APPLICATIONS FOR RESEARCH ETHICS REVIEW USING THE ONLINE ETHICS SYSTEM 'ERM'

GUIDE FOR STUDENT APPLICANTS

2021-22

Revised: August 2021

1 ERM APPLICANT ACCOUNTS 4

2 CREATING AND SUBMITTING AN APPLICATION FOR ETHICS REVIEW 5

2.1 OVERVIEW OF YOUR APPLICATION ACCOUNT 5

2.2 CREATE AN APPLICATION: STEP-BY-STEP 11
2.2.5 Sharing your application with your supervisor 13
2.2.6 The Application Form 15
2.2.13 Confirming your Application, Requesting a Supervisor Signature 21
2.2.16 Checking the status of your signature request 25

3.1 MANAGING YOUR APPLICATIONS AFTER SUBMISSION 28
3.2 Managing your Applications after Submission: Step-by-Step 28
3.2.1 Receiving decisions 28
3.2.2 Responding to and acting on decisions 29

4 OTHER FUNCTIONS FOR MANAGING YOUR APPLICATIONS 32
4.1 Required form updates after system updates are performed 32
4.2 Withdrawing an application that you have submitted for review 33
4.3 Transferring a project to another user 35
4.4 Duplicating a project 36
4.5 Deleting a project 37

5 ADDITIONAL APPLICATION FORMS (‘Sub Forms’) 38
5.1 Request to make amendments to a previously approved application 38
5.2 Report a problem on a project that has been previously approved 42

6 OBTAINING HELP AND SUPPORT 46

The sections above are all hyper-linked and you can click on them to go directly to the section named.

TEESSIDE ONLINE RESEARCH ETHICS REVIEW SYSTEM: 'ERM'

STUDENT APPLICANT GUIDE

The 'ERM' is an online system for making applications for research ethics review for any project defined as 'research' in the University's *Policy and Procedures on Research Ethics*. This means: undergraduate research projects; postgraduate master degree final projects; the Advanced Independent Work (AIW) project for professional doctorates; and all work conducted for the research degrees, PhD and MPhil.

The online system is designed to work on any web browser and works well on both PC and tablet screens. It will also work on a phone browser, but some of the web screens are complex and working on a phone will not be simple using text and documents in the application. The system works particularly well on Safari on an iPad. In order to make an application for research ethics review, you must **access the ERM on a web browser while logged into your Teesside University account with your University user-name** and **password**. If you are logged into your University account, the ERM will allow you to access without further user-name or password being required. **If you access the ERM remotely when not logged into your University account you will be required to enter your University email address/user name and password via a University account log-in page**.

Your ERM applicant account will host your application(s) and is the place where you will **receive notifications** once your application has been submitted. Notifications will most often be to tell you that further actions are required on your application, but they will also allow you to see whether electronic signatures from your supervisor(s) have been completed. In addition to receiving notifications in your applicant account, **all communication about your application will be sent by email to your University email account**. These emails will sometimes contain an attached document with further information and usually contain a live link to your application. Using the link in any emails will take you directly to your applicant account as long as you are logged in via your University username and password. **You should bookmark the ERM URL** as you will need to browse to it several times when making an application.

This guide provides an overview of the basics of creating and managing your applicant account; a step-by-step guide to making an application; and how to manage your application once it has been submitted and reviewed by a research ethics committee.

There is also an online help menu available within your account, containing various forms of help and FAQs.

1 ERM APPLICANT ACCOUNTS

The application system is accessed by setting your browser to the URL:

https://apply-ethics.tees.ac.uk/

Bookmark the URL as you will be returning more than once to this page.

If you are accessing the URL while logged in using your Teesside University user name and password, you will automatically have access to an ERM account. The system will verify your user credentials and log you in to the ERM. If you access the URL remotely, you will be taken to a University sign-in page to enter your University username and password for access. Whenever you need to access your account, such as from links in emails that you will receive, as long as you are logged in with your University username and password, you will be taken directly into your account and your applications.

The landing page for the URL above is:

Clicking on the ‘Log In’ link at the top right of the landing page will take you into the ERM.

If you access the ERM remotely, you will be taken to a standard Teesside University log-in page, where you must enter your University user name and password.

2 CREATING AND SUBMITTING AN APPLICATION FOR ETHICS REVIEW

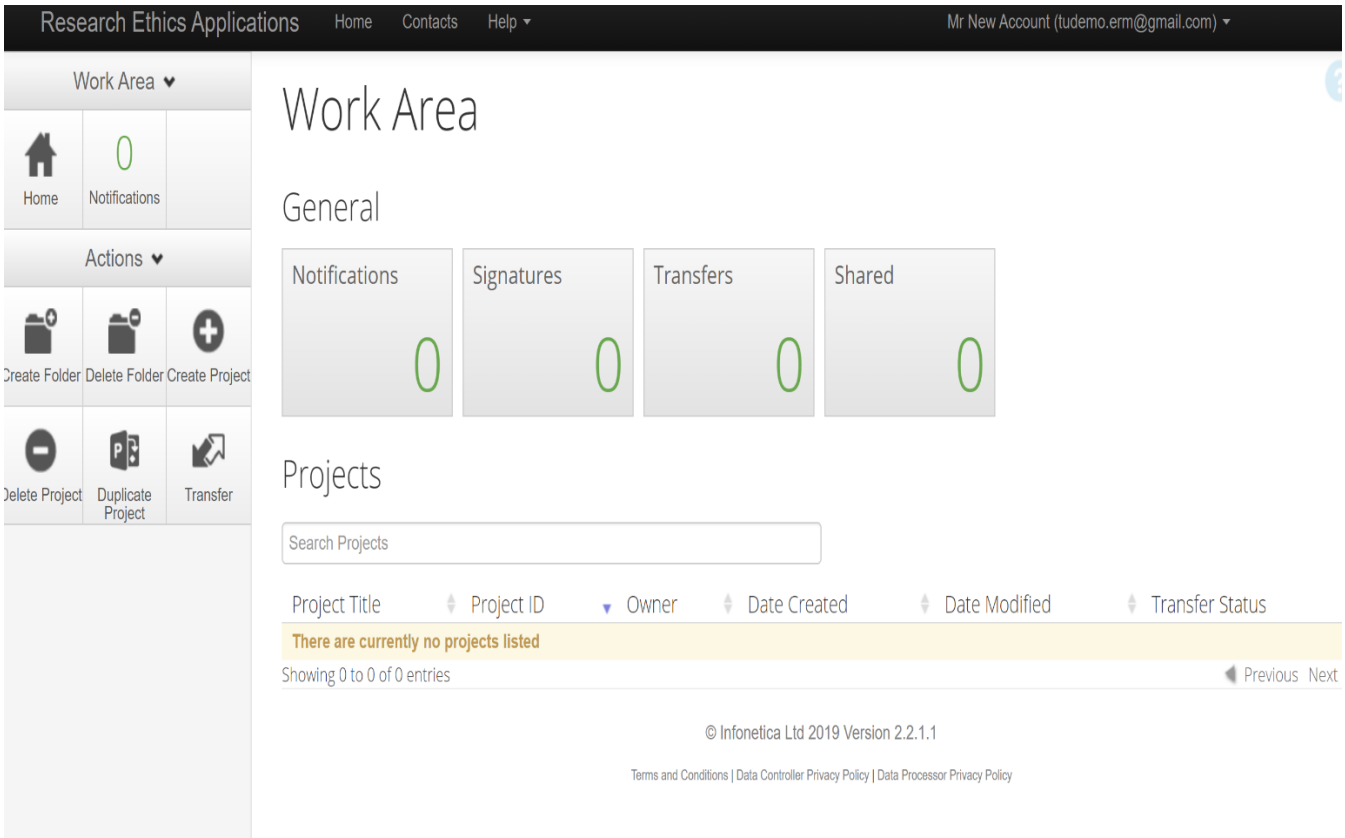
This section is in two parts. The first part gives a summary of the application system and how it works. The second part gives a step-by-step guide to making your first application.

2.1 OVERVIEW OF YOUR APPLICATION ACCOUNT

Your account allows you to create and submit an application for research ethics review and then manage any actions required once the application has been reviewed. Everything you may need to do with an application can be managed within your account online, but you will also receive email notifications referring to your application. Links within email notifications will provide direct access back to your account and the application that you have submitted. You can submit and manage multiple applications in your account and use folders to manage them if you have multiple applications.

The main page of your account is arranged in what is called the '**WORK AREA'.**

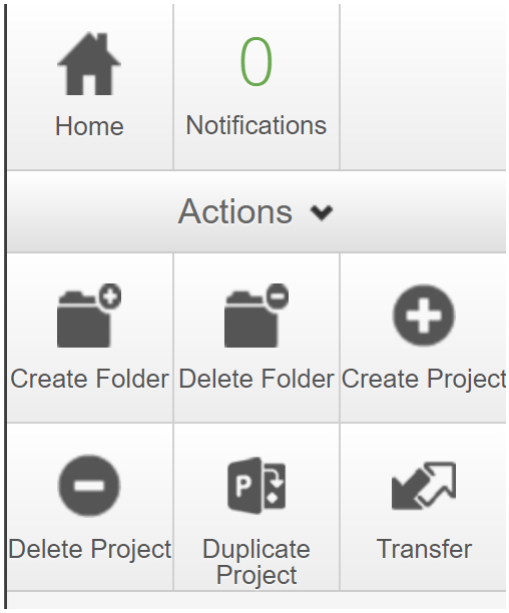
When you first create your account, you will see a webpage that looks like this:



The Work Area is divided into three main sections: **Sidebar**, **Tiles**, and **Projects**.

Sidebar

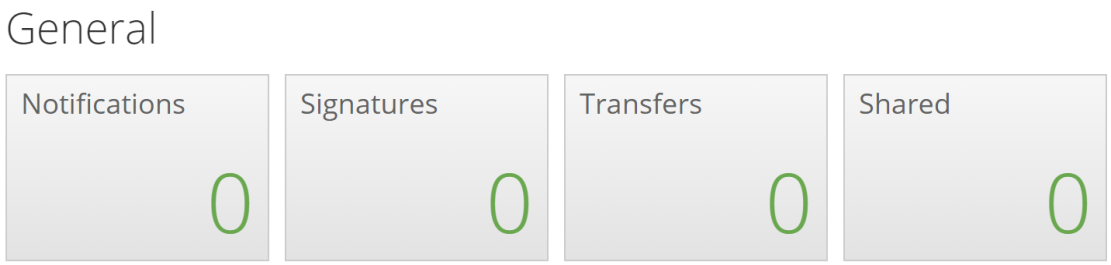
The **Sidebar**, which is placed on the left-hand side, contains various buttons to take actions. You may never use some of these buttons, but you will always need to use 'Create Project' to make an application.



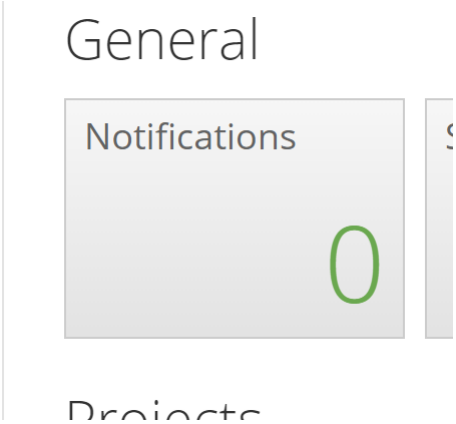
The Sidebar is also a feature which appears in all areas of your account, not just in your Work Area, but will appear differently depending on where in your account you are. These different Sidebars will be explained at the relevant points later in this guidance.

Tiles

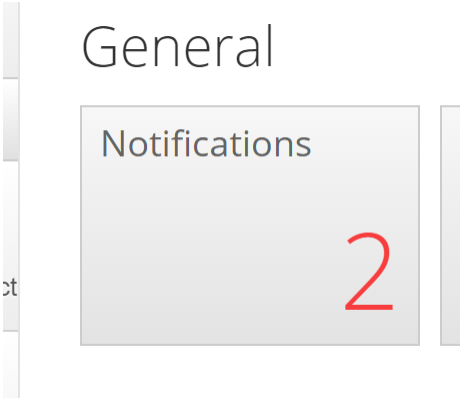
At the **top** of the Work Area under the heading 'General' are four large oblong **Tiles**, each with a number on their face. When you first create your account these will all show '0' but as you make applications, the numbers on some tiles will change.



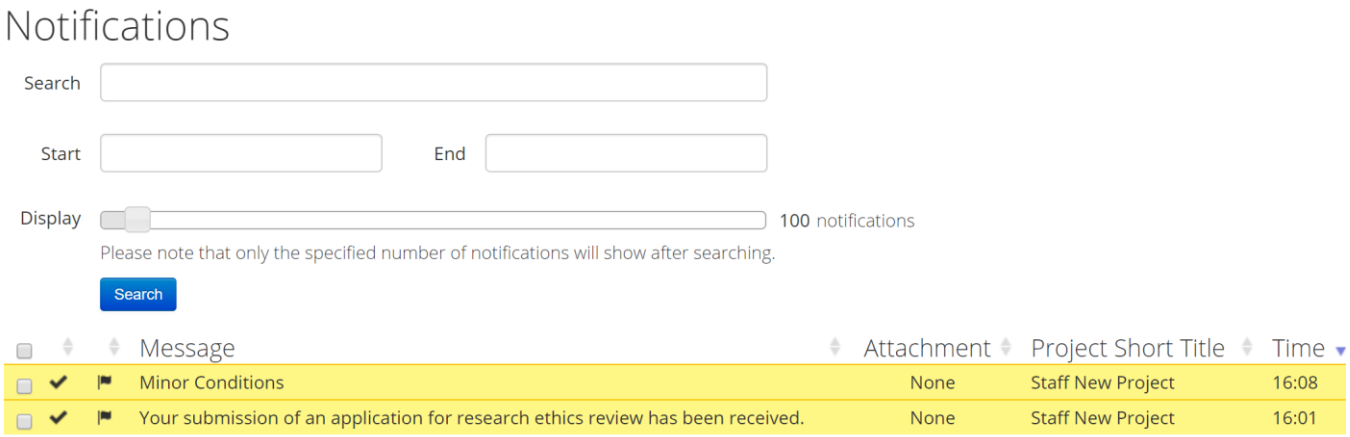
The Tile that you will use most often is ‘Notifications’. This Tile shows when you have been sent notifications about your application(s) and will tell you how many notifications have been received. Most student applicants will not need to use ‘Transfers’ tile and your ‘Signatures’ tile will not be used by you as an applicant but by your supervisor. The ‘Shared’ tile will show applications that you have shared with another person. Student applicants will normally share their application(s) with their supervisor.



