Requesting a letter of ethical exemption

1 The ethics decision tool 1

2 Accessing the ERM system 1

3 Creating a request for a letter of ethical exemption 1

4 Navigation page 2

5 Project Type 2

6 Applicant details 3

7 Project Details 4

8 Supporting documents 4

9 Declarations and signature 5

1 The ethics decision tool

Before starting your exemption request form*, you must have used the Ethics Decision Tool to verify that your study does not require ethical review at the University of Manchester. Please ensure that you save a screenshot of the tool outcome screen as you will be required to attach this to your request in ERM.

**If you are submitting an exemption letter request for a collaboration with full NHS REC approval, you do not need to use the decision tool.*

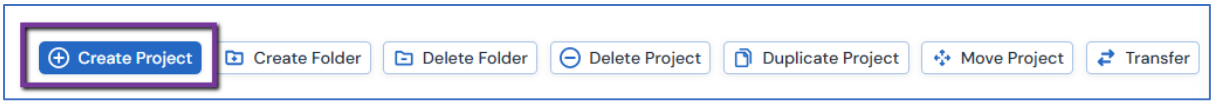
2 Accessing the ERM system

To create a new request for an exemption letter you will need access the ERM system, by following the URL below and logging in with your University of Manchester username and password (the same information you use to access your email):

https://submission-ethicalreview.manchester.ac.uk

3 Creating a request for a letter of ethical exemption

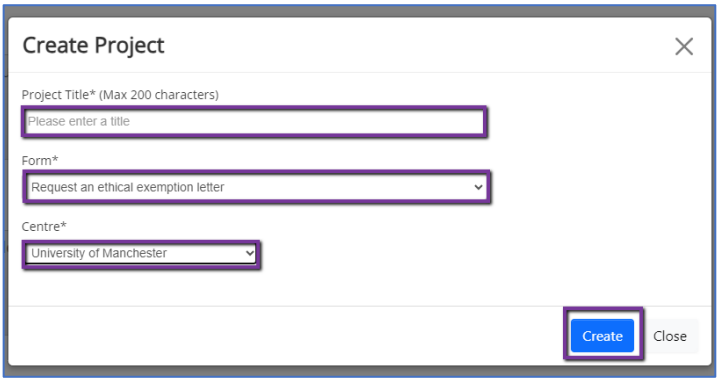
To create a new request, log in to ERM and click on Create Project from the action buttons in the middle of your screen.



Insert your project's title (200 characters maximum). The title you enter here will be used in your exemption letter.

Choose *Request an ethical exemption letter* from the form dropdown menu.

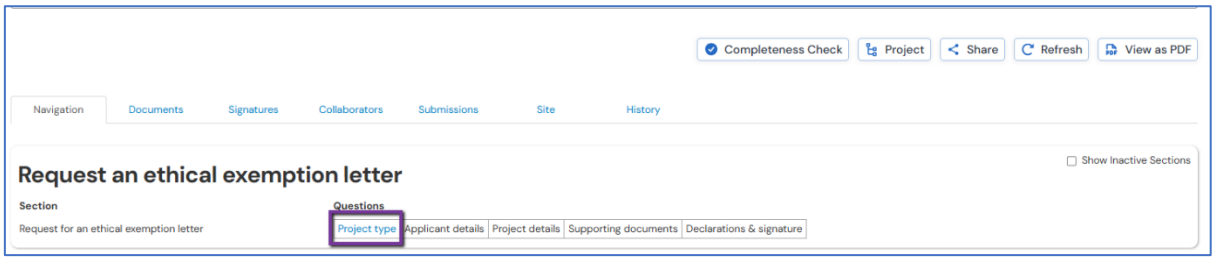
Choose *University of Manchester* from the centre dropdown if this is not already selected and click Create.



4 Navigation page

The navigation page displays the pages of the application form. All the pages that are available to you will be displayed in blue text while those in black text are not currently available. These sections will turn blue as you answer questions in the form.

To begin completing the form, click on the Project Type section.



5 Project Type

You will be asked to provide some basic details about your study in this section.

Question 1 asks you to confirm the type of study.

UoM led studies

If your project is a study led by UoM, select this option.

You will then be asked to confirm the type of project (e.g. evaluation, market research, work with professionals).

Collaborations led by another institution

Please ensure you have read the collaborations guidance before proceeding.

You should select this answer if the project is a collaboration with another institution, which is led by that institution (i.e. the PI is based there and, if applicable, they hold the funding). If UoM is the lead on a collaborative project, please select 'this is a new study'.

