NELSON MANDELA UNIVERSITY

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

- Institutional lines of authority and responsibilities
- REC-H: Composition and documentation of activities

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

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1 INSTITUTIONAL LINES OF AUTHORITY AND RESPONSIBILITIES

1.1 INSTITUTIONAL LINES OF AUTHORITY

1. REC-H reports directly to the Research Committee (REC) under chair of the DVC Research, Innovation and Internationalisation (DVC: RII).

1.2 REC-H RESPONSIBILITIES

1. REC-H is responsible for developing and implementing processes and procedures to ensure that research involving human participants meets the highest standards and norms in terms of protecting, in particular, the welfare and rights of human participants in research.
2. All research involving human participants conducted on the premises of Nelson Mandela University or on other premises under the auspices of the university must be reviewed and approved by REC-H prior to commencement of the study.
3. REC-H is authorised to perform the functions outlined below.
    a. Approve, require revisions, or disapprove all research submitted for review. The criteria used in the review of applications is based on ethical principles, regulatory guidance, applicable law, scientific merit of the methodology, sensitivity to community standards and attitudes and, where applicable, professional standards of practice and conduct. To approve research with human participants, REC-H must review the full research proposal, consent forms as well as all supplementary material, including, but not limited to, recruiting materials and data collection instruments. A description of the review and approval process is summarized in Figure 1.
    b. For negligible/minimal/low risk studies, an expedited approval process is conducted. To this end at least two (2) co-opted trained reviewers with the required disciplinary expertise from the Faculty from where the study originates review and provide relevant feedback to the applicant/researcher. All Faculty approved studies are ratified at the next REC-H meeting. As a quality control measure, REC-H inspects samples of these protocols that have been approved in an expedited manner.
    c. For ethics approval of research stemming from a support division (including those not for degree purposes) the application goes to the related faculty, and then to REC-H where relevant as per normal protocols.
    d. For medium/high risk studies, the protocol serves at the relevant Faculty Postgraduate Studies Committee (FPGSC), or equivalent where it is reviewed for scientific rigor of the methodology. Only once the proposal has been approved at Faculty level does the protocol escalate to REC-H for human ethics review.
    e. Any collaborative research is required to have the PRP affiliated with Nelson Mandela University. This includes protocols stemming from a PI registered at another university.
    f. For any study serving at REC-H, at least 2 REC-H members will review the submission in depth and lead relevant discussions at a meeting. Formal feedback to the applicant/researchers is in the form of a resolution (i.e., NOT APPROVED; RESUBMISSION; APPROVED WITH MAJOR MODIFICATIONS; APPROVED WITH MINOR MODIFICATIONS; or APPROVED WITH NO CORRECTIONS) supported by detailed anonymised mandatory and advisory feedback (form RECH-REV-01 Review Criteria and Feedback). In the case of provisional approval of an application, a REC-H member is nominated as the liaison between the committee and the applicant to ensure that the applicant comprehends and implements the feedback of the committee in a satisfactory manner so that the study is granted final approval. To be approved, all mandatory feedback is required to be addressed within a maximum period of 3 months from date of the original application serving at a REC-H meeting. Neglecting to finalise the approval of a study timeously results in the protocol being recorded as

withdrawn and the process has to commence all over again. Advisory feedback is intended to be considered at the discretion of the Faculty, PRP and PI.

g. All of the above also applies to the review of doctoral studies.
h. Conduct ongoing review of approved research at least once a year. This process is the responsibility of the PRP and PI who initiate the process with the completion and submission of a progress report (form RECH-004 Progress Report), usually submitted no later than 15 November annually. Neglecting to submit the progress report timeously might result in the suspension of the study.
i. Suspend or terminate approval of research not conducted according to sound ethical and scientific principles or regulatory requirements, or that is associated with unexpected risk or harm to participants.
j. Audit, or have a third-party audit, the conduct of the research to verify compliance with REC-H requirements and conditions, if applicable.
k. Observe, or have a third party observe, the recruitment, enrolment and consent process(es).
l. Respond to complaints about the unethical conduct of a study. REC-H must protect whistle-blowers who, in good faith, disclose unethical conduct. Refer to the section: **Error! Reference source not found.**

