Worktribe Ethics

Applicant user guide



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Introduction

The University of Oxford requires ethics approval for all research involving human participants, human tissue and/or personal data. This user guide is intended for researchers who are preparing an ethics application within Worktribe Ethics for review by one of the CUREC subcommittees. Its focus is on how to use the Worktribe Ethics system to prepare and submit an ethics application.

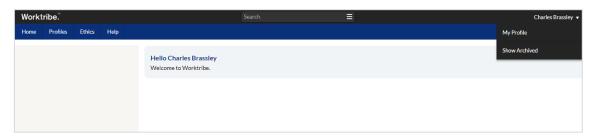
Further guidance:

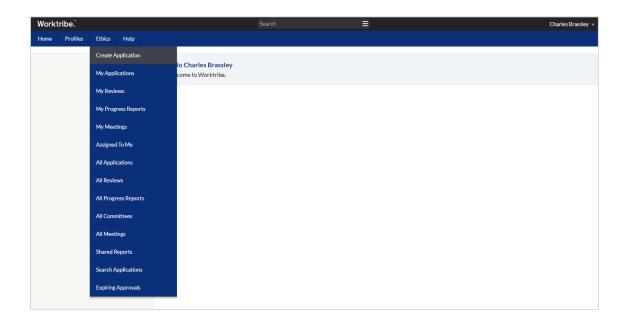
- Research Ethics Policy
- Where and how to apply for ethics review
- Research integrity and ethics training courses
- Obtaining participants' informed consent guidance and templates
- CUREC's Best Practice Guidance
- CUREC's Approved Procedures

Getting started

Worktribe Ethics can be accessed via https://ox.worktribe.com. Use your Oxford Single Sign On (SSO) to log into the system.

The dark grey and blue bars along the top of the screen contain drop-down menus:





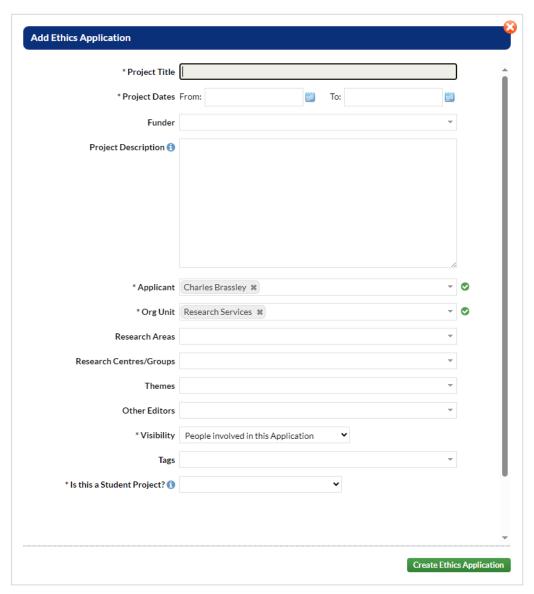
As yes/no and other questions with options are answered, the response you select will be highlighted green:



To create a new ethics application

Ethics menu > Create Application

The following dialog box appears:



Project title: Enter the title of your research project

Project dates: Enter the start and end dates of the overall project (rather than just the dates for the element of the project for which you are applying for ethics approval).

Funder: Please enter the name of the funder. If funding is not from an external source, select 'departmental funding' where the specific internal source is not listed. If a funder is not listed, please email worktribe-ethics@it.ox.ac.uk to ask for that funder to be added to the system.

Project description: Enter a short lay summary of the project, including research aim, background, justification/value of research and a brief outline of the research (Max 500 words). Note that details of methodology are requested elsewhere. **Whilst Worktribe does not mandate this as a required field,** <u>it must be completed</u> for CUREC ethics review.

Applicant: If you are not the main applicant, you can choose to replace your name with the name of the main applicant. NB: The applicant does not have to be the Principal Investigator. For all student applications, the student is expected to be the applicant.

An application for a group of projects conducted for a taught student programme or module (formerly the CUREC 1C application) need to be made by the module leader/ course director.