Notifications will communicate many different types of information to you: to confirm your submission has been made; changes in your application’s status; inform you when there are actions to take on your application once it has been reviewed; and finally when your application has been approved. The Tile below shows that two notifications have been received:

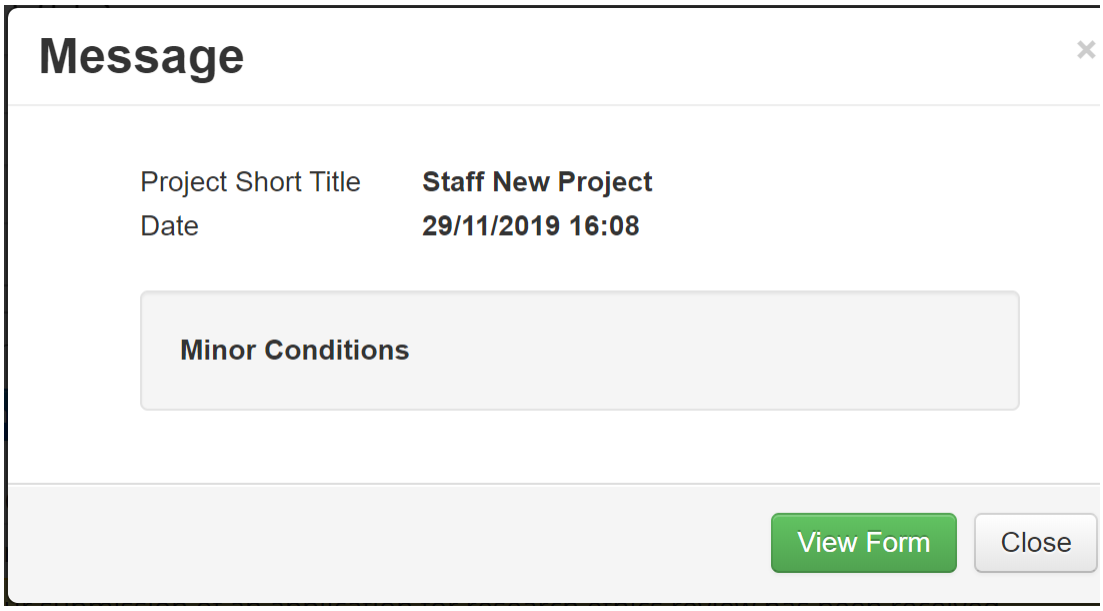


Clicking on the Notifications tile will take you to a list containing notification(s):

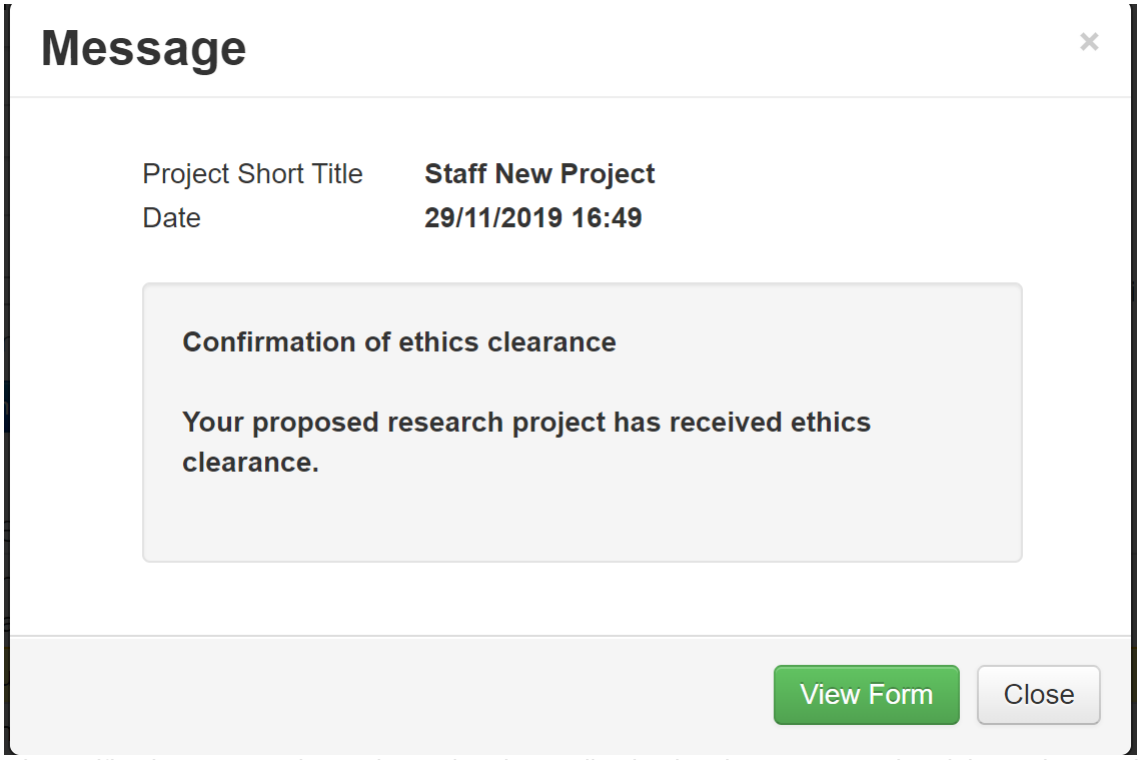


This notifications list shows that a submission was submitted and successfully received (lower notification); and that a decision was taken when the application was reviewed to require minor changes to the application (upper notification).

Clicking on any of the notifications in this list will bring up a pop-up window with further information and a button taking you to the application form to which the notification applies:



The Notification pop-up above shows that the application has minor conditions attached to it, meaning that minor changes are required to the application before it can be approved.



The notification pop-up above shows that the application has been approved and the project could now begin.

You will also **receive all the communications sent via notifications to your email address**, so you do not have to monitor your account continually. However, notifications in your account are detailed and easily accessed when you are logged in. You must still go via your account to manage any elements of your applications, even when receiving email alerts, although links to your application in your account will usually be provided in any email alerts sent.

Projects

In the ERM, applications are called 'Projects'. In the lower section of your Work Area is the 'Projects' list where you will be able to see all your applications. Your projects are shown with a small arrow to the left of the name.

Clicking on this arrow unfolds all the application forms associated with this project:

Bench work (AR) test 2	6422	Dr Andrew Rawnsley	07/07/2021 12:53	07/07/2021 13:13

Form Title	Form Reference	Review Reference	App Type	Status	Form Owner
Application for Teesside Ethics Research Ethics Review 21-22 - Rawnsley	Application for Teesside Ethics Research Ethics Review 21-22 - Rawnsley	2021 Jul 6422 Rawnsley	Test application	Approved	Dr Andrew Rawnsley
Amendments to previously approved application	Amendments to previously approved application	2021 Jul 6422 Rawnsley	Test application	Approved	Dr Andrew Rawnsley

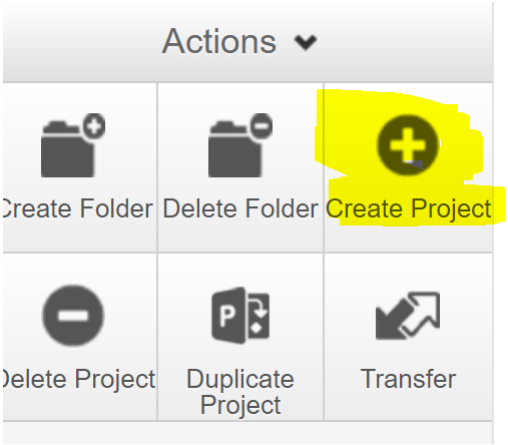
In the project above, there is the main application itself and an associated application for amendments to the project. The main sections of this guidance cover the functions of making a main application. The other application forms that may appear – Amendments to a previously approved application – and -Report an adverse event- are covered in Section 5 of this guidance, as they will only be used by a small number of applicants. Other functions related to withdrawing, duplicating or transferring applications and projects, as well as how to update a pending application prior to submission following system updates to the online system, are covered in Section 4.

Much of the time, you may only have one active project in this list, but if you are creating and managing many applications both current and archived, you can also search using the search bar at the top. The search function is intelligent and will find anything in the list based on any character typed into the search bar. You can also organise all your projects into folders, using the ‘Create Folder’ button on the Sidebar.

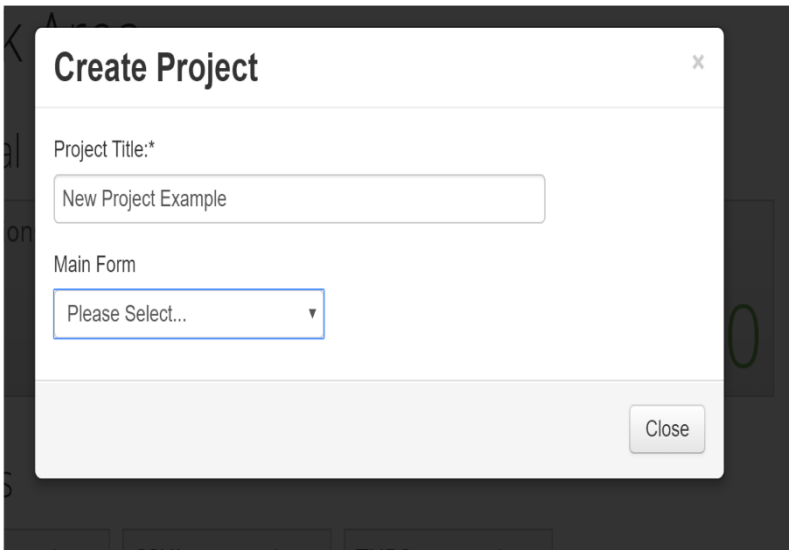
2.2 CREATE AN APPLICATION: STEP-BY-STEP

Creating your first application

2.2.1 On the left sidebar click the 'Create Project' button. Note that the arrangement of the buttons may change depending on the size of your browser window, so may look different on a PC, tablet or phone screen:



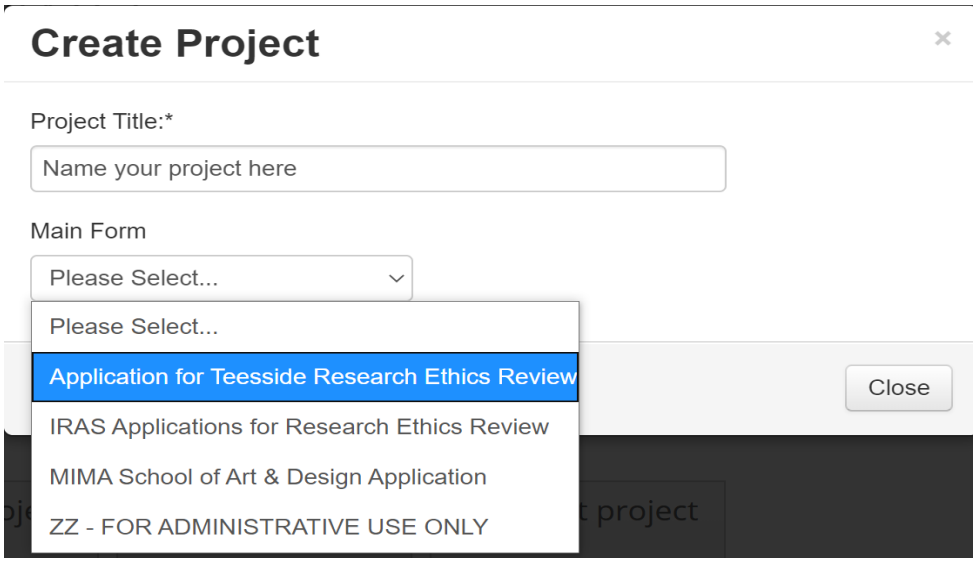
2.2.2 A pop-up window will appear called 'Create Project':



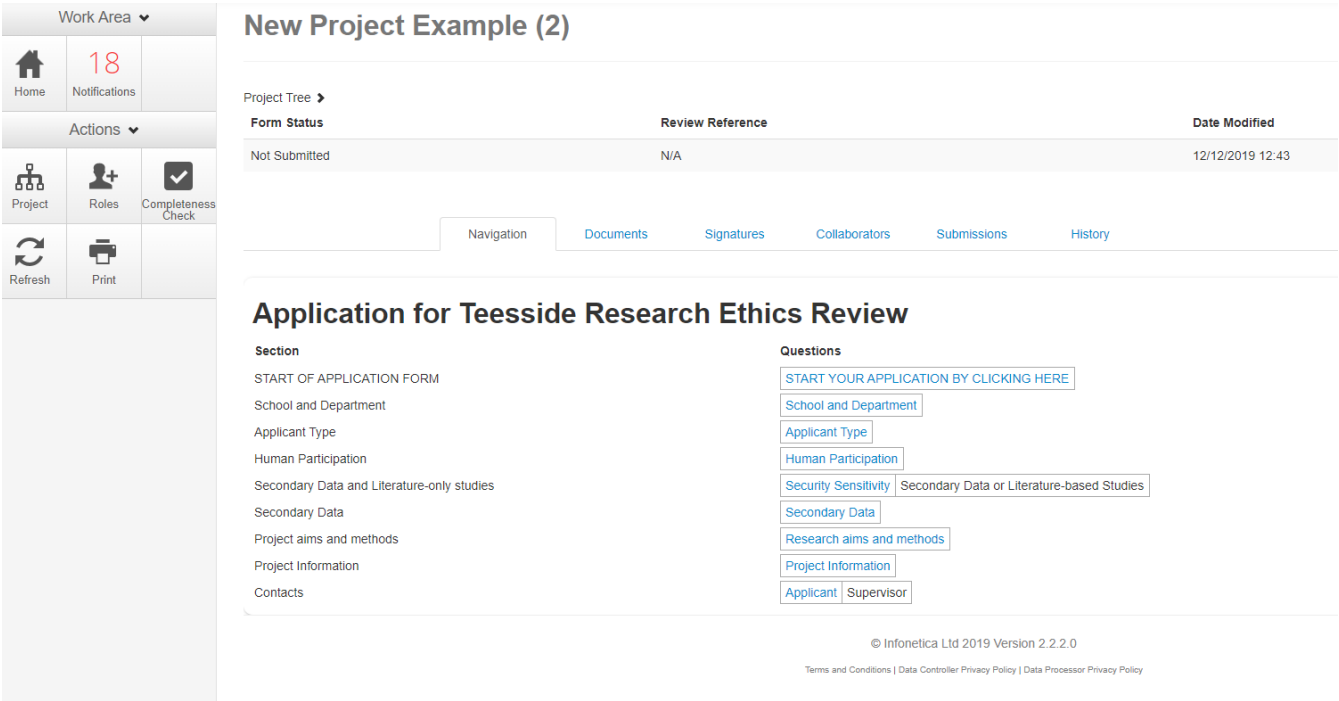
2.2.3 Enter a title for your project application in the upper field 'Project Title'. You will have the opportunity to change the name of your project later in your application form, if you want.

2.2.4 Next, in the drop down menu called ‘Main Form’, select the type of application you are making. **The majority of student applications will need to select the “*Application for Teesside Research Ethics Review 21-22*’** option, which is the option at the top of the list.

You should only select the “IRAS Applications for Research Ethics Review” option if you are making an application that will also be submitted for review using the IRAS application portal. **Students in MIMA School of Art should use the ‘MIMA School of Art and Design’ option.**[1]



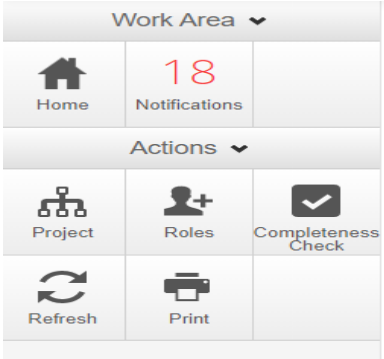
Your project will be created and you will be taken to the ‘**Project Area**’



[1] The last option in the drop down menu is for administrative use only. If you select this option, you will not be able access any functionality as a non-administrative user and anything you do here will be invalid.

The Project Area will always have the title of the current application project across the top: here it is '*New Project Example (2)*'

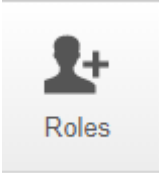
As in the main Work Area, there is also a left-hand **Sidebar** with buttons for taking actions. The 'Notifications' tile also shows at the top of the sidebar for when you are within your project and cannot see the main Work Area tile:



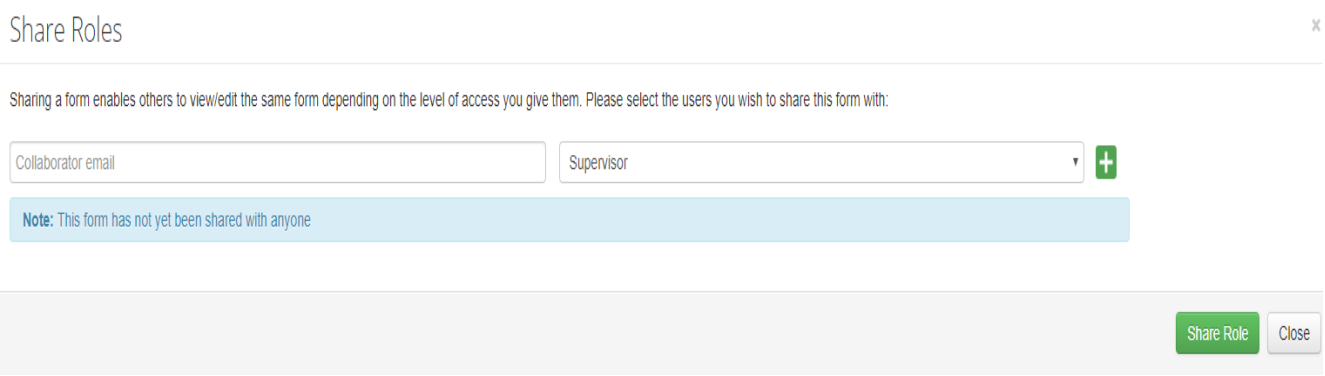
2.2.5 Sharing your application with your supervisor

This is a vital step in ensuring that your application can be submitted. If you do not share your application, you will not easily be able to have your application signed prior to submission. Share your application at the very start before doing anything else.