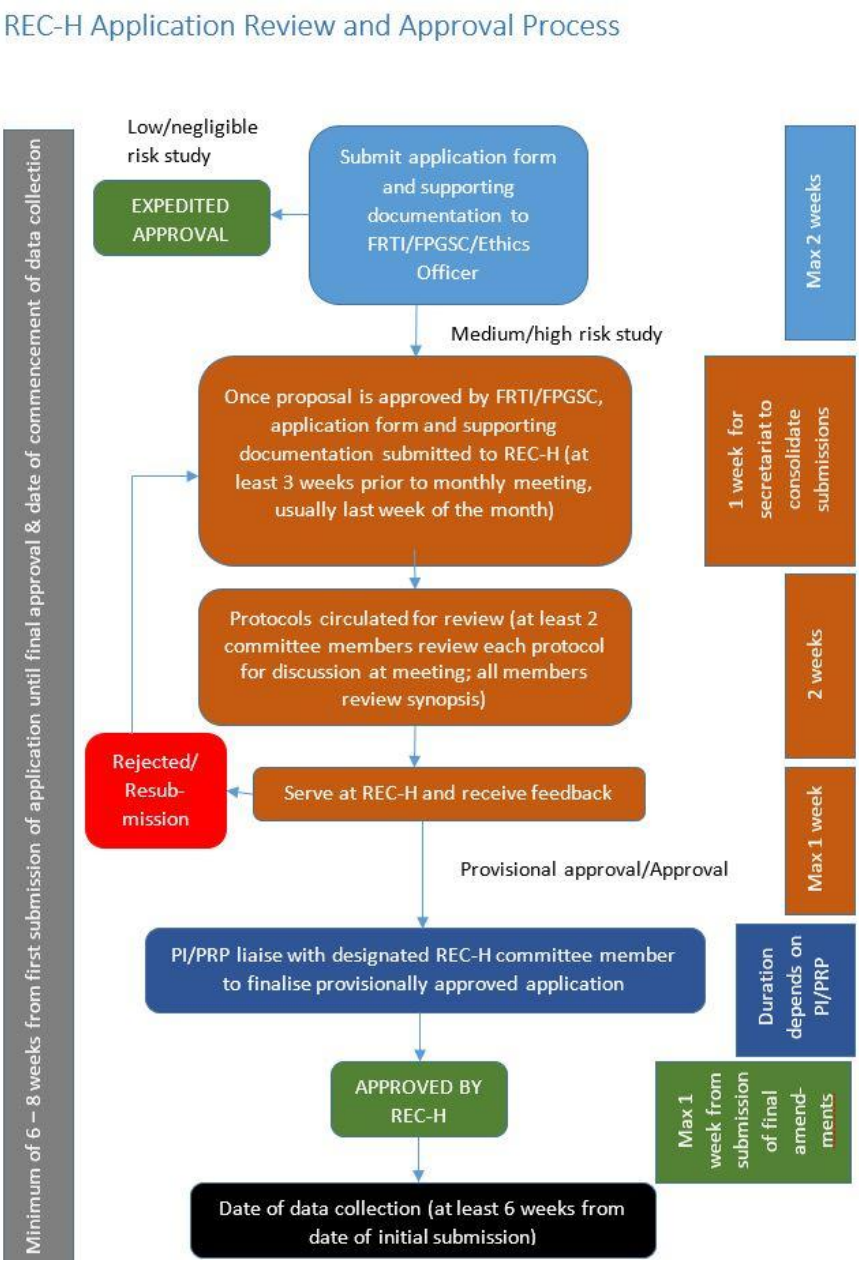

Figure 1: REC-H Application Review and Approval Process

1.3 PRP AND PI RESPONSIBILITIES

1. The Primary Responsible Person (PRP) is a full-time staff member, research associate or professional associate for an internal study, and usually the supervisor of the student in the case of the study being for the purposes of acquiring a qualification.
2. In the case of a reciprocal study with a university registered with the NHREC, the PRP should be the main researcher who obtained ethics approval from the institution he/she is affiliated to.
3. In the case of a study where:
   a. the main PRP is from another university,
   b. and the PI is a staff member engaging in the study for degree purposes at that other university,

c. and the study involves the collection of data from Nelson Mandela university students or staff,
d. an application for ethics approval must be submitted through the most related Nelson Mandela faculty,
e. with the support of a willing PRP from the related Nelson Mandela faculty,
f. and follow the usual ethics approval protocol.

4. Prior to completing and submitting an application form for review, the primary responsible person (PRP) and primary investigator (PI) are expected to familiarise themselves with the contents of at least the following documentation (available on the REC-H website)
   a. Department of Health Ethics in Health Research Guidelines (2015)[7]
   b. Department of Health Guideline 3.4.1 Major incidents and research, including public health emergencies [26]
   c. Protection of Personal Information Act (POPIA) Summary
   d. USAf adopted Code. 2020. POPIA Industry Code of Conduct: Public Universities[24]
   e. ASSAfs Code of Conduct for Research (2022 update for POPIA)[25]
   f. Nelson Mandela University Code of Conduct for Researchers
   g. Nelson Mandela University Research Ethics Policy
   h. Risk Assessment for the study (available as pp 6 – 10 of the RECH-001 application form template)
5. The PRP and PI (collectively referred to as the researchers) have the ultimate responsibility for the ethical, scientific, financial and administrative conduct of the study. All official REC-H correspondence is addressed to both the PRP and PI with a copy to the relevant faculty administrator. Any correspondence from stakeholders in the study to REC-H must be directed to REC-H via the researchers. Only in exceptional circumstances, for example in the case of suspected irregularities in a study, will REC-H accept direct correspondence from such stakeholders.
6. The researchers must:
   a. Observe and apply the ethical and regulatory principles detailed in the REC-H Standard Operating Procedures.
   b. Have thoroughly read, understood, critically analysed and be in agreement with the study protocol and all accompanying documentation including recruitment material, consent forms and survey materials (where applicable).
   c. In the recruitment information to be shared with potential participants and the consent forms, have ensured that:
      i. the application for ethics approval includes a copy of the NHREC newsletter (https://rd.mandela.ac.za/Research-Ethics/Research-Ethics-Committee-Human-(REC-H)/NHREC-Newsletter-May-2022)
      ii. participants are informed that complaints or concerns can be expressed to the researcher, REC-H, then to NHREC, and then to SAHPRA,
      iii. the REC-H ethics approval number is included in the consent form, and
      iv. the contact details of the researcher(s), the REC-H (rd@mandela.ac.za), and the relevant regulatory authority is included in the consent form.
   d. Submit prospective research for faculty peer review via the FPGSC (or equivalent) to determine its scientific merit prior to submission for ethics review. Submissions are thus conducted via the relevant FPGSC upon conclusion of a successful departmental peer review process.
   e. Be in receipt of an official approval letter from REC-H and have submitted acknowledgement and acceptance of the approval conditions to REC-H prior to the commencement of any data collection involving human participants. The approval conditions include, but are not limited to, a declaration by the researchers that they will -
      i. undertake only scientifically sound peer-reviewed research designed to produce valid results,
      ii. conduct the study according to the REC-H approved protocol,
      iii. have a working knowledge of ethical and regulatory requirements applicable to the study,