Org Unit: Enter the name of the applicant's department. If more than one department is involved, select the department where the Principal Investigator is based.

Leave the following fields blank: Research Areas, Research Centres/Groups, Themes, Tags.

Other Editors: Enter the names of anyone else involved in completing the ethics application form to give them access to the form. This grants the person added access to the application, allows them to edit text fields, and make comments. If the applicant is a student, then their supervisor needs to be added here. If the applicant is not the PI, then the PI should be included here. This field can also be used to add internal department reviewers who need to review (and edit) prior to submission to the ethics committee. Do not add the Ethics Committee Secretariat – they automatically gain access.

Visibility: If you would like to give anyone else access to view the application, select **People involved in this Application and...** and enter their names in the **View Access** field below. This grants that person access to the application and allows them to make comments, but they will not be able to edit any text fields. Your ethics committee will automatically gain access to your application when it is submitted.

Is this a Student Project? Select the answer from the drop-down menu.

Enter the name of the supervisor and module code (if applicable), if prompted. Note that when the student submits the application, it is routed to the supervisor to endorse. Hence, the supervisor cannot be the applicant.

Assigning an additional reviewer: If it is necessary to assign an additional reviewer, use the **Other Editors** field to do so, e.g., if an internal departmental reviewer needs to review (and edit) the application prior to submission.

NB: Please double-check your answers before clicking on **Create Ethics Application**, as once the application has been created it may not be possible for you to edit these fields.

Click on **Create Ethics Application**.

This creates the ethics application. Tabs for the different sections will appear. The number in red indicates the number of questions to be answered in each section:



Answers to questions in the scope tab will generate other tabs and questions relevant for the project.

Completing the ethics application

Starting with the **Scope** section, answer the questions in each section, referring to the information button for further guidance if needed. Note that the Scope questions take a little time to populate based on previous responses, so do wait for the next question before moving to another tab.



NB. Questions in the system are not numbered due to the dynamic nature of the form.

The red square Indicates that there are answers required in a section.

The speech bubble symbol next to each question enables you to tag someone else involved in the project, for example if you wanted to ask another member of the research team a question about an answer to a particular question. Note that all comments made on an application (at all stages) will be retained in the system in perpetuity as part of an audit trail, and can be viewed in the comments tab. Please ensure all comments are kept professional and relevant.

On completing the Scope section, complete the questions in the tabs that have been generated on the basis of the scope answers.

Please remember to include a project description in the **Details** tab if you did not enter one when first creating the application. This should cover:

- Aim/purpose What question(s) are you trying to answer, and why?
- Brief justification for/value of the research
- Brief outline of what your research will involve in order to answer the research question

Note that details of methodology are requested elsewhere in the application.

Uploading supporting documents

It is necessary to submit relevant supporting documents with your application, for example:

- recruitment invitation letters, emails and adverts
- information sheet(s)
- the consent form or script you will be using
- surveys, questionnaires and interview questions
- a copy of the approved risk assessment, if relevant
- debrief, if applicable

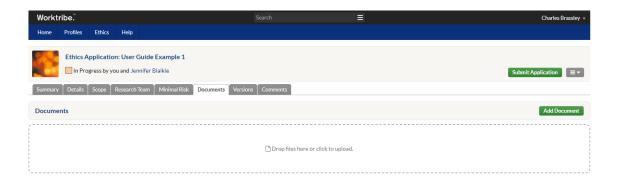
The Research Support website contains <u>guidance on obtaining participants' informed consent</u> and includes templates that you are welcome to use, but remember to adapt them to your project and to your participants.

Please name these documents with short, clear titles, such as 'poster', 'recruitment email', 'PIS', 'Consent' etc., so it is obvious what they are once uploaded. Please also add a version number to each document filename. 0.1, 0.2 etc., should be used for revisions up until the point of approval, then the approved documents should be v1.0.

Documents should be uploaded as Microsoft Word documents, where possible, to facilitate review.

Documents can be uploaded either by dragging and dropping files into the designated area or by clicking on the **Add Document** button. It is recommended that you use the **Add Document** button so that you can give each a title and assign document type.

