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Ethical Approval

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

To find out if your research needs ethical review, start by using the <u>Ethics Decision tool</u>. It works best in Firefox, Edge, or Safari. Students must check the outcome of the tool with their supervisor.

If the tool tells you that ethical review is required please log into the <u>ERM</u> system and <u>create a new project</u>. Please also ensure you read the guidance notes featured throughout the form.

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 Engagement 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?

- Students/supervisors in the following areas should contact their <u>School Chair</u>:
 - o Faculty of Humanities
 - o Civil Engineering & Management or Computer Science (FSE)
 - o Pharmacy & Optometry (Pharmacy UG & PGT only)
 - o Psychology & Mental Health or Psychology, Communication & Human Neuroscience
- All others (including staff conducting their own projects) should contact the <u>Research Governance</u>,
 <u>Ethics & Integrity (RGEIT) Support Officers</u>.

When contacting the Chair or Support Officers please include:

- o The outcome screen from the tool
- o Your proposed data collection tools
- o An outline of who your participants are and how they will be recruited

3. What type of ethical approval do I need?

Please refer to the *Types and routes of ethical review and approval* section of the **Research Ethics website** for guidance and specific requirements. If you are still uncertain, consult the following:

- Students/supervisors in the following areas should contact their <u>School Chair</u>:
 - o Faculty of Humanities
 - Civil Engineering & Management or Computer Science (FSE)
 - Pharmacy & Optometry (Pharmacy UG & PGT only)
 - o Psychology & Mental Health or Psychology, Communication & Human Neuroscience
- All others (including staff conducting their own projects) should contact the <u>Research Governance</u>,
 Ethics & Integrity (RGEIT) Support Officers.

Please provide a copy of your proposed data collection tools and an outlines of who your participants are and how they will be recruited when seeking advice on the appropriate route of review from the Support Officer or Chair

4. Can the ethics decision tool tell me what type of ethical approval I need?

No, the tool cannot tell you whether your study is suitable for school / division / department review, proportionate UREC or full UREC. To determine this please refer to the *Types and routes of ethical review and approval* section of the <u>Research Ethics website</u>

- 5. Where can I find the criteria for Proportionate UREC and school / division review?

 You can find the full list of criteria for both Proportionate UREC and school / division review on the
 Research Ethics website under the Types and routes of ethical review and approval section.
- 6. The ethics decision tool says my study is exempt from ethical review, can I get formal proof of this? If the tool outcome is that your study is exempt, staff and postgraduate students can apply for a letter of ethical exemption that you can use if asked for evidence of ethical review from a funder or journal. Please read the guidance under the Ethical Exemptions section of the website for more information, including guidance on how to apply.





7. 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.

The Research Governance Team (RGT) have published a <u>quick guide to approvals</u> to help researchers understand what approvals are needed.

If you still require further information please contact the RGT via UoMRGT@manchester.ac.uk

The RGT has also prepared a helpful information pack for researchers applying for

NHS REC and/or HRA approval. You can access the pack here: http://documents.manchester.ac.uk/Doculnfo.aspx?DocID=29041

8. 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>Governance Pack</u>, which contains details guidance.

For all queries relating to IRAS, NHS REC or HRA approval and sponsorship please contact the Research Governance Team UoMRGT@manchester.ac.uk

9. What happens at a full UREC 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>.

- 10. My research is a collaboration with another University or external company, do I need UREC approval? Please refer to the collaborations arm of the ethics decision tool to help you determine this. Additional guidance can be found in the guidance on collaborations.
- 11. 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 external approvals for more information.

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

No, UREC only reviews projects affiliated with **UoM staff or students**. We require oversight of the research to ensure our requirements or expectations in relation to research integrity are met.

13. 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 under your **UoM affiliation** you can currently apply for UoM ethical approval. You must adhere to UoM's best practice guidelines, even where a study may be exempt from ethical review.

