School Ethics Application Process

This page outlines the process for applying for ethical approval for research in the School of Medicine. Researchers are advised to also consult the <u>University Teaching and Research Ethics Committee</u> (UTREC) web pages for further information, as the School of Medicine Ethics Committee is a subcommittee of UTREC, and follows its policies and procedures.

Ethical review and approval are required if you are conducting research with human participants, their data or samples. Ethical approval must be in place prior to the start of the research project. Carrying out research without the relevant ethical approval can constitute research misconduct, as defined by the University of St Andrews: <u>https://www.st-andrews.ac.uk/policy/research-conduct-and-ethics/research-misconduct-policy.pdf</u>. Please contact the chair of the SEC if you have any questions or concerns as to whether your research requires review and approval.

These requirements apply to Undergraduate Honours, Masters and PhD students as well as members of staff. Ethical approval from St Andrews is still required even if projects are being led by other institutions, or have been approved by the relevant committee of those institutions, or by other review boards, such as the NHS. Please note that, for students, if a dissertation or thesis fails to include evidence of ethical approval, then it could be failed. Students should ensure their ethical approval letter is bound into the appendix before submission.

Applicants should use the forms on the <u>UTREC web pages</u> (please make sure you are using the most up-to-date form, as they change regularly). Submit applications as email attachments (in Word) to the Ethics Administrator, Fiona Paterson: <u>medethic@st-andrews.ac.uk</u>

School of Medicine Ethics Committee Meetings

The Medicine SEC meets on the first Thursday of each month, with a submission deadline for applications falling two weeks prior. Failure to submit on time may result in your application being put back to the following month. Consideration of the need for ethical review should occur early in the research planning process and researchers should allow six weeks from the submission deadline to obtain approval, in case multiple rounds of revision are required. If a quicker turnaround is required, then please contact the Ethics Administrator to discuss.

Monthly SEC meetings	Meeting date	Submission deadline
September 2021	2 September 2021	19 August 2021
October 2021	7 October 2021	23 September 2021
November 2021	4 November 2021	21 October 2021
December 2021	2 December 2021	18 November 2021
January 2022	13 January 2022	30 December 2021
February 2022	3 February 2022	20 January 2022
March 2022	3 March 2022	17 February 2022
April 2022	7 April 2022	24 March 2022
May 2022	5 May 2022	21 April 2022
June 2022	2 June 2022	19 May 2022

Please note that currently our peak time for applications is from November to March.

School of Medicine Application checklist

Note: Incomplete forms will be returned for revision and will have to be resubmitted.

- 1. Check that if the application is funded, the funders/sponsors are on the automatically approved list (this list is found under the '<u>Approved Funders List</u>' tab on the UTREC web pages). If they are not, please apply for funder/sponsor approval.
- 2. If your application includes many attachments, please label each file clearly and provide details on your covering email so that all the paperwork is understandable.
- 3. UTREC provide <u>template documents</u> including the following which can be appropriately modified for projects:
 - Participant advertisement
 - Participant information sheet
 - Consent form
 - Debrief

Exemplar documents are also available on the website.

- 4. In the 'Project description' and 'Ethical considerations' boxes (page 1 of <u>ethical application</u> <u>form</u> please make sure you do not exceed 900 characters for each section for database purposes otherwise the application will be returned which will cause delays.
- 5. Check that each section that is appropriate is completed, in particular, Q3, 'If applicable, have you obtained permission to access the site of research?' Please provide permission documentation in the application; a copy of an e-mail will suffice.
- 6. Although it is not stated on the UTREC guidelines, the School of Medicine requires that you include a **research protocol** along with the ethical application and other supporting documentation.
- 7. The application will be reviewed by the School Ethics Committee; allow at least 10 days from the monthly meeting for the outcome letter. If revisions are required, please submit the revised application as a Word file; please reference and highlight any additions/amendments in yellow block with a cover letter detailing your changes. Following approval by the SEC/Chair's action the project can start. However, in certain cases where substantial ethical issues are involved, the School Ethics Committee may refer the application to UTREC.

For research involving the NHS

NHS approvals must be obtained first and then ratified by the SEC. Contact <u>researchintegrity@st-andrews.ac.uk</u> to check whether you need any NHS approvals and, if so, which approvals you need and how to obtain them. Get in touch as early as possible as acquiring NHS approvals may take months. When applying for NHS ethical approval, researchers are still required to use the University's <u>template documents</u>.

For research overseas

Different countries have different ethical review and approval processes. Please contact the SEC early in the planning process to discuss.

Amendment Application Process

<u>Amendment Applications</u> for ethical approval can be submitted any time and should be submitted by e-mail as a word document to the School Ethics Committee Administrator: <u>medethic@st-andrews.ac.uk</u> In most cases Amendments can be reviewed under Chair's action, but in certain

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cases the application may be referred to the School Ethics Committee. Please allow at least 10 days for the outcome letter. Simple amendments such as adding a researcher or amending contact details can be made by completing a Simple Amendment Application form.

Renewal Application Process

When ethics applications have expired, and the project is still ongoing, a new application must be submitted under the same conditions as the new application process.

Ethical Funders applications

Funders applications are dealt with by UTREC not the School of Medicine Ethics Committee and must be fully completed before sending to UTREC. UTREC hold a <u>current list</u> of all approved funders on their web pages, along with the <u>review process</u> for new funder applications.

Research Governance

Ethical approval is one aspect of research governance, but there may be other aspects relevant to your work such as legal requirements when handling data, safety risk assessments, or permissions to approach certain populations. It's the researcher's responsibility to ensure all necessary approvals and requirements are in place prior to commencing research.

SEC Contact Details

- Convener: Morven Shearer
- Member: Robert Humphreys
- Member: Anita Laidlaw
- Member: Jo Cecil
- Member: Derek Sloan
- Member: Paul Reynolds
- Administrator: Fiona Paterson
- e-mail: medethic@st-andrews.ac.uk

Fiona is based in the Research Support office (Room 223) or on Teams.

Author:	Executive Administrator (DCM)	Approval Committee:		
Consultees:	Morven Shearer & Fiona Paterson			
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Date	Revision Description	Major Changes
01/11/19	Published version	
17/09/21	Updated version	