NELSON MANDELA UNIVERSITY

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

- Protocol review process
- Appeals process

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1 PROTOCOL REVIEW PROCESS

1.1 POLICY

1. All protocols must undergo scientific review by a departmental research committee or other equivalent body prior to submission to the Human Research Ethics Committee. In turn, protocols must undergo ethical review by the Human Research Ethics Committee prior to commencement of a study.

1.2 PURPOSE

1. The purpose of this policy is to outline requirements or criteria for scientific and ethical review and describe the process of full-committee and expedited ethical review.

1.3 DEPARTMENTAL SCIENTIFIC REVIEW

1. Departments, Divisions or Institutes are responsible for establishing an explicit and formal scientific review process that evaluates the scientific merit and potential risks of each protocol before that protocol is submitted to the Human Research Ethics Committee. The Committee retains the authority to examine a study's scientific design to determine its impact on the safety and well-being of potential participants.
2. Scientific quality is improved when study objectives and methods are clearly thought through and described. A well-written protocol facilitates high quality science and is an invaluable tool as investigators develop and conduct their studies. A protocol is the formal design or detailed action plan of a study. The protocol explains what will be done, when, how, where, and why.
3. The research question and methodology must be presented in enough detail to permit evaluation of the scientific merit of the study. At a minimum any protocol, including retrospective chart or database reviews, requiring departmental scientific review must include the following elements:
    a. Study purpose and rationale
    b. Description of study population, inclusion, and exclusion criteria
    c. Statement of recruitment practices
    d. Sample size and how sample size was determined
    e. Design and detailed description of methodology
    f. Definition of end points
    g. Measurement instruments, data collection forms
    h. Data analysis plan
    i. Ethical considerations
    j. References
4. The following criteria, where applicable, should be considered during the scientific review of quantitative or clinical research:
    a. Are the specific aims, research questions and corresponding hypotheses clearly stated?
    b. Are the primary and secondary outcomes (endpoints) stated and defined?
    c. Is the literature review adequate, current, and relevant (wherever possible, the literature review must include pertinent references to local research in the proposed field of study)?
    d. In the context of previous studies, what is the contribution of the present research?
    e. Will the question or hypothesis being tested add important knowledge to the field?
    f. Are there adequate preliminary data in the literature (or pilot studies) to justify the research?
    g. Will the study design (e.g., cross-sectional survey, medical record review, clinical trial) address the study's aims and objectives?
    h. Is it feasible or reasonable to achieve the results in the proposed time frame, including the time to recruit, retain, or follow participants?

i. Are the proposed tests or measurements appropriate, valid, and reliable to answer the scientific question in the local context?
j. Are ALL the proposed tests or measurements needed to answer the scientific question?
k. Is the use of socially constructed categories, such as race, ethnicity, gender, adequately justified, for instance is the use of racial classification required by the funding agency? Have these categories been explicitly defined?
l. Are the individuals conducting the research properly qualified and trained to perform the study interventions or measurements?
m. Does the research present risk to participants and, if so, is it acceptable?
n. Does the research design minimise risk to participants?
o. How do the risks of the new treatment or therapy compare to standard treatment or therapy?
p. Is any standard of care denied as part of this study?
q. If the study includes a placebo or a requirement to withhold treatment that might present a risk (no matter how small) to participants, are these interventions essential for the conduct of the study? Have or should other designs be considered?
r. Is the location of the study adequate to assure participants' safety and comfort (e.g. appropriate equipment for monitoring and emergencies, a child-friendly setting for paediatric research)?
s. Is there an appropriate plan for safety monitoring? Is there a need or plan for performing an interim data analysis? Is there a need for an independent data and safety monitoring board? Are there explicit, operationally defined stopping rules?
t. Is the study adequately powered and statistically sound?
u. Are potential limitations or criticisms of the study discussed?
v. Is there a plan for disseminating the findings?
w. Is the bibliography complete? Is the style of referencing consistent?
x. Are the ethical issues described and justified? Although assessment of ethical issues is not a requirement of scientific review, it makes sense to highlight ethical omissions or to seek research ethics advice prior to submission for Human Research Ethics Committee review.

