University of the Witwatersrand, Johannesburg
(“University” / “Wits”)

Human Research Ethics Committee Non-Medical
(“HREC (Non-Medical)”)

Standing Operating Procedures
(“SOP”)
# TABLE OF CONTENTS

1. OBJECTIVES ............................................................................................................. 4
2. THE PURPOSE OF THE HREC (NON-MEDICAL) .................................................. 4
3. SCOPE OF THE HREC (NON-MEDICAL) ............................................................... 5
4. CONSTITUTING THE HREC (NON-MEDICAL) .................................................... 6
5. COMPOSITION ........................................................................................................... 6
6. SCHOOL SUB-COMMITTEES OF THE HREC (NON-MEDICAL) ("SUB-COMMITTEES" / "SCHOOL COMMITTEE") ......................................................................................... 12
7. APPLICATION REQUIREMENTS FOR HREC (NON-MEDICAL) REVIEW .............. 14
8. HREC (NON-MEDICAL) FULL REVIEW ..................................................................... 19
9. AMENDMENTS / MODIFICATIONS PROCESS TO BE FOLLOWED BY APPLICANT .... 24
10. EXPEDITED REVIEW OF PROTOCOLS BY THE HREC (NON-MEDICAL) .......... 25
11. WAIVER FOR PROTOCOL BY THE HREC (NON-MEDICAL) ............................... 25
12. DECISION-MAKING WITHIN THE HREC (NON-MEDICAL) AND SCHOOL SUB-COMMITTEES ........................................................................................................ 26
13. REVIEWS OF RESEARCH PROPOSALS OF APPLICANTS NOT FROM THE UNIVERSITY - NON-AFFILIATED APPLICANTS OR EXTERNAL APPLICATIONS ......................... 30
14. COMPLAINTS AND APPEALS PROCEDURES ....................................................... 30
15. WHISTLEBLOWING ................................................................................................. 32
16. SERIOUS ADVERSE EVENT/S .............................................................................. 33
17. DOCUMENTATION AND ARCHIVING .................................................................. 35
18. ADOPTION OF, AND CHANGES TO, THIS STANDARD OPERATING PROCEDURE ... 36
19. AUDITING AND ACCREDITATION OF THE HREC (NON-MEDICAL) ................. 37
20. REGULATORY FRAMEWORK ................................................................................... 37
21. POLICIES AND GUIDELINES ................................................................................. 37
22. DEFINITIONS ............................................................................................................ 38
23. REFERENCES ............................................................................................................. 42
24. ACKNOWLEDGEMENTS .......................................................................................... 42
25. APPROVAL HISTORY OF THE SOP

ANNEXURE 1 Application Form;

ANNEXURE 2 Guidelines for Human Research Ethics Clearance Application (Non-Medical);

ANNEXURE 3 Guidelines for designing Participant Information Sheets and Consent Forms;

ANNEXURE 4 Organogram showing the complaints and appeals processes and the appropriate forms; and Non-Disclosure Declaration (Chairperson, Co-Chairperson and members);

ANNEXURE 5 Wits Code of Conduct for Researchers

ANNEXURE 6 University Research Ethics Policy

ANNEXURE 7 TOR for HREC (Non-Medical)
Standard Operating Procedures for the Human Research Ethics Committee (Non-Medical)

1. OBJECTIVES

1.1. The overarching objective of this Standard Operating Procedures (“SOP”) is to promote and ensure a culture of ethically responsible research at the University in the social, behavioural, economic and educational sciences.

1.2. The specific objective of this SOP is to contribute to the promotion of quality and consistency of ethics applications submitted to the HREC (Non-Medical) and also in reviewing the ethical aspects related to social, behavioural, economic and educational research conducted at the University by upholding a high standard of ethical practice and research integrity. The HREC (Non-Medical) is informed by the University Research Integrity Policy and its Terms of Reference.

2. THE PURPOSE OF THE HREC (NON-MEDICAL)

2.1. The purpose of this HREC (Non-Medical) in reviewing research is to contribute to safeguarding the dignity, rights, safety, and well-being of all actual or potential participants in social, behavioural, economic and educational research conducted by the University and its researchers, balancing it with the innately intrusive nature of such research.

2.2. Also, the purpose of the HREC (Non-Medical) is to facilitate sound ethical practice by Applicants and students through training and support.

2.3. The HREC (Non-Medical) provides independent, competent, and timely reviews of the ethical risks related to research proposals, and can recommend measures aimed at avoiding or minimizing these risks – acknowledging that the ethical dimensions of research can never be fully separated from the scientific dimensions of research (that include, amongst others, methodological, theoretical and institutional aspects). The HREC (Non-Medical) can also require that certain measures be taken by the Applicants to minimise or avoid potential ethical risks. The HREC (Non-Medical) has a risk level descriptor for research in order to provide guidelines for the Applicants to follow.
2.4. The HREC (Non-Medical) is responsible for acting in the full interest of potential research participants (i.e. human participants) and affected communities, taking into account the interests and needs of the Researchers, and having due regard for the requirements of applicable professional bodies and academic societies, relevant regulatory agencies, applicable laws, and relevant institutional requirements.

2.5. The HREC (Non-Medical) will maintain a record of all the research proposals, protocols, reviewer reports, emails and correspondence that have been considered in ethical terms, including those:

2.5.1. approved by Research Ethics Committees ("REC") of other institutions that were submitted to the HREC (Non-Medical) for commentary, ratification and / or endorsement.

3. SCOPE OF THE HREC (NON-MEDICAL)

3.1. Any research undertaken by any students or staff of the University ("Researchers" / "Applicants") involving but not limited to human subjects (i.e. human participants) excluding animals, must be submitted for review by the HREC (Non-Medical) or by the appropriate School sub-committees of the HREC (Non-Medical), irrespective of the level of ethical risk and vulnerability of the research participants involved. The School sub-committees of the HREC (Non-Medical) will only review applications which are of no risk and/or of minimal, low or negligible risk. The HREC (Non-Medical) will uphold all the University's necessary rules and regulations and in so doing reviewing applications for degree and non-degree purposes.

