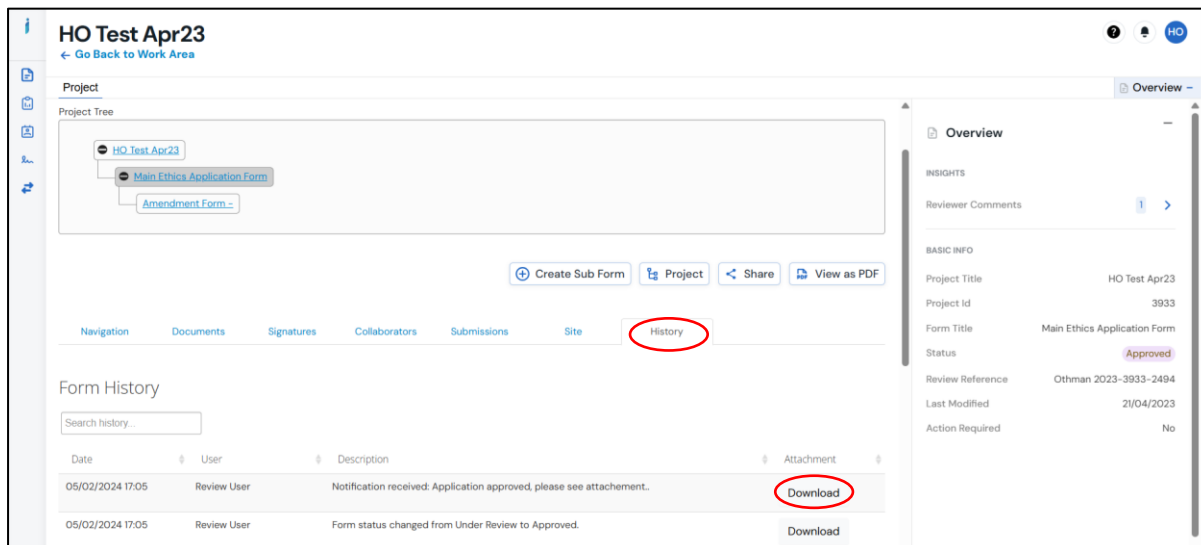
To resubmit, complete the 'Declaration' page again (as detailed in step 5) and your application will be resubmitted automatically.

Step 7: Managing your approved 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.

If, further down the line, you need to submit an amendment to your project, please consult the 'Amendment User Guide' on the 'Training and Guidance' webpage.

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