

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

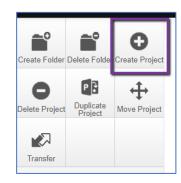
3 Creating a request for a letter of ethical exemption

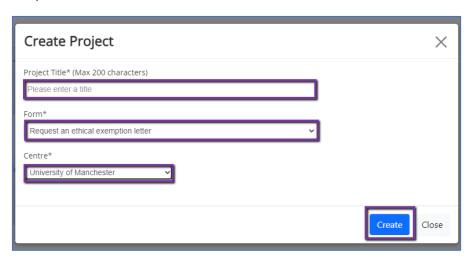
To create a new request, log in to ERM and click on **Create Project** from the **Action** buttons on the left-hand side of your screen.

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**.



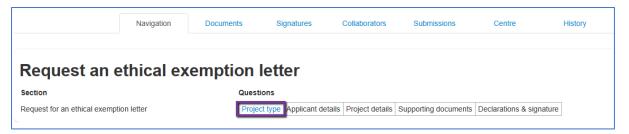




4 Navigation page

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.

New studies

If your project is led by UoM and is a new study yet to begin either recruitment or data collection, select this option.

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

Collaborations with another UK institution

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'.

If your study is a collaboration with another UK institution and they have obtained full NHS REC approval, you will be asked to provide both the NHS REC and IRAS reference numbers and will be able to continue with the form to request a letter of ethical exemption. Please note the approved REC application must have included detail of UoM's role in the project.

If your study is undergoing ethical review at the collaborator's institution, UoM will usually accept this in lieu of seeking approval here (unless UoM is either PI or grant holder), however you cannot request an exemption letter for these projects in ERM. Please exit the system and refer to the collaborations guidance (p3) for more information on how to proceed.

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



The University of Manchester

system. Please refer to the <u>digital handbook</u> (section 11.4 Changes to sponsorship) for guidance on all types of transfer studies.

If your study is a new project or a collaboration with NHS REC approval, click on **Next page** at the bottom of the screen to continue on to the **Applicant Details section**. You can also use the **Next** action button on the left-hand side of the screen to continue. Clicking the **Navigate** button will take you back to the **Navigation page**.





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.

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 <u>log in to ERM</u> 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.



7 Project Details

If your project is a new study, you will also be asked to provide the following, depending on the type of project:

- Audit/evaluation/market research/PPIE/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 if this is a collaboration with full NHS REC approval you will not need to complete this section.

8 Supporting documents

You will need to upload a copy of the ethics decision tool outcome screen for your project, as well as the following:

- Audit/evaluation/market research/PPIE/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.
- Collaborations with NHS REC approval: a copy of the REC/HRA approval letter, the IRAS form and all supporting documents.

9 Declarations and signature

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

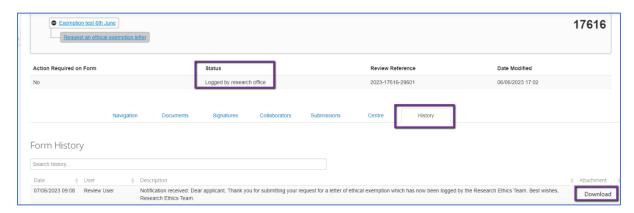
Once you have completed the declarations, please click the **Sign** button to submit. Please note that only the individual completing the form need to sign.



The Research Ethics Team aim to process exemption requests submitted in the ERM system within 5 working days 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 part-way down the page, underneath the project tree.



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 being sure to 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.