3.2. When reviewing research proposals, special attention will be given to research that includes certain individuals or categories of participants who may be vulnerable* to undue influence and/or duress (for example, the poor and the marginalised, children below the age of eighteen (18), people with disabilities, people in prison, refugees, the elderly, people in hospital, people attending a clinic) or vulnerable due to their occupation (e.g. sex workers, illegal miners).
4. **CONSTITUTING THE HREC (NON-MEDICAL)**

4.1. In executing its duties the HREC (Non-Medical) will ensure that it is free from bias and influence that could affect its independence. In its structure and functioning, and in the execution of its duties and responsivities, the HREC (Non-Medical) will follow the principles and guidelines stipulated in:

4.1.1. The National Health Research Ethics Council in so far as it is relevant to research in the social sciences and humanities;

4.1.2. The provisions of the National Health Act 61 of 2003 (”National Health Act”) and its amendments in so far as they are relevant to research in the social sciences and humanities;


4.1.4. Any relevant legislation, regulations and guidelines, including international guidelines and standards in so far as they are applicable to research in the social sciences and humanities;

4.1.5. Official documents of professional bodies and scientific organisations, in so far as they are relevant to research in the social sciences and humanities;

4.1.6. The University Research Integrity Policy; and

4.1.7. The University Code of Conduct for Researchers and/or REC members.

5. **COMPOSITION**

5.1. **MEMBER COMPOSITION**

5.1.1. The representatives of the broader community are appointed by the Director: Research Development:

5.1.1.1. Members of the HREC (Non-Medical) are appointed for a period of five (5) years, as per National Health Research Ethics Council (”NHREC”) National Guidelines 2015;
5.1.1.2. Members of the HREC (Non-Medical) can be re-appointed for a second and subsequent third (3rd) five (5) year term in succession;

5.1.1.3. The HREC (Non-Medical) must be representative of the research communities it serves within the University and, increasingly, reflect the demographic profile of the population of the Republic of South Africa as best and reasonably as possible;

5.1.1.4. The HREC (Non-Medical) must include members of both genders, although not more than 70% (seventy percent) should be either male or female;

5.1.1.5. The HREC (Non-Medical) must have at least nine (9) members in order to be constituted as a HREC (Non-Medical), including the Chairperson but at a HREC (Non-Medical) meeting, a minimum of 9 (nine) members must be present in order to constitute a quorum. For School Sub-Committees, a minimum of 3 (three) members must be present in order to constitute a quorum.

5.1.2. Membership should consist of:

5.1.2.1. at least one (1) layperson, preferably from the community in which the research is to take place. A lay person is viewed as an ordinary person for example, a member of the community, with no specific qualification in a profession and/or does not have specific knowledge of a certain discipline / field. “Community” means a grouping of people that live in the same area or having common characteristics;

5.1.2.2. at least one (1) member with knowledge of, and current experience in, the professional care, counselling or health-related treatment of people. Such a member might be, for example, a medical practitioner, psychologist, social worker
or nurse. This could be a member of the HREC (Medical) that is an observer of the HREC (Non-Medical);

5.1.2.3. at least one (1) member with professional training and experience in qualitative and quantitative research methodologies;

5.1.2.4. a member with expertise in bio-statistics and research ethics:

5.1.2.5. a member with expertise in pastoral care;

5.1.2.6. at least one (1) member who hold a legal qualification or is legally qualified.

5.1.2.7. The proposed membership of the HREC (Non-Medical) for the following year is sent to the URC and the DVC: R&PGA annually in order for the DVC: R&PGA to approve and the URC to note such memberships in line with the University’s rules and regulations.

5.1.2.8. All the new HREC (Non-Medical) members will receive a formal induction and introduction into the HREC (Non-Medical). The main way of training being a member on the HREC (Non-Medical) is through the observation and “on the job” experience. More experienced members on the HREC (Non-Medical) will be able to provide any guidance that maybe required by any new members.

5.1.2.9. The HREC (Non-Medical) members must attend research ethics training sessions to keep abreast with the latest changes in this field. All HREC (Non-Medical) members are required to complete an accredited ethics content course and provide proof of completion to the Chair / Co-Chair of the HREC (Non-Medical). This is to be renewed every 3 (three) years.

5.1.2.10. HREC (Non-Medical) members will receive an introductory pack electronically, which will consist of the following, but not
limited to: Letter of Appointment, University Research Ethics Policy, HREC (Non-Medical) Terms of Reference, HREC (Non-Medical) Standard Operating Procedures, Wits Code of Conduct, Non-Disclosure Declaration (to be signed by the members and returned to the Secretariat), National Guidelines 2015 and other documents that maybe required.

5.1.2.11. HREC (Non-Medical) members will receive a certificate of service at the end of the year that they have served on the HREC (Non-Medical). This certificate will support the member’s involvement with the HREC (Non-Medical) and their academic citizenship in the University.

5.2 MEMBER PARTICIPATION

5.2.1 Functioning of Members, Chairperson, Co-Chairperson/s and Deputy Chairperson/s of the HREC (Non-Medical)

5.2.1.1 Chairperson and Deputy Chairperson/s

5.2.1.1.1 A Chairperson will either hold the Chair individually or may hold the position with another Chairperson in order to have more than 1 (one) Chairperson. They will hold the same responsibilities as if there was only 1 (one) Chairperson.

5.2.1.1.2 Subject to the University’s requirements, a Chairperson and / or Co-Chairperson/s of the HREC (Non-Medical) should be elected at the first meeting of year by the members of the HREC (Non-Medical). The Chairperson and / or Co-Chairperson/s of the HREC (Non-Medical) serve a term of 1 (one) calendar year, and may be re-elected annually for a maximum period of 5 (five) years in succession.