To share your application once you have created it, click the '**Roles'** button on the Sidebar:

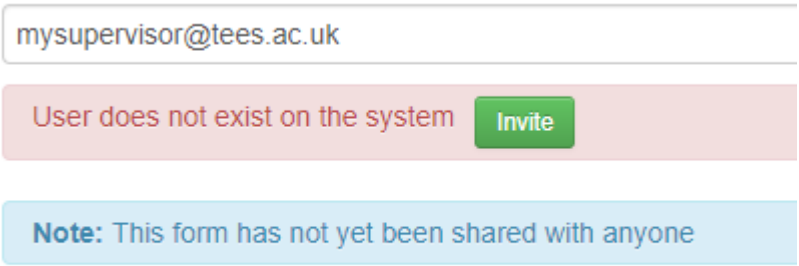


This will bring up a pop-up window, called 'Share Roles':



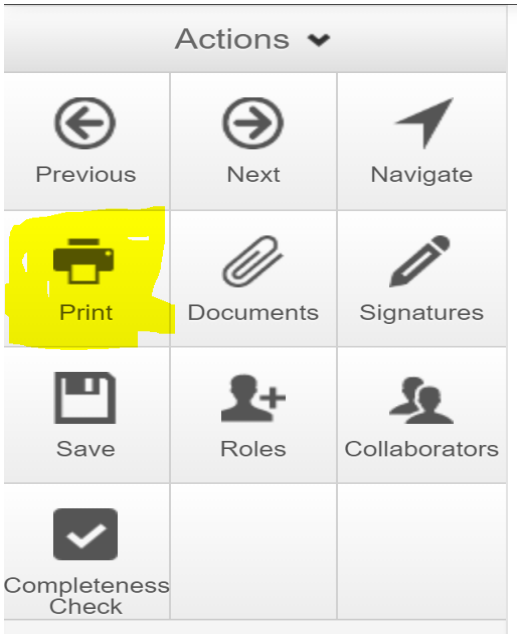
In order to share your project, you need to **enter your supervisor's email address into the first box** and make sure that 'Supervisor' is shown in the field on the right. Then click the green 'Share Role' button. You can share your form with multiple supervisors, if need. Just click the 'Share Role' button again. Shared roles will be listed below once you have added them.

If your supervisor has not yet been active on the ERM system, their email address may not be recognised. A pop-up will appear to inform you that the 'User does not exist on the system' if this is the case.



Simply **click the green 'Invite' button** which will send an email prompting your supervisor to access the ERM to accept your sharing invitation. If your supervisor has already been active on ERM, you will not need to do this.

You may also create a PDF version of your form by using the **'Print' button**. You can then share a PDF version of your form with your supervisor, but this will require them to annotate the PDF and you would then need to make changes in the online form separately yourself. Of course, you can also create a PDF of your application form for your own use offline when putting together an application.

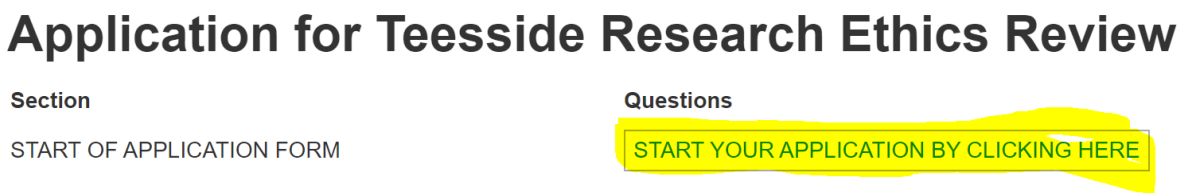


2.2.6 The Application Form

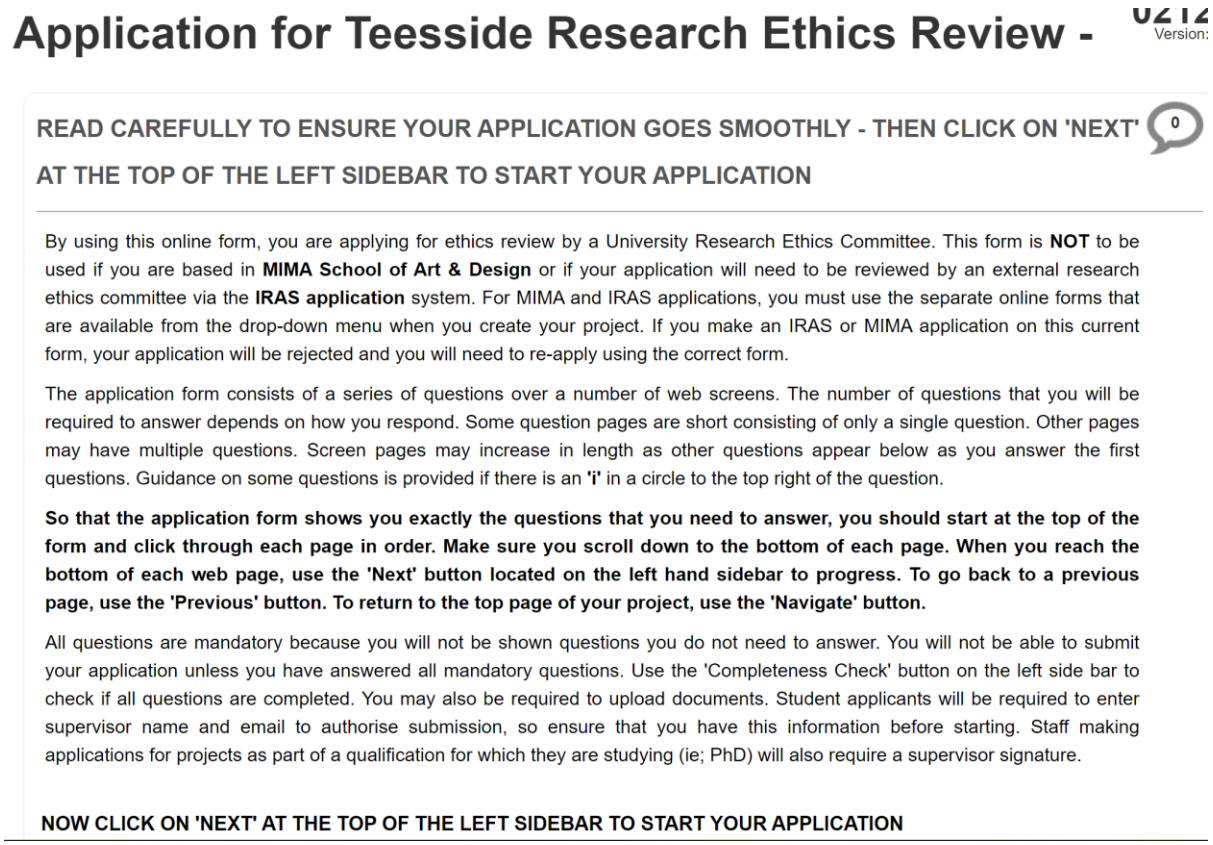
In the lower part of the page is the actual application form you will need to complete. The application form is organised into titled 'Sections' and a series of 'Questions' which are organised using live links. If a link is 'greyed out' it means that it is not live and does not contain a question that you need to answer. Links may change status once you start making an application, with new live links appearing in this list or other links changing to greyed out. This is because the application form is responsive to how you answer questions within it in real time.

In order to start your application, you will need to use the live links.

To start completing your application form click on the link called:
"***Start your Application by Clicking Here'***



2.2.7 This will take you to the first page of the application form that gives important information about navigation within the application form, which is also summarised here in this guide at 2.2.8. The first page of the application looks like this:



Application for Teesside Research Ethics Review - 0212 Version:

READ CAREFULLY TO ENSURE YOUR APPLICATION GOES SMOOTHLY - THEN CLICK ON 'NEXT' AT THE TOP OF THE LEFT SIDEBAR TO START YOUR APPLICATION

By using this online form, you are applying for ethics review by a University Research Ethics Committee. This form is **NOT** to be used if you are based in **MIMA School of Art & Design** or if your application will need to be reviewed by an external research ethics committee via the **IRAS application** system. For MIMA and IRAS applications, you must use the separate online forms that are available from the drop-down menu when you create your project. If you make an IRAS or MIMA application on this current form, your application will be rejected and you will need to re-apply using the correct form.

The application form consists of a series of questions over a number of web screens. The number of questions that you will be required to answer depends on how you respond. Some question pages are short consisting of only a single question. Other pages may have multiple questions. Screen pages may increase in length as other questions appear below as you answer the first questions. Guidance on some questions is provided if there is an **'i'** in a circle to the top right of the question.

So that the application form shows you exactly the questions that you need to answer, you should start at the top of the form and click through each page in order. Make sure you scroll down to the bottom of each page. When you reach the bottom of each web page, use the 'Next' button located on the left hand sidebar to progress. To go back to a previous page, use the 'Previous' button. To return to the top page of your project, use the 'Navigate' button.

All questions are mandatory because you will not be shown questions you do not need to answer. You will not be able to submit your application unless you have answered all mandatory questions. Use the 'Completeness Check' button on the left side bar to check if all questions are completed. You may also be required to upload documents. Student applicants will be required to enter supervisor name and email to authorise submission, so ensure that you have this information before starting. Staff making applications for projects as part of a qualification for which they are studying (ie; PhD) will also require a supervisor signature.

NOW CLICK ON 'NEXT' AT THE TOP OF THE LEFT SIDEBAR TO START YOUR APPLICATION

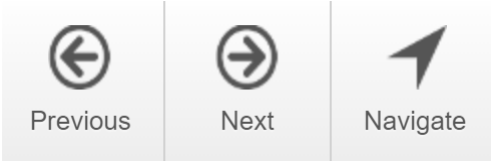
Navigation in the application form

2.2.8 The application form consists of a series of questions over a number of web screens. The number of questions that you will be required to answer depends on how you respond to each question. Some question pages are short consisting of only a single question. Other pages may have multiple questions. Screen pages may increase in length as other questions appear below as you answer the first questions. Many questions also include prompts and guidance so that you can better answer what is being asked for. Read the questions fully! Additional **guidance** on some questions is provided. If available, more detailed guidance is shown by an **'i' in a circle to the top right of the question**:

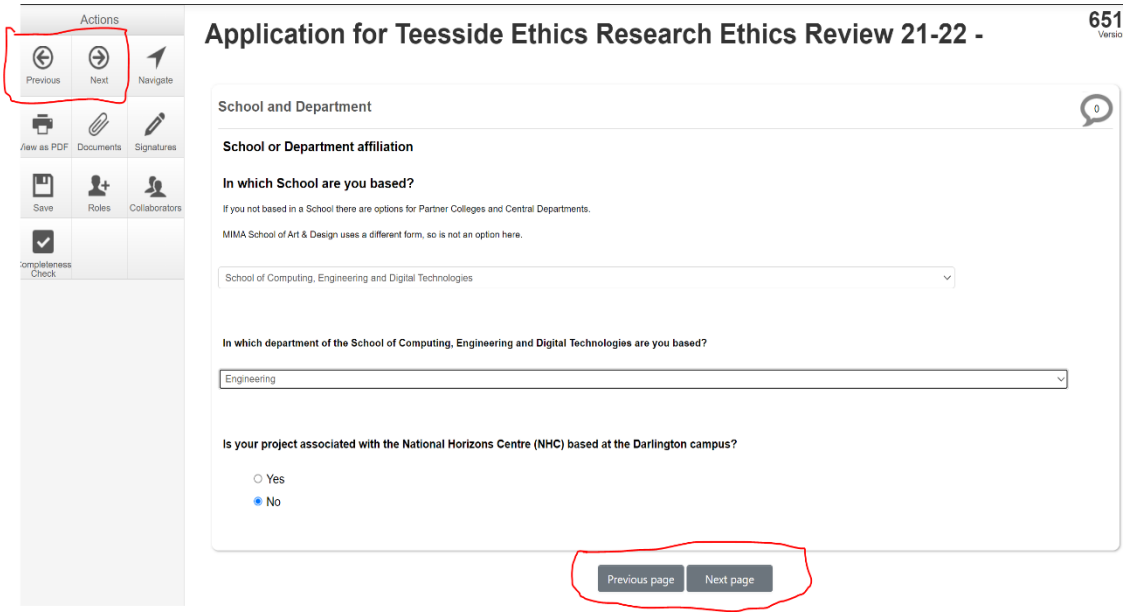
Clicking on this symbol will bring up a pop-up box with help for that question. If you are not sure what a question is asking, USE THE HELP!

Make sure that you always scroll down to the bottom of each page. When you reach the bottom of each web page, **use the 'Next' button located at the top of the left hand sidebar to progress to the next**

page of questions. To back to the previous page of questions, use the 'Previous' button. To return to the top page of your project, use the 'Navigation' button.



You may also progress forwards and backwards in the application form using the 'Previous page' and 'Next page' page buttons at the bottom of each screen, but be aware that on a long screen you will only see these screen buttons by scrolling to the very end of the page, whereas the 'previous' and 'next arrows' will always be showing:



All questions are mandatory, because you will not be shown questions that you do no need to answer. **You will not be able to submit your application unless you have answered all mandatory questions**. Use the 'Completeness Check' button on the left hand sidebar to check if all questions are completed. A final pre-submission check will also run prior to accepting your submission and incomplete questions will be identified for you to complete.

You may also be required to **upload documents** at certain points in your application form. **If uploads are required, templates for the required document are available to download from the form itself**. However, some of these documents may be very detailed, so you may need to download the template for completion and then come back and complete your application once you have completed the templates for upload. If an upload is mandatory, you will not be able to submit your application until required uploads have been made.

All student applicants will be required to enter their supervisor name and supervisor email in order for their application to be authorised by their supervisor. You will not be able to submit your application without these details, so ensure that you have them before starting your application or attempting to submit it. You can always complete the majority of questions and then save your project, which will remain un-submitted but still available in your account, and come back to it.

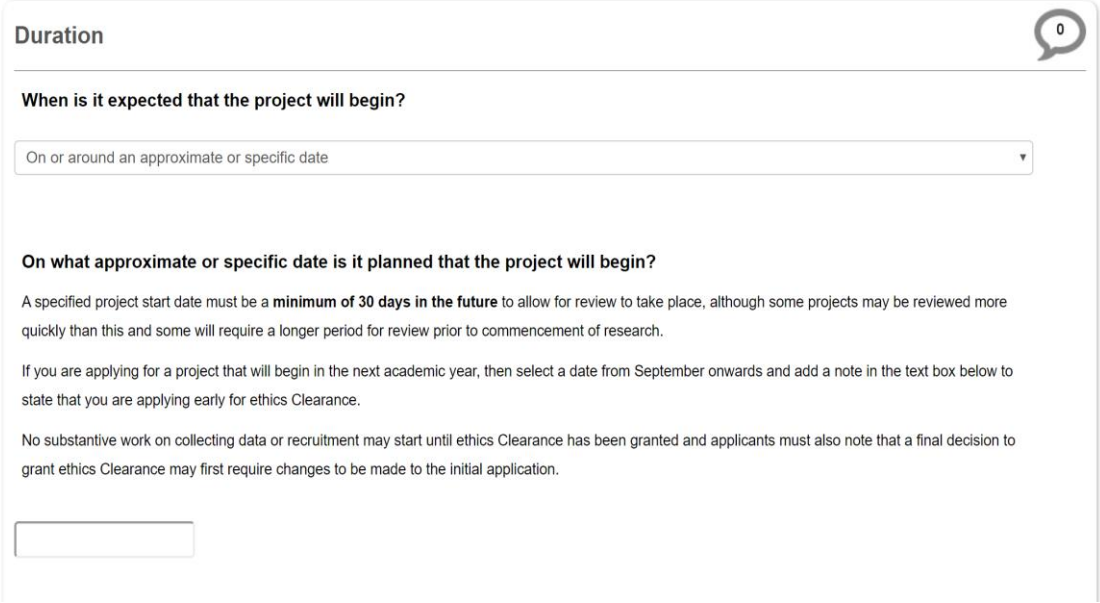
2.2.9 **To complete your application form and make an application submission**, **it is now just a case of progressing through each web screen, which will take you through the application form, answering all the questions that appear and uploading documents when required. Scrolling down to the bottom of each web screen to ensure that all questions have been answered and then clicking 'Next' will let you progress to the next web screen in the application form.**

Remember, if you need help on questions in the form, questions that include an 'i' in a circle to the top right of the question will show you guidance notes for that question in a pop-up window if you click on the 'i'.