5. The following criteria should be considered during the scientific review of qualitative research:
   a. Is the phenomenon of the study clearly stated?
   b. Is the aim of the study clearly stated and related to the strengths of a qualitative design?
   c. Is the significance of the study adequately explained?
   d. Are the variables operationally defined?
   e. Is the literature review clear? Does it identify gaps in the literature, is it appropriately detailed depending on the qualitative method chosen, and does it discuss the major concepts being studied?
   f. Is the theoretical premise of the method clearly described?
   g. Is the design clearly described and appropriate?
   h. Are the population and sample clearly described?
   i. Is the method of sample selection appropriate and clear as to how the researcher will determine when adequate sampling has occurred?
   j. If the sample size cannot be delineated before the study begins, are a rationale and plan provided?
   k. Is the procedure for data collection explicit and appropriate for the specifically chosen qualitative design?
   l. Are data analysis plans explicit, appropriate to the question and design, and complete with plans to address the rigor of data collection and analysis?
   m. Are the limitations stated, complete and appropriate to the specifically chosen qualitative design?
   n. Does the researcher demonstrate an understanding of the qualitative paradigm and method chosen?
   o. Does the researcher have experience in conducting qualitative research?
   p. Is the scope of the study feasible within the available time and resources?

1.4 Human Research Ethics Committee Review

1. The primary responsibility of the Human Research Ethics Committee is to safeguard the rights and welfare of human participants. Therefore, a principal investigator must provide enough information for the Committee to determine that human participants will be adequately protected and that the research will comply with ethical and regulatory requirements.

1.5 Requirements for Human Research Ethics Committee Review

1. The following criteria should be considered when an investigator is preparing a protocol for submission for Human Research Ethics Committee review:
    a. Specific Aims, Background and Significance
        i. Are the study aims and objectives clearly specified?
        ii. Are there adequate preliminary data to justify the research?
        iii. Are adequate references provided?
        iv. Why is this research important to conduct?
        v. Why is it worth doing in this particular setting?
    b. Scientific Design
        i. Is the scientific design adequate to answer the study's questions?
        ii. Is the scientific design adequately described and justified?
        iii. Does the study involve a placebo?
        iv. If so, why is a placebo needed?
        v. Could the study be done without a placebo?
        vi. Are study aims and objectives achievable in the given time frame?
        vii. Does the protocol have scientific merit?
        viii. Do the principal and co-investigators have adequate experience to conduct the study?
    c. Inclusion and Exclusion Criteria
        i. Are inclusion and exclusion criteria clearly stated and reasonable?
        ii. Are any individuals inappropriately included as participants?
        iii. Are any individuals inappropriately excluded as participants?
        iv. Does the study include vulnerable groups such as children, prisoners, psychiatric patients, individuals with impaired decision-making capacity? If yes, are adequate safeguards included to protect their rights and welfare?
        v. Is the inclusion of vulnerable populations justified?
        vi. Can the study be done without involving vulnerable populations?
        vii. Will the study target or exclude a particular ethnic or language group?
        viii. Who, in the research team, will decide if an individual participant is eligible?
        ix. Is the selection of participants appropriate for the question being asked?
        x. Are laboratory parameters appropriate?
    d. Recruitment and Enrolment
        i. Are recruitment methods well-defined?
        ii. How and by whom will individuals be identified for recruitment into the study?
        iii. Is the individual responsible for recruitment suitable for the task?
        iv. Is the location, setting, and timing of recruitment acceptable?
        v. Are all recruitment materials submitted and acceptable, e.g. flyers, posters, advertisements, radio announcements?
        vi. Are procedures for screening participants prior to recruitment acceptable?
        vii. If recruitment will occur during a critical or stressful period, what precautions are in place to assist voluntary decision-making?

e. Research Procedures
   i. Are the rationale and details of research procedures adequately described and acceptable?
   ii. Is there a clear differentiation between research procedures and standard of care?
   iii. Are there adequate plans to inform participants about specific research results, e.g. incidental findings, clinically relevant findings?
   iv. Are there adequate plans to inform participants about specific research results that might affect their decision to continue participation?
   v. Are individuals who are performing procedures adequately trained?
   vi. Is the location for performing procedures acceptable?