If the research involves MRI scans or brain stimulation, note that you do not need to upload safety screening forms for these, unless modified from approved versions.



Assignment of risk levels

The system automatically assigns risk, based on responses to questions throughout the application:

	MS IDREC	OxTREC	SSH IDREC and DRECs
Low	N/A	N/A	Application is reviewed by the supervisor (if a student project), or by an academic colleague (if a staff project).
Medium	Review is conducted by the MS IDREC Secretariat on behalf of the Committee.	Review is conducted by the OxTREC Secretariat on behalf of the Committee.	The application is reviewed by the DREC, if there is one. If the Department or Division does not have a DREC the application is reviewed by the SSH IDREC Secretariat on behalf of the Committee.
High	Review is conducted by the committee.	Review is conducted by the committee.	Preliminary review by the DREC, if there is one PLUS Final review by the SSH IDREC.

Upon receipt by the committee, risk levels will be checked and may be adjusted.

Low-risk Social Sciences and Humanities applications

On the Scope tab you will be asked whether the research involves any of the following:

- a) Deception of participants
- b) Participants considered vulnerable in the context of the research
- c) Risk of criminal prosecution or significant harm to participants
- d) Issues relevant to the Counter-Terrorism and Security Act
- e) Topics that could be considered sensitive
- f) Risks to the safety and wellbeing of researchers or others involved in the research
- g) Participants taking part in the research without their knowledge and informed consent (e.g. covert observation)
- h) International or collaborative research where there may be issues of local practice and/or political sensitivities
- i) Potential conflicts of interest
- j) Permission from a gatekeeper required for access to the participants
- k) Researchers in a position of authority over participants
- I) Third parties collecting data
- m) Potential for incidental findings, e.g. concerns for the safety or wellbeing of participants

Carefully consider each of these before answering the question. If you are a student, do discuss these with your supervisor if you are unsure. You are also welcome to contact your ethics committee for advice.

If you answer **No** to these questions, the **Minimal Risk** tab becomes available.

Answer all the questions on this tab. If you indicate that the project will involve secondary data, a further three questions about this will appear.

Use the **Documents** tab to upload your supporting documents (such as the recruitment email, information sheet and consent form).

For low-risk applications made by a student, the supervisor will conduct the ethics review.

For low-risk applications submitted by a member of staff, the applicant needs to suggest an academic peer who would be willing to conduct the ethics review. It is courteous to check with them first, and once they have agreed to conduct the review, make a note of the name of the reviewer in the last question of the **Minimal Risk** tab so that the ethics administrator knows who is to conduct the review. The ethics administrator will request the review within the system from the assigned member of staff once they receive your application - you do not need to do this.

Once the application is submitted, an ethics administrator will check that your application meets the criteria for low risk review. The ethics review will then take place.

Taught student modules (within Social Sciences and Humanities only)

Programme or Module Leaders may apply for approval from their DREC or the SSH IDREC for a devolved process for the ethics review of individual student projects. Previously, the CUREC 1C application was used for these types of applications. Students conduct similar, small-scale projects with minimal ethical issues as part of the requirements for a taught student module.

The Worktribe ethics application must be made by the Programme Leader or Course Convenor. Further information about this type of application is available from the SSH IDREC application process webpage.

On the Create Ethics Application screen, answer **No** to the question "Is this a Student Project?"

Answer all the questions on the **Scope** tab.

On the **Scope** tab, answer **Yes** to the question "Are you a Module Leader/ Convenor seeking block ethics approval for a specific taught student module that does not involve any of the following?"

Answer all the questions in the **Taught Module** tab.

Applications can be made to cover a maximum of three years.

Use the **Documents** tab to upload examples of the information sheets and consent forms the students will use. You may like to tailor the University's template information sheets and consent forms to the Programme or Module.

Internal Department Review

If your department/project requires an internal review/check prior to submission to the ethics committee, then you should:

Enter the name of the person(s) who should review/check the study into the 'other editors' field (if you did not already do this when creating the application).