2.2.10 After you have answered all the main questions in the application form, a series of final web screens will appear that relate to your project details and to you and your supervisor.

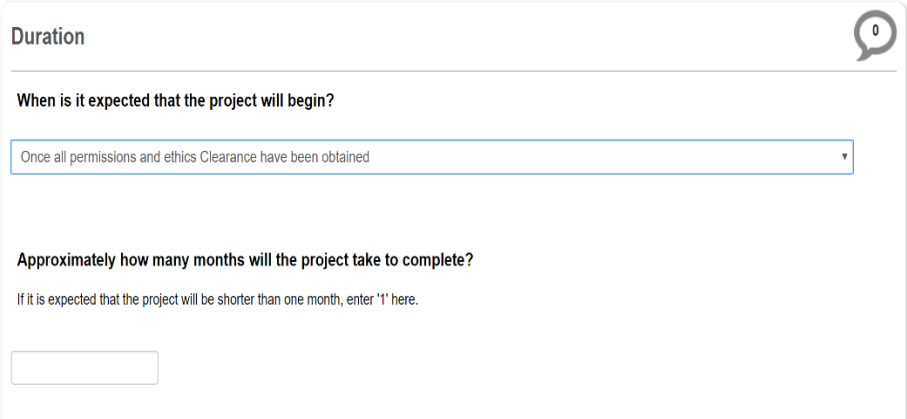
The first will require you to enter 'a title by which your project will be known'. This field will automatically populate with whatever title you gave your project when you created it. However, it is worth giving your project a specific and individual title (ie: '*John's Smith's MSc dissertation in Biochemistry'* rather than just 'My dissertation', which many applicants could use); or a title which is very specific (ie: '*An enquiry into the effect of social media use on mental health*").

You will also be asked to enter a project start date and the project duration. There are two options for entering project start dates, you may choose *a specific date* or enter that your project will only begin once ethics Clearance has been obtained.

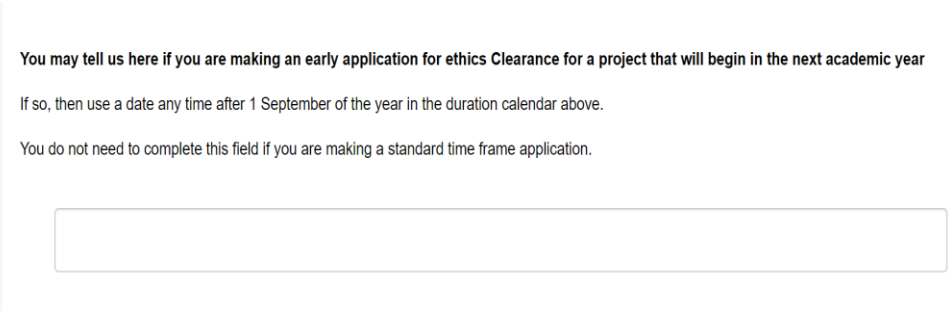


For a specific date option for the start of the project, you will not be able to enter a date in the past and will only be given a calendar in which certain dates in the future are greyed out. This is because your project should not commence until the application has been reviewed and the process of review takes time after you have submitted. The time to review will depend on the kind of application you are making.

If you do not know when your project will commence, use the option for post-ethics Clearance, which will not require you to use the calendar:



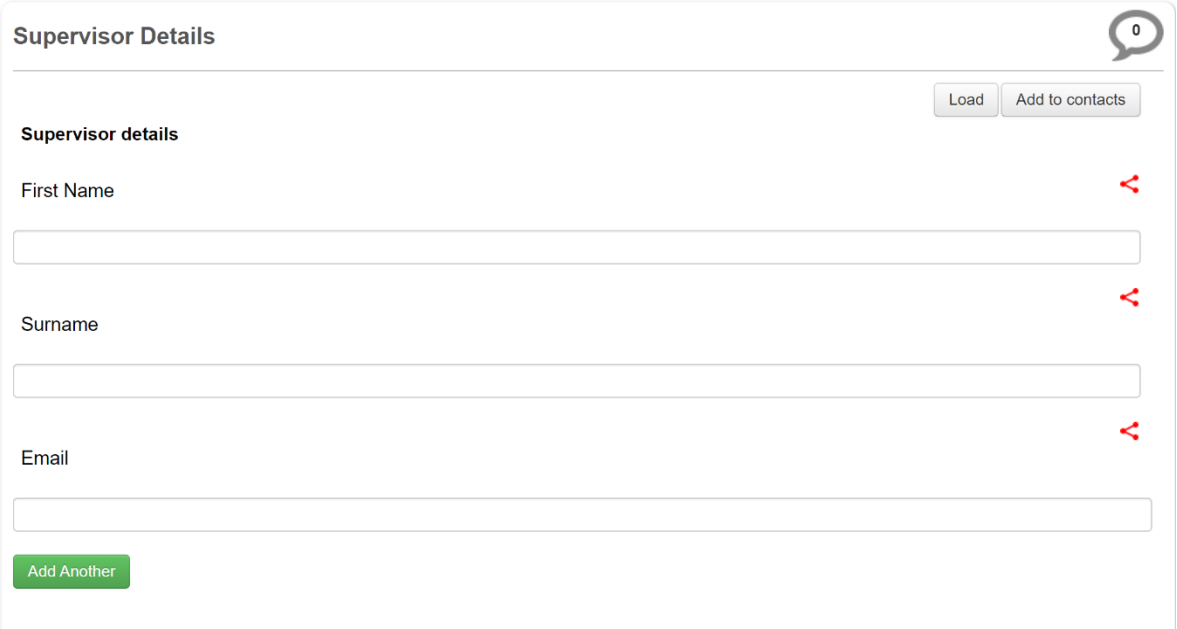
If you are applying early for ethics Clearance (for instance as part of a module prior to your dissertation the following year), then you can enter this information as part of the project duration information and choose ‘the Once all permissions and ethics Clearance have been obtained’ option.



You should enter an approximate duration in the field below in a numeral indicating the number of months (ie: '2'). If you expect that the project will be shorter than 1 month, then enter '1' here.

2.2.11 The penultimate web screen that all applicants will come to is called "Applicant Details". Your Applicant Details will automatically populate with the details entered on your account. Check that the details are still correct. If they are not correct, then go to your main account Work Area and change your details in your account which must always be up to date.

2.2.12 The final web screen that all student applicants will come to is called "Supervisor Details":

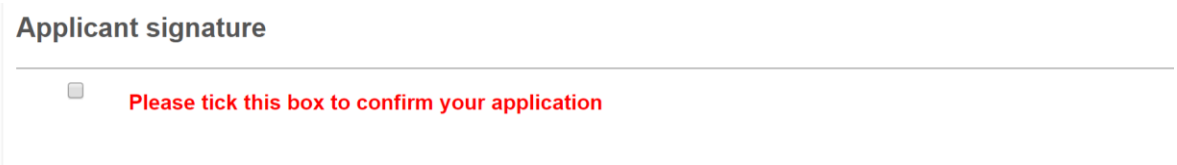


All student applications must be 'signed' digitally by their academic supervisor in order for their application to be authorised**.** The application system will not automatically know who your supervisor is even if you shared your application with them, so you will need to enter your supervisor's **first** and **last names** and **email address** in these fields. Make sure names are spelled correctly! There is the option to 'Add Another' supervisor (the green button at the bottom) but you will only ever need to use this if you need to add details about a second supervisor who may be signing your application in your main supervisor's absence. **Click 'Next'.**

2.2.13 Confirming your Application and Requesting a Supervisor Signature

IMPORTANT: requesting a supervisor signature will 'lock' your application so that further changes cannot be made. You must ensure that you have shared your application with your supervisor if any pre-submission changes are expected to be requested by your supervisor as you will not be able to make any changes once the form is locked! The form becomes locked when you request a signature from your supervisor, so <u>CREATE</u> your application, then <u>SHARE</u> with your supervisor, and ask them to check your work BEFORE you request them to sign your application.

You will now see a web screen that asks you to confirm your application. Ticking the box to confirm your application is how you 'sign' the form before requesting your supervisor's signature:



Note that this confirmation may differ on your application form, as it depends on the type of application you are making, but many applications will see the confirmation request in the format as it is here or in a very similar format. If this confirmation appears, you confirm your application by ticking the box:

If this tick box is not shown for the type of application you are making, you will just be shown an 'Applicant Declaration', as shown below:

APPLICANT DECLARATION

I confirm that I have read and understand the University's Six Principles of Research Ethics and that my research will abide by the following:

- Harm to research participants must be avoided: the protection of the dignity, rights, safety and well being of all actual and potential participants, researchers, non-participating members of the public, and the environment takes precedence over scientific, or any other, considerations or interests.
- Research should be designed, reviewed and undertaken to ensure adherence to the highest standards of quality, integrity, ethical propriety and governance, and legal compliance.
- Researchers and participants must normally be informed as fully as possible about the purposes, methods and intended possible uses of the research, what their participation in the research entails, and what risks and benefits are involved. This information should be accurate, clear, and easily understood by the potential participant, who should have the capacity to understand what is involved in their participation. Research proposing variation from this principle may be approved but only in very specific contexts in which the lack of proper information must be justified by the value of the research.
- Research participants must consent to participate in a voluntary way, free from any coercion, undue influence, or manipulation. Use of inducements to encourage participation must be carefully monitored.
- The confidentiality of information supplied by research participants, and their anonymity, must be respected except in cases where illegal behaviour is discovered. All data and other materials from and about research participants will be collected, processed, retained, stored, and disposed of, in accordance with current legal requirements.
- The independence of research must be clear, and any conflicts of interest or partiality must be disclosed. Publication of research results must be done fairly and with the public good taking priority over private

I confirm that I have the competence and experience to undertake the proposed research safely and ethically.

AS A STUDENT APPLICANT, YOU MUST NOW REQUEST A SIGNATURE FROM YOUR ACADEMIC SUPERVISOR TO AUTHORISE YOUR SUBMISSION. DO THIS BY CLICKING ON THE '*REQUEST SIGNATURE*' BUTTON BELOW.

You will be asked to add your supervisor's email address in a pop-up window to send this request before submitting.

Request Signature

All student applicants will see a button at the bottom of this web screen called '**Request Signature'**.

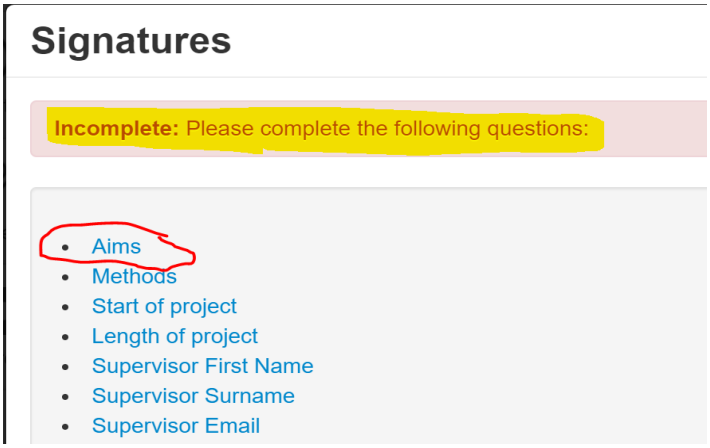
AS A STUDENT APPLICANT, YOU MUST NOW REQUEST A SIGNATURE FROM YOUR ACADEMIC SUPERVISOR TO AUTHORISE YOUR SUBMISSION. DO THIS BY CLICKING ON THE '*REQUEST SIGNATURE*' BUTTON BELOW.

You will be asked to add your supervisor's email address in a pop-up window to send this request before submitting.

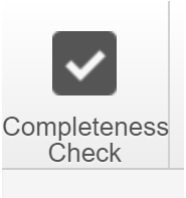
Request Signature

Click this button to submit your application by sending a request to your supervisor to authorise your submission. The system will then check that your application form is complete before confirming submission.

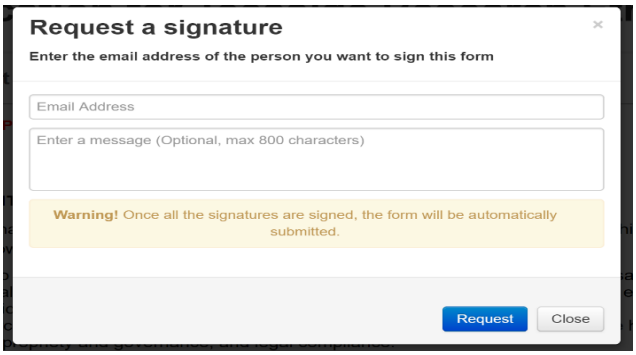
2.2.14 If your application contains any incomplete questions, you will see a pop-up box showing which questions are incomplete. **Clicking on the links in the pop-up will take you back to those questions in order to complete them**. You will need to return to the 'Request Signature' button and click again once you have completed incomplete questions. You will continue to see the 'Incomplete' pop-up until every question has been completed and not able to submit until all are completed.



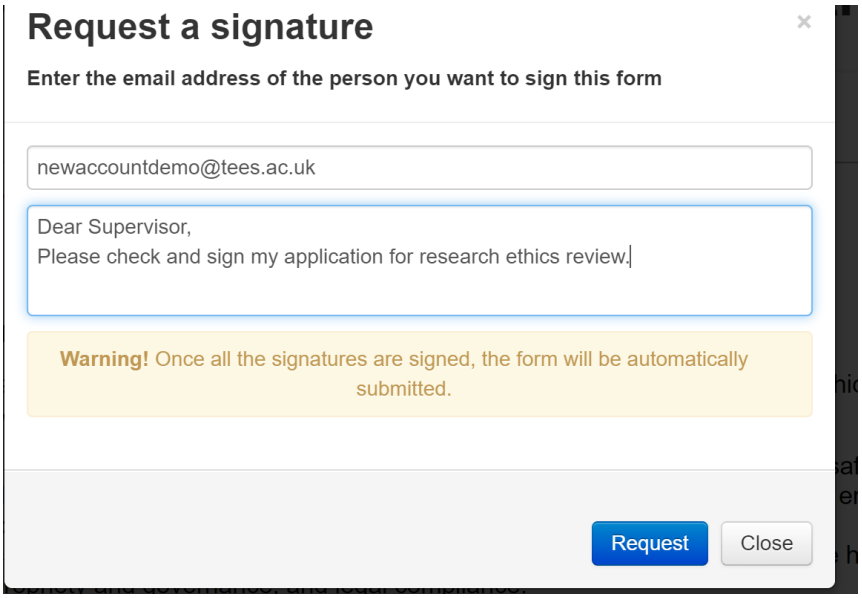
As noted earlier, you can also use the 'Completeness Check' button on the left-hand sidebar of your project before you get to this point to check that all questions are complete so you do not have to complete questions via the pop-up above. This will save time when trying to submit your application.



2.2.15 When your application is complete, you will see a pop-up box called 'Request Signature' into which you will need to enter the email address of your supervisor.