f. Drug, Device and Biologics Considerations
   i. Is the status of the drug or device adequately described?
   ii. If necessary, is the supporting documentation from the sponsor included with the submission; for example, investigator's brochure, package inserts/ labelling, South African Health Products Regulatory Authority (SAHPRA) approval?
   iii. What has the preclinical or initial clinical research shown?
      - Does any evidence suggest the possibility of clinically significant toxicities, such as carcinogenesis or teratogenesis?
      - Is there any evidence of immunogenicity?
      - Is there any evidence to suggest either that it may be unsafe to undertake the study or to justify special safety monitoring?
   iv. Are the drug dose and route of administration appropriate?
   v. Are the drug or device safety data sufficient to warrant the proposed phase of testing?
   vi. If the study involves a marketed drug or device for an unapproved or off-label indication is South African Health Products Regulatory Authority (SAHPRA) approval necessary?
   vii. Does the protocol describe acceptable measures for storage, access and control of the drugs, devices or biologics?

g. Risks and Benefits
   i. Are risks and benefits adequately identified, evaluated and described, including physical, psychological, social, and economic?
   ii. Are there risks to the community or a particular group of individuals, e.g. stigmatisation?
   iii. Do risks stated in the protocol match the risks described in the informed consent form?
   iv. Are risks reasonable in relation to anticipated benefits?
   v. Are risks reasonable in relation importance of knowledge to be gained?
   vi. Are risks minimised to extent possible?
      - Study uses procedures which are consistent with sound research design.
      - Study uses procedures which do not unnecessarily expose participants to risk.
      - Where possible, study procedures are already being performed on participants for diagnostic or treatment purposes

h. Process of Obtaining Informed Consent and Assent
   i. Is the process well-defined?
   ii. Does the process minimise the possibility of undue influence?
   iii. Does the process provide sufficient time, privacy, and an adequate setting for participants to decide?
   iv. Who will obtain consent or assent? Is the individual obtaining consent or assent adequately trained?
   v. Is the setting where individuals are being recruited or would report for research-related activities the same as where they are seen for clinical care? If so, this may cause confusion about what is research activity and what is standard care.
   vi. Are issues relating to participants' comprehension considered?

vii. How will a researcher decide if a participant has decision-making capacity to choose to enrol in a study?
viii. Is the language used in the consent form appropriate for participants' level of understanding?
ix. Are terms such as 'randomisation' clearly defined and illustrated (e.g., like flipping a coin)?
x. Will an interpreter be necessary to obtain consent?
xi. Will consent forms need translation? Participants are entitled to information in the language of their choice.
xii. Do consent forms include all the elements needed to comply with regulatory and ethical standards

i. Privacy and Confidentiality
   i. Privacy refers to persons and to their interest in controlling access of others to themselves. Confidentiality refers to data. (See related policies: Collection of Data or Biological Specimens for Research and Databases, Registries and Repositories)
   ii. Are provisions to protect participants' privacy adequate? If participants will be contacted in person, it should be by someone who has reason to know confidential information.
   iii. Are provisions to protect confidentiality of data during and after research adequate?
   iv. Are provisions for storage, coding and use of identifiers adequate?
   v. If the data are not going to be destroyed, who will be responsible for maintaining anonymity, confidentiality and security over time?
   vi. In the case of focus groups, are participants told that confidentiality cannot be guaranteed as group members may disclose what was discussed when they leave the research setting?
   vii. If audio or videotaping is used, how will tapes be stored and for how long?

j. Storage of Human Biological Specimens
   i. Will the study generate new samples, use existing samples or both?
   ii. If the study uses existing samples, how were they obtained and were donors informed of their intended use?
   iii. If samples are identifiable, how will donors' privacy and confidentiality be protected?
   iv. Will biological specimens be stored for future use?
   v. In the case of uniquely identified specimens, especially those containing genetic material, do the participant and his family understand where and how their genetic material will be stored and protected and who will have access to it and why?
   vi. How will this understanding be verified, and what will be done if a participant withholds or withdraws consent for such a donation?
   vii. Does the PI anticipate potential future use of samples, given technological progress? If so, is this addressed in the informed consent form?
   viii. Does the PI anticipate sharing the samples with other investigators? Is this addressed in the informed consent form