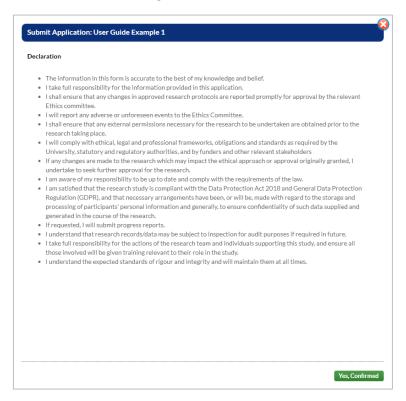
Go to the comments tab and tag that person (using @) in a comment, requesting their review. They will then receive an email notification informing them. The reviewer should tag you in another comment when the review is complete so that you receive email notification to address anything raised through internal review. This will also indicate to the ethics committee that internal review was conducted.

Submitting the ethics application

When you are ready to submit your ethics application, click the blue **Submit Application** button:

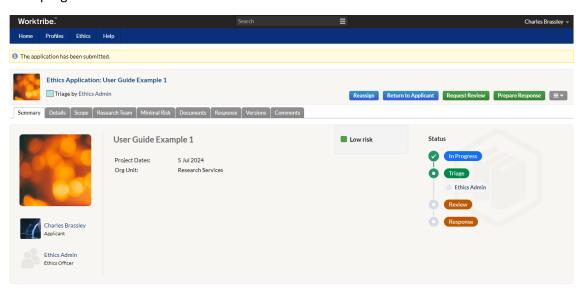


You will then be asked to confirm the following:



A message will appear in yellow across the top of the screen confirming that the application has been submitted. If you are a student, the application will be routed to your supervisor for review and then they will submit the application to the ethics committee. All other applications will be routed straight to committee. If the applicant is not the PI, then please ask the PI to access the application and write in the **comments** tab that they have reviewed and support the application.

The summary tab will show the status of the ethics application. This information is updated as the application progresses.



You will receive a notification that the application has been submitted.

Comments

The Comment Box allows you to comment on any part of the application. To write a comment, click on the speech bubble next to that section to open a comment box, type your comment and press **Enter**.

Note that all comments and discussions between the applicant and their research group are fully visible to ethics administrators throughout the application process and after submission, regardless of resolution status.

The **Comment Thread** is a date and time ordered list of events and comments on a record. It is visible on the **Comments** tab within the full view of the record. This serves as an audit trail of the application and this function cannot be amended/disabled.

Editing and deleting

Answers to questions within ethics applications can be edited or deleted. Click on the edit button open the record for editing. If the pencil is greyed out the record is not available for editing. You may first need to open a record in order to edit it.

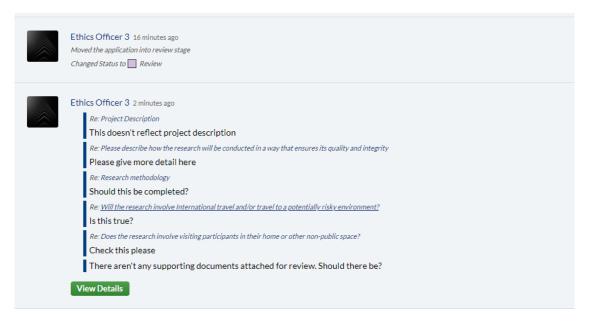
When you see the delete icon (white cross in a red circle) you can select it to delete the record.

Note that you will not be able to edit the application whilst it is with reviewers.

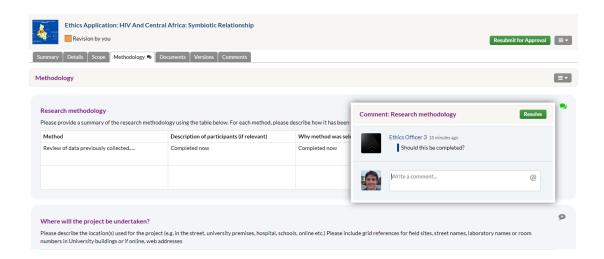
Addressing reviewers' comments

If the reviewer / ethics committee asks questions or for changes to be made, you will receive a notification by email that the application has been returned to you. Please wait to receive this email before you try to address comments. It is possible that multiple people may look at your application at different times and make comments, so waiting for the email ensures that review is complete.

The comments tab shows a summary of the reviewers' comments:



<u>Comments made on the application</u> can be seen next to questions on each individual tab. You should respond to each point by making changes on the application itself. Do not delete or resolve the comments – leave them visible and open for the reviewers to refer to when the application is resubmitted.



<u>Supporting documents</u> should be downloaded and amended with track changes turned on. When addressing comments that have been added to supporting documents, do not delete comments, or mark as resolved, leave that for the reviewers to do once they have reviewed your response and changes. The new version should be labelled with the next incremental version number (0.2, 0.3 etc.) and then uploaded using the **add** button.

Once all comments on the application have been addressed, and revised supporting documents uploaded, return the application by selecting **Resubmit for Approval** at top right.

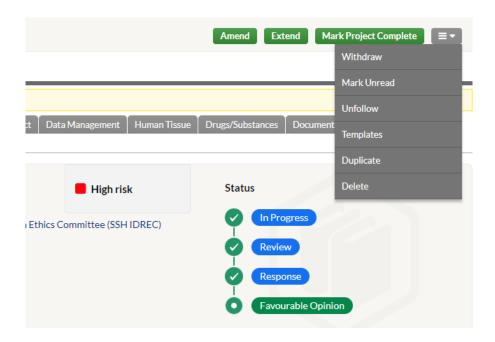
Further revision

It is possible that you may be requested to further revise the application and/or supporting documents. If this is the case, proceed as above.

Application and decision letter download

A word copy of the completed application can be downloaded for use outside of Worktribe.

At the top right, hover over the 3 lines in the grey box, and select **Templates**.



A new window will open, from which you can download the application. Please note that any documents labelled 'Office use only' are not for applicant use.

Once the application has received favourable opinion, the letter confirming this can also be downloaded from the same location as a copy of the application. If you attempt to download the letter before favourable opinion is granted, there will be information missing that indicates approval has not been granted.

A record of your Worktribe ethics applications

You can view a list of your current and previously submitted ethics application by selecting one of the following menu options:

- My Applications
- Assigned to me
- All Applications

To view the details of a particular Ethics Application, select its title.

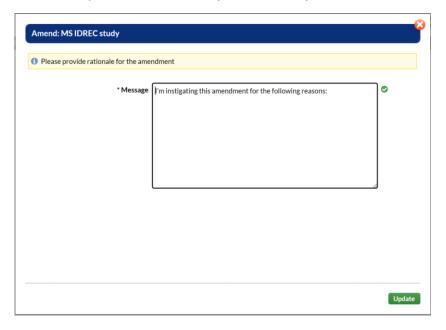
Amending a previously approved ethics application

During the transition to Worktribe, requests for amendments to previously approved projects should be submitted using the same system or process as the original application. If the original application had used a Microsoft Word form, the request for an amendment should be submitted using the Microsoft Word amendment form. If the original application was submitted via Worktribe, the request for an amendment should also be submitted via Worktribe.

The workflow action to amend an Ethics Applications is available from the Action menu within that application. Select **Extend** if the only change is to request extension of the duration of approval, otherwise select **Amend**.



Once you have selected 'amend', a new dialog box asks for rationale for the amendment. **Please list each change being made here, with justification as to why it is necessary**.



Navigate to the tabs of the application where you need to make changes and edit the form. Upload any revised supporting documents. The Comments tab should be used to add any further comments or explanation of the changes.

Once the application has been amended select Submit for Approval.

• You will be presented with the same declaration as for original submission. Select **Yes, Confirmed** once you have read and agreed to the declaration.

Confirmation of the action is displayed, and you will receive a notification that it has progressed to the next stage.

Further guidance

Further information about Worktribe is available at https://itservicesprojects.web.ox.ac.uk/worktribe-research-ethics-system.

Email worktribe-ethics@it.ox.ac.uk with any questions about the use of the Worktribe system.