5.2.1.1.3 The Chairperson and / or Co-Chairpersons must be assisted by at least 1 (one) Deputy Chairperson/s as this will promote succession planning for the HREC.
The Deputy Chairperson/s is to be elected at the first meeting of year by the members of the HREC (Non-Medical). The Deputy Chairperson/s of the HREC (Non-Medical) serves a term of 1 (one) calendar year, and may be re-elected annually for a maximum period of 5 (five) years in succession.

5.2.1.4 The Co-Chairperson/s and Deputy Chairperson/s will be elected by the members and be expected to assist the Chairperson with responsibilities and inter-meeting matters as well as to step into the role of the Chairperson when necessary.

5.2.1.5 Once the Chairperson, Co-Chairperson/s and Deputy-Chairperson/s of the HREC (Non-Medical) are elected as above, and then their respective identities are to be reported to the DVC: R&PGA for approval and the URC for noting.

5.3 APPOINTMENT AND REAPPOINTMENT OF MEMBERS

5.3.1 Appointment and reappointment of the HREC (Non-Medical) members are subject to approval by the Chairperson of the HREC (Non-Medical) and then approved by the DVC: R&PGA and the URC.

5.3.2 If a member, including Chairperson, Co-Chairperson/s and Deputy-Chairperson/s is absent from a meeting for four (4) consecutive meetings without an apology, his or her absence will be addressed by the Chairperson/s or Co-Chairperson/s in writing to the specific member, after which the Chairperson/s or Co-Chairperson/s can make a recommendation, and in this context, has the authority to remove such member reported as non-attending from the HREC (Non-Medical) and propose another representative for the remainder of the disqualified member’s term, such appointment to be confirmed by the URC and the DVC: R&PGA.
5.3.3 Resignation from the HREC (Non-Medical) can be initiated by the Chairperson/s or Co-Chairperson/s or any other member of the HREC (Non-Medical), and must be in writing to the HREC (Non-Medical) Secretariat and the Chairperson.

5.3.4 Upon appointment to the HREC (Non-Medical) new members must sign applicable non-disclosure agreements, the University's Code of Conduct, Conflict of Interest Document and any other relevant documentation that may be required.

5.3.5 The HREC (Non-Medical) can co-opt members when needed with appropriate training.

5.4 ROLES AND RESPONSIBILITIES

5.4.1 The HREC (Non-Medical) will function according to this set of Standard Operational Procedures (SOP) formulated in this document and under the HREC (Non-Medical) ToR.

5.4.2 The HREC (Non-Medical) must ensure that it is adequately informed on all aspects of a research protocol, including its scientific validity, that are relevant to deciding whether the protocol is both acceptable on ethical grounds and conforms to the principles of this document.

5.4.3 The HREC (Non-Medical) will have the responsibility to ensure that research conducted in the social, behavioural, economic and educational sciences by the University is in accordance with National and International guidelines and standards for ethically responsible research.

5.4.4 In making these decisions the HREC (Non-Medical) focuses in particular on:

5.4.4.1 actual or potential ethical risks related to research methods of data collection and analysis described in the proposal; and

5.4.4.2 measures to avoid or minimize such risks.
5.4.5 The HREC (Non-Medical) may review protocols for projects of other organisations that collaborate with the University and any affiliated Applicants / external applications, subject to fee payment.

5.4.6 The HREC (Non-Medical) will review amendments to approved projects, following the same process of the original review.

5.4.7 The HREC (Non-Medical) will be available to render researchers, upon formal request, with expert opinion regarding research ethics, and advice regarding application procedures will be addressed on an informal and ad hoc basis by the Chairperson and/or Co-Chairperson/s with the University Research Office. The HREC (Non-Medical) also provides Applicants with methodological comments in order to assist in making the research better.

5.4.8 The HREC (Non-Medical) has to notify Applicants in writing regarding their decisions within 15 (fifteen) to 20 (twenty) working days after the HREC (Non-Medical) monthly meeting. This will be dealt with in more detail herein.

5.4.9 The HREC (Non-Medical) will review applicant's annual progress reports which should be submitted yearly on or before 31 December for each year of the project (for Minimal and Low Risk projects). For Medium or High Risk projects, progress reports should be submitted twice yearly, on 30 June and 31 December, for each year of the project.

5.4.10 Amendments to approved applications from Sub-Committees should be reported and ratified at the HREC (Non-Medical) meeting. Such amendments will need to be done at the school level before the HREC (Non-Medical) sees the amended approved application.

6. SCHOOL SUB-COMMITTEES OF THE HREC (NON-MEDICAL) ("SUB-COMMITTEES" / "SCHOOL COMMITTEE")

6.1 School-level research ethics committees are constituted as Sub-Committees* of the main HREC (Non-Medical). The Sub-Committees of the HREC (Non-Medical):
6.1.1. are to comply fully with the HREC (Non-Medical) SOP as they will be held responsible as they are part of the HREC (Non-Medical). Please take note that when the SOP refers to the HREC (Non-Medical) this also includes Sub-Committees;

6.1.2. are required to keep good record of their meetings, decisions and clearance certificates for auditing purposes in terms of this SOP;

6.1.3. will only review applications which are of no risk and of minimal, low or negligible risk as defined herein and only reviews ethics applications from undergraduate, Honours students’ projects and Masters by Coursework and Research Report;

6.1.4. research ethics applications by Masters by Dissertation and PhD students and staff members cannot be reviewed by such School Sub-Committees;

6.1.5. a member of the Sub-Committee may also serve as a member of the HREC (Non-Medical);

6.1.6. will be monitored and may be audited by HREC (Non-Medical) as per National Guidelines 2015, the URC and the University Research Office;

6.1.7. will submit a monthly Excel spreadsheet to the HREC (Non-Medical) with all the specific school applications to be listed, including details on student name, student number, supervisor’s name, abstract, project title, approval status, risk level;

6.1.8. provisional decisions will be taken by the Sub-Committees that will be discussed and ratified at the next meeting of the HREC (Non-Medical). Where any application at school level involves vulnerable categories or is deemed of medium risk or high risk, then this application is referred directly to the HREC (Non-Medical). These applications are then considered as normal applications to the HREC (Non-Medical).