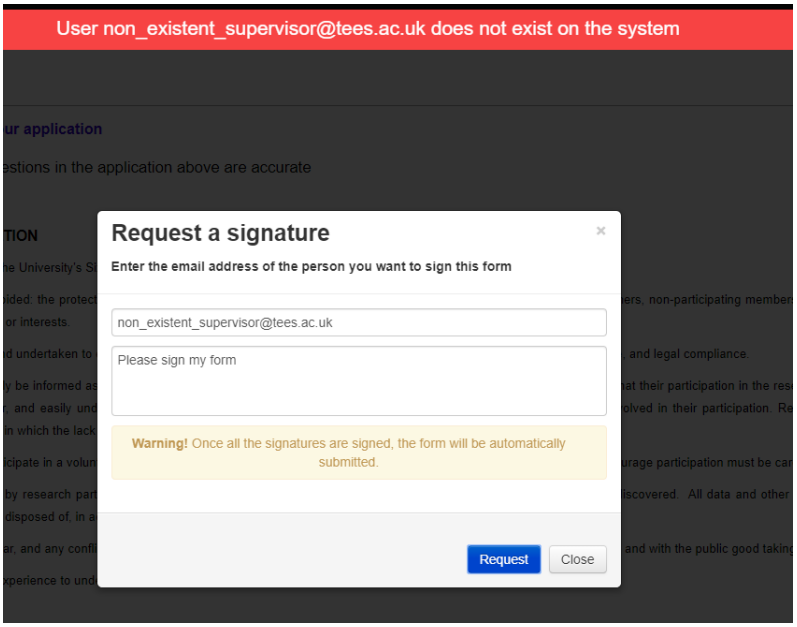


If you have already shared your application with your supervisor as instructed at Section 2.2.5 above, and your supervisor has accessed the ERM, their email address will appear in this field when you begin typing it. Select it from the list. You can also add a message in the box below the email field. Your supervisor will be sent the signature request and any message to the email account you have entered:



Clicking on the blue 'Request' button on this pop up will submit your application for signature by your supervisor. Note the 'Warning!': once you have requested your supervisor's signature, your application will become 'locked' and once signed by your supervisor will be submitted for review. Once you have made this request, you will not be able to make any changes before it is reviewed by the research ethics committee.

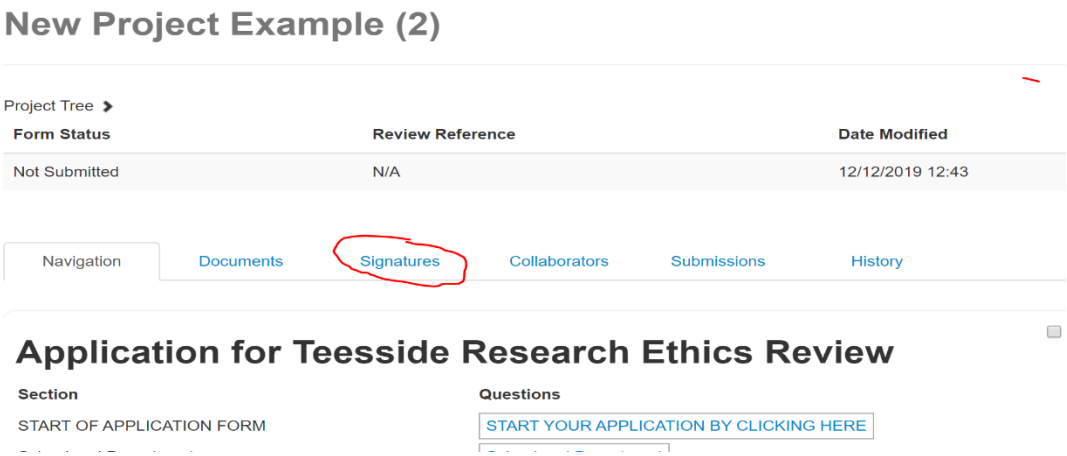
IMPORTANT: If you have not shared your application with your supervisor, there is a possibility that your supervisor's email will not be found and you will see the following message:



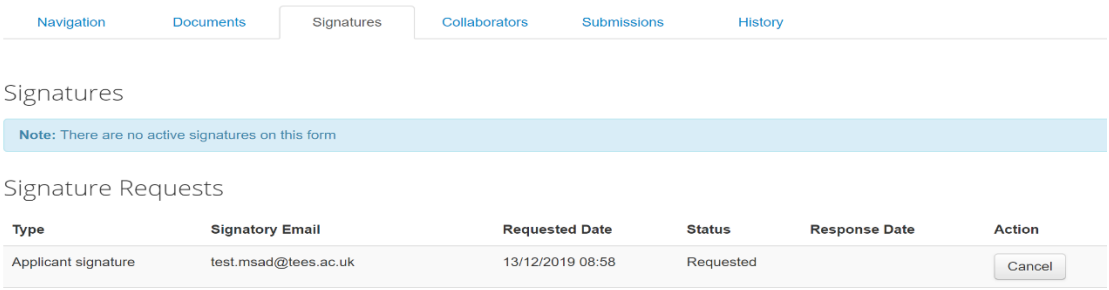
Receiving this message at the point of making a request for a signature means that you will not be able to finalise your application and make the request until your supervisor has accessed the ERM. You will need to EITHER go back to the top of your application and, as at Section 2.2.5, **Share Roles and your application with your supervisor**; OR, send them an email with the link https://apply-ethics.tees.ac.uk/ asking them to click the link to access the ERM. Once they have done this, entering your supervisor's email address in the Request a Signature box will pull up their email address for you to select and make the request.

2.2.16 Checking the status of your signature request

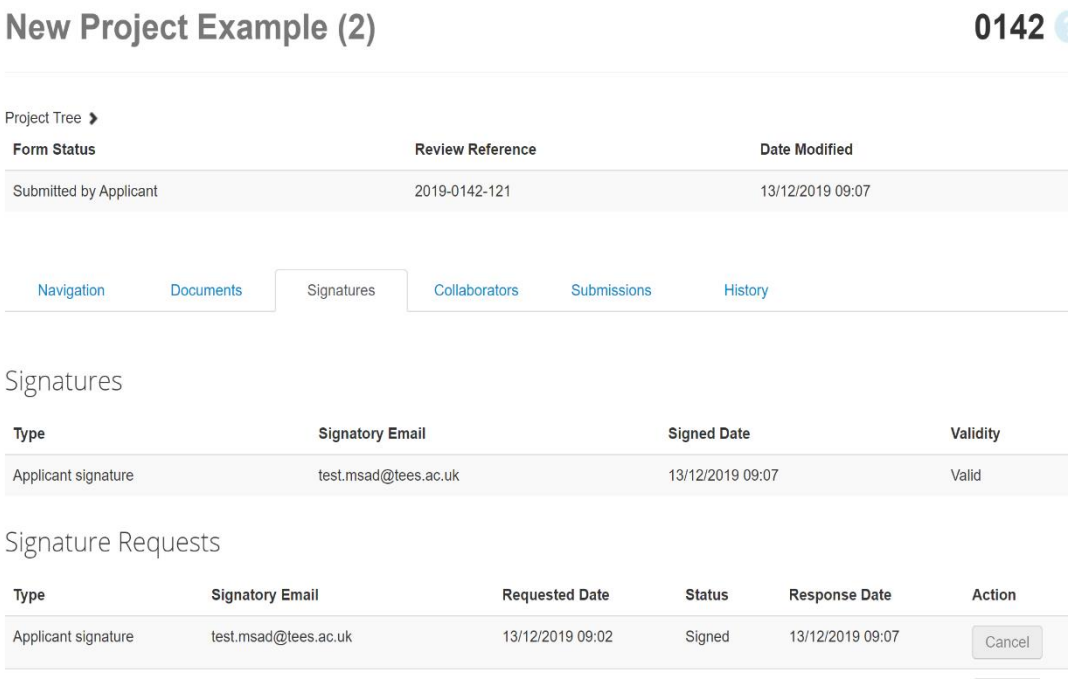
You can check the status of your requested signatures at any time by using the 'Signatures' tab in the project main page:



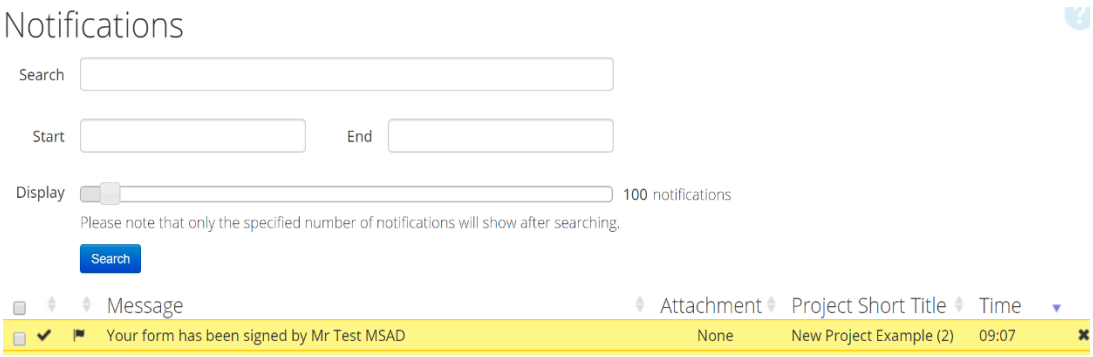
Clicking on the 'Signatures' tab will bring up a list of requests and signatures made:



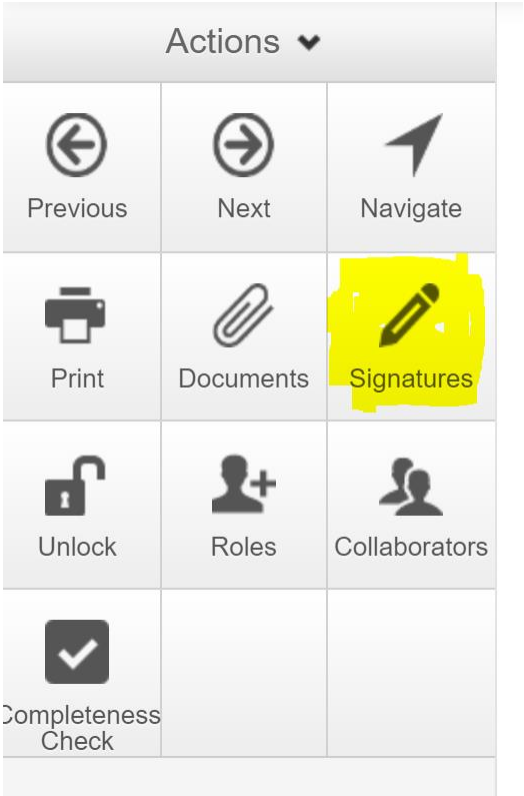
Once the signature has been confirmed, it will show at the top of this list:



You will also receive a notification confirming when a signature has been made:



You can also check for signatures when *inside your application*, using the ‘Signatures’ button on the Sidebar:



2.2.17 **Confirmation of Submission of Application**

You will receive an email confirmation once submission has been received – and also a notification which will appear in your Notifications Tile and in the Notifications list on your account. You will only receive this confirmation when your supervisor has signed your application following your signature request. If you do not receive the confirmation, check that your supervisor has responded to your signature request.

> Thank you for your application for ethics review.
>
> **This email only confirms that your submission has been received and does not mean that your project has been given ethics review Clearance.**
>
> You will receive communications from the Research Ethics Committee if there are changes required to be made to your application and you will also be contacted to confirm its status, including when your application has been reviewed favourably and has been approved.
>
> You must not undertake the data collection for this project prior to receiving confirmation of approval.
>
> *on behalf of*

3.1 MANAGING YOUR APPLICATIONS AFTER SUBMISSION

Once you have made your application, the form is sent to the Research Ethics Committee in the School in which you are based. After your application has been reviewed, you will receive a decision on your application. You will receive **an email alert to inform you of the decision and any actions required; you will also receive a notification in your account.** The email will also be sent to the supervisor who signed your application.

If changes are required to your application, the required changes will be sent along with the email and will be available for you to act on in your application in your account. **A resubmission of an application following changes will require your supervisor to sign the resubmission.**

3.2 Managing your Applications after Submission: Step-by-Step

3.2.1 Receiving decisions

Once your submitted application has been reviewed, a decision will be made about the status of your application. You may receive a decision that your application has received ethics Clearance straight away, which will mean that you do not need to do anything else in your Applicant Account. In such cases, you would receive an email informing you of this decision and such emails would also have an attachment letter:

Confirmation of research ethics Clearance

Dear Dr Andrew Rawnsley

RE: Staff New Project 2019-0119-107

Your application has been reviewed and I can confirm that this study has received ethics review Clearance and can proceed as soon as you receive this confirmation.

The attached letter can be used as evidence of authorisation

Good luck with your study

Yours sincerely,

However, in many cases the decision will be that you will need to make changes to your application before you can start the research. Changes can be either ‘major’ or ‘minor’ and in the ERM these are called ‘Major Conditions’ or ‘Minor Conditions’. The way that both of these required

changes are handled is the same, the only difference is the amount of changes required.

If this decision is reached, then you will receive an email alert informing you:

Review Decision: Minor Conditions - changes to application required

Thank you for your application to the Social Sciences REC . Your application has been reviewed and the reviewers would like to offer comments below to inform minor changes that must be made to your application before it can receive a favourable opinion and ethics review Clearance. **All the review comments are also enclosed in the attached document.**

Please respond to each of the comments made.

The reviewer comments are assigned by referring to the title of each relevant section of your electronic application form. You must address each change by entering the referenced section of the form and making changes to respond to the comments. You may do this by using the 'Navigation' area of your application account page for this project. Click the live project link below and then use the section links to enter the section where changes are required. You may also click on the 'Reviewer Comments' tab (left hand side of your project screen) which will bring up each comment in your form for you to make changes. Any changes made will then be stored in your application.

If previously uploaded documents require changes, then please revise those documents according to the comments made and then assign any revised documents with an updated version number (ie: Version 2) before uploading the revised versions.

3.2.2 Responding to and acting on decisions

At the bottom of an email message communicating a decision, there will be a '**Live Project Link'**, which will take you to your application, via log-in to your account, if you click it.

The email will also have an attached document containing the text of the email and the list of comments, which will be useful for reference if the list is long.

In the example below, only **one comment** is shown, meaning that only one change is required to the application:

Live Project Link:

https://teesside.forms.ethicalreviewmanager.com/Project/Index/121

Comments:

Title	Comment
Use of secondary data	Please provide details about the source of the secondary data

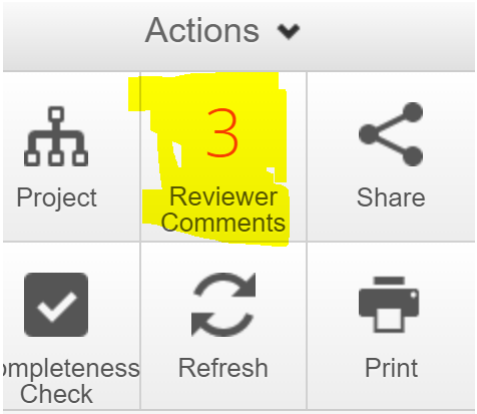
In this case, the section of the application where the change is required is the section ‘Use of secondary data’, and the comment tells you what needs to be changed or added.

The same information is available directly in your application account. You will receive a notification that Minor Conditions are required.