You will then be asked if the study is led by either a UK-based university or by an international one.

If the study is led by a UK institution, you will be able to continue with the form.

If the study is led by an international institution, you will only be able to request an exemption letter if the study is exempt from ethical approval in accordance with UoM policy. If the ethics decision tool indicates the study requires ethical review, you must submit for UoM ethical approval as we are unable to accept the ethical approval of institutions outside of the UK in lieu of our own.

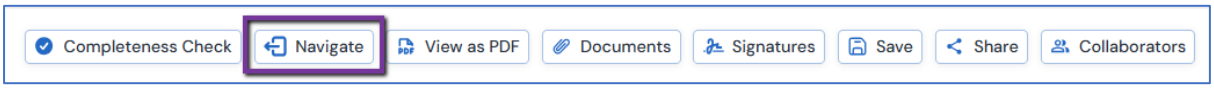
Collaborations led by another institution that has obtained full NHS REC approval

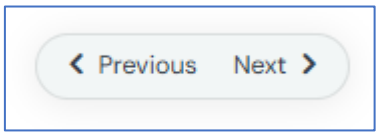
Select this only if the study has obtained full NHS REC approval. You will be asked to provide both the NHS REC and IRAS reference numbers. Please note the approved REC application must have included detail of UoM's role in the project.

This is a transfer of an approved study from another UK institution

Studies of this type may be exempt from obtaining UoM UREC approval if they have already begun prior to you joining UoM, however you cannot request an exemption letter in the ERM system. Please refer to the digital handbook (section 11.4 Changes to sponsorship) for guidance on all types of transfer studies.

Use the previous / next buttons at the bottom of the page to move on to the next section. You can also use the Navigate button at the top of the page to return to the project tree page at any point.





6 Applicant details

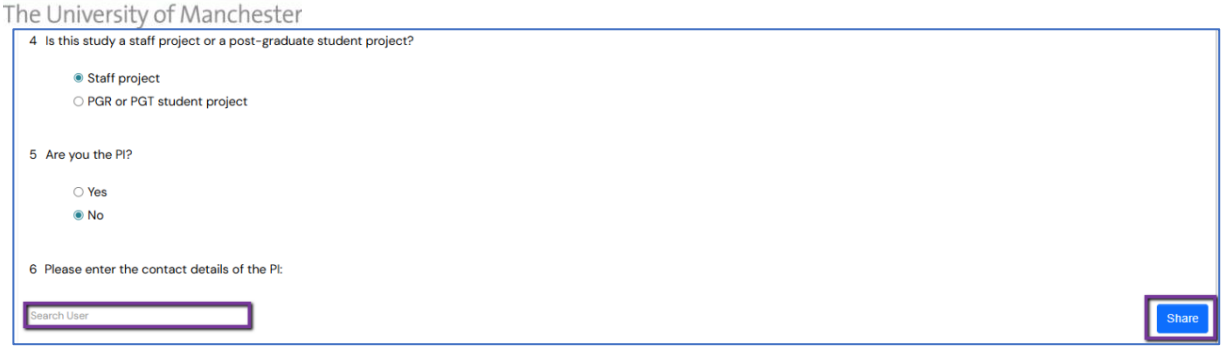
You will be asked to provide your contact details, whether this is a staff or PGT/PGR project and your role in the project. Please note that this form cannot be used for undergraduate projects.

If this is a staff project and you are not the PI you will be asked to provide their details.

If this is a student project and you are the student investigator you will be asked to provide your primary supervisor's details.

If this is a PGT/PGR student project and you are the supervisor, you will be asked to provide your student's details.

To add the PI or your student/supervisor to the form, use the **search user** function to find them in the system. If the individual is not listed this means they do not yet have an ERM account. Please ask them to log in to ERM using their UoM username and password and you will then be able to find them using the search function.



To share the form with your co-applicant, click the **Share** button and select the relevant permissions in the pop-up box.

If the study is a collaboration with NHS REC approval, you will be asked to provide the full title, name and institution of the Chief Investigator. Please note external colleagues will not be named in the final letter or copied in to any emails from the ERM system.

7 Project Details

If your project is led by UoM you will also be asked to provide the following, depending on the type of project:

- Audit/evaluation/market research/work with professionals: details on how your participants will be recruited, what they will be asked to do and what your intended outputs are.
- For secondary data studies you will be asked to provide details of the datasets you propose to use and what permissions you will obtain.
- For human tissue studies you will be asked to provide details of where samples will be sourced from.