6.1.9. The HREC (Non-Medical) secretariat / administrative support will communicate decisions to the Sub-Committees chair, based on the discussion and minutes of the HREC (Non-Medical) meeting. The Sub-
Committee’s chair will then communicate the final decision to the applicant at school level. The HREC (Non-Medical)’s chair will provide support throughout, and will advise the Sub-Committee’s chair and school applicants if required.

6.1.10. Amendments to approved applications from Sub-Committees should be reported and ratified at the HREC (Non-Medical) meeting. Such amendments will need to be done at the school level before the HREC (Non-Medical) sees the amended approved application.

6.1.11. Sub-Committees’ members must attend research ethics training sessions to keep abreast with the latest changes in this field and the Sub-Committees’ members will need to provide proof of evidence at least once every three (3) years to the HREC (Non-Medical).

7. APPLICATION REQUIREMENTS FOR HREC (NON-MEDICAL) REVIEW

7.1. Requirements for submitting an application to the HREC (Non-Medical) are available to prospective applicants on the HREC (Non-Medical) website, https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/, website of the Research Office, and include the following aspects:

7.2. DOCUMENTATION REQUIRED

7.2.1. An application to the HREC (Non-Medical) for review, the following documentation is required:

7.2.1.1. a fully completed Application Form dated and signed by the Researcher and their Supervisor (if applicable).

7.2.1.2. a research proposal together with supporting documents.

7.2.1.3. the Application Form should include:

7.2.1.3.1. an identification of risk categories, as defined by the HREC (Non-Medical);

7.2.1.3.2. permission letters if applicable;
7.2.1.3.3. research instruments; i.e. Interview schedules, questionnaires, surveys and observation schedules intended for research participants and, when required and/or appropriate, should be translated into other languages relevant to the research;

7.2.1.3.4. an overview of the process that will be used to recruit potential participants, when applicable, i.e. how, where and by whom will prospective participants be approached;

7.2.1.3.5. a description of the process to be used to obtain and document free and informed consent, required when human research participants, institutions or organisations are involved, taking into account that:

7.2.1.3.6. written and other forms of participant information sheets for potential research participants (if required and/or appropriate) in the language(s) understood by the potential research participants and, when relevant, in other languages;

7.2.1.3.7. informed Consent Form in the language(s) appropriate to the potential research participants (where required and/or appropriate) and, when relevant, in other languages. A sample of an informed consent form and participation information sheet can be found on the HREC (Non-Medical) website, https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/;

7.2.1.3.8. a statement describing any incentives for participation in the research, including expenses
and access to travel, psychological or other care/support, to be given to research participants, when applicable;

7.2.1.3.9. in cases where students, staff or alumni of the University will be participating in the research, a statement that an application for institutional permission has been, or will be submitted to the Registrar or Deputy Registrar: Academic Administration of the University;

7.2.1.3.10. a description of the arrangements to ensure confidentiality and anonymity of research data during the research process, as well as in reporting on it;

7.2.1.3.11. a description of the arrangements to ensure that there will be no unauthorised access to research data, i.e. how the data will be kept safe while the research is in progress; and

7.2.1.3.12. a description of what will happen to the data after completion of the research, including any archival storage, in appropriate.

7.2.2. SUBMISSION AND PROCESSING OF APPLICATIONS

7.2.2.1. The application form has a checklist as a preamble. The following guidelines apply to the submission and processing of applications:

7.2.2.1.1. An application for review of the ethics of proposed research should be submitted by a qualified researcher, or a researcher (student) in training supported by an Applicant, a researcher (student) in training supported by a qualified supervisor responsible for the ethical and academic conduct of the research;
7.2.2.1.2. Along with their application, Applicants must attend research ethics content training either online or face-to-face and to provide proof of evidence of qualification of such training at least once every three (3) years to the HREC (Non-Medical), as described on the completed application form;

7.2.2.1.3. If the Applicant is a student, the application must be approved by the relevant supervisor and/or school/ department/unit or must have been submitted to the specific Higher Degrees Committee;

7.2.2.1.4. One (1) copy of the entire application including supporting documents must be submitted in hard copy format and must be signed by all relevant parties; and all applications must be submitted electronically through the online submission system found on the HREC (Non-Medical) website, https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/, including uploading all supporting documents that are required for the application;

7.2.2.1.5. The proposal must be submitted in English but the applicant must provide translated information and consent documentation, if required.

7.2.2.1.6. The application form has to be completed in full, and must be signed by all relevant parties.

7.2.2.1.7. The submission deadlines and meeting dates of the HREC (Non-Medical) will be published on the HREC (Non-Medical) website,
https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/and submissions must reach the HREC (Non-Medical) Secretariat before the listed submissions deadline of the appropriate meeting of the HREC (Non-Medical);

7.2.2.1.8. Applicants will be notified in writing about the outcome of the application within 10 (ten) working days after the regular meeting of the HREC (Non-Medical) has taken place. If there are any delays, then the HREC (Non-Medical) will inform the relevant Applicants/ Applicants of such and will indicate a new timeline;

7.2.2.1.9. The procedure and requirements for any amendments required to the research application/proposal/protocol, the recruitment material, the potential research participant information, or the consent form will be made available in writing to the applicant(s) and on the website. The amendment procedure is set out below;

7.2.2.1.10. The responses from Applicants to the HREC (Non-Medical) will normally be processed within 14 (fourteen) days of receipt by the HREC (Non-Medical) Secretariat;

7.2.2.1.11. If a revised version of the original submitted application has not been received, addressing the reviewers' comments, within five (5) months of the original decision letter, the application shall be considered to be null and void. A new application must then be submitted for review;
7.2.2.1.12. In all instances, Applicants must submit a detailed letter indicating what changes have been made in response to the reviewers’ comments. If a student, the applicant must confirm that the supervisor(s) has seen and approved the revised submission.