iv. possess the necessary expertise and/or qualifications to conduct the study, and conduct research within the scope of their practice or involve a co-researcher relevant for the specific discipline of the study as per the Health Professions Act and the Regulations Defining The Scope Of The Profession
v. ensure that all research personnel are adequately trained and supervised,
vi. protect the rights and welfare of participants, including their privacy and confidentiality,
vii. disclose any potential conflict of interest,
viii. follow relevant professional standards and norms,
ix. report promptly on any new information, changes or unanticipated events/problems,
x. implement changes to a study only after REC-H approval,
xi. submit progress reports, at least annually,
xii. accommodate active monitoring of the study at the request of REC-H, and
xiii. obtain annual re-approval as required.

f. Provide REC-H with comprehensive information and supporting materials about the research so that REC-H is empowered to fulfil its responsibilities to protect participants' safety and wellbeing in terms of national and international ethical and regulatory guidelines.
g. Be forthcoming and declare any conflict of interest.
h. Ensure that all research collaborators and personnel assisting with the research are listed as such.
i. Ensure that adequate resources and facilities are available to conduct and complete the study.
j. Ensure that all listed collaborators and personnel assisting with the research are appropriately qualified and competent to conduct the research component in which they are involved.
k. Ensure that, where data collection is planned to exceed one year, to apply for (for example) Phase 1 approval, then at the end of that year, an application for an extension is submitted, along with an amendment form to notify the REC-H of Phase 2 changes in methodology.
l. Ensure that all listed collaborators and personnel assisting with the research are fully informed of current and amended study procedures and requirements for recruitment, enrolment and acquiring consent form participants.
m. Address any concerns and questions raised by any member of the research team. This includes (but is not limited to) -
    i. meeting regularly with team members to review progress of the study and reflect on any arising concerns about the study in general, or any participant in particular,
    ii. reassuring team members that concerns may be raised without any fear of repercussions,
    iii. investigating concerns and responding appropriately to individuals who raised such concerns,
    iv. reporting to REC-H on any matters that raise concerns about participants' safety, compliance with the approved research protocol, informed consent violations or the integrity of the research data, and
    v. reporting to REC-H on any matters that raise concerns about research team members' safety or compliance with the approved research protocol.
n. Protect participants' privacy and the confidentiality of their data (by removing personal identifying information from data collection materials and computer files, storing codes linking individuals to data in a secure storage away from the actual data collected, and allowing access to identifying data only to authorised persons via password-protected control mechanisms) by -
    i. complying with the Mandela University research data management policy and procedure, which includes the requirements for a research data management plan and valid research consents,
    ii. completing the Mandela University privacy impact assessment to identify research projects which have critical privacy implications for research participants,
    iii. completing certified training for all PIs in research data management and privacy, and

iv. all other researchers to complete awareness training in research data management and privacy.

o. Use data and/or biological samples only for purposes approved by REC-H.

p. For research which prospectively assigns human subjects to one or more health-related interventions to evaluate the effects on health outcomes are encouraged to register such research with the South African National Clinical Trial Registry after REC-H approval has been granted. This will allow research by NMU researchers of health-related topics to be widely publicized and to maintain some exclusivity whilst the research is being conducted.

q. Ensure the ongoing ethical conduct of research approved by REC-H by -
   i. obtaining informed consent from participants or their legally authorised representatives prior to participants taking part in the study,
   ii. offering a copy of the informed consent documentation to each participant (or the participant's legally authorised representative) and keeping the record of consent for the researcher records. Researchers may delegate to suitably qualified and trained collaborators and personnel assisting with the research the authority to obtain consent; however, the researchers are ultimately responsible,
   iii. keeping participants fully informed of any new information that may affect their willingness to continue taking part in the study,
   iv. obtaining REC-H approval for any modifications to previously approved research, including extension of data collection period, changes to the informed consent process and document, except for those modifications necessary to prevent immediate hazards to participants. In the case of modifications made to the study without REC-H approval to prevent immediate hazards to participants, the researchers shall report such changes to REC-H promptly, and
   v. promptly reporting to REC-H acts of serious and/or continuing non-compliance with the current approved research protocol.

r. The signatures of the researchers (both PRP and PI) on the relevant REC-H application forms testify that the researchers are ultimately responsible for all actions, procedures and interventions performed in the study, and that these actions, procedures, and interventions performed in the study will be conducted according to applicable university, national and international ethical and regulatory policies governing research with human participants. Further, the signatures of the researchers (both PRP and PI) testify that any modifications to the protocol as originally approved or extension of data collection after the approval period has lapsed, will be submitted to REC-H for approval prior to implementation.

s. Submit progress reports in time for REC-H to carry out continuing review before the lapsing of the current approval period, in order to have the study extension approved.

t. Promptly submit to REC-H and, if applicable, sponsors and regulatory authorities any unanticipated problems or serious adverse events involving risks to participants.

u. Submit all external reports, if applicable, to REC-H.

v. Ensure that, in the situation of both expected and unexpected adverse events, every reasonable effort is made to provide the participants involved with adequate and suitable care to correct and/or alleviate the consequences of the adverse event.

w. Report any adverse event immediately to the relevant FPGSC and REC-H.

x. Maintain current and accurate records of research data, consent forms, correspondence with REC-H and sponsors, amendments and progress reports and adverse events.

y. Inform REC-H promptly, giving reasons, if the study is voluntarily terminated or suspended before the anticipated completion date.

z. Submit a closure or completion report to REC-H at the end of a research study (i.e., upon completion or suspension). In addition:

i. Honour any other commitments made at the outset of the study, including, but not limited to, the provision of feedback on the study to participants in an approved format.
ii. In collaborative research with pharmaceutical or other companies, make sure there is no interference with the right to publish.
iii. Where applicable, submit a summary of trial results to the South African Clinical Trial Register within a year of trial completion.

aa. Address concerns raised by participants before, during and after the conducting of the study.
bb. Maintain research records for a period of at least 5 years on completion of the study (15 years in the case of clinical trials).

7. A comprehensive account of the responsibilities of the principal and other investigators in clinical trials is provided in Section 3 of Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa. Second Edition, 2006.

1.4 Non-Compliance and the Principal Investigator

1. Every researcher must be familiar with the policies and regulations governing research in health.
2. Non-compliance with these policies and regulations include, but is not limited to, the following:
   a. Failure to disclose a conflict of interest.
   b. Conducting research with human participants without a protocol and / or without Human Research Ethics Committee approval.
   c. Allowing Human Research Ethics approval to expire without renewal.
   d. Not complying with the requirements of continuing review, including annual progress reports, amendments, serious adverse events and unanticipated problems.
   e. Conducting research not covered by the approved protocol or contradictory to the protocol (defined as a protocol violation).
   f. The Human Research Ethics Committee takes non-compliance seriously, and, depending on the degree of non-compliance, may open an investigation of research misconduct. See sections on protocol deviations, non-compliance, suspension and termination and compliance.

1.5 Heads of Departments and Chairs of Faculty Research Committees' Responsibilities

1. Departmental and relevant Faculty Heads and Chairpersons must ensure that -
   a. only well-designed and scientifically sound peer-reviewed research studies are submitted to REC-H for ethics review,
   b. researchers are sufficiently competent to undertake the study,
   c. postgraduate-level research meets the stringent university-wide scientific requirements for postgraduate degrees. REC-H cannot make this assessment although it will indicate when a protocol so lacks scientific merit and is deemed unethical, and
   d. all departments should be represented in their faculty ethics committee (one primary and one secundus per department) on a rotational basis.
2. The signature of the Departmental Head assures that the researchers have appropriate qualifications/training/expertise/resources to conduct the study. The signature of the relevant Faculty Postgraduate Studies Chairperson testifies that the protocol is of sound scientific design which is adequate and appropriate to answer the posed research question(s), minimises risks to human participants and has been subjected to a rigorous peer-review process within the Faculty structures.

1.6 ETHICS ADMINISTRATIVE SUPPORT RESPONSIBILITIES

1. The Research Development (RD) division provides administrative support to REC-H. Secretariat support is provided by the Record and Information Administration (RIAS) division. None of these staff is solely dedicated to the administration of REC-H.
2. Specific responsibilities include -
    a. keeping copies of the REC-H written policies and procedures,
    b. preparing and posting on the website an annual schedule of dates and deadlines for REC-H meetings and protocol submissions (REC-H meet 10 times a year, usually on the last Wednesday of each of the months February – November),
    c. providing logistical support for monthly REC-H meetings: a meeting venue, refreshments, and, if required, assisting lay members with travel arrangements,
    d. serving as a resource for researchers on general administrative information and assisting with forms and applications for REC-H review,
    e. preparing (with assistance from the REC-H Chair) and circulating the agenda prior to full committee meetings,
    f. timely distribution of meeting materials to committee members: main reviewers receive a full package of materials electronically and/or in print. All members receive synopses, consent documents, data collection instruments and recruitment aids electronically and/or in print. In addition, any member may request the full documentation of specific studies prior to a meeting.
    g. assigning studies to reviewers with assistance from the Chair, or in the absence of the Chair, with assistance from the Deputy-chair,
    h. following-up with reviewers to ensure feedback is received in time for monthly meetings,
    i. determining attendance for upcoming committee meetings,
    j. taking minutes during meetings in sufficient detail to show attendance, actions taken by the Committee and the basis for requiring changes in or disapproving studies, and a summary of controversial matters and their resolution,
    k. distributing minutes to members prior to the next meeting, and filing minutes once approved,
    l. in the week following the meeting, sending detailed feedback to researchers specifying REC-H's decision on the study and guiding on required changes, if applicable,
    m. processing and responding to all correspondence between researchers, sponsors, and REC-H,
    n. maintaining a secure database and tracking system of all studies submitted to REC-H for review,
    o. maintaining a current REC-H membership schedule (including Faculty secondi and co-opted members),
    p. referring researchers' requests for amendments and continuing reviews, adverse events information and any other related matters to the Chair, or in the absence of the Chair, to the Deputy-chair, for further action,
    q. keeping accurate records of all correspondence to and from REC-H that is not related to a research protocol, and
    r. maintaining intra-institutional relationships with relevant divisions in the University.
3. Because of the volume of active studies at any one time, the administrative support staff are unable to guarantee the timely notification of studies requiring annual renewal. Annual renewal is therefore not an automatic function. It remains the responsibility of the researchers themselves to submit a timely application to REC-H for an extension of a study.

