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Frequently Asked Questions (FAQs)

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Ethical Approval

1. Where can I find out if I need ethical review?

First seek advice via the <u>Ethics Decision tool</u> (we recommend you use Firefox, Edge or Safari to access). If the tool tells you that ethical review is required please log into the <u>ERM</u> and <u>create a new project</u>. Please also ensure you read the guidance notes featured throughout the form. Students must verify the outcome of the tool with their supervisor.

Please note, student projects refer to studies that are carried out as part of a University of Manchester degree programme (i.e. Undergraduate, Master's, PhD, etc) and are supervised by a University of Manchester member of staff. Students are not permitted to seek ethical approval through the University of Manchester for research studies that are not a part of their coursework or programme requirements.

All studies must comply with the University of Manchester's <u>Policy on the Ethical Involvement of Human</u> <u>Participants in Research</u> and students must not conduct any unsupervised research.

2. I'm not confident in the outcome of the Ethics Decision tool, where can I go for more information? If you are a student or supervisor in the Faculty of Humanities, the departments of Civil Engineering & Management or Computer Science in FSE or the divisions of Pharmacy & Optometry (Pharmacy UG & PGT



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only), Psychology & Mental Health or Psychology, Communication & Human Neuroscience please contact your <u>School Chair</u>.

If you are a student/supervisor from any other area or a member of staff conducting your own projects please contact the <u>Research Governance, Ethics & Integrity (RGEIT) Support Officer</u>. Please include a copy of the outcome text that you received when using the tool, a copy of your proposed data collection tools and an outline of who your participants are / how they will be recruited when contacting either your Chair or the RGEIT Support Officer.

3. What type of ethical approval do I need?

To find out please visit the <u>research ethics website</u> for guidance on the types of ethical approval and specific requirements. If you're still unsure, seek advice from the <u>RGEIT Support Officer</u> or your <u>School Chair</u>. As above, please provide a copy of your proposed data collection tools.

4. I need to obtain ethical approval via the Health Research Authority (HRA) or the NHS Research Ethics Committee (NHS REC). Can I use the ERM system?

The ERM system should only be used for applications made to the University Research Ethics Committee (UREC) or a Division/School panel. All applications to the HRA or NHS REC should be made via IRAS which is a separate system to ERM. For more information on which type of ethical approval is needed for your study, please first use the <u>Ethics Decision Tool</u>. If you still require further information please contact:

Faculty Governance Team <u>FBMHethics@manchester.ac.uk</u>

The Faculty Governance Team has prepared a helpful information pack for researchers applying for NHS REC and/or HRA approval. To access the pack, please click on the icon or go to http://documents.manchester.ac.uk/Doculnfo.aspx?DocID=29041



5. I need HRA approval as well as UREC approval, can I use ERM?

Yes, you can use ERM for the UREC application but you will still need to complete an IRAS application for the HRA portion. Please see our website for <u>guidance on applying for both UREC and HRA approval</u> and ensure that you also consult the <u>Faculty Governance Pack</u>.

For all queries relating to IRAS, NHS REC or HRA approval and sponsorship please contact the Faculty Governance Team <u>FBMHethics@manchester.ac.uk</u>

- 6. I've submitted for full UREC review, what should I expect to happen at the Committee meeting? If you've not attended a University Research Ethics Committee before or if it's some time since your last application, we recommend reading our <u>guidance on attending UREC meetings</u>.
- 7. My research is a collaboration with another University or external company, do I need UREC approval? Please refer to the collaborations arm of the <u>ethics decision tool</u> to help you determine this. Additional guidance can be found in the <u>guidance on collaborations</u>.
- 8. My research involves an external body (i.e. Ministry of Defence or HM Prison & Probation Service), do I need UREC approval?

Please refer to the guidance on our website relating to <u>external approvals</u> for more information.