If the project is under your **NHS Trust affiliation** or independent work you cannot seek UoM ethical approval and must explore alternative approval routes.

14. 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

15. Where can I log into ERM?

- Student & staff applicants, Supervisors & PIs: Create, submit or sign an application https://submission-ethicalreview.manchester.ac.uk
- Reviewers (ethics panel members only): Review submitted applications https://review-ethicalreview.manchester.ac.uk

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.

16. 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.

17. I've not used the ERM system before, how do I complete an application?

User guides for both staff projects and student projects are available on our website.

My Application Form

18. 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.

- 19. 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 our website, however please speak to your local School Safety Advisor(FBMH, FSE, Humanities) for specific guidance and support as these activities are managed through your local School.
- **20.** 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.

21. I'm a staff member and 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.

22. Can I print my application form?

Yes, for instructions on generating a PDF of your application to share or print please see the user guides for staff projects or student projects

23. 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 then please contact the IT Services Helpdesk for assistance.

24. 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.





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

External supervisors or colleagues without a UoM login cannot access ERM or receive system-generated emails. If they need to review the application, refer to the user guide for instructions on printing or generating a PDF copy for <u>staff</u> and <u>student</u> projects.

Please note that all student research projects must be supervised by a UoM member of staff.

26. 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.

27. 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'.

28. 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.

29. 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 as you will be unable to see it in your work area otherwise.

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

Please open the application in the ERM system and look towards the top of the page for the Sign button (it has an image of a pencil on it).

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

Ethical Review Process

31. 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. As a general guide, 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.

If submitting for Proportionate UREC review please ensure that you carefully read <u>the criteria for this route</u> before submitting your application as selecting the wrong route will result in significant delays.

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.

32. 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
- Division/School

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

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.



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 RGEIT Support Officer. 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 (propUREC@manchester.ac.uk, UREC1@manchester.ac.uk, UREC1@manchester.ac.uk, UREC2@manchester.ac.uk, UREC4@manchester.ac.uk)



Note: IMPORTANT: If the form status says 'not submitted' please ensure your form has been signed by the relevant individuals (please refer to item 25 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.





34. 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 two years. If you are interested, please ensure you have your line manager's support and email research.ethics@manchester.ac.uk 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, Civil Engineering & Management, Computer Science, Pharmacy & the two Psychology Divisions), please <u>contact the relevant area</u> directly for more information.

After Submission

35. 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.

36. I'm leaving the University or going on long term leave 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)

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Actions

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P ?

Duplicate Project N/A

Transfer

37. 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 your project continues during your absence:

- Transfer ownership to a collaborator for them to submit amendments and update the form as needed
- Submit an amendment if a new team member is covering your role. Ensure any relevant supporting documents are updated and included.
- Progress reports should be submitted by your team.

If your project is paused:

- You do not need to notify the Committee but please ensure your data collection window allows time to resume after your return.
- If needed, prior to your leave submit an amendment to extend the data collection period (max 5 years from original approval). You do not need to give a reason.
- You won't need to submit progress reports, but ERM will still send reminders as these cannot be switched off. Please submit a progress report on your return if you have missed a prompt.

38. 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).

39. 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 etc) where your old supervisor was named, if you are still recruiting and collecting data.

40. 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.

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

Log into ERM and check your Notifications tile at the top of the screen. Alternatively, locate the relevant application and select the History tab. You should then be able to see the original notification message with a copy of the letter attached. For more details please refer to the <u>user guide</u>

For archived (non-ERM) projects email <u>research.ethics@manchester.ac.uk</u> Please note that the original date and route of your historic approval may mean we are unable to assist.

42. 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 Section A 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.

43. I need to withdraw my application. How can I do this?

If you are certain that your application no longer requires ethical review through the ERM, then you can withdraw your application by selecting the relevant project in ERM and selecting the 'Withdraw application' button in the sidebar. You will need to enter a reason for the withdrawal as this information is required for audit purposes. If your project is currently under review by the signatory or committee then you will not be able to withdraw the application and should contact the Research Ethics Team for assistance.