k. Data Analysis and Monitoring
   i. Does the protocol include a well-formulated plan for interpretation of data and statistical analysis?
   ii. Is the rationale for the proposed number of participants reasonable?
   iii. Are the plans for data and statistical analysis defined and justified, e.g., stopping rules, end points?
   iv. Are there adequate plans for monitoring data?
   v. Is a data safety monitoring board part of the study? If so, where is the board located, who are its members, and how will the principal investigator communicate with the board? Is it independent?
   vi. In the case of non-interventional or qualitative research is there a mechanism, such as a reference or event monitoring group, to provide ongoing oversight and impartial analysis of

unanticipated incidents?

l. Resources
   i. Are the resources to conduct the study appropriate and sufficient (equipment, staff, space, funding)?
   ii. Will counselling or support services be available, if required?

m. Reimbursement
   i. **Note**: Financial or other forms of compensation are not considered to be a benefit but rather recompense for research-related inconvenience.
   ii. Is the compensation to participants reasonable?
   iii. If the participant does not complete the study, will compensation be pro-rated?
   iv. Are there adequate plans to avoid out-of-pocket expenses and costs incurred by participants (e.g., travel expenses, parking costs, and lost wages)?
   v. If children or adolescents are involved, who receives the compensation?
   vi. Does compensation cover extra costs when parents or caretakers are expected to accompany participants on research visits?

n. Insurance
   i. Is there provision for insurance for research-related injuries, if applicable?
   ii. In the case of investigator-initiated research, is there cover in terms of NMU's insurance policy?
   iii. For clinical trials involving human participants, does it comply with the SAHPRA guidelines[30] for liability insurance for clinical trials?
   iv. For clinical trials involving human participants, does it comply with ABPI Guidelines[31] on Insurance and compensation in the event of an injury in for commercially sponsored research?

o. What Happens at the End of the Study?
   i. In the case of Phase III safety and efficacy trials, will the investigational intervention, if proven safe and efficacious, be offered to participants at the end of the study and under what conditions; for example, until the drug is licensed in South Africa or for a specified period? If a sponsor does not intend to provide post-trial access, the informed consent document must spell out in bold lettering:
      - That even if a participant's condition improves on the study drug it will no longer be provided by the sponsor at the end of the study.
      - How participants/patients will be managed at the end of a clinical trial, for example will they resume their previous treatment regimen?
   ii. Will the study offer long-term benefits to the community in the form of capacity building and/or medical or research infrastructure?
   iii. If proven safe and efficacious, is it likely that the investigational drug will be available in an open- label extension study?
   iv. How will participants be informed of important findings?
   v. How will findings be disseminated to the wider population and research community?

p. Stakeholder Participation
   i. Who are the major stakeholders in the research? Describe how those affected by the study can express their views, clarify their needs, and contribute to the research.

q. Conflicts of Interest
   i. Will any research staff receive incentives for recruiting participants or for any other purpose directly related to the study?
   ii. Do any personnel involved in the design, conduct or analysis of the research have any proprietary interests (e.g., royalties, patents, trademarks, copyrights, or licensing agreements) involving any agent, device or software being evaluated in the study?

r. General
   i. Does the study comply with the latest version of the Helsinki Declaration?
   ii. Is there a table of contents for long protocols so that submissions are easier to read and review?
   iii. Are pages numbered consecutively?
   iv. Has the principal investigator or a colleague proofread the proposal and performed a spell-check?

1.6 Primary Reviewer System

1. The Human Research Ethics Committee uses a system of primary or main reviewers for initial reviews, continuing reviews, and reviews of amendments and adverse or unanticipated events.
2. The Chair and/or Deputy Chair selects two or three primary reviewers for reviews requiring full committee review based on members' knowledge, experience, or expertise.
3. If a Committee member or consultant believes that he or she cannot be a reviewer for any reason, including lack of expertise or a conflict ofinterest, the Chair or administrative staff should be notified immediately.
4. If no Committee members have the required expertise, a consultant will be invited to perform the review.
5. The Chair, Deputy Chair or designee serves as primary reviewer for research meeting the criteria for expedited review.
6. Each Committee member must receive sufficient information to be able to take part actively and constructively in the discussion of the protocol.

1.7 Responsibilities of Primary Reviewers

1. Primary reviewers must:
   a. Conduct an in-depth review of the research materials using review criteria outlined under 'General Requirements for Human Research Ethics Committee Review'.
   b. At reviewers' discretion, contact investigators directly or via the administrative staff to clarify issues identified during the review.
   c. Lead the discussion on the initial or ongoing reviews at full committee meetings.
   d. Submit a written report for presentation if unable to be present at the convened meeting.
   e. At reviewers' discretion, make 'editing' recommendations directly onto consent forms in legible handwriting. Documents with suggested changes can be returned to investigators.
   f. Make a decision for expedited reviews (approve, require revisions, send for full committee review).

1.8 Categories of Review

1. Expedited Review

   a. The type of review depends on the level and type of risk involved. Expedited review is a valuable mechanism that allows the Human Research Ethics Committee to triage studies to an appropriate level of review. This means that the time and resources of full committee meetings can be concentrated on protecting participants facing the greatest levels of risk or discomfort. Criteria for approval by expedited review are the same as those of the full committee and the expedited review should be as substantive and rigorous as that of a convened meeting.
   b. The Chair or Deputy Chair has the final responsibility for determining which new protocols, continuing reviews and amendments are eligible for expedited review and has the authority to designate one ormore experienced Committee members to perform an expedited review. No member with a conflict of interest may serve as a reviewer for any expedited item. A monthly

report of all research approvedthrough an expedited procedure is distributed to members before the full committee meeting.

2. Eligibility for Expedited Review

a. Types of research that may undergo expedited include:
   i. Research classified as no greater than minimal risk, depending on the details of the study. Minimalrisk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations.
   ii. Annual renewals of studies that initially qualified for expedited review or were determined to be minimal risk at a convened Committee meeting, provided no serious adverse events or ethical problems have occurred.
   iii. Amendments to previously approved research where changes to the study protocol or consent documents do not result in significantly increased risk to participants.
   iv. When, in the Chair's opinion, using an expedited procedure would be in the public interest.
   v. Additional categories of minimal risk research as defined by a convened Committee meeting.

3. Applicability Criteria

a. Research activities that:
   i. Present no more than minimal risk to human participants, and
   ii. Involve only procedures listed in one or more of the following categories.
b. The categories in the list below apply regardless of participants' age, except as noted.
c. The expedited process may not be used where identification of participants and/or their responses would reasonably place them at risk of criminal or civil liability; be damaging to their financial standing, employability, insurability, or reputation; or be stigmatising, unless reasonable and appropriate protections are implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
d. The expedited process may not be used for classified research involving human participants.
e. Categories one to seven pertain to both initial and continuing review.

4. Research categories

a. Category 1: Clinical studies of drugs and medical devices only under the following conditions:
   i. Research on drugs for which an investigational new drug application is not required,but only if the research does not significantly increase the risks, or decrease the acceptability of the risks, associated with the use of the product.
   ii. Research on medical devices for which (i) an investigational device exemption application is not required, or (ii) the medical device is cleared or approved for marketing and the medical device will be used according to its cleared or approved labelling.
b. Category 2: Collection of blood samples by finger prick, heel stick, ear stick or venipuncture as follows:
   i. From healthy, non-pregnant adults who weigh at least 50 kg. Amounts drawn may not exceed 550 ml in an eight-week period and collection may not occur more frequently than two times per week; or
   ii. From other adults and children, considering age, weight and health, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. The amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an eight-week period and may not occur more than two times per week.
c. Category 3: Prospective collection of biological specimens for research purposes by non-invasive means. Examples:
   i. Hair and nail clippings in a non-disfiguring manner.
   ii. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction.
   iii. Excreta and external secretions, including sweat.

iv. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or applying a dilute citric solution to the tongue.
v. Placenta removed at delivery.
vi. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labour.
vii. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished according to accepted prophylactic techniques.
viii. Mucosal or skin cells collected by buccal scraping or swab, skin swab, or mouth washings.
ix. Sputum collected after saline mist nebulisation.