9. Can the UREC review ethics applications from independent researchers?

If the project is not affiliated with a UoM member of staff or conducted by one of our students as part of a UoM degree programme we would be unable to take the project through our ethical review process as we would have no oversight of the research and could not impose our requirements or expectations in relation to research integrity.



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10. I work for a local NHS Trust and also hold an UoM honorary appointment, can I apply for UREC approval for my research study?

If the project is being conducted under your UoM affiliation you may be able to apply for UoM UREC approval. Please note that you will be required to adhere to all relevant UoM regulations in the same way as any substantive member of staff would be. This includes a requirement to follow all best practice guidelines even where a study may be exempt from ethical review.

If the project is being conducted under your NHS Trust affiliation or is your own independent work, you cannot apply for UoM UREC approval and must seek alternative arrangements.

11. Do you know of any independent Research Ethics Committees that independent researchers could use? Unfortunately we are not aware of any independent RECs who would provide ethical review.

Accessing ERM

12. Where can I log into ERM?

Applicants, Supervisors & PI's <u>https://submission-ethicalreview.manchester.ac.uk</u> to create, submit or sign an application

Reviewers <u>https://review-ethicalreview.manchester.ac.uk</u> to review **submitted** applications (ethics panel members only)

You will need your **University of Manchester username and password** to access the system. If you need assistance with this, please contact the IT Services Helpdesk.

Please refer to the troubleshooting section below if you are having difficulty accessing the site.



Note: IMPORTANT! Applicants (students, supervisors, staff) should only access the **Submission** side only <u>https://submission-ethicalreview.manchester.ac.uk</u>

13. Can I access the ERM system off-campus?

Yes, the system can be accessed from any location in which you have a stable internet or Wi-Fi connection. Please use the following browsers

Recommended: MS Edge or other industry-standard web browser of equivalent or better functionality such as Firefox, Chrome or Safari.

Browser versions are subject to on-going support by the browser manufacturer and may change over time.

14. I've not used the ERM system before, how do I complete an application? User guides for both <u>staff projects</u> and <u>student projects</u> are available on our <u>website</u>.

My Application Form

- 15. Where can I find the UK GDPR templates and other example documentation? You can find these and other resources on the <u>research ethics website</u>. Links are also provided from the relevant questions in the ERM system.
- 16. I need support with lone working arrangements and/or risk assessments, who should I contact? General guidance can be found under the fieldwork / risk assessment / lone working submenu of <u>our</u> <u>website</u>, however please speak to your local School Safety Advisor(<u>FBMH</u>, <u>FSE</u>, <u>Humanities</u>) for specific guidance and support as these activities are managed through your local School.





17. I am affiliated with 2 different Divisions or Schools, how do I know which one to select on my form? Please ensure you select the Division or School of your primary supervisor or if you are a member of staff,

the Division or School that is your primary affiliation.

18. I'm a staff member and also a student, how do I fill in my application form?

You need to consider in what capacity you are conducting the research project. If this is part of a staff project then select the Staff option in section A. If this is part of the degree programme that you're on (UG/PGT/PGR) then please select the Student option in section A.

19. Can I print my application form?

Yes, for instructions on printing please see the user guides for staff projects or student projects

20. My contact details are incorrectly displayed on my ethics application. How can I change these?

The ERM system automatically imports your contact details from the University's Open Directory. If these are incorrect, please first visit your Open Directory entry: <u>http://directory.manchester.ac.uk/</u> From here, please click on the purple button at the bottom of the screen entitled 'Change Your Details' and update your profile accordingly. If you are unable to change your details then please contact the <u>IT Services</u> <u>Helpdesk</u> for assistance.

21. How can my supervisor(s) or colleagues read/contribute to my form?

Please ensure you first **share the form** with your supervisor or colleagues. For instructions on sharing, please refer to the <u>user guides on our website</u>. Once you have shared the form with your supervisor or colleagues, they will be able to read and contribute to your form.

