

GUIDANCE FOR SUBMITTING TO THE SCHOOL OF HEALTHCARE RESEARCH ETHICS COMMITTEE (SHREC)

Do I need to submit my project to SHREC for ethical approval?

All research (including evaluation) to be undertaken by School of Healthcare staff or students which involves primary research with human subjects, and that is outside of the NHS ethical approval must be submitted to SHREC. The full terms of reference are available at:

<http://www.healthcare.leeds.ac.uk/downloads/SHREC-Terms-of-Reference.pdf.pdf>

How do I submit to SHREC?

To submit to SHREC you need to look at the dates of the SHREC meetings and decide at which meeting you want your project to be considered.

SHREC meet monthly throughout the academic year. The dates of the meetings and submission dates are arranged a year in advance and are available at:

<http://www.healthcare.leeds.ac.uk/downloads/SHRECnewMeeting-Dates-2010-2011.pdf>.

Please note that the deadline for applications to be received on the submission date is *12.30 pm*.

You then need to download and complete the University of Leeds Research Ethics Committee Application Form. This is available at:

http://researchsupport.leeds.ac.uk/images/uploads/docs/Ethical_Review_Form_V3.doc.

In completing this Application form you will need to think about the perceived risks to your research participants, other ethical issues and your proposed action to address these. Useful advice is available at <http://www.leeds.ac.uk/ethics>

What do I need to submit?

You need to complete and submit the following 4 documents:

1. Your completed University of Leeds Research Ethics Committee Application Form.

If you are a student making an application, the declaration page must be signed by you and your supervisor. It is important that your supervisor has read and agrees with your application, so this page should be scanned and submitted with the application and supporting documentation. If you are not able to get the form signed prior to submitting the application, please ask your supervisor to email the SHREC Secretary (FMHUniEthics@leeds.ac.uk) to confirm that they have read, edited and agree with the application. You must then ensure that your supervisor signs the declaration page and that it is sent to the SHREC secretary as soon as possible. Review of your project may be delayed if the application is received without signatures.

2. Your 'Participant Information Sheet' that you plan to give to your research participants.

Guidance on how to write a participant information sheet and a template is available at <http://www.healthcare.leeds.ac.uk/downloads/Information-Sheet-Template.doc>

3. Your 'Consent Form' that you will be using with your research participants.

Guidance on how to write a consent form and a template is available at <http://www.healthcare.leeds.ac.uk/downloads/Consent-Form-Template.doc>.

4. Your data collection materials e.g. questionnaire, interview schedule.

You need to email all these documents to the SHREC Secretary (FMHUniEthics@leeds.ac.uk) at least two weeks before the SHREC committee meeting at which you want your project to be considered.

The deadline dates for submitting your documentation are available at http://www.healthcare.leeds.ac.uk/downloads/SHRECMeetingDates2010_11.pdf.

What happens next?

You will receive an email confirming receipt of your documentation and detailing the date of the SHREC meeting at which your project will be considered.

Your documentation will be circulated to SHREC members who will consider it at the appointed SHREC meeting. You do not need to attend this meeting.

A decision about your project will normally be made at that meeting. You will be informed by letter of the decision in writing normally within 10 *working* days of the meeting.

There are 4 possible outcomes:

1. Your project is approved and you may commence your research.

Projects would normally begin within 12 months of SHREC approval.

2. Your project is approved subject to you making some amendments.

If this happens you need to make the amendments and submit them to the SHREC secretary within 3 months. The Chair of SHREC may grant ethical approval or may require these amendments to be considered at the next SHREC meeting. Once approval is granted you will receive a final letter of approval.

3. You are asked to provide more information before a decision can be made.

If this happens you need to submit this information to the SHREC secretary before the deadline for the next SHREC meeting. Your project will then be considered at the next meeting.

4. Your project is refused ethical approval.

If this happens you cannot commence your research.

If you disagree with the decision of SHREC to reject the proposal then you may ask that it be referred to the Faculty of Medicine and Health Research Ethics Committee.

Contact details for SHREC

SHREC Secretary: Rachel de Souza
Faculty Research Ethics and Governance Administrator
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