8. HREC (NON-MEDICAL) FULL REVIEW

8.1. MEETINGS

8.1.1. Meetings will be scheduled to be held on a monthly basis, unless decided otherwise by the Chairperson of the HREC (Non-Medical). Meetings will normally take place once a month from January until November of each year, inclusively. The applications submitted during December will be reviewed during the next meeting in January. No meetings will take place if no applications have been submitted during the time period specified.

8.1.2. Late applications not submitted by the given deadline will be stood over until the next month’s meeting.

8.1.3. The scheduled dates of all meetings and deadlines are available on the website of HREC (Non-Medical) website, https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/.

8.1.4. With the permission from the HREC (Non-Medical) committee members, meetings of the HREC (Non-Medical) will be recorded by means of minute-taking, electronic recording and electronic record keeping.

8.1.5. Minutes of meetings will be included in the agenda of the next meeting of the HREC (Non-Medical) for approval and to deal with matters arising. The agenda will include a section on conflict of interest of reviewers and confirmation that reviewers do or do not have any conflict of interest. These must be captured in the minutes and attendance register of that meeting.
8.1.6. The agenda and documentation for scheduled meetings will be circulated to the HREC (Non-Medical) at least 7 (seven) days prior to the meeting.

8.1.7. Extraordinary meetings may take place under special circumstance and notification of such meetings will be provided to the HREC (Non-Medical) members at least three (3) days before such meeting.

8.2. CONFLICT OF INTEREST OF MEMBERS

8.2.1. HREC (Non-Medical) members should disclose information that may lead to perceptions of conflict of interest.

8.2.2. HREC (Non-Medical) members should not review or make decisions about research proposals in which they are involved personally or financially. When such a proposal is to be discussed, the member concerned should declare the potential conflict and offer to recuse himself / herself from the meeting for that time. Should the member be permitted to remain for the discussion at the discretion of the Chairperson or Co-Chairperson then the member may not participate in the final decision-making on the application in question.

8.3. MINUTE TAKING AND KEEPING

8.3.1. The HREC (Non-Medical) will keep written records of all research applications / protocols / proposals for review, including information sheets, consent forms and relevant correspondence, as in the form provided for by the electronic submission system. Electronic records are acceptable by the HREC (Non-Medical), provided that signatures, especially on the finally approved documentation, are properly documented on the hard copy of the application and included in the record and an applicant is to request that a hard copy be printed by the Secretariat.

8.3.2. The HREC (Non-Medical) records must provide a reliable and authoritative record of the business of the HREC (Non-Medical) that will stand up to scrutiny in the event of queries, conflict and audit.
8.3.3. The HREC (Non-Medical) should correspond primarily with the principal investigator but if the need arises for the HREC (Non-Medical) to correspondence with the Faculty, School or with participants then the HREC (Non-Medical) chair will be permitted to do so with good reason.

8.3.4. The record should include at least the following:

8.3.4.1. Name of principal investigator / Researcher;
8.3.4.2. Protocol identification number;
8.3.4.3. Title of the project;
8.3.4.4. Reviewer name and their comments submitted;
8.3.4.5. Date of approval or rejection;
8.3.4.6. Conditions of approval, if applicable;
8.3.4.7. Whether approval was expedited;
8.3.4.8. Copy of the signed final protocol approved;
8.3.4.9. and through the life cycle of that protocol the following:

8.3.4.9.1. Whether and how consultation occurred;
8.3.4.9.2. Records of adverse events;
8.3.4.9.3. Records of amendments;
8.3.4.9.4. Reports of adverse and serious adverse events and action taken;
8.3.4.9.5. Other relevant information such as complaints from participants.

8.4. ATTENDANCE OF APPLICANTS/ APPLICANTS / OTHER PARTIES

8.4.1. Any member of the URC, the DVC: R&PGA or his / her nominee and any member of the University Research Office, the Researcher, Supervisor,
Dean of a Faculty or Head/Chairperson of a School or a Department, or any other University personnel can attend a meeting of HREC (Non-Medical) as an observer to hear their own application being considered or for good reason, following the procedure given in the documentation available on the HREC (Non-Medical) website, https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/, the Research Office website. Attendance as an observer can only take place following the notification of the HREC (Non-Medical) Secretariat at least twenty-four (24) hours before the HREC (Non-Medical) meeting and written confirmation or rejection must be given by the Chair or a Co-Chairperson of the HREC Non-Medical. If a rejection is provided then good reason must be provided for such a rejection. If such a request is granted, then that person will need to complete the same non-disclosure agreement that the HREC (Non-Medical) members complete at the meeting. These observers will need to complete the same non-disclosure agreement that the HREC (Non-Medical) members complete.

8.5. ELEMENTS OF THE REVIEW

8.5.1. REVIEW PROCESS

8.5.1.1. REVIEW BY THE HREC (NON-MEDICAL)

8.5.1.1.1. The primary task of the HREC (Non-Medical) lies in the ethics review of research proposals. In this review, the Application Form and research proposal, as well as all supporting documents are considered, with special attention given to the recruitment of potential participants, the status and characteristics of participants, (for example, whether they are vulnerable or not), and the informed consent process and the documentation provided to research participants. The HREC (Non-Medical) takes into account guidelines, where appropriate, provided by professional
bodies as well as the requirements of applicable laws and regulations. The following is considered in particular in the ethics review, as applicable:

8.5.1.1.2. The risk-benefit profile of the proposed research. The HREC (Non-Medical) will provide a risk level descriptors in order for the risk to be determined by the Applicant as well as the HREC (Non-Medical) reviewers;

8.5.1.1.3. Criteria to withdrawal of research participants before completion of the research;

8.5.1.1.4. The measures of support provided at no cost or reasonable cost to participants if they need it during or after the research;

8.5.1.1.5. The adequacy of provisions made for monitoring and auditing the conduct of the research, including considerations related to data safety, and what happens to the data upon completion of the research; and

8.5.1.1.6. The manner in which the results of the research will be reported and published; in particular, whether individual participants are identifiable.