22. How can my external supervisor/colleagues read/contribute to my form?

It is not possible to share the form in ERM with external individuals who do not have a UoM email address and they will not be copied in to any system generated emails. Details of any external supervisors/colleagues should be entered in section B. If your external supervisor or colleagues would like to review the content of your application please see the relevant section of the user guides for <u>staff projects</u> or <u>student projects</u> for instructions on printing or generating a PDF copy.



Note: IMPORTANT! All student projects MUST be supervised by a UoM member of staff

23. I have 2 supervisors, where do I put their details?

Please ensure you list your primary supervisor (as they have to sign your application) under the appropriate section of the Contact Information question (Section B). Then use the 'Add Another' button to add the details of your second supervisor.



Note: IMPORTANT! Remember to use the search field located above the contact question to locate the name of your supervisor(s) and auto-populate their correct contact details. Your Supervisor **MUST** login in ERM at least once in order to activate their account in order for you to use this feature.

24. How do I submit my form?

Please refer to the PDF training guides for <u>staff projects</u> or <u>student projects</u> or the <u>video</u> entitled 'How to sign or request signatures' and 'How to respond to a signature request'.



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25. Who should sign the form?

If a **student or member of staff who is not the project PI** created the form: You will need to use the 'request signature' button in Section S of the form to request the signature of the supervisor or PI.

If the **supervisor or PI** created the form: Only the supervisor/PI needs to sign by pressing the blue 'sign' button in Section S of the form.

IMPORTANT: The system now features an updated submission function which will automatically queue your application for submission after all required signatures are obtained. If you do not receive email confirmation within 1 hour of signing the form that the application has successfully submitted please refer to the troubleshooting section at the end of this guide for more advice.

26. My student/colleague can't request my signature. What do I do now?

Please ensure that you have activated your ERM account. To do this, log into the <u>submission side of the</u> <u>system</u> and then log back out again. The system will retain a copy of your details for future use. Please also ensure your student or colleague is using your correct email address.

Your student/colleague must also remember to share the form with you (see above for more information)

27. I'm a supervisor/PI, how do I respond to a signature request?

Please open the application in the ERM system and look on the left-hand side of the screen for a button which looks like this:



Please press this button to sign the form and remain logged in to ERM until you receive email confirmation your signature has been accepted and the application has successfully submitted.

Ethical Review Process

28. How long does the ethical review process take?

This will depend on whether you are seeking review via the University Research Ethics Committee (UREC) or at Division/School level. On average, the process can take:

- 10-12 weeks for full UREC
- 7-9 weeks for Proportionate UREC
- 4-6 weeks for Division/School Review.

Submitting a well-prepared application with all necessary supporting documentation included and responding promptly to the Committee's feedback will help speed up the process. Please also ensure that you include a cover letter detailing your response to the Committee's feedback if you are asked to make revisions to the project at any stage. Failure to attach a letter to your resubmission will result in delays as the application will be returned to you.

Please consult the information listed on the splash page of the ERM system (when you submit your project) for approximate timeframes of key stages. Please ensure you take into account these timeframes when submitting your project to allow for plenty of time to complete the ethical review procedure.

Please also note that the **full UREC Committees do not meet over August** and therefore review times are likely to be longer during the summer months. The Proportionate UREC Committee and School/Division Committees however review all year long.

29. What are the different stages of the ethical review process?

Please see the flowcharts of the steps involved in applying for the different types of review:

• Full UREC





- Proportionate UREC
- <u>Division/School</u>

30. How can I see the status of my application during the review process?

First, log into ERM and locate your application. Once opened you will see 'status' which appears just below the project tree in the middle of the screen.

| test 19112020 Ethics Application | | |
|----------------------------------|---------------|---|
| Action Required | Status | 1 |
| Yes | Not Submitted | |

The status will let you know where your application is during the course of the review. If you have queries regarding the status of your submitted application, please contact the following individuals:

For Division/School review: Please contact your <u>Division/School Administrator</u> for assistance at any stage of the review process.