d. Category 4: Collection of data through non-invasive procedures (that do not involve general anaesthesia or sedation) routinely employed in clinical practice, excluding procedures that involve X-rays or microwaves. Where medical devices are employed, they must be cleared or approved for marketing. Examples:
i. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy.
ii. Weighing or testing sensory acuity.
iii. Magnetic resonance imaging.
iv. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography.
v. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given age, weight and health of the individual

e. Category 5: Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes such medical treatment or diagnosis.

f. Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.

g. Category 7: Research on individual or group characteristics or behaviour (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behaviour) or research that employs survey, interview, oral history, focus group, programme evaluation, human factors evaluation, or quality assurance methodologies.

h. Category 8: Continuing review of research previously approved by the convened IRB as follows:
i. The research is (i) permanently closed to the enrolment of new participants, and (ii) all participants have completed all research-related interventions, and (iii) the research remains active only for long-term follow-up of participants; or
ii. No participants have been enrolled and no additional risks have been identified; or
iii. The remaining research activities are limited to data analysis.

i. Category 9: Continuing review of research, not conducted under an investigational new drug application or investigational device exemption, where categories two (2) through eight (8) do not apply, but the REC-H has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

1.9 Full Committee Review

1. All research involving greater than minimal risk is reviewed at a full committee meeting where at least 30% of voting members are present and including at least one member whose primary concerns are non-scientific.

1.10 Initial Reviews

1. For initial reviews requiring full committee approval, the following materials are sent to the primary reviewers about three weeks before a scheduled meeting:
   a. Human Research Ethics Committee application.
   b. Full research protocol, including sponsor-generated protocol for commercial trials.
   c. Investigator's brochure, if applicable.
   d. Informed consent and assent documents in English (translation is required only once the English version is approved).
   e. Recruitment materials such as advertisements, flyers, posters.
   f. Questionnaires, surveys, interview or focus group scripts and assessment tools or scales.
   g. Genetic addendum, if applicable.
   h. Letters of support or approval from off-site health or educational facilities.
   i. South African Health Products Regulatory Authority (SAHPRA) approval or application, if applicable.
   j. Principal investigator's CV, if applicable.
   k. Budget summary

1.11 Duration of Approval

1. The Human Research Ethics Committee must conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once a year. (See related policy: Continuing Review).

1.12 DECISION- MAKING PROCESS

1. 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.
2. All applications are required to be submitted via their relevant Faculty approval structures within a reasonable timeframe to ensure that they will serve at an appropriate REC-H meeting (dates available on the REC-H website). Faculties observe internal protocols for adhering to these guidelines. It is the researchers'' responsibility to determine timeously the extent of these Faculty internal protocols. Failure to do so might delay the review and approval of the submission. For a study coming from a staff member linked to a support division (i.e., the research is not for degree purposes) the application is submitted to the related faculty, and then to REC-H, where relevant.
3. For negligible/low risk studies, an expedited approval process is conducted. This process may only occur once the proposal has been approved at Faculty level. 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 researchers. 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.
4. For medium/high risk studies, the protocol serves at the relevant Faculty Postgraduate Subcommittee (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.
5. For any study serving at REC-H, at least two REC-H members will review the submission in depth and lead relevant discussions at a meeting. All other REC-H members will participate in discussions and have access to all documentation.

6. Formal feedback to researchers is in the form of a resolution (NOT APPROVED, RESUBMISSION, APPROVED WITH MAJOR MODIFICATIONS, APPROVED WITH MINOR MODIFICATIONS, 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 with minor or major corrections, a REC-H member is nominated as the liaison for the study to see it through to final approval. To be approved, all mandatory feedback is required to be addressed within a maximum period of 3 months from date of 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 must commence all over again. Advisory feedback is intended to be considered at the discretion of the Faculty, PRP and PI.
7. See related section on 'REC-H: Composition and Documentation of Activities' for more information on the Committee's decision- making process.