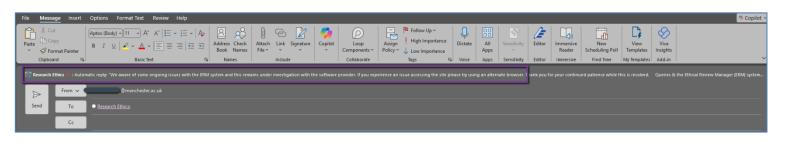
Troubleshooting

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

We recommend first trying a hard refresh (Ctrl + F5 (pc) / Shift + Command + R (mac). If you continue to experience issues, please try clearing your browser cache & cookies or using an alternative browser.

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

Known issues will be reported in the auto-reply on the Research Ethics email account. This information will be visible in the new message window, without needing to send an email.



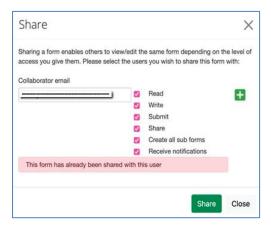




45. Why can't I find my supervisor/student/colleague in the search field of ERM to add them to my application?

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 https://submission-ethicalreview.manchester.ac.uk/ and log in with their usual UoM details. You will then be able to find them using the search function.

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



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.

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

Unfortunately as the form is dynamic and expands 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.

48. 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.

49. 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.

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

If you are unable to sign or request a signature:

- Ensure there are no pending updates.
- Run the **Completeness Checker** to identify any missing responses.
- If the issue persists, contact <u>research.ethics@manchester.ac.uk</u> with a screenshot of any error messages, along with your project ID.

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

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

You will however need to re-request any signatures that have not been granted after an update has been run.

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

For issues related to Data Management Plans or DMP Online, please contact the Office for Open Research.

Please note that while a data management plan (DMP) is a UoM requirement for all research projects (staff, PGR), from April 2025 DMPs are no longer required as part of ethics applications.

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

If you do not receive an email confirming successful submission within 1 hour of signing the form, please do the following:

- 1. Check your junk/spam folder.
- 2. Open your form and verify the status:
 - i) If it shows **submitted**, **resubmitted**, or **sent to**, contact your School/Division Administrator or UREC Secretary to check the application has been received.
 - ii) If it shows **not submitted**, **returned**, or **changes requested**, check:
 - a. Section S includes a valid signature.
 - b. No extra blank signature boxes are present.
 - c. No pending updates (indicated by a red bar).
 - d. If all the above have been done and it has not submitted email research.ethics@manchester.ac.uk (please include your project reference number)
- 3. If the status is **submission failed** or remains on **submission in progress** for more than two hours please email <u>research.ethics@manchester.ac.uk</u> with your project reference number for assistance.





54. 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.

55. 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 (approximately). 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.

56. Resources

- Research ethics policy
- Ethics Decision Tool: we recommend using Firefox, Edge or Safari to access
- <u>Do I need ethical approval:</u> additional information to help you decide
- Types of Ethical Approval
- UREC meeting timetable
- Submission side of the ERM system
- <u>Information on the ERM System</u>: training guides and videos
- Example Template Documents: 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)
 - Recruitment (section 4)
 - o Research with children (section 6)
 - Overseas research (section 7)
 - o Disclosures (section 8)
- Making amendments to approved applications
- Data management and protection
- Guidance on the use of Social Media/CCTV
- Guidance on vulnerability
- Guidance on the use of survey tools
- 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
- Records Retention Schedule
- Managing research data
- <u>DMP Online system</u>: for creating a data management plan





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- Managing and sharing data from participants: 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
- Ministry of Defence Research Ethics Committee (MoDREC)
- Research with His Majesty's Prison & Probation Service (HMPPS)
- Health Research Authority approval and IRAS