For UREC Applications: If your application has not yet been to Committee, please contact the <u>RGEIT</u> <u>Support Officer</u>. If you have queries regarding an application's status after your project has been reviewed by one of the URECs, please contact the relevant Committee Secretary (<u>propUREC@manchester.ac.uk</u>, <u>UREC1@manchester.ac.uk</u>, <u>UREC2@manchester.ac.uk</u>, <u>UREC3@manchester.ac.uk</u>, <u>UREC5@manchester.ac.uk</u>)



Note: IMPORTANT: If the form status says 'not submitted' please ensure your form has been signed by the relevant individuals (please refer to item 24 above) and that there are no pending updates on your form (indicated by a red warning bar). You **MUST** obtain the required signatures in order to submit your application in the ERM system.

31. I'm interested in becoming a member of an ethics Committee, how do I go about this?

We periodically recruit for new UREC members, who will need to be able to commit to approximately one full day per month (half a day to read applications and half a day to attend a meeting or review digital applications) for an initial period of three years. If you are interested, please ensure you have your line manager's support and email <u>research.ethics@manchester.ac.uk</u> for more information. If there are no current suitable vacancies, your details can be kept on file for future opportunities.

If you are interested in joining a School or Division Committee (AMBS, SALC, SEED, SoSS, Computer Science, MACE, Pharmacy & the two Psychology Divisions), please <u>contact the relevant area</u> directly for more information.

Please note that Committee membership is only open to members of staff.



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After Submission

32. I made a mistake and need to retrieve my submitted form. What should I do now? If this occurs, please contact your Division/School Administrator, or RGEIT Support Officer/Committee Secretary and request that your form is returned to you.

33. I'm leaving the University and need to hand over my application to a colleague. What should I do now?
Please use the 'Transfer' function in ERM to transfer ownership of the form to your colleague who must be a UoM member of staff. For specific steps of how to do this, please refer to the PDF training guide for both staff and

- student guide, topic Transferring ownership.
 - How to transfer ownership for Staff (section 14)
 - How to transfer ownership for Students (section 14)



34. I'm going on planned long-term leave, do I need to inform the Committee and will I still need to submit progress reports?

If you will be taking planned long-term leave such as maternity, paternity or adoption leave or a leave of absence you should consider what will happen to your project while you are away.

If the project is a collaboration with other UoM staff or students and will be continuing during your absence then please ensure ownership is transferred to one of your collaborators so that they can continue to submit amendments and update the form as necessary. Progress reports should be submitted as normal by your colleagues. If your role in the research team will be temporarily backfilled by a new team member, an amendment should be submitted to notify the Committee of this. Please also ensure any relevant supporting documents are updated and included with the amendment.

If you are the sole researcher and the project will be paused during your absence you do not need to inform the Committee but should ensure your data collection window allows you sufficient time to resume the project on your return. If the data collection window will end during your planned absence, an amendment should be submitted prior to your leave to request an extension (please note that the maximum time permitted for data collection is 5 years). **Please note**: your extension request does not need to give a reason; it is sufficient to simply request more time to collect your data. You do not need to submit progress reports during your absence though please be aware that the ERM system will automatically send email reminders.

35. I need to make a change to my approved research project in ERM. What do I do now?

Please submit an amendment request. For specific instructions on submitting an amendment request via the ERM system, please refer to the <u>user guide</u> on amendments.

For more information on the criteria for submitting an amendment to an approved application, please read the <u>guidance information</u> (also linked to in your letter of ethical approval).

36. I have a new supervisor, how do I notify the ethics committee of this?

To notify the committee of any changes to the research team, including supervisory team, please submit an amendment in ERM. You should include updated and version controlled copies of any supporting documents (PIS, consent, adverts, DMP etc) where your old supervisor was named, if you are still recruiting and collecting data.

37. I received ethical approval for an application that did not go through the ERM system and now need to seek an amendment. What should I do now?

Please contact research.ethics@manchester.ac.uk for advice.





38. I've lost the email that had my letter of ethical approval, how do I get another copy?

The ERM system automatically saves a copy of all emails and letters generated in the system. You can locate your letters by logging into ERM and going into your Notifications tile at the top of the screen. For more details on locating your letter of ethical approval, please refer to the <u>user guide</u> entitled 'How to make an amendment to an application approved in ERM'. For all archive projects (those approved outside of ERM), please email <u>research.ethics@manchester.ac.uk</u> for assistance in obtaining your letter of ethical approval.

39. My project was granted an unfavourable ethical opinion, what do I do now?

Please consult your letter of unfavourable ethical opinion sent to you via email or stored in ERM. The letter will outline if your project is eligible for a resubmission. If so, you will need to prepare a new ethics application in ERM and submit via the normal process but being sure to indicate in Question A2.2 that this is a re-submission. Otherwise, you will need to re-think your research project and develop a new one that does not pose the same ethical issues as your previous submission. You should then submit a new proposal if applicable.

Troubleshooting

40. I'm having trouble accessing the ERM system or specific content within?

Please ensure you clear all of your cache and perform a hard refresh of your browser by pressing the control key + F5 at the same time (Shift + Command + R on a Mac).

Please note that ERM uses the University's login service (Shibboleth) and in the event there is an issue with this service it is likely access to ERM will also be impacted.

41. Why can't I find my supervisor/student/colleague in the search field in section B?

If you cannot find the individual in the search field this means they have not activated their ERM account. Please ask the individual you are trying to add to your form to go here <u>https://submission-</u> <u>ethicalreview.manchester.ac.uk/</u> and log in with their usual UoM details. You will then be able to find them using the search function.

42. Why can't my supervisor/PI/colleague see the form in their work area if ERM says it's already been shared with them?

| Sharing a form enables others to access you give them. Please so | o view/edit th elect the user | e same form depending on s you wish to share this for | the level on with: |
|---|----------------------------------|--|--------------------|
| Collaborator email | | | |
| | -) 🛛 | Read | + |
| | 2 | Write | _ |
| | 2 | Submit | |
| | | Share | |
| | | Create all sub forms | |
| | | Receive notifications | |
| This form has already been s | hared with thi | s user | |
| | | | |

An error message like this is usually caused by trying to share the form after it's been locked through a signature request or submission.

To resolve the issue, please unlock the form using the Unlock action button. You should then be able to share the form with the relevant individuals.





Please note that you must then re-request the signature as unlocking will have cancelled any current requests.

43. I'd like to download a blank copy of the ethics form, how can I do that?

Unfortunately as the form is interactive and expands/removes questions based on your answers it's not possible to download a blank copy. You can however start a new project, answer only the multiple-choice questions in the form and then use the 'print' function to print a (mostly) blank PDF copy to use offline.

44. I'm trying to create an amendment but the 'create sub-form' action button isn't visible, what should I do now?

Please ensure you use the 'update' button at the top of your screen to update your application form to the latest version. Once you do this the create sub-form action button will become visible.

45. Why is there a red warning message at the top of my screen asking me to perform an update?

Warning: The project owner must update your project in order to submit this form Update

The system administrators periodically need to release new versions of the application form to correct bugs or add new compliance information and guidance. When this occurs you will be asked to update your form to the latest version to ensure it corrects any current issues.

If you are not the project owner (the person who originally created the form) you will not have the option to update and must ask the relevant individual to do so.

Please note that if an update is run after a signature has been requested, you must re-request the signature after the update.

46. Why can't I sign/request a signature from my supervisor/PI?

If you've checked that there's no pending for update, we recommend running the completeness checker, found on the far left of the screen in ERM, to see if any questions have been missed. If the checker does not find any outstanding questions and you have confirmed no updates are pending, please contact <u>research.ethics@manchester</u> for assistance, ensuring your provide a screen shot of any error messages and your project ID number.



47. The update warning at the top of my screen says it will invalidate all signatures. Will this affect my existing ethical approval?

