NELSON MANDELA UNIVERSITY

Standard Operating Procedures
Research Ethics Committee (Human) (REC-H)

- **Extensions**
- **Amendments**

REC-H Chairperson, Dr Dalray Gradidge
Email: dalray.gradidge@mandela.ac.za
Tel: 041 504 2511

Version 1.5, June 2024

TABLE OF CONTENTS

1 STUDY EXTENSION

1. Extensions of low-risk faculty-approved protocols may also be approved by the Faculty Ethics Committees, and not at REC-H. The following conditions must be adhered to:
   a. Extension of medium and high-risk protocols must serve at REC-H.
   b. Original ethics approval is granted for one-year. Thereafter, two extensions may be approved bringing the total period of the ethics approval to three years.
   c. If data collection for a study is required to continue after the three-year period, a new application for ethics approval must be submitted and approved.
   d. An extension of ethics approval cannot be granted on a lapsed protocol. If the original ethics approval period has expired, a new application for ethics approval must be submitted and approved. Data collection may not commence or continue if ethics approval has lapsed.
   e. A progress report must be submitted together with the application for extension. All documentation must be retained for audit by the National Health Research Ethics Council (NHREC).
   f. All extensions approved at faculty level must be submitted to RECH for noting, together with all new applications approved at faculty level.
   g. All medium and high-risk protocols need to be approved by REC-H, and all low risk which were originally approved via RECH needs to come back to RECH for approval of an extension.
   h. If a study requires an extension beyond the three years permitted (and ethics has not lapsed), the PI is to submit a progress report under the old application – but only if the study requires a time extension. If the project needs to be amended as well, then a new application must be submitted.
   i. An extension can be approved from the date of the original expiry.
   j. All extensions will be for a one-year period.

2 AMENDMENTS REVIEW

2.1 DEFINITIONS

1. Minor Amendments

   a. A minor amendment is defined as a change that does not materially affect the balance of risks and benefits in a study or does not substantially change the specific aims or design of the study. Examples of minor amendments include:
   b. Administrative or informational amendments:
      i. Changes in research staff.
      ii. Change in telephone numbers.
      iii. Changing the study title (e.g. just a reshuffling of words).
      iv. Addition or removal of qualified investigators, study sites.
      v. Revision of format of consent documents, recruitment materials or questionnaires.
      vi. Correction of typographical errors.
   c. Procedural amendments
      i. Drawing slightly different amounts of blood.
      ii. Changing frequency at which blood is drawn.
      iii. An increase or decrease in proposed number of participants supported by a statistical justification.
      iv. Narrowing the range of inclusion criteria.
      v. Broadening the range of exclusion criteria.
      vi. Changing the amount of compensation, within reasonable limits.

vii. Revisions to the informed consent documents to improve clarity, to include missing elements or to revise lay language.
viii. Decreasing drug dosage or frequency of administration.
ix. Decrease in number of study visits provided such a decrease does not affect collection of relevant safety-related data.
x. Minor adjustments in the duration of the study for retrospective reviews

2. Major Amendments

a. Such amendments involve significantly increased risk to participants and often reflect changes in the direction of a study that may substantially change its purpose or goal. Changes that alter the overall purpose or objective of a study may require a new study submission.
b. Examples of changes that may affect the balance of risks and benefits include:
   i. Change of study title
   ii. Adding a new activity that may increase risk to participants.
   iii. Changing drugs or medications as well as dosages.
   iv. Changing levels of radiation exposure.
   v. Adding a vulnerable population.
   vi. Adding or changing invasive procedures.
   vii. Adding a research arm to the study.
   viii. Substantially extending the duration of exposure to the test material or intervention.
c. To obtain Human Research Ethics Committee approval for amendments, the principal investigator must submit an amendment application form describing all proposed modifications. This applies to the protocol and the informed consent forms. In addition, all proposed changes must be indexed and highlighted in the revised protocol and consent documents. Major changes must be incorporated in the protocol and a revised protocol submitted. The approval of an amendment does not alter the original approval or expiry dates assigned to the protocol.

2.2 Requesting an Amendment

1. Nelson Mandela University researchers (staff and/or students) of currently active studies making use of human participants who require an amendment to a currently active study in terms of data collection activities are required to complete and submit a request for the review and approval of such an amendment PRIOR to implementing the amendment, except where it is essential to prevent and/or exclude immediate hazards and/or risks to currently enrolled participants (in case of the latter situation, please alert Imtiaz.Khan@mandela.ac.za for advice on the required procedure to follow). Failure to request an amendment prior to implementation thereof may result in the immediate suspension or termination of all data collection activities linked to the study.
2. Amendments to studies include but are not limited to changes in research protocol, written/oral information/consent documents and/or data collection instruments. If the amendment involves only a change to the primary responsible person (PRP), primary investigator (PI) or any other researchers collaborating with the study, the following procedure detailed at https://rd.mandela.ac.za/Research-Ethics/Research-Ethics-Committee-Human-(REC-H)/Request-for-Change-in-Study-Researchers must be followed.
3. Unless there are extenuating circumstances, continuous applications for amendments to a particular study will not be viewed in a favourable light. This procedure described below is NOT for requesting approval for an extension/renewal of a previously approved protocol (for this purpose please refer to https://rd.mandela.ac.za/Research-Ethics/Research-Ethics-Committee-Human-(REC-H)/Extension-of-a-Study

2.3 Minor Amendments

1. Minor amendments to a currently active study are subject to expedited approval. Minor amendments are restricted to the following:
   a. Any modification that would not significantly affect the assessment of the risks and/or benefits of the study.
   b. Any change that does not significantly affect the aims and/or design of the protocol for the study.
   c. A decrease/increase in sample size, supported by relevant statistical motivation.
   d. Administrative changes such as researcher contact details, the removal/addition/replacement of research personnel and/or study sites.
   e. Reducing the inclusion criteria.
   f. Increasing the exclusion criteria.
   g. Modifying data collection points or volume of data collected as long as any safety regulations/constraints are retained.
   h. Changes in compensation and/or reimbursement with adequate rationale.
   i. Any editorial modifications that serve to clarity but not alter the existing meaning of a document.
   j. Any translations of documents previously reviewed and approved by REC-H.

2.4 Procedure for requesting a Minor amendment

1. The procedure for requesting approval for a minor modification is by means of written communication on a signed letterhead to Imtiaz.Khan@mandela.ac.za citing the study reference number and providing a detailed description of each change, supported by a rationale for each change as well as any and all relevant revised documentation for each change.
2. One copy of each amended study document which clearly highlights the changes must be submitted (highlighting of changes can be implemented by means of tracked changes, striking through "old text" and showing the "new text" in bold, underlined or in italics, or similar).
3. Additionally, one clean copy of the each amended document should accompany the written request.
4. Failure to submit both copies of modified documents and/or rationale for proposed modifications will delay the review and approval process.

2.5 Major Amendments

1. Major amendments to a currently active study are subject to full REC-H review. Examples of major amendments include but are not limited to the following:
   a. Increasing the inclusion criteria.
   b. Reducing the exclusion criteria.
   c. Emergence of new and/or serious and/or significant risks to either participants and/or researchers.
   d. Requirement for new and/or additional study documentation to be distributed to or viewed by
   e. participants that include information and/or data collection items significantly different to that in materials previously approved by REC-H.
   f. Any other change that does not qualify as a minor amendment (see list above).
2. Researchers are advised to familiarise themselves with the Amendment Guidelines prior to completing and submitting a request for a major amendment.
3. Failure to do so might result in a delay in the review and approval of the amendment request, thereby impacting on the ability of the study to continue.