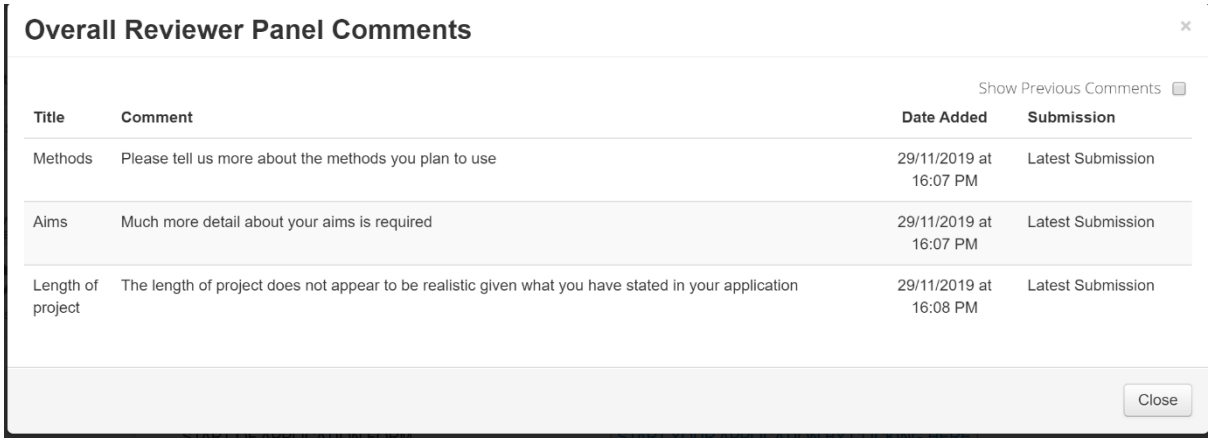
The screen shot below shows a longer list of notification for an application, where Minor Conditions were required at two points:

Message	Attachment	Title	Time
Confirmation of ethics clearance Your proposed research project has received ethics clearance.		Staff New Project	16:49
Your submission of an application for research ethics review has been received.	None	Staff New Project	16:48
Minor Conditions		Staff New Project	16:35
Your submission of an application for research ethics review has been received.	None	Staff New Project	16:18
Minor Conditions	None	Staff New Project	16:08
Your submission of an application for research ethics review has been received.	None	Staff New Project	16:01

Inside the project application, the **left-hand sidebar** will show the comments which have been attached to your application during review. Comments may apply to the whole form or to specific questions. Below is shown an application for which three comments have been made that require changes:



Clicking on the ‘Reviewer Comments’ button in the left-hand sidebar will bring up a pop-up window in which each of the comments will be displayed:



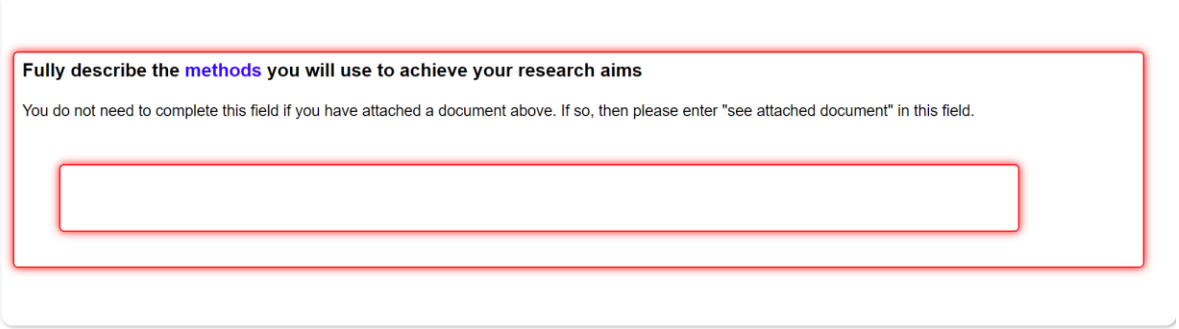
Overall Reviewer Panel Comments

Show Previous Comments

Title	Comment	Date Added	Submission
Methods	Please tell us more about the methods you plan to use	29/11/2019 at 16:07 PM	Latest Submission
Aims	Much more detail about your aims is required	29/11/2019 at 16:07 PM	Latest Submission
Length of project	The length of project does not appear to be realistic given what you have stated in your application	29/11/2019 at 16:08 PM	Latest Submission

Close

Clicking on each comment in the pop up window, will **take you directly to that section of the application in which changes are required**. Inside the application form, the section referred to by the comment will be outlined in red, as below:



3.2.3 Any comments linked to questions, will also show in a bubble to the top right of the question in the application form:

3.2.4 After you have made the changes required by responding to all the comments linked to your application, **you will then need to re-submit your application. You will need to navigate to the last section of your application and confirm your re-submission. You will also need to request your supervisor's signature again for the re-submission**.

3.2.5 Your re-submission will be confirmed by email and in your notifications.

4 OTHER FUNCTIONS FOR MANAGING YOUR APPLICATIONS

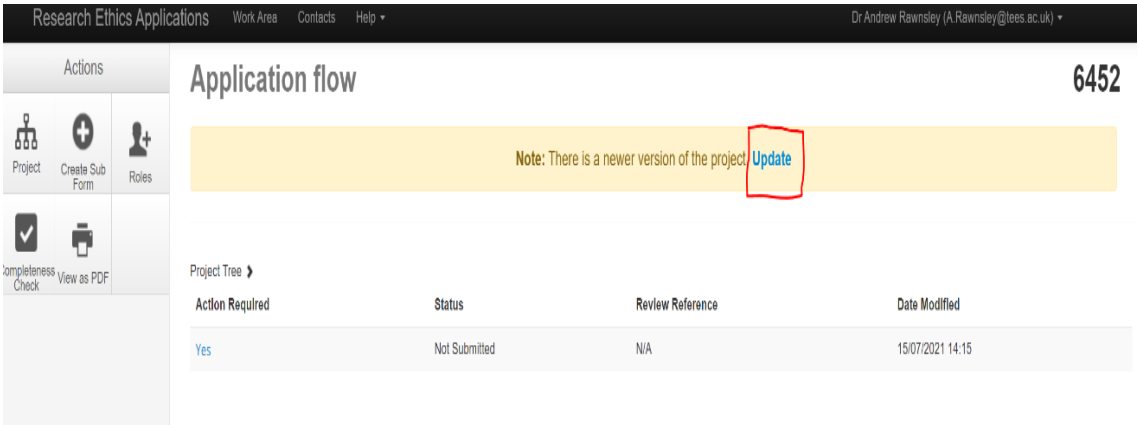
4.1 Required form updates after system updates are performed

When the online system is changed via a system-wide update, any pending applications in the system that have been created but not yet submitted must be updated so that they are able to be submitted. If you have a pending application that has not yet been submitted, you must manually update your application.

Required form updates are notified to applicants in two ways.

Splash screen: when you go to the application webpage, you will see a splash screen, which has messages. When the system has been updated, it shows the *date of the most recent update* in yellow highlighting as below. If you first created your application prior to this date and you have any form of pending application, your application will need to be updated in order for you to submit it.

Update message on your application main page: Your application main page will show you a message if your application form needs to be updated. This is also where you need to perform the update:



The message will tell you that "*There is a newer version of the project'*. To update the application, all you need to do is click the 'Update' link in blue font shown with red circle in the above image and then confirm via a pop-up window. If you do not update where this is required, you will not be able to submit your application or request a signature and you may receive a message that your application is invalid or blocked. Note that **if you requested a supervisor signature <u>before</u> the system update was made and your supervisor <u>did not sign the form before the update</u>, you will need to update your application and request the signature again**.

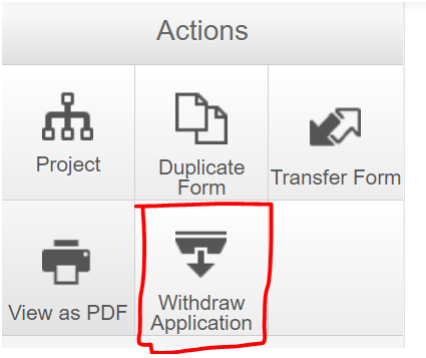
System updates are not made frequently and usually take place in the summer period between June and September. Occasionally, updates are needed at other times to correct bugs or problems with the system, so it is important to check for the splash screen message and update alert message on any pending applications every time you log in to work on a pending application.

4.2 Withdrawing an application that you have submitted for review

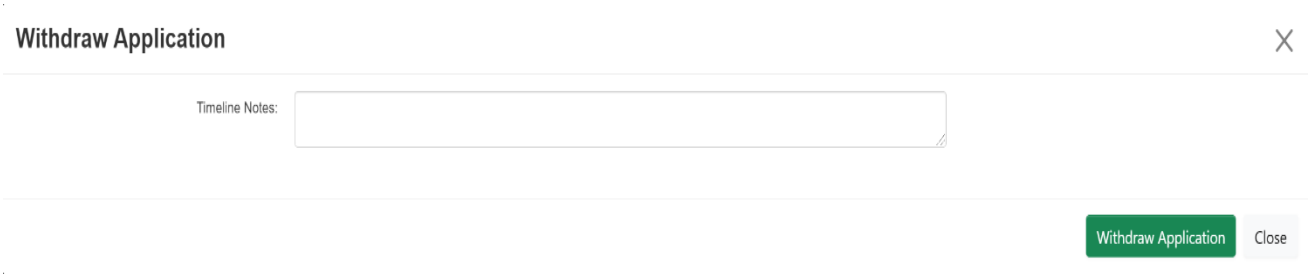
If you have submitted your application and need to withdraw it, you can do this by using the 'Withdraw Application' button. This button appears on the left-hand sidebar inside the application that you want to withdraw.

You can withdraw an application *at any time once it has been submitted up to the point at which a final review decision is given*. Once an application has been given an approval or rejected decision, it can no longer be withdrawn. However, you *can* withdraw applications that have been given a 'Major Conditions' or 'Minor Conditions' decision if you no longer want to progress them by making the required changes.

To withdraw an application, click the 'Withdraw Application' button, inside the application you want to withdraw:



This will bring up a pop-up. To confirm withdrawal of the project, click the green 'Withdraw Application' button at the bottom:



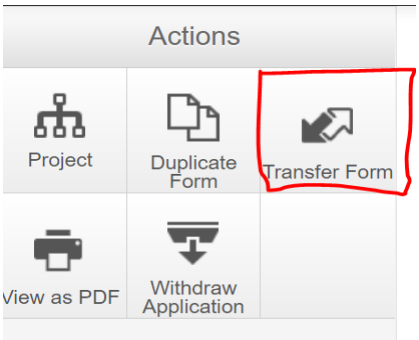
Once you have withdrawn a previously submitted application, it will be automatically assigned an application status of 'Invalid Application'. You may then either do further work on the application before resubmitting the application; or transfer, delete or duplicate the project as needed.

If you have submitted a project that has been reviewed and has been given a review decision of 'Major Conditions' or 'Minor Conditions', and *you then decide not to resubmit but submit a new application entirely*, <u>then you should withdraw the application.</u> Un-resubmitted applications will result in your being sent increasingly frequent email reminders. Withdrawing applications that have been un-resubmitted will stop you from receiving frequent email reminders about resubmission. Once you have withdrawn an application in this way, you may either duplicate the application to create the basis for a new application using the Duplicate function (see 4.4.) or if you do not plan on using the application any further, you may delete it entirely (see 4.5).

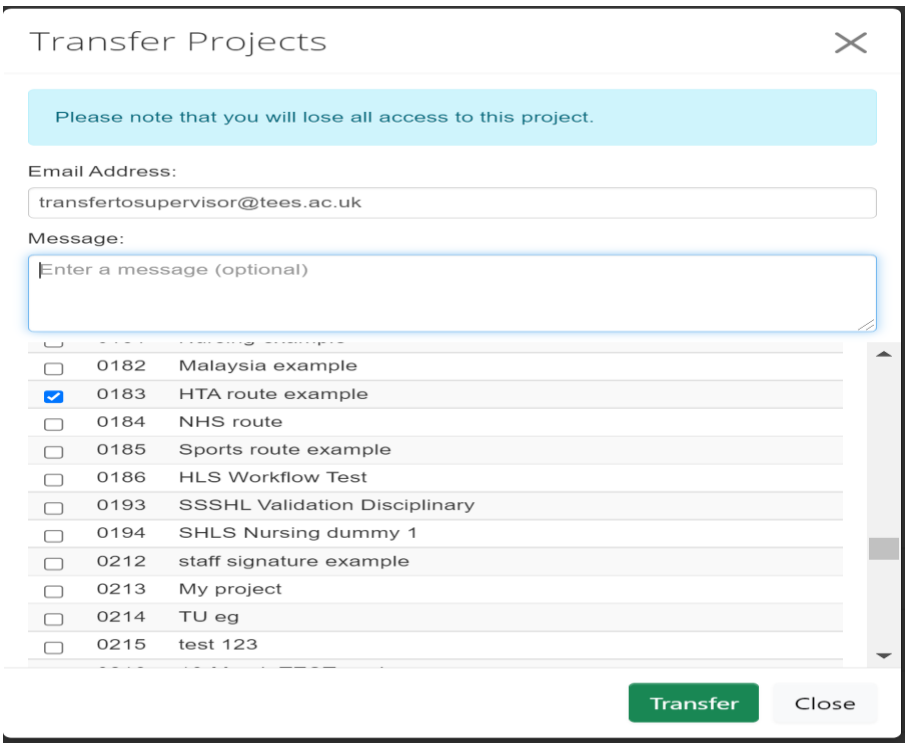
4.3 Transferring a project to another user

Any projects that you have created can be transferred to another ERM user. Transferring projects will give the user to whom the form is transferred complete ownership of the project and remove you entirely as a project owner. If you want to retain input into the project after having transferred the project, you will need to request that the new owner of the project shares the project with you after it has been transferred.

To transfer a project to another use, click the 'Transfer Form' button:



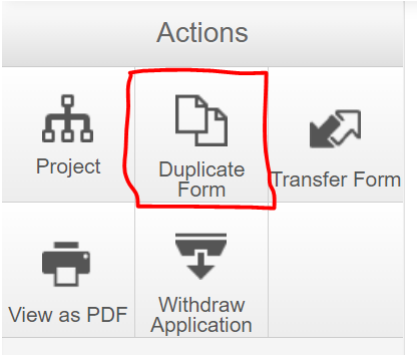
This will bring up a pop-up window with a list of all your current projects. It will only show a single project if you have no more than a single project. To transfer a project, select the project that you want to transfer and click the green 'Transfer' button at the bottom. Any message that you want to send to the new user can be added as an option.



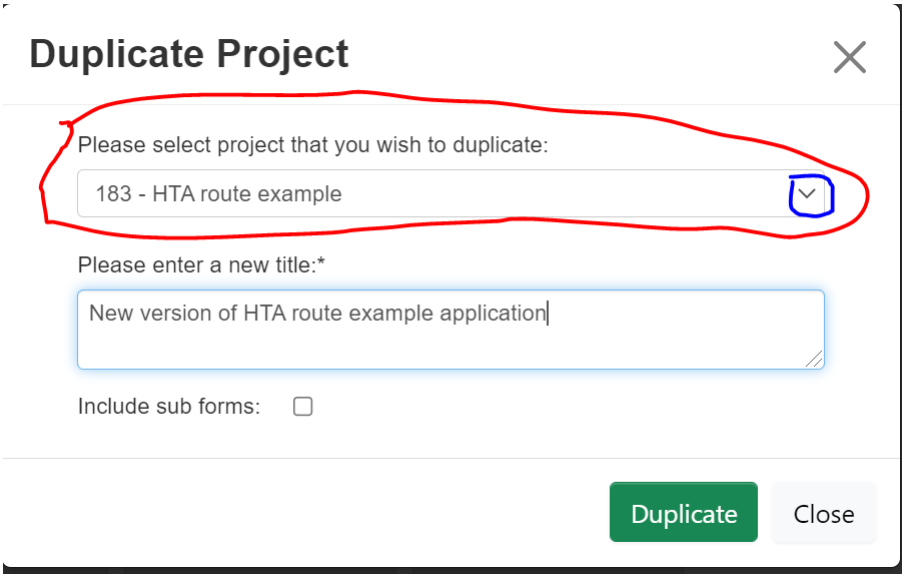
4.4 Duplicating a project

It is possible to duplication any project in your account, which allows you to create a new application on the basis of an existing application. This is useful, for instance, if you need to make a new application to change a substantial part of a project design but retain a lot of what is still relevant from the original application, saving a lot of extra work.