No, the update will only affect signatures on a form or sub-form (e.g. amendment) that has not yet been approved.

If you had already requested your supervisor or PI's signature before running an update, you must rerequest the signature once the update has completed.

48. I'm having trouble accessing DMP online/can't find the Manchester outline section, who should I contact?

All queries relating to the DMP Online system or data management plans should be directed to The Library.

49. Why haven't I received confirmation my application has been submitted?

If you do not receive an email confirming successful submission (please check your junk mail folder) within 1 hour of signing the form, please do the following:

1. Open the application and double check the form status as it should be listed as *submitted*, *resubmitted* or *sent to*. If the status is one of these, please email the RGEIT Support Officer, School Administrator



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or UREC Secretary as applicable to double check that they have received your application.

2. If the form status is listed as 'changes requested', 'not submitted' or 'returned' then please double check:

a. That an appropriate signature has been obtained in Section S (it should say for example: Mr Smith has signed on 5/7/2024 at 13.15pm)

b. That no additional blank signature boxes are listed in Section S

c. That the application is not pending a mandatory update (shown by a red bar at the top of the screen)

d. If you have performed all of these checks and the application has still not automatically submitted, please email <u>research.ethics@manchester.ac.uk</u> and provide your project reference number and a member of the team will be able to assist you.

- 3. If the form status is *submission failed* or has displayed *submission in progress* for more than an hour, please contact <u>research.ethics@manchester.ac.uk</u> and provide your project reference number and a member of the team will be able to assist you.
- 50. I can't open the template PIS or consent form or other documents linked from the website, is there a workaround?

This is usually due to an issue with the Chrome browser. Please either right-click on the document link and select open in a new tab or alternatively please use another browser such as Edge, Safari or Firefox.

51. Why is ERM logging me out of my account when I'm writing an application?

ERM will log users out for security reasons after a period of inactivity. The system counts inactivity as remaining on the same page for more than 30 minutes (approx.)*. Please note that typing responses to questions will not count as activity, only pressing action buttons or navigating to another page is counted. To ensure your work is regularly saved, we advise regularly pressing an action button (eg. Save, Navigate) or using the Previous/Next buttons to move between pages.

*Since UoM updated the CAS authentication system in summer 2024 it appears that this window is being overridden by University systems. We would advise contacting UoM IT Services if you experience more frequent forced log outs.





52. Resources

- <u>Research ethics policy</u>
- Ethics Decision Tool: we recommend using Firefox, Edge or Safari to access
- Do I need ethical approval: additional information to help you decide
- <u>Types of Ethical Approval</u>
- <u>UREC meeting timetable</u>
- Submission side of the ERM system
- Information on the ERM System: PDF training guides and videos
- <u>Example Template Documents</u>: participant information sheets, consent forms, distress protocols, debrief sheets, confidentiality agreements and more
- Helpful Ethics Information: insurance requirements, lone working, fieldwork considerations and more
- Application Preparation Handbook
 - Consent (section 3)
 - o Recruitment (section 4)
 - Research with children (section 6)
 - Overseas research (section 7)
 - Disclosures (section 8)
- Making amendments to approved applications
- Data management and protection
- Guidance on the use of Social Media/CCTV
- <u>Guidance on vulnerability</u>
- <u>Guidance on the use of survey tools</u>
- Guidance on collaborations
- Guidance on the exclusion of inauthentic participants in research projects
- <u>Information Governance</u>: for queries relating to UK GDPR, international data transfer, terms and conditions of websites and acceptability of survey platforms
- <u>Records Retention Schedule</u>
- Managing research data
- <u>DMP Online system</u>: for creating a data management plan
- <u>Managing and sharing data from participants</u>: a series of modules to help apply the principles of data protection as well as how to engage with and take informed consent from your participants
- <u>Ministry of Defence Research Ethics Committee (MoDREC)</u>
- <u>Research with His Majesty's Prison & Probation Service (HMPPS)</u>
- Health Research Authority approval and IRAS