

## **Ethics Application Guidelines and Checklist**

All researchers or postgraduates applying for ethics must read the following document carefully and ensure that they are thoroughly prepared for the online submission process.

## 1. General Ethics Application Information - Researchers' Responsibilities

- The Principle Investigator (PI) is the only person that can submit the research proposal and supporting documents electronically, as this ensures that the PI takes full responsibility for all documents submitted and also for all research done.
- The researchers' responsibility is to take note of application status. Comments made by the DEC after meetings will be forwarded to principal investigator (i.e. the applicant).
- Note your unique ID associated to your application upon the initiation of your application as this number is used to access your application / track your application progress.

## 2. Who should apply?

- All individuals wishing to initiate postgraduate research projects, research fellows, intern medical biological scientists as well as departmental researchers must apply for ethical approval from the DEC in order to commence with a research project.
- A full protocol/proposal needs to be submitted for consideration by the DEC for all research studies to be conducted especially studies dealing with commercial cell lines, blood samples, human tissues, human bodily products and/or "in vitro" work, indigenous knowledge, human participants as well as for systematic reviews.
- The DEC is required to evaluate all research proposals/protocols even if the project is a pilot study or subset of another study (sub-study/ under the umbrella of another study), which has already been approved by the Ethics Committee.

- Please indicate clearly and refer to the umbrella study title and protocol number in your application.
- As the latter submission needs to refer to the study already approved, it may consequently be less comprehensive (for example, the previously approved Participant Information and Consent Documents may suffice).
- If the research is classified as a clinical trial or is case reports/case studies another subset of permission documents are required.
- Researchers who are not UNAM staff members, students or affiliates may submit ethics applications at the discretion of the DEC.
- 3. What is required?
  - Ethics application must follow the receipt of an approval letter from the MSc/PhD Committees, Postgraduate Committee School of Healthcare Sciences, Academic Advisory Committee, and Academic Programme Committee *where the research is for degree purposes.* This is not necessary for applications that are not for degree purposes.
  - On the electronic ethics application form (generated on PeopleSoft platform) the researcher needs to indicate that he/she will abide by the principles of the Declaration of Helsinki\*. In addition, the Declaration of Storage\* needs to be completed.
  - o Furthermore, the PI needs to complete the PI's commitment section within the application (declaration of commitment). \*Documents can be found under the research tab on the UNAM website (see no. 5).
- 4. When should you submit?
  - Researchers need to take note of the submission deadline for a specific monthly meeting. These are available on the UNAM website <u>https://research.unam.edu.na/research-excellence/</u>
  - No late submissions will be accepted by the DEC chairperson for evaluation for a specific DEC meeting. Late submissions will be allocated to the next DEC meeting for evaluation.
- 5. How to Apply
  - In preparation of your research protocol/proposal you will acquire a lot of the information necessary for the ethics application. However, additional information/documentation will be required.
    - A comprehensive description of the process of preparing for the ethics submission is described in ethical clearance requirements document 'Submission Checklist'.

- This document contains a breakdown of all the documentation and additional information that will be required of you for your submission and is printable to act as a checklist for your submission process.
- Ensure that all relevant documents are compiled timeously. Additionally, ensure that your research protocol/proposal contains all the relevant sections by referring to the ethical clearance requirements document 'Submission Checklist.
- To begin your application: Access the UNAM website page, click on the 'Research' tab (top right corner), select 'Research, Innovation and Development', click on the 'Research' tab on this page which is on the top right corner and finally click on the 'Apply Online' tab; or simple use the link <u>https://research.unam.edu.na/research-excellence/</u>

## 6. Post submission process

- The Online Application System will forward an e-mail to the applicant to alert them that comments made by the DEC need to be addressed.
- Researchers need to respond with a cover letter that addresses the DEC comments in a- point-by-point letter format. This needs to be submitted before the deadline stipulated on the comments letter. All amended documents should be attached.