To do this, click the 'Duplicate Form' button on the left-hand sidebar:

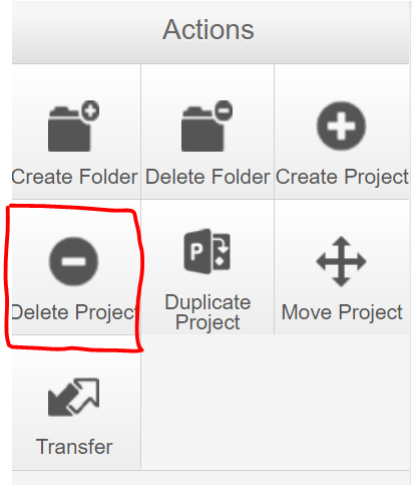


This will bring up a pop-up allowing you to select from a drop-down list of all your projects (blue open arrow to the right). To duplicate the project, you need to choose a new title for the duplicated project and click the green 'Duplicate' button at the bottom:

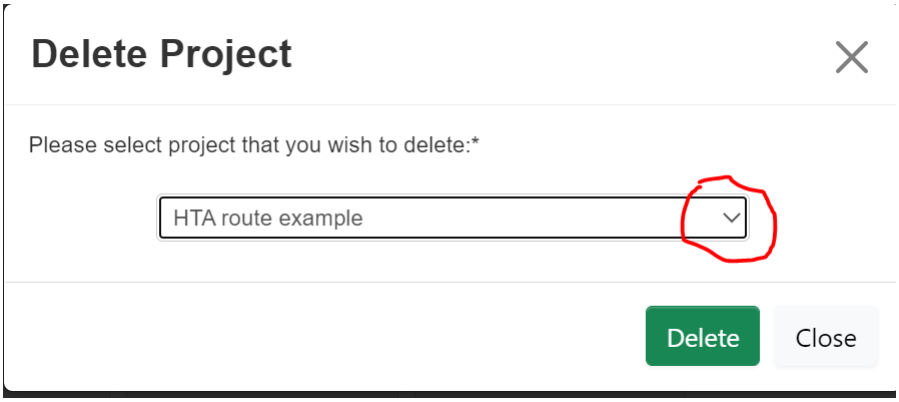


4.5 Deleting a project

Any project can be deleted. From the main ‘Work Area’ page, on the left-hand sidebar, click the ‘Delete Project’ button:



This brings up a pop-up in which you can select the project that you want to delete using the drop-down list (opened using the arrow on the right, circled in red in the image below) and confirm the deletion using the green ‘Delete’ button at the bottom:



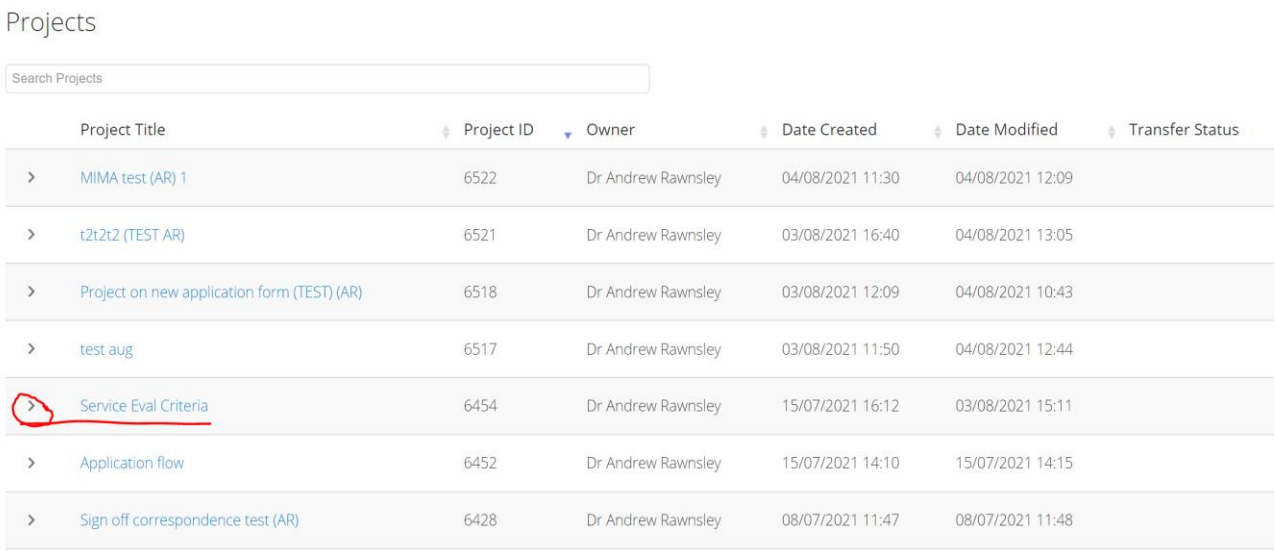
5 ADDITIONAL APPLICATION FORMS (‘Sub Forms’)

5.1 Request to make amendments to a previously approved application

‘Amendments’ are used when you have had an application final decision of ‘Approval’ and you need to make minor changes to the original application research design. For example, if you need to change the population, recruitment, methods or other elements of the study following approval, you need to request amendments to the original application. Note that this is NOT the same as the required changes to an application *prior* to a final decision, covered in Section 3, which are called ‘Conditions’.

To request to make amendments to a previously approved study, there is a separate form available that is linked to your original application. This is called a ‘sub-form’. The title of the form is ‘*Amendments to previously approved application’*. The sub-form is linked directly to the original application and is both created and accessed via the original application. It will also share the Project ID of the original project.

To create an application to request amendments, go into the original application for which amendments are being requested by clicking the arrow to the left of the name of the project on your main project list:

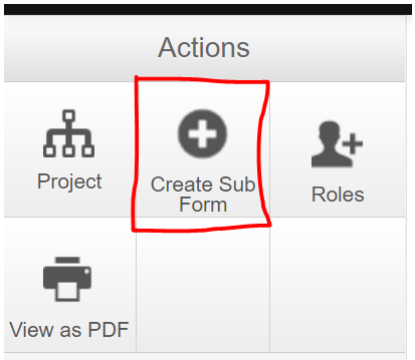


Project Title	Project ID	Owner	Date Created	Date Modified	Transfer Status
MIMA test (AR) 1	6522	Dr Andrew Rawnsley	04/08/2021 11:30	04/08/2021 12:09	
t2t2t2 (TEST AR)	6521	Dr Andrew Rawnsley	03/08/2021 16:40	04/08/2021 13:05	
Project on new application form (TEST) (AR)	6518	Dr Andrew Rawnsley	03/08/2021 12:09	04/08/2021 10:43	
test aug	6517	Dr Andrew Rawnsley	03/08/2021 11:50	04/08/2021 12:44	
Service Eval Criteria	6454	Dr Andrew Rawnsley	15/07/2021 16:12	03/08/2021 15:11	
Application flow	6452	Dr Andrew Rawnsley	15/07/2021 14:10	15/07/2021 14:15	
Sign off correspondence test (AR)	6428	Dr Andrew Rawnsley	08/07/2021 11:47	08/07/2021 11:48	

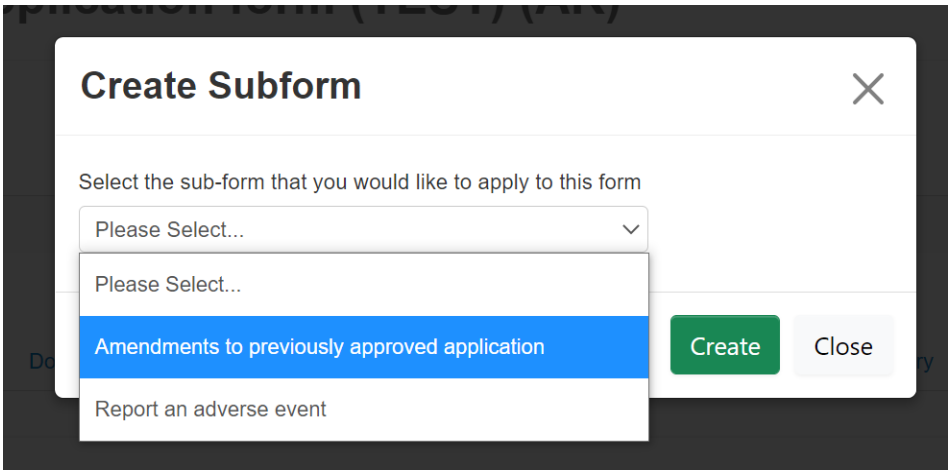
This will open the application forms associated with that project. If you have not yet created any sub-forms, this will only show the original application for that project but once you have created any sub forms, it will show all the forms linked to this project title. In the example below, only the original application is shown prior to the creation of sub-forms:

Click on the title of the original application form to open the original application form. This will then take you into the main application page for this project's original application form.

On the left-hand sidebar, then click the 'Create Sub Form' button. Note that if the project has *not* been previously approved, this button will not appear:

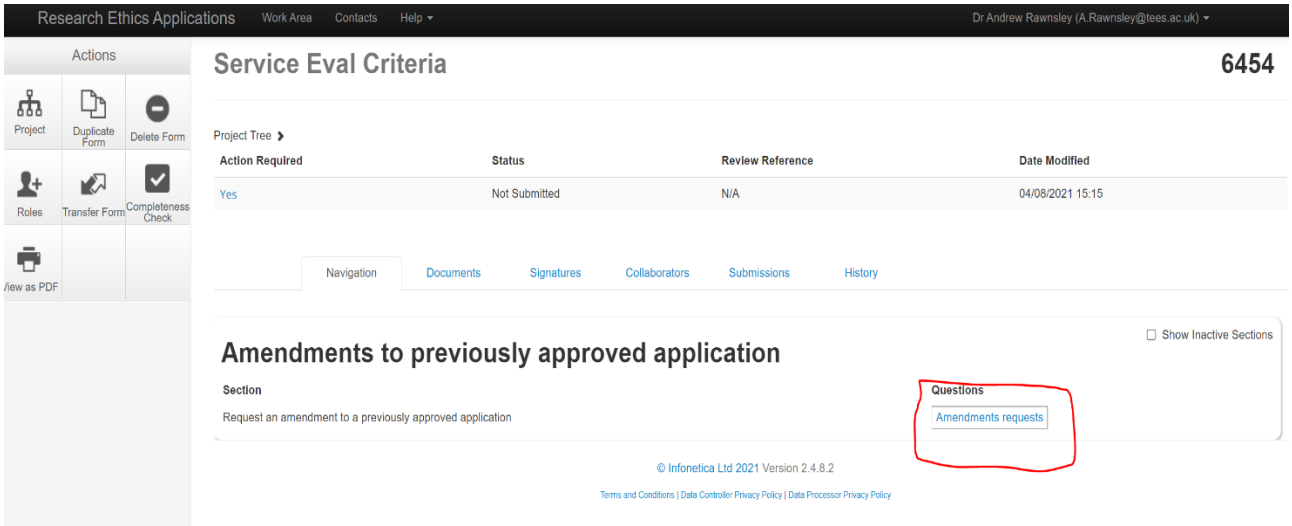


This will bring up a pop-up window with a drop-down list of the available sub-forms:



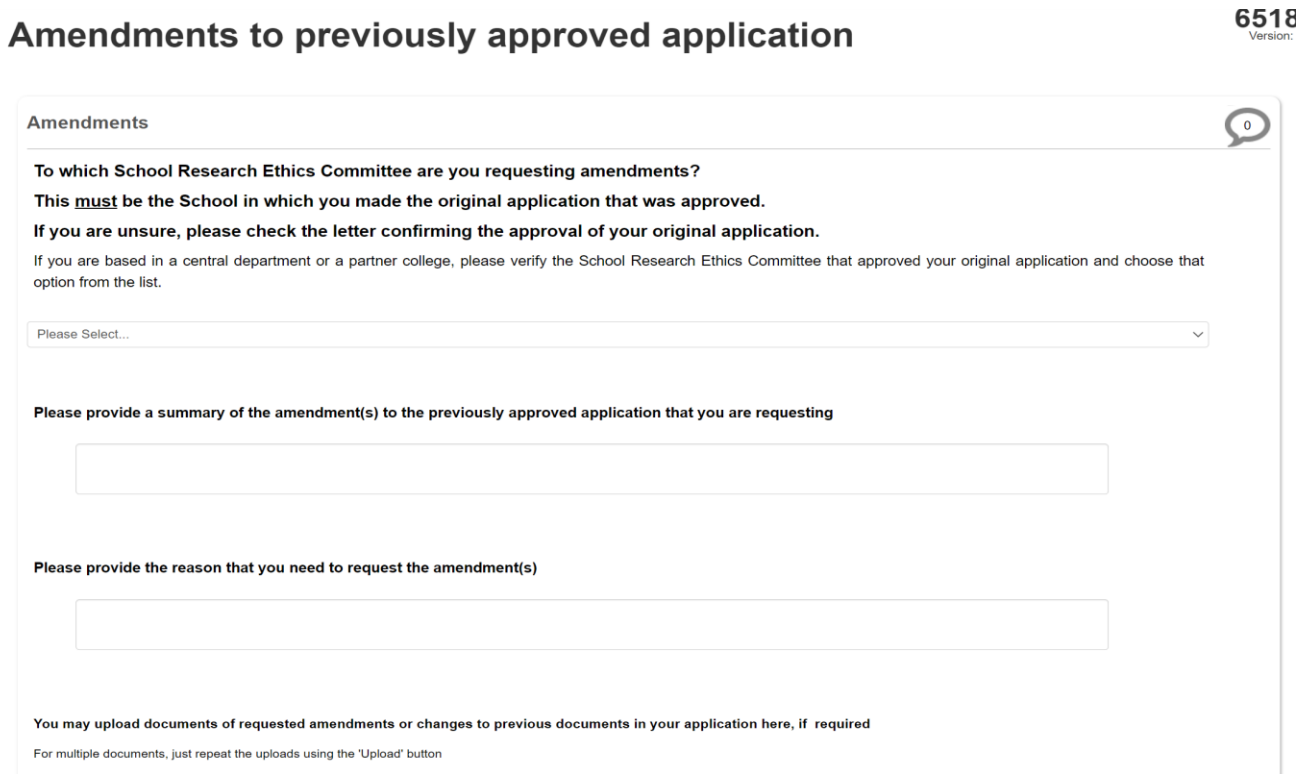
Select 'Amendments to previously approved application' and click the green 'Create' button to create the new form.

The main application page for the new form will appear as the image below. To start completing the application, click on the live blue link on the righthand side of the form:



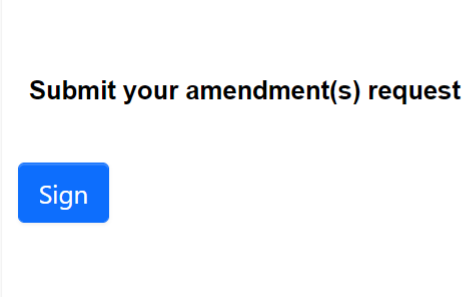
This will then present you with a very simple single page of questions, similar in format to the original application form, for you to complete.

Ensure that you select the same School Committee as approved your original application:



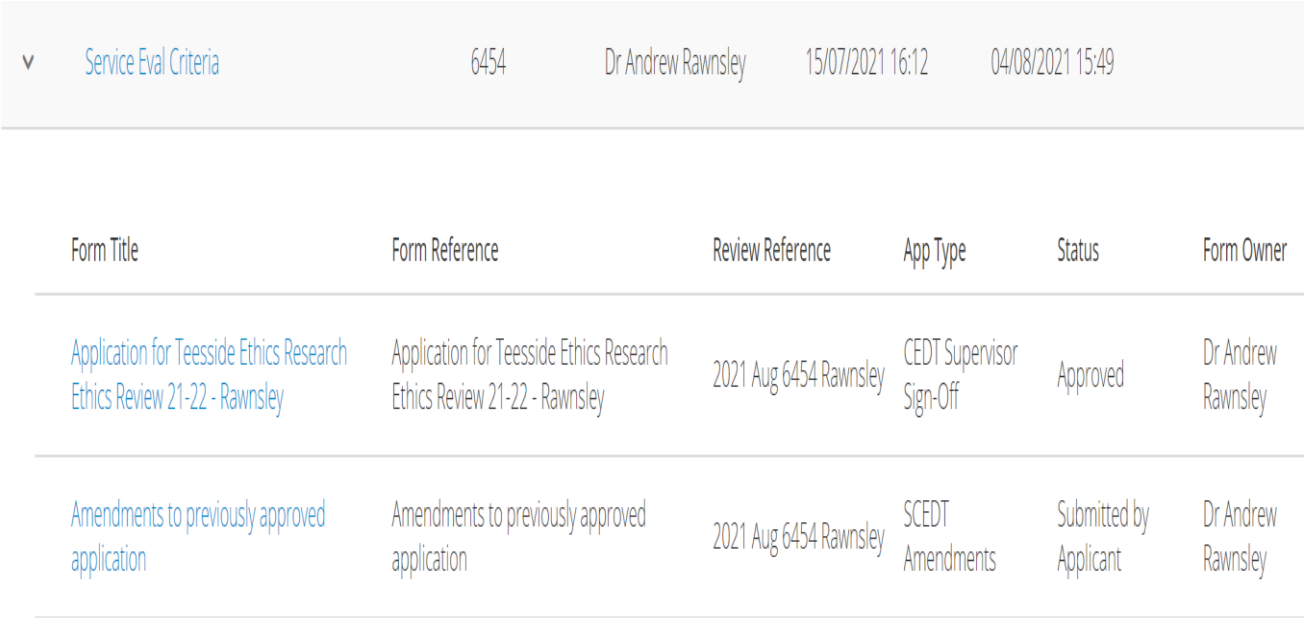
As part of this form, you can provide details of what you want to amend and upload any new documents as needed. Upload of documents is unlimited and you can upload as many as you need by repeated use of the ‘Upload’ button.