Please note that work classed as PPIE / community engagement is not considered research activity and you cannot request an exemption letter via this process or via the Research Ethics Team.

If the project is led by an international institution and is considered exempt under UoM policy, you will be asked to provide some information on UoM's role in the project, how data will be shared and what outputs are planned.

Projects led by another UK institution or with NHS REC approval do not need to provide project details.

You may also be asked to provide additional information relating to the timing of the letter request. Please ensure that you provide a detailed explanation in response.

8 Supporting documents

You will need to upload a number of supporting documents, depending on the nature of your project.

UoM led projects:

- A copy of the ethics decision tool outcome screen and one of the following:
    - Audit/evaluation/market research/work with professionals: a copy of all data collection tools.
    - Human tissue studies: evidence of appropriate consent (original PIS/consent or letter of assurance from the provider), original ethical approval letter if applicable. Please note all projects using or storing human tissue on UoM premises must be registered.
    - Secondary data studies: evidence of data controller permission for you to use the data, evidence the proposed use falls within the original consent arrangements of the data subjects.

Studies led by another UK HEI:

- A copy of the collaborator's ethical approval AND a copy of the approved ethics application form
  OR
- Written confirmation from the lead collaborator's institution that the study is deemed to be ethically exempt under their policy

Studies led by an international HEI that are exempt under UoM policy:

- A copy of the UoM ethics decision tool outcome screen showing the study is exempt
- A copy of all data collection tools (eg. interview topic guide, focus group guide, survey questions)

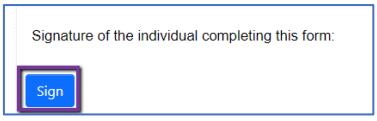
Collaborations with NHS REC approval:

- A copy of the REC/HRA approval letters
- A copy of the IRAS form and all supporting documents (excluding CV's).

9 Declarations and signature

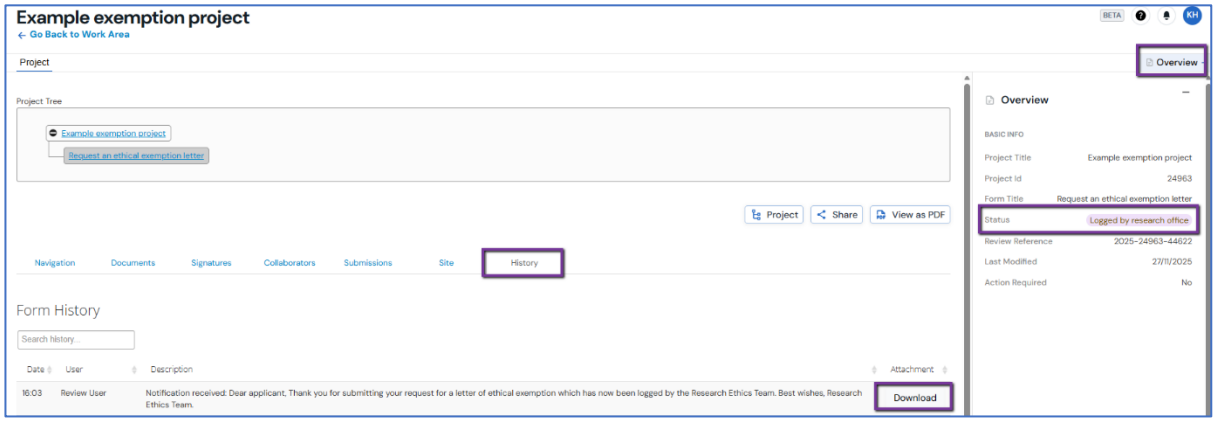
Please read through the declarations and tick each box to confirm your understanding and agreement.

Once you have completed the declarations, please click the Sign button to submit. Please note that only the individual completing the form need to sign.



The Research Ethics Team aim to process exemption requests submitted in the ERM system within 5 working days where possible and you can check the status of your request at any time by logging in to ERM and opening your application, where the project's status will be displayed in the Overview pane on the right-hand side. If you cannot see the Overview, click on Overview + to expand the pane.

Once your request has been processed you will receive an email from the ERM system with your letter attached. You can also retrieve a copy of your exemption letter by going to your application and clicking on the History tab, followed by the Download button.



If you have not received your letter within 5 working days of submitting your form and the project status is *Submitted by Applicant* or *Submission in progress* please contact research.ethics@manchester.ac.uk ensuring you include your project reference number.

If your status is *Logged by research office,* please follow the steps above to retrieve a copy of your letter.