

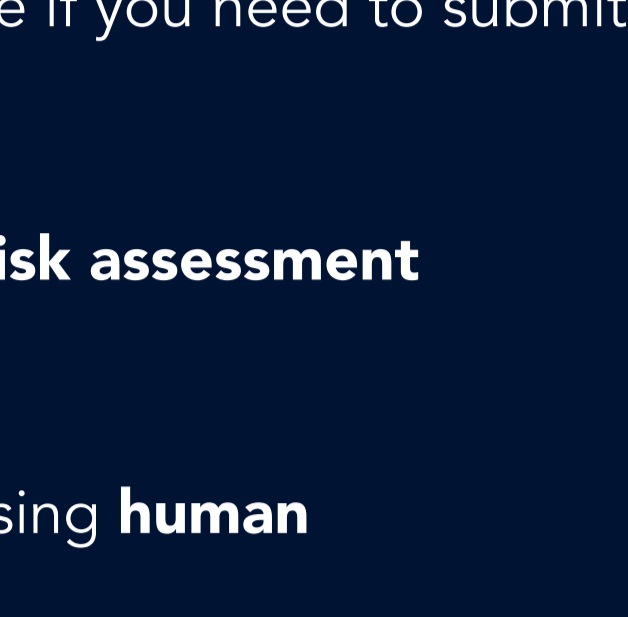


RESEARCH ETHICS: How to get Ethical Approval for my study

Our Research Ethics Committee: Human (REC-H) requires that all research projects are conducted in such a way that protects the dignity, rights, safety and wellbeing of all human participants. In order to do this, postgraduate research students must submit an ethics application for us to review before data collection can begin. Follow this step-by-step guide to submit your ethics application and receive ethical approval.

STEP 1

DETERMINE IF YOUR STUDY REQUIRES ETHICAL REVIEW AND APPROVAL



Completing a **risk assessment form** will estimate the risk of your study and determine if you need to submit an ethics application or not.

You will need to complete a risk assessment form if:

- You wish to conduct research using **human participants**
- If your research does not involve human participants you do not need ethical approval

STEP 2

COMPLETE YOUR RISK ASSESSMENT FORM

- Download the RECH 002 [risk assessment form](#)
- Read through the questions and select all of the boxes that contain a statement that **is applicable** to your study
- If **any** applicable statements fall within the **Negligible to Low risk, Medium risk or High risk** columns **you will need** to apply for ethical approval
- If **all** of the applicable statements fall within the **No risk** column **you will not** have to apply for ethical approval
- Expedited review:** If you did not select **any** statements in the **High risk** column, but did select applicable statements in the Medium risk column you will be eligible for an **expedited review** which occurs at faculty level

STEP 3

FAMILIARISE YOURSELF WITH THE NECESSARY RESOURCES



Before you can take the next step and fill out your ethics application form you must read:

- REC-H Standard Operating Procedures**, with emphasis on the section on the responsibilities of the primary responsible person (PRP) and primary investigator (PI)
- Department of Health Research Ethics Guidelines (2015)**, with emphasis on consideration for the mental and physical well-being of all human participants
- Any and all relevant documentation regarding ethical and legal aspects of research studies making use of human participants (refer to pp 12 of document b. above)
- The Belmont Report** summarised for your convenience by a 3rd party and available as [video presentation](#)
- Summary of the Protection of Personal Information Act (POPIA)**
- Nelson Mandela University Code of Conduct for Researchers**
- Nelson Mandela University Research Ethics Policy**

STEP 4

COMPLETE YOUR ETHICS APPLICATION FORM

Important things to note before submitting your ethics application form:

- Your research proposal must first be approved by the FPGSC
- Your ethics application must first be screened by the FPGSC for assessment of risk and possible ethics clearance
- This application process is only applicable for individual projects and is not applicable for [umbrella projects](#)

How to complete your ethics application:

- Download the RECH-001 form
- Copy your previous answers from the Risk Assessment form into the current form
- Complete Section B
- Complete Section 1-8 in typescript. You may copy and paste information from an existing Word document
- Append the required information. Take note of the mandatory appendices:
 - Appendix 1: Research proposal (mandatory)
 - Appendix 2: Gatekeeper/Permission for access/Institutional permission draft letters (mandatory)
 - Appendix 3: Evidence of Researcher Competence (if applicable)
 - Appendix 4: International Ethics Approval Process (if applicable)
 - Appendix 5: Restrictions/conditions applicable to publication of results (if applicable)
 - Appendix 11: Data collection instruments (mandatory)
 - Appendix 12: Recruitment information (mandatory) – written and/or oral
 - Appendix 13: Enrolment information (mandatory) – written and/or oral
 - Appendix 14: Consent form(s) (mandatory)
 - Appendix 15: Assent forms(s) (if applicable for minors)
 - Appendix 16: Budget for reimbursement/remuneration/incentives (if applicable)
- Complete the table for Supporting Documentation
- Remove the instruction block and definition of terms
- Sign and initial all pages in your application either electronically or by hand
- Get sections 9 and 10 signed by the relevant parties either electronically or by hand
- Save your completed form
- Name your form as follows:

Name REC-H
Application Form
e.g. "J Smith REC-H Application Form.doc"

NB!

Handwritten forms will not be accepted
Ensure your appendices are correctly labelled and are in the correct order

Incomplete or incorrectly completed application forms might result in a delay of the review and approval process

STEP 5

SUBMIT YOUR ETHICS APPLICATION FORM



Submit your signed and completed application form to your [Faculty FPGSC representative](#)

Please note that there is a minimum 6-8 week review period for high-risk studies

#MADEFORMORE

For more info about postgraduate studies, [email us](#) or visit the [Nelson Mandela University](#) website.