When you reach the end of the questions page, just click ‘Sign’ to submit your request:



Your request for amendments will be reviewed and either approved or rejected. You will receive an email confirmation of submission of the request and of the decision. If your request is rejected, you will be given reasons, but usually this will be because your request requires substantial changes to your original application. In this case, you will be asked to submit a new application. You can use the ‘Duplicate’ project function shown at 4.4 to save work in creating the new version of the application for submission.

If you need to access the new request form, you can do so via the project list, which will show your new application form beneath the original application to which it is linked, and will have the same Project ID:



5.2 Report a problem on a project that has been previously approved

If problems arise on a project that you have been conducting that have either ***ethical or legal implications***, such as harm to participants, breach of confidentiality or other serious issues, you need to report this using the 'Adverse Events' form.

To report adverse events on a previously approved study, there is a separate form available that is linked to your original application. This is called a 'sub-form'. The title of the form is '*Report an adverse event'*. The sub-form is linked directly to the original application and is both created and accessed via the original application. It will also share the Project ID of the original project.

To create an adverse report form, go into the original application for which you need to report an adverse event by clicking the arrow to the left of the name of the project on your main project list:

Projects

Search Projects

	Project Title	Project ID	Owner	Date Created	Date Modified	Transfer Status
>	MIMA test (AR) 1	6522	Dr Andrew Rawnsley	04/08/2021 11:30	04/08/2021 12:09	
>	t2t2t2 (TEST AR)	6521	Dr Andrew Rawnsley	03/08/2021 16:40	04/08/2021 13:05	
>	Project on new application form (TEST) (AR)	6518	Dr Andrew Rawnsley	03/08/2021 12:09	04/08/2021 10:43	
>	test aug	6517	Dr Andrew Rawnsley	03/08/2021 11:50	04/08/2021 12:44	
>	Service Eval Criteria	6454	Dr Andrew Rawnsley	15/07/2021 16:12	03/08/2021 15:11	
>	Application flow	6452	Dr Andrew Rawnsley	15/07/2021 14:10	15/07/2021 14:15	
>	Sign off correspondence test (AR)	6428	Dr Andrew Rawnsley	08/07/2021 11:47	08/07/2021 11:48	

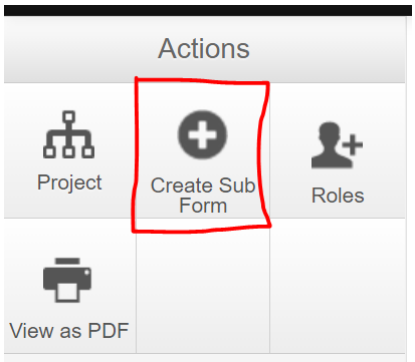
This will open the application forms associated with that project. If you have not yet created any sub-forms, this will only show the original application for that project but once you have created any sub forms, it will show all the forms linked to this project title. In the example below, only the original application is shown prior to the creation of sub-forms:

⌄	Service Eval Criteria	6454

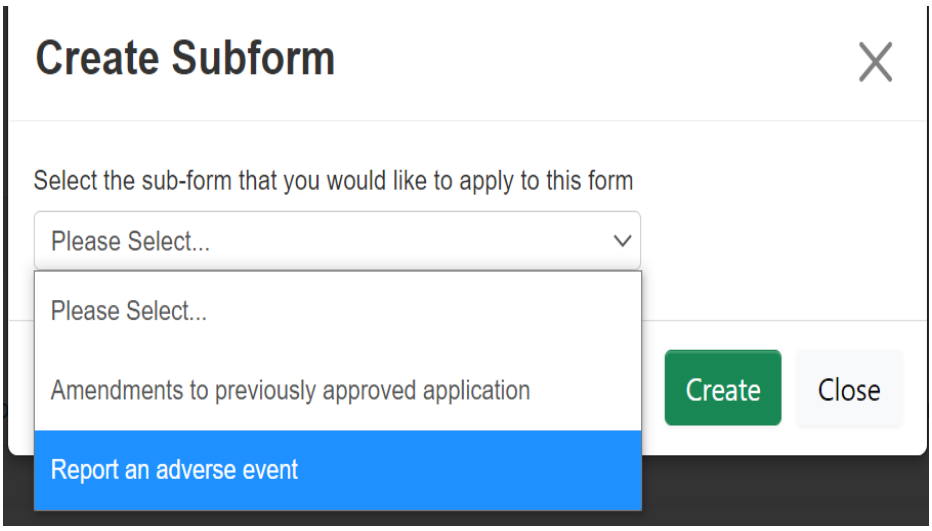
Form Title
Application for Teesside Ethics Research Ethics Review 21-22 -

Click on the title of the original application form to open the original application form. This will then take you into the main application page for this project's original application form.

On the left-hand sidebar, then click the 'Create Sub Form' button. Note that if the project has *not* been previously approved, this button will not appear:

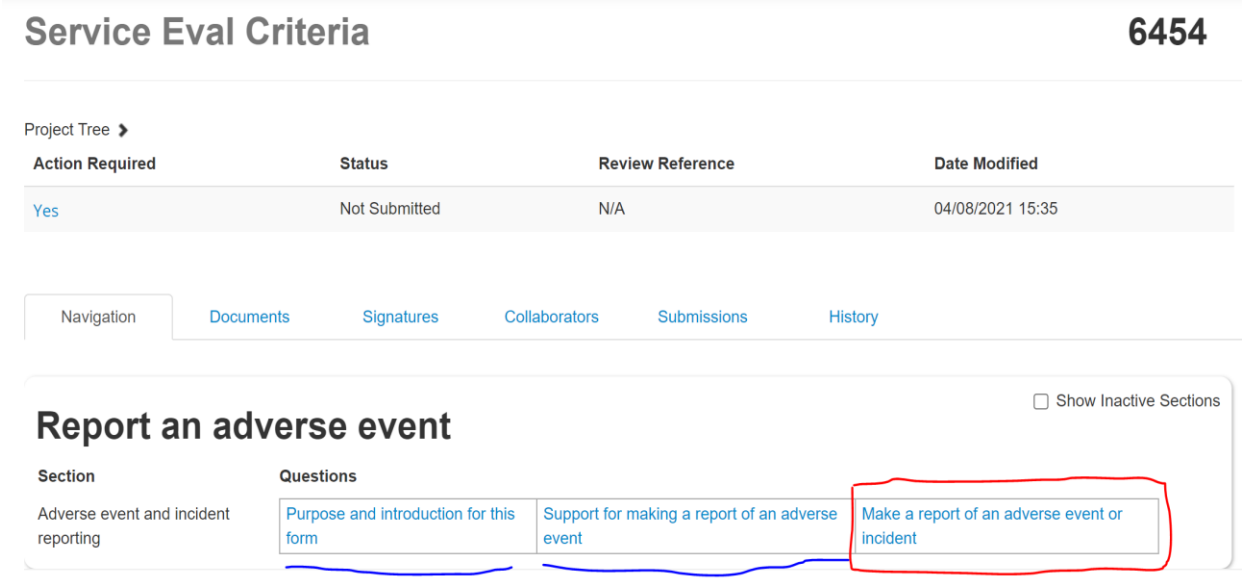


This will bring up a pop-up window with a drop-down list of the available sub-forms:

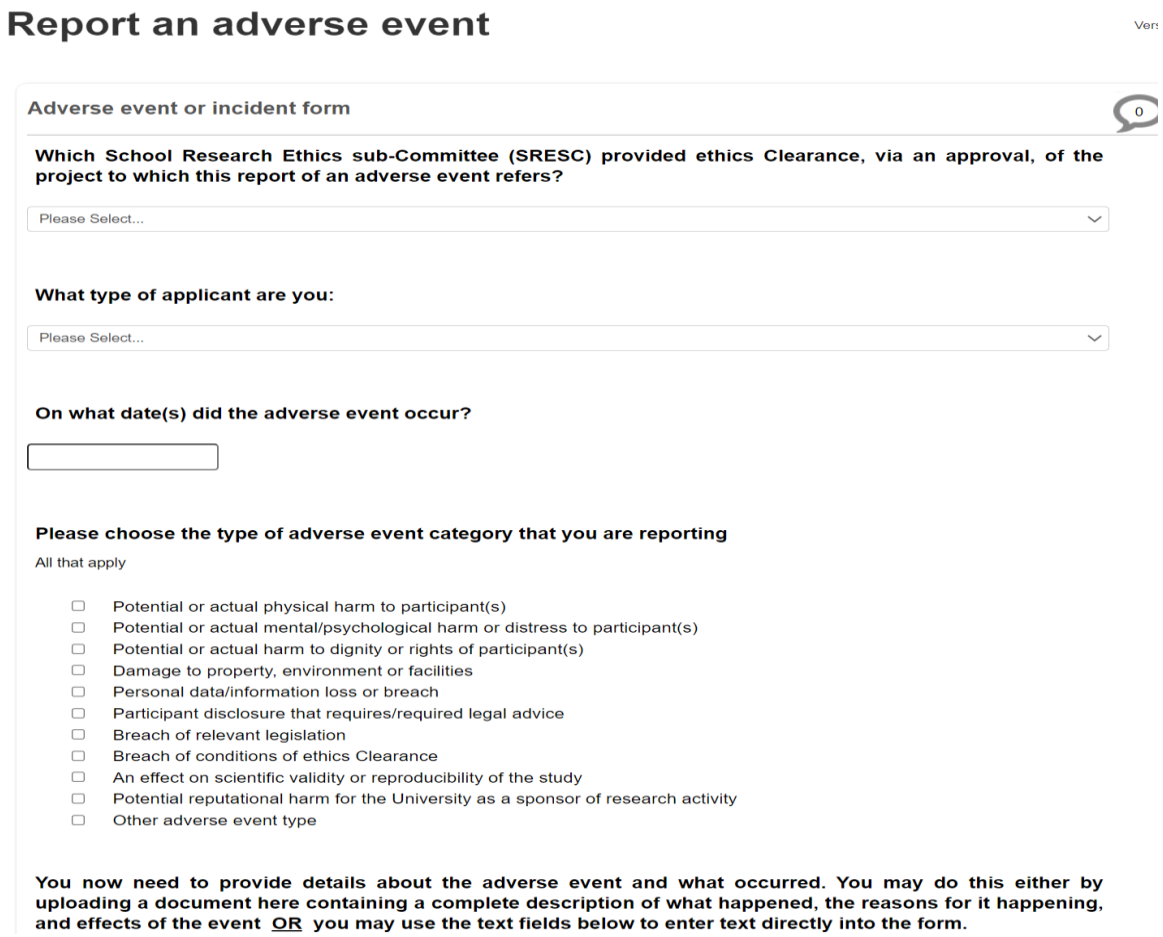


Select 'Report an adverse event' and click the green 'Create' button to create the new form.

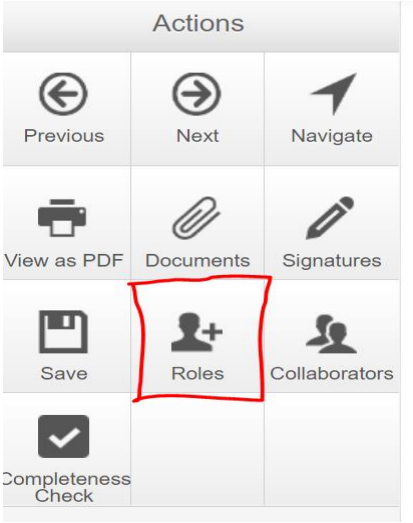
The main application page for the new form will appear as the image below. There are three blue live links on the first line of the application. The first and second links provide you with information and support about making an adverse event report, shown with blue underline in the image below. To start completing the report, click on the third link on the right, shown with red circle:



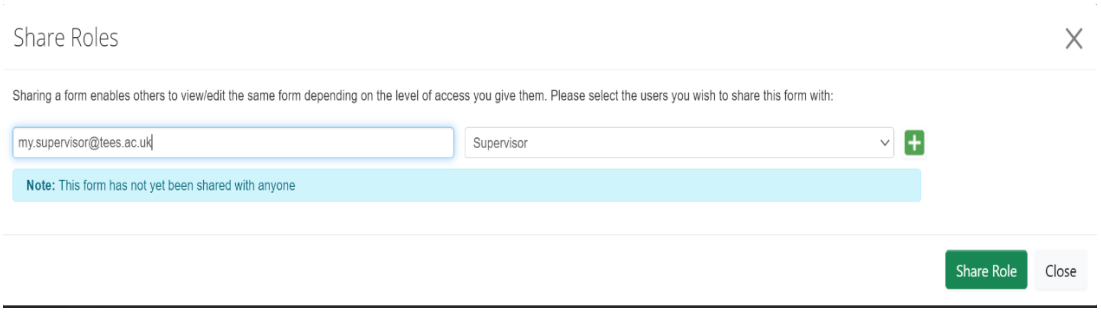
This will then present you with a very simple single page of questions, similar in format to the original application form, for you to complete.Ensure that you select the same School Committee as approved your original application:



It is important that your supervisor is involved with making an adverse report. The first thing that you need to do is to ensure that your new form is shared with your supervisor. Click the ‘Share Roles’ button on the left-hand side-bar:

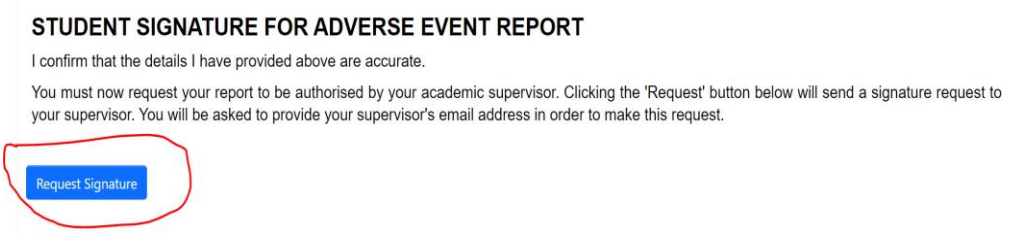


Then enter your supervisor’s email address into the pop-up and click the green ‘Share Role’ button:



As part of this form, you can provide details of what occurred and upload any documents as needed. Upload of documents is unlimited and you can upload as many as you need by repeated use of the ‘Upload’ button.

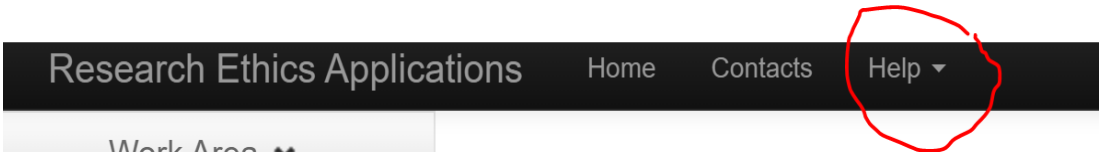
When you reach the end of the questions page, you will need to then request an authorising signature from your supervisor:



6 OBTAINING HELP AND SUPPORT

Help is available at all times from within your account.

In the top bar of your account, there is a ‘Help’ drop down menu:



This drop-down contains:

Contact Information:	ERMHelp@tees.ac.uk
Help page:	With basic navigation information
FAQs:	Organised by topics, which include: All of this applicant guidance Some guides to question types Detailed training material on research ethics
Templates:	Templates for uploaded documents
About:	Details about the ERM