1.7 Reciprocal Reviews

1. The Department of Health (DoH) guidelines (2015) allow for reciprocity of reviews (section 4.5.1.4) as follows:

   "4.5.1.4 Reciprocal recognition of review decisions:
   i. RECs may, at their own discretion, recognise prior review and approval of a research proposal by another registered REC to avoid duplication of effort.
   ii. Reciprocal recognition means that two or more registered RECs decide to recognize each other's prior review.
   iii. RECs that recognise prior review in this manner must determine the nature of the documents to be filed locally, which must, at minimum, include a copy of the approval letter from the other REC".
2. REC-H currently follows a reciprocal review system whereby the REC-H administrator and Chairperson acknowledges ethics clearance by other South African RECs registered with and accredited by the National Health Research Ethics Council (NHREC). Applications submitted by external researchers for reciprocal approval are assigned by the REC-H Chairperson to the Director of Research Development for review and also under extenuating circumstances, to other REC-H members.
3. Researchers external to Nelson Mandela University who have obtained ethics approval from an accredited research ethics committee, and who are requesting access to University staff and/or students for the purpose of research are required to complete and submit a request for such access a reasonable time period prior to initiating any contact with University staff and/or students. Retrospective approval of such requests is not permitted.
4. The process for external researchers to follow for requesting access to University staff and/or students for a study can be obtained on https://rd.mandela.ac.za/Research-Ethics/Research-Ethics-Committee-Human-(REC-H)/External-Parties-wishing-to-conduct-Research-using

2 REC-H: Composition and Documentation of Activities

2.1 Introduction

1. REC-H is established to oversee the safety, rights and welfare of human participants in research.
2. The composition and functions of REC-H strives to meet the minimum standards and requirements, as set out in the Department of Health (2015) *Ethics in health research: Principles, structures and processes*.
3. Details of current office bearers are available on the REC-H website.

2.2 Chairperson: Appointment and Responsibilities

1. The Chairperson is elected by REC-H members for a term of three years which is renewable for a maximum of 2 cycles.
2. The Chairperson's responsibilities are to:
   a. Lead monthly REC-H meetings.
   b. Conduct expedited reviews or delegate this task to suitably qualified individuals who may or may not be REC-H members.
   c. Identify suitable reviewers to perform initial and ongoing protocol reviews.
   d. Engage with researchers on research ethics-related issues.
   e. Compile an annual report on the activities of REC-H for submission to the Research Innovation and Internationalisation Committee, Senate and to the National Health Research Ethics Council (NHREC). The latter report is for the purpose of maintaining accreditation and registration as a

compliant health research ethics committee.

f. Participate in non-compliance investigations.
g. Contribute to the development of REC-H policies and procedures.
h. Liaise with the Deputy Vice-Chancellor via the Department of Research Development regarding appropriate and sufficient administrative support and resources to function optimally.
i. Liaise with and assist REC-H administration to prepare the agenda before meetings, and to review minutes after meetings.
j. Review and sign letters to researchers conveying REC-H's decisions relating to their submitted research protocols.
k. Consult with chairpersons of FPGSCs (or equivalent) and where appropriate advise on best practice regarding research protocol ethics reviewing.
l. Consult with Chairpersons from other human research ethics committees throughout the country in order to develop and promote best practices in research ethics oversight.

2.3 Deputy Chairperson: Appointment and Responsibilities

1. The Deputy Chairperson is elected by REC-H members for a term of three years which is renewable for a maximum of 2 cycles.
2. The Deputy Chairperson's responsibilities are to:
   a. Perform functions delegated by the chairperson, including conducting expedited reviews.
   b. Perform the functions of the Chairperson in his/her absence.

2.4 REC-H Committee members: Composition, Appointment and Responsibilities

1. The primary mandate of REC-H is to protect the rights and welfare of human participants in research. The Committee therefore requires diverse membership to provide expertise in and sensitivity to a broad range of scientific and ethical considerations.
2. Furthermore, the composition and functions of the REC-H must meet the minimum standards and requirements, as set out in:
   a. Department of Health. 2015. *Ethics in Health Research: Principles, Processes and Structures.* Department of Health: Pretoria, South Africa.
   b. Department of Health. 2006. *Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa*. Department of Health: Pretoria, South Africa.
3. According to the Department of Health requirements as stipulated in Ethics in Health Research: Principles, Processes and Structures 2nd Edition (2015) REC-H membership must meet the following requirements -
   a. at least nine members with a quorum being a simple majority,
   b. where the number of members is more than 15, the quorum may be 33%,
   c. at least one layperson,
   d. at least one member with knowledge of, and current experience in, the professional care, counselling or health-related treatment of people. Such a member might be e.g., a medical practitioner, psychologist, social worker or nurse,
   e. at least one member with professional training and experience in qualitative research methodologies,
   f. members with professional training and experience in quantitative research methodologies,
   g. a member with expertise in bio-statistics,
   h. a member with expertise in research ethics, and
   i. at least one member who is legally qualified.
4. RECH members and their respective secondi are nominated for appointment by:

a. The respective FPGSC (or equivalent) according to the number of members per faculty allocated by the REC-H:
    i. Humanities (at least 1 member)
    ii. Business and Economic Sciences (at least 1 member)
    iii. Education (at least 1 member)
    iv. Engineering, the Built Environment and Information Technology (at least 1 member)
    v. Health Sciences (at least 2 members)
    vi. Law (at least 1 member)
    vii. Science (at least 2 members)
    viii. LT Collab (at least 1 member)
b. REC-H, in the case where a shortfall of expertise and or knowledge in a particular area is identified.

5. Nominated candidates are appointed as REC-H members for a three-year renewable term if they meet at least the following criteria:
    a. Provide evidence of having successfully completed at least the following training
        i. TRREE Module 1: Introduction to Research Ethics
        ii. TRREE Module 2.1: Research Ethics Evaluation
        iii. TRREE Module 3.1: Informed Consent
        Or
        i. Macquarie University's Online Ethics Training Module for the Social Sciences and Humanities
    b. If the above has not been completed in the 3 years prior to appointment, provide evidence of any additional ethics training acquired in the 3 years prior to appointment.
    c. Have a working knowledge of the Department of Health Research Ethics Guidelines (2015) and POPI Act.
6. New appointments are staggered to ensure appropriate balance and maintain continuity. Members are informed in writing that they have been appointed on the REC-H. On appointment, RECH members are required to sign a statement undertaking that:
    a. All matters of which he/she becomes aware during the course of his/her work on the REC-H will be kept confidential.
    b. Any conflicts of interest, which exist or may arise during his/her tenure on the REC-H will be declared.
7. Members are not offered remuneration, except in exceptional cases lay members who may be reimbursed for traveling expenses to attend meetings.
8. The membership and composition of the REC-H will be continuously monitored to ensure appropriate representation. The Chairperson and Deputy Chairperson will perform an annual review of the composition, expertise and contribution of members. When a member resigns from the REC-H, the choice of a replacement takes into account the Faculty from which the member was nominated, the overall balance of the REC-H and specific expertise that is needed.
9. The university will provide protection in respect of liabilities that may arise when members are acting in good faith whilst performing their REC-H responsibilities.
10. REC-H members' responsibility include -
    a. proof of research ethics training, refreshed at least once within the period of appointment,
    b. GCP training, evident by certificate issued not more than 2 years previously, for members who review clinical trials proposals,
    c. attending meetings on a regular basis and not leaving until meetings are adjourned,
    d. attending a minimum of seven meetings per year (excluding sabbatical or other leave periods),
    e. maintaining strict confidentiality regarding information, reviews and decisions and all matters discussed at committee meetings,
    f. disclosing conflict of interest and where conflict does exist with respect to a study, not reviewing the protocol or leaving the room during discussion of and voting on the protocol,

g. indicating with a signature on the attendance register that they will maintain confidentiality of all proceedings and declare any conflict of interest.
h. respecting each other's views and the deliberative process,
i. deciding independently if the design and conduct of proposed studies will protect participants' safety, rights and welfare,
j. remaining impartial and objective when reviewing protocols,
k. serving as main reviewer at the request of the Chairperson, preferably but not necessarily, in their areas of expertise,
l. serving as general reviewer of all research discussed at committee meetings,
m. deciding by vote or consensus, whether to approve, require revisions, not approve or defer studies following deliberation at committee meetings,
n. performing expedited reviews **of minimal risk studies**,
o. keeping up to date with national and international research ethics and regulatory guidance, and
p. taking part in research ethics-related continuing education.

2.5 Ad Hoc/Co-opted Reviewers: Appointment and Responsibilities

1. REC-H may make use of *ad hoc* reviewer(s) to evaluate specific protocols. Such reviewers may be asked to review a specific protocol or attend a meeting to provide expert opinion on any relevant issue under consideration by REC-H. Such reviewers -
   a. must have access to the relevant study documentation, submitted to REC-H,
   b. may attend the relevant REC-H meeting, contribute to the discussions, make recommendations, but may not vote,
   c. must declare no conflict of interest in respect of the relevant study under review,
   d. must pledge confidentiality regarding the specific protocol and the meeting proceedings by signing a confidentiality and non- disclosure agreement, and
   e. may provide information about a specific study by written report, attending the meeting or both.
2. Where expedited approval of minimal risk studies is required, REC-H may make use of appropriately trained reviewers as co-opted reviewers from the faculty from which the studies originate to evaluate specific protocols. Such reviewers may be asked to review a specific protocol or attend a meeting to provide an opinion on any relevant issue under consideration by REC-H. Such reviewers -
   a. must have access to the relevant study documentation, submitted to the Faculty and REC-H,
   b. may attend the relevant REC-H meeting, contribute to the discussions, make recommendations, but may not vote,
   c. must declare no conflict of interest in respect of the relevant study under review,
   d. must pledge confidentiality regarding the specific protocol and the meeting proceedings by signing a confidentiality and non- disclosure agreement, and
   e. may provide information about a specific study by written report, attending the meeting or both.
3. At the very least, co-opted reviewers must have:
   a. Successfully completed at least the following <u>training modules -</u>
      i. TRREE Module 1: Introduction to Research Ethics
      ii. TRREE Module 2.1: Research Ethics Evaluation
      iii. TRREE Module 3.1: Informed Consent

      Or

      i. Macquarie University's Online Ethics Training Module for the Social Sciences and Humanities
   b. If the above has not been completed in the 3 years prior to being requested to conduct the review, provide evidence of any additional ethics training acquired in the 3 years prior to appointment.
   c. Have a working knowledge of the Department of Health Research Ethics Guidelines (2015) and POPI Act.

4. Co-opted reviewers are, for each study reviewed, required to submit a written review on the study for safe keeping by REC-H. The FPGSC (or equivalent) records and summarises the contributions of all co-opted reviewers for tabling at a REC-H meeting.

2.6 Observers and Guests

1. Observers and guests may attend a REC-H meeting at the Chairperson's discretion or invitation. Such observers and guests -
   a. do not contribute to the quorum, and
   b. must pledge confidentiality with respect to the protocols and proceedings by signing a confidentiality and non-disclosure agreement.

2.7 Ex-officio Members

1. Ex-officio member means an individual is an automatic committee member by virtue of the individual's status. Ex-officio representatives on the committee are:
   a. Deputy Vice-Chancellor Research Innovation and Internationalisation (DVC: RII).
   b. Director of Research Development (RD).
   c. REC-H Administrative support staff.
2. Ex officio members -
   a. may participate in REC-H's deliberations to provide information and expertise,
   b. may not vote on any REC-H decision, and
   c. must comply with REC-H's conflict of interest requirements.

2.8 Quorum

1. Except when an expedited procedure is used, the REC-H must review initial and continuing studies at committee meetings at which a quorum is present. A quorum is considered to be upheld if 50% + 1 of appointed REC-H members, including the Chair- and Deputy Chairperson, are in attendance. A quorum must be maintained for each vote. If a quorum fails at any point during a meeting, further studies cannot be approved and must be held over until the next convened meeting.
2. Any member with a conflict of interest with respect to a specific study must leave the room during deliberations and decision-making relating to the study. This member may not vote on the study. Voting by proxy is not allowed. Ad hoc/co-opted reviewers and ex officio members may not vote.
3. Generally, decision-making at REC-H meetings is by consensus. At the Chairperson's discretion, voting may be decided by a show of hands.

2.9 Permissible Actions of REC-H on Review

1. On review the full committee may:
   a. Approve the protocol with no corrections, implying that no change to any aspect of the protocol or consent forms are required.
   b. Approve the protocol with minor modifications, implying that a simple agreement is required from the researcher and that the Chairperson, or a designee could approve the researcher's compliance via an expedited procedure.
   c. Approve the protocol with major modifications based on the magnitude and/or number of concerns identified. The Committee will decide whether the revisions must be submitted to a convened meeting, the main reviewer(s), the Chairperson, or a designee for a decision to approve or require further changes.
   d. Reject/not approve the protocol.

e. Not approve the protocol in its present form and call for a re-submission of the protocol.
f. Defer a decision until the following meeting. A protocol may be held over to the next convened meeting for one or more of the following reasons:
    i. Lack of appropriate expertise at the meeting.
    ii. Insufficient information to conduct an adequate review.
    iii. Loss of a quorum.
    iv. Lack of time.
g. Condone the approval given by co-opted reviewers from relevant FPGSC (or equivalent) to minimal risk protocols.

2.10 Conflict of Interest

1. Conflict of interest of a REC-H member generally includes the following:
    a. Relationship to the research study: The REC-H member (his/her spouse or immediate family member) is listed as -
        i. one of the research team members of the study,
        ii. one of the supervisory team of a postgraduate student's study,
    b. Personal relationship: The REC-H member has an immediate family relationship or other close relationship with one of the researchers (immediate family' means the REC-H member's spouse or domestic partner and dependent children).
    c. A financial interest: The REC-H member holds significant equity or stock options, receives or expects to receive compensation with a value that may be affected by the outcome of the study, has an ownership interest (including patent, trademark or copyright interest) in the drug, product or technology that is the subject of the research, or receives a significant amount annually as a salary, consulting income or other compensation from the sponsor.
    d. A fiduciary relationship to the sponsor: The REC-H member serves as an executive to a company sponsoring the research or serves on the company's board of directors.
    e. Other examples of conflicting interests include but are not limited to the following:
        i. Committee member has an interest that he/she believes conflicts with the member's ability to review a protocol objectively.
        ii. Committee member is in direct competition with the investigators for limited resources, funding, sponsorship or research participants, or the Committee member is considered a personal or professional adversary of the investigator. Since such situations may depend on the circumstances, the Committee member should raise such a situation as soon as possible with the Chairperson. The standard used by the Chairperson is whether an independent observer could reasonably question whether the individual's actions or decisions would be based on factors other than the rights, welfare and safety of participant.
        iii. Any other reason for which the Committee member believes he/she has a conflicting interest with the research.
2. The procedure to follow when a conflict of interest is identified:
    a. The REC-H member discloses those interests that pertain to the subject of the research proposal and that might otherwise reasonably be perceived to affect their independent unbiased judgment with respect to the review of the protocol or related matters.
    b. The REC-H member should not accept the relevant protocol for review and should return it for assignment to another reviewer.
    c. The Chairperson must ensure that the relevant REC-H member does not participate in the discussions or vote on the protocol and leaves the room.
    d. Should the Committee need information on the study from the member with a conflicting interest, the member may remain in the meeting room during the presentation of the study. The member

must then leave the meeting room during the deliberative discussion and voting on the protocol.

e. The REC-H member with a conflict of interest will not be counted as part of the quorum for the review of the study. If the quorum fails, the Committee cannot take further action or vote on the study.
f. The name of the person leaving the room due to a conflict of interest will be recorded in the Minutes as recused.
g. In the event that the conflict of interest involves the Chairperson, he/she will appoint the Deputy Chairperson, or another member as acting chairperson (with approval of the REC-H). The acting chairperson will conduct the meeting, for the remainder of the discussion of the item in question.

2.11 Minutes and Record Keeping of REC-H Activities

1. REC-H will have 10 meetings per year.
2. Prior to a scheduled meeting, the agenda and supporting documents are prepared by the Administrator.
3. After being approved by the Chairperson they are electronically circulated to REC-H members.
4. Documenting the activities of REC-H is via minutes of Committee meetings and comprehensive record keeping of protocols reviewed by the Committee. Minutes should be:
    a. A reflection of the agenda of the meeting and must record the discussion and action taken on each agenda item.
    b. An accurate reflection of the matters considered and the justification for the subsequent decisions taken.
    c. Detailed enough to reconstruct its decisions at a later date if necessary to protect itself and the institution.
    d. Such that it shows concern for participant's rights, safety and well-being.
5. Draft minutes are reviewed by the Chairperson prior to distribution.
6. Corrections or comments on the minutes are made at the following convened meeting. If none is made, a motion to approve the minutes is made and voted on. After approval, the REC-H administrative staff member files a copy of the minutes in the REC-H record depository. The REC-H Secretariat also keeps copies of all documentation (agenda, minutes, protocols and approval letters) on the secure University Scorpio Drive.
7. Approved minutes are distributed to REC-H members, Research Ethics Committee (REC) for their records. Action memos are distributed to PI, PRP and relevant REC-H liaison person.
8. Minutes must include at least the following:
    a. Starting time, end time, date and location.
    b. Approved changes to and final approval of minutes of previous meeting.
    c. Attendees and their relevant designations (or reasons for attending if not an official REC-H member).
    d. Which and when a member was recused from discussions and voting due to a conflict of interest. The minutes will also indicate whether prior to recusing him/herself the member remained in the room to provide information at the committee's request.
    e. For all protocols under review at the meeting, the minutes must reflect:
        i. The REC-H reference number, names of PRP and PI, and study title.
        ii. Deliberations, actions and votes (if applicable) on each study undergoing initial or continuing review, and each amendment or revision requiring full-committee review.
        iii. Actions taken: voting is recorded as follows:
            - Not approved
            - Resubmission
            - Approved with minor modifications
            - Approved with major modifications
            - Approved with no corrections

- Deferred

iv. If a protocol is approved conditionally (i.e. revisions are required before approval), the minutes must state whether subsequent revisions and/or recommendations are required to be reviewed by the Chairperson, a designee or by the full committee.
v. Reasons for specific decisions.
vi. Duration of approval, usually 1 year.
vii. The minutes will include a summary of the discussion of controversial issues and resolutions. Opinions expressed by members will be reported impartially and shall not be attributed to them by name.
viii. Minutes will not be made available to others outside the university administration unless otherwise required by law or external regulations.
ix. Expedited/electronic approvals and any other relevant matters discussed will be captured in the minutes.

9. Meeting resolutions and relevant feedback on the studies are communicated to the PI (with a copy to the PRP as well as the relevant REC-H designee) within three to six days working days of the REC-H meeting. The following information is included in the feedback to researchers upon the study serving at a meeting:
   a. Protocol reference number.
   b. Title of the study.
   c. The Committee's decision: approved, revision required (minor or major), not approved, deferred, resubmission.
   d. Date of meeting.
   e. If revisions are required, a list of conditions with reasons, and a statement that the study may not begin until the researcher receives formal notification of REC-H approval after review of the response to the revisions.
   f. If disapproved, the reason for the decision.
   g. If deferred, the reasons why the study had to be held over until the next meeting.
10. Upon approval of a study, a letter of approval, including any standard regulatory requirements and/or conditions that must be agreed to before approval, is clearly outlined in a letter drafted by the REC-H Secretariat. Usually, a standard set of conditions is applicable, but in exceptional circumstances the Chairperson or in his/her absence the Deputy Chairperson reviews and signs the approval letter which is then forwarded to the PI (with a copy to the PRP as well as the relevant FPGSC, or equivalent). The following information is included in each letter of approval:
    a. Protocol reference number.
    b. Title of the study.
    c. If approved, the duration of approval and date of approval.
11. The final approval letter reminds the researchers of ethical and regulatory requirements governing their research and these may include:
    a. The study must be conducted in strict accordance with the protocol approved by REC-H.
    b. Any changes to the protocol or relevant consent documents must be approved by REC-H before implementation.
    c. Adverse events or unanticipated problems must be reported promptly to REC-H.
    d. Participants must receive a copy of the consent form, where requested.
    e. The PRP and PI take responsibility for the study conduct.
    f. Future correspondence must include the protocol reference number, study title and its current status.