2 APPEALS PROCESS

2.1 GENERAL

1. Researchers have the right to appeal decisions made by the Faculty PGSC or the REC-H or may have concerns regarding the administration process.
2. All appeals will be treated confidentially, as far as possible.
3. In summary: appeals may be submitted via email by the principal investigator through the REC-H Administrator who will forward it to the Chairperson of the REC-H, copied to the Chairman of the FPGSC, who will discuss it with REC-H Chairman.
4. The Ethics Committee reference number must be included on the correspondence.
5. There must be a clear motivation for the appeal.
6. The REC-H Chairperson or delegated member(s) may then seek outside consultation about the research project. This will then be reported back to the REC-H members along with recommendations regarding the appeal.
7. The REC-H committee will then reconsider the entire protocol with the new motivations and a decision will be made.
8. The decision after the appeals process is final.
9. This document describes the procedures for appealing a determination by the REC-H.

2.2 POLICY

1. The REC-H may determine that some or all of a proposed research activity cannot be approved, or may require the researcher to make changes to the research in order to obtain approval. REC-H requirements and disapprovals that are consistent with regulations and policies may not be reversed by any official or agency, including another similar committee.
2. A researcher may appeal to the REC-H to do a formal re-review of a decision. The only grounds for requesting an appeal are when -
   a. there have been multiple unsuccessful efforts by the researcher and the REC-H to resolve a disagreement, and
   b. the researcher believes that the REC-H's decision is due to -
      i. inadequate or inaccurate information,
      ii. REC-H non-compliance with REC-H policy, national and/or international regulations.
3. The REC-H Chair has the authority to determine whether an appeal request will be accepted.
4. Only one appeal will be allowed on a given matter. The concluding determination made by the REC-H regarding the appeal is final and not subject to further appeal.

5. Complaints about REC-H-related business must be directed to the REC-H in the first instance. If the matter remains unresolved, it may be escalated to an appeal committee appointed by the RTI committee for a decision and then to the National Health Research Ethics Council (NHREC) for further adjudication.

2.3 PROCEDURES

1. The appeal must be requested by the researcher within 30 calendar days of the date of the most recent REC-H review letter to the researcher concerning the decision that is being appealed.
2. The appeal request consists of sending the following to REC-H Administration:
    a. A cover letter outlining the basis for the appeal.
    b. Any supplemental documentation that supports the appeal.
    c. Within three business days of receipt, the REC-H Administration: Provides the REC-H Chair with a copy of the materials; and sends the researcher an acknowledgment of receipt of the appeal request.
3. The REC-H Chair reviews the appeal request to determine whether an appeal is appropriate, as defined above. This may include consultation with the researcher, REC-H Administration, the initial REC-H reviewer(s) and others, as needed.
4. REC-H Administration informs the researcher by email if the appeal request has been accepted.
5. The appeal is heard at an REC-H meeting. This may be a regularly scheduled REC-H meeting, or it may be a meeting convened specifically for this purpose.
6. The researcher is required to attend the REC-H meeting and to present the appeal to the REC-H members. REC-H Administration works with the REC-H and the researcher to schedule a mutually acceptable review date as soon as possible.
7. REC-H Administration follows standard procedures to identify the REC-H member who will be the primary reviewer of the appeal (usually the initial primary reviewer), and to provide all relevant materials (including those provided by the researcher) to all attendees at the meeting.
8. During the REC-H meeting:
    a. The REC-H Chair may hold a closed session without the researcher and colleagues, prior to the appeal portion of the meeting, to establish the key issues and questions to consider.
    b. The researcher is invited to present information and rationale to the REC-H.
    c. The researcher's colleagues (if present) are invited to present.
    d. There is a question-and-answer session with the researcher and colleagues.
    e. The researcher and colleagues leave the meeting room.
    f. The REC-H members and other meeting attendees discuss the appeal.
    g. The REC-H moves and then votes whether to take one of the following actions -
        i. approve the appeal and modify the original decision;
        ii. disapprove the appeal and uphold the original determination; or
        iii. defer the appeal and obtain additional information or consultation to make a final decision.
9. REC-H Administration communicates the REC-H's appeal determination, and any considerations or requirements associated with it, to the researcher in a letter within 7 business days of the REC-H's determination. If appropriate, the determination may also be communicated by email or telephone call with follow-up email, by the REC-H Chair.
    a. All REC-H correspondence must be addressed to the principal investigator or delegated signatory unless dictated by particular circumstances.
    b. REC-H Administration works with the REC-H Chair and/or the primary reviewer to draft the letter.