8.6. INSTITUTIONAL PERMISSION

8.6.1. The following will be considered with respect to obtaining institutional permission: If a central authority/ies are involved, copies of the institutional permission that was obtained, or, if such institutional permission is still pending at the time of submitting the application, proof that institutional permission was requested.

8.6.2. The research is not permitted to be undertaken at any institution without previously obtaining permission from that institution, if required by the HREC (Non-Medical).
8.6.3. Permission letters should be in written form on an official letterhead, signed and dated, specifically mentioning the Applicant, the title of the Applicant's project by name. Email correspondence is not an acceptable form of permission.

8.6.4. Instances where permission is not required must also be confirmed in writing by the HREC (Non-Medical).

9. **AMENDMENTS / MODIFICATIONS PROCESS TO BE FOLLOWED BY APPLICANT**

9.1. The procedure and requirements for any amendments required to the research application / proposal / protocol, the recruitment material, the potential research participant information, or the consent form will be made available in writing to the applicant(s) as well as on the website, https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/.

9.2. An amendment(s) to an approved protocol can be submitted to the Secretariat of the HREC (Non-Medical) in the event of a change(s) in the research project or instrument/s used or methods of data collection or analysis or participating groups or research site(s). This can be done by writing a short letter to the Secretariat of the Non-Medical indicating the relevant change(s) including the updated documents etc. Same is then reviewed by the Chairperson / Co-Chairperson and the 2 (two) original reviewers.

9.3. Any amendments made must be considered by the Chairperson and two (2) reviewers with approval of such amendments at a HREC (Non-Medical) meeting.

9.4. If the revised version of the original submitted application is not submitted to the HREC (Non-Medical) before the due date of submission for the next HREC (Non-Medical) meeting then that revised version will be considered at the next meeting as per the HREC (Non-Medical) due dates.

9.5. All amended applications will be sent to the next HREC (Non-Medical) meeting for approval and minuted as such.
10. **EXPEDITED REVIEW OF PROTOCOLS BY THE HREC (NON-MEDICAL)**

10.1. The HREC (Non-Medical) has established procedures for expedited review which will be for applications that need to receive urgent attention due to the exceptional circumstances surrounding such research, such as a restriction in time or availability of participants.

10.2. Once the application is received by the Secretariat then such application for expedited review will be sent to the HREC (Non-Medical) Chairperson / Co-Chairperson. S/he will review such expedited application and allocate the application to 2 (two) other reviewers in order for them to review the application within 10 (ten) working days.

10.3. The Chairperson / Co-Chairperson will then provide their comments as per the normal process but just to each other in order for the Chairperson / Co-Chairperson to be able to consider meeting each other or to consolidate all the 3 (three) inputs into one document and then it is approved by the 3 (three) HREC (Non-Medical) members.

10.4. Once the Chairperson / Co-Chairperson have approved such feedback then the secretariat will send same to the applicant.

10.5. If amendments are required then the applicant will be given five (5) months to provide their revised application in order for the Chairperson / Co-Chairperson and the 2 (two) members to finalize the approval of such application.

10.6. The expedited applications will be ratified at the next HREC (Non-Medical) meeting for ratification and minute as such.

11. **WAIVER FOR PROTOCOL BY THE HREC (NON-MEDICAL)**

11.1. The HREC (Non-Medical) has established procedures for waiver of applications. This process is for research being carried out which does not have contact with human participants.

11.2. The Applicant would apply for a waiver by completing a waiver application form. This form must include the full research proposal and all required documents in order for the HREC (Non-Medical) to provide a full review of such waiver.
11.3. Once the application is received by the Secretariat then such application for waiver will be sent to the HREC (Non-Medical) Chairperson / Co-Chairperson. S/he reviews such waiver application and s/he will determine if the application should be waivered or not. If it is waivered, then the Applicant will be provided with a waiver letter.

11.4. The waivered letters will be ratified at the next HREC (Non-Medical) meeting for approved and minuted as such.

12. DECISION-MAKING WITHIN THE HREC (NON-MEDICAL) AND SCHOOL SUB-COMMITTEES

12.1. In making decisions on applications for the ethics review of research, the HREC (Non-Medical) and the School sub-Committees will make use of the following procedures and considerations:

12.1.1. Any conflict of interest of a committee member should be indicated to the Chairperson / Co-Chairperson prior to the review of the application and recorded in the minutes at the HREC (Non-Medical) meeting;

12.1.2. Decisions should only be made at meetings where a quorum is present. In cases where a quorum is not present, the HREC (Non-Medical) can make recommendations of decisions on individual applications, but that these decisions cannot be confirmed and must be held over to a subsequent meeting at which a quorum is present;

12.1.3. Two (2) independent reviewers are allocated to each application by the Chairperson / Co-Chairperson or his / her nominee being a member of the Secretariat, and these reviewers consider the application and provide a written report using the reviewer template provided by the Secretariat. If, for some reason, a reviewer or both reviewers are absent from the meeting, then written protocols can be provided and forms part of the decision making process at the meeting, a decision may be taken via email circulation when the completed reports are provided to the Chairperson / Co-Chairperson before the meeting. All committee members, be it in the HREC (Non-Medical) or the School Sub-
Committees, should have access to all applications and not just the applications allocated to them;

12.1.4. The documents required for a full review of the application should be complete and the relevant elements mentioned above should be considered before a decision is made. If a significant proportion of documents are missing from the application, then the application is considered to be incomplete and the application is returned to the Application for resubmission;

12.1.5. Decisions at meetings of the HREC (Non-Medical) are arrived at through consensus, where possible. When a consensus appears unlikely, it is recommended that a vote is taken, in which a simple majority, 51% (fifty one percent) is required. If there is a tie, the Chairperson / Co-Chairperson of the HREC (Non-Medical) can cast a deciding vote;

12.1.6. Voting will take place by a show of hands or electronically, unless indicated by the Chairperson / Co-Chairperson;

12.1.7. In cases of conditional decisions, such as where permission letters are needed, the nature of these conditions must be made clear;

12.1.8. The decisions of resubmission, major, moderate or minor revisions on an application must be supported by clearly stated reasons and suggestions to amend the application and/or supporting documents;

12.1.9. An approval is valid for three (3) years from the date of the clearance certificate. In order for the three (3) years approval to be valid, the Applicant is obligated to provide the HREC (Non-Medical) with annual or regular report/s, for all projects at any risk level, dues on 31 December annually for Minimal or Low Risk projects, or twice yearly on 30 June and 31 December for Medium or High Risk projects, each year for the duration of the project. These progress reports should report on the progress of the research as well as any incidents and / or adverse event that may have taken place which must include how this was resolved.

12.1.10. If a research project stretches more than three (3) years, it is the responsibility of the Applicant to apply to the HREC (Non-Medical) for an
extension of not more than two (2) years of the approval before the validity of the approval has lapsed. If there are no fundamental changes to the research project, this request for extension can be in the format of a short letter of motivation supported by a short report on the ethical aspects of the research, stating whether any new or unforeseen ethical issues were encountered during the initial three (3) years, and how they were addressed. If there are substantive changes to the research project, a full application will have to be submitted again as the nature of the initial project would have changed.

12.2. Decisions that the HREC (Non-Medical) can make, include:

12.2.1. The HREC (Non-Medical) HREC can make the following decisions, including but not limited to:

12.2.1.1. The approval of a research proposal as submitted with no amendments (APPROVED);

12.2.1.2. Minor amendments (MINOR AMENDMENTS), Moderate amendments (MODERATE AMENDMENT) or Major amendments (MAJOR AMENDMENTS) required before approval without the need for the response to come back to the full HREC (Non-Medical);

12.2.1.3. Rejected with recommendation for RESUBMISSION (RESUBMISSION).

12.2.2. In addition to the above, the HREC (Non-Medical) HREC (NON-MEDICAL) can in terms of the National Guidelines 2015, after due consideration, take the following actions at any point in time during the research, including but not limited to:

12.2.2.1. Monitoring the research;

12.2.2.2. Inspecting a research site;

12.2.2.3. Requesting an immediate report on the ethical aspects of a research project;
12.2.2.4. Temporarily suspending a research project with good reason;

12.2.2.5. Suspending a research project with good reason; and / or

12.2.2.6. Investigating an allegation of a breach of ethics in the research being conducted.

12.3. COMMUNICATING OF A DECISION AND DECISION ON RESUBMITTED REVISED APPLICATIONS (REVISION PROCESS)

12.3.1. The decision of the HREC (Non-Medical) HREC after reviewing an application will be communicated in writing to the applicant, normally within 15 (fifteen) to 20 (twenty) working days after the HREC (Non-Medical) meeting at which the decision was made or the decision of revised applications which were resubmitted. The content of the communication will be generated from the details provided in the application and revised applications, but will at least, include the following:

12.3.1.1. The exact title of the research proposal reviewed;

12.3.1.2. The name and title of the applicant;

12.3.1.3. The date of the decision;

12.3.1.4. The name of the HREC (Non-Medical);

12.3.1.5. A clear statement of the decision reached;

12.3.1.6. Any advice by the HREC (Non-Medical);

12.3.1.7. In the case of a conditional decision, any requirements by the HREC (Non-Medical), including suggestions for revision and the procedure for having the application re-reviewed; and

12.3.1.8. In the case of a decision of RESUBMISSION, clearly stated reason(s) for the decision.
13. REVIEWS OF RESEARCH PROPOSALS OF APPLICANTS NOT FROM THE UNIVERSITY - NON-AFFILIATED APPLICANTS OR EXTERNAL APPLICATIONS

13.1. The HREC (Non-Medical) can review research proposals / Protocols / applications of Applicants that are only affiliated to the University, or external applications subject to payment of a cost (“Review Fee”) levied for such service in the current amount of R15,000.00 (fifteen thousand Rand) plus VAT (currently at 15%) as per the Value Added Tax Act as amended from time to time, which Review Fee is payable upon submission. The Review Fee may change from time to time. The Review Fee is not for any Applicants within the University. The Review Fee is subject to the HREC (Non-Medical) Chairperson’s discretion, in consultation with the Secretariat and Research Office. The review can be waived or discounted subject to the HREC (Non-Medical) Chairperson’s discretion on a case-by-case basis.

13.2. A Researcher not affiliated with the University who wishes to do research on students, staff or alumni of the University, must obtain institutional permission for the research from the Deputy Registrar: Academic Administration of the University. In cases where Applicants do not have a current ethics clearance certificate from their own institution, they must apply to the HREC (Non-Medical) as an external applicant.

13.3. Applicants with no affiliation to the University or are considered to be external applications to the University can approach any of the NHREC-registered RECs of the University to review and approve their research proposals, where such a REC may on a case-by-case basis decide whether it is the appropriate REC to deal with the matter and whether the REC is willing and has proper expertise and capacity to evaluate the application.

14. COMPLAINTS AND APPEALS PROCEDURES

14.1. For applicants who wish to complain about the workings, procedures or decisions of the HREC (Non-Medical):

14.1.1. The complaint or appeal must be in writing to the HREC (Non-Medical) via the Secretariat and Chairperson and / or Co-Chairperson of the HREC
(Non-Medical), and must contain a clear motivation as to the reasons for the appeal or complaint.

14.1.2. The Chairperson and / or Co-Chairperson of the HREC (Non-Medical) will consider the appeal or complaint and will communicate a decision to the applicant in writing within seven (7) working days of receipt.

14.1.3. If the Applicant is still aggrieved, the second phase in the Standard Operating Procedure can then be activated by submitting a further appeal or complaint to the University's Head of the Office of Research Integrity which falls under the DVC: R&PGA in writing.

14.1.4. The Head of the Office of Research Integrity will investigate such appeal or complaint and will provide a report to the DVC: R&PGA in order for the DVC: R&PGA to make a determination in order to refer the matter in accordance with the University's Disciplinary Procedure for Staff or for Students or if a different process should be commissioned by the adjudication by an independent Standing Committee, namely the Advisory Committee on Ethics (ACE), chaired by the DVC: R&PGA or his/her nominee.

14.1.5. Guidelines can be found in the University Research Integrity Policy.

14.2. For Applicants who wish to appeal or complain about the working or decisions of School Sub-Committees HREC (Non-Medical):

14.2.1. The appeal or complaint must be in writing to the Chairperson of the appropriate School Sub-Committee, and must contain a clear motivation as to the reasons for the appeal.

14.2.2. The Chairperson of the appropriate School Sub-Committee will consider the appeal or complaint and will communicate a decision to the applicant in writing within seven (7) working days.

14.2.3. If the Applicant is not satisfied, the second phase in the Standard Operating Procedure can then be activated by submitting a further appeal or complaint in writing to the Chairperson HREC (Non-Medical).
14.2.4. If the Applicant is not satisfied with the HREC (Non-Medical) Chairpersons findings then the Applicant can follow the same procedure as set out above for the HREC (Non-Medical) in terms of clause 14.1.3 above.

14.3. For complaints about the ethical conduct of a Researcher who has received ethics clearance from the HREC (Non-Medical):

14.3.1. The complainant should complete the COMPLAINTS FORM available on the HREC (Non-Medical) website, [https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/](https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/) and submit the completed form following the procedures outlined on the website.

14.3.2. A meeting will take place between the Secretariat, Legal Advisor and Research Compliance Manager, Chairperson or Co-Chairperson of the HREC (Non-Medical) website, [https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/](https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/) and the researcher or the supervisor about whom the complaint has been made. The outcome of this meeting will be communicated to the complainant in writing within fifteen (15) working days.

14.3.3. If the complainant is not satisfied, the APPEALS FORM available on the HREC (Non-Medical) website, [https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/](https://www.wits.ac.za/research/researcher-support/research-ethics/ethics-committees/) should be completed and submitted, following the procedures outlined on the website. The appeal will be adjudicated by the ACE chaired by the DVC: R&PGA or his/her nominee. The outcome of this adjudication will be communicated to the complainant in writing within fifteen (15) working days.

15. WHISTLEBLOWING

15.1. Any person externally or internally to the University will be able to report any infringement or offence in relation to research by a HREC (Non-Medical) member, Chairperson, Co-chairperson, Deputy Chairperson, Secretariat, administrator
officer, researcher, applicant, School Sub-Committee Chair and member, research participant, any University personal linked to research or any other person that may have committed such an offence.

15.2. Such reporting must be sent to the ACE in writing, who will deal with the matter with confidentiality as per the University's internal Whistleblowers procedures. The report will remain anonymous as far as possible in law. The DVC: R&PGA will consult with the ACE and the relevant University's representatives in order to find a way forward to process such report and to resolve such report.

16. **SERIOUS ADVERSE EVENT/S**

16.1. All Applicants conducting research that encounter incidents or adverse / serious adverse events should report it to the HREC (Non-Medical) and the University Research Office within 24 (twenty four) hours. Care should be taken to describe how the incident / adverse event was contained and how the matter will be resolved. The Applicant then electronically reports the incident / adverse event and how it will be resolved, as well as the steps to be taken to prevent further incidents / adverse events of this nature to the HREC (Non-Medical) and University Research Office.

16.2. The HREC (Non-Medical) with the University Research Office has to effectively manage the reported incident / adverse event within a 24 (twenty four) hour period. It should also be followed up telephonically by phoning the HREC (Non-Medical) Chairperson / Co-Chairperson indicating that an incident or adverse event has occurred.

16.3. When such an incident or adverse event happens the Applicant must stop the study immediately and take all reasonable and appropriate steps to avoid further occurrences.

16.4. The Chairperson / Co-chairperson will notify all members of the HREC (Non-Medical) and the Research Office of such incident / adverse event at the next HREC (Non-Medical) meeting in order for transparency reasons.

16.5. Support staff including the Secretariat, but excluding the DVC: R&PGA, Director: Research Development and the Legal Adviser and Research Compliance Manager,
are not confined during this process to ensure that the privacy of all involved is maintained while the incident is being handled.

16.6. A meeting is scheduled as soon as possible with the HREC (Non-Medical) Chairperson and 2 (two) other members of the HREC (Non-Medical) and the University’s Research Office to decide how the incident / adverse event will be handled.

16.7. If additional assistance is required in the incident management strategy, other members could be co-opted.

16.8. Any further reports from the researcher are sent directly to the Chairperson / Co-Chairperson. The Chairperson / Co-Chairperson then sends these to the DVC: R&PGA, director: Research Development and the Legal Adviser and Research Compliance Manager.

16.9. Once the incident / adverse event has been satisfactorily dealt with, according to the agreement of the HREC (Non-Medical) members, DVC: R&PGA and other parties, and all outstanding documentation has been received, the incident / adverse event report is finalised and signed by the Director: Research Development, the Chairperson / Co-Chairperson and other members of the HREC (Non-Medical).

16.10. If it is deemed necessary to include the Dean of the Faculty, a specific Head of School, and the Applicant’s supervisor if the Applicant is a student, a meeting is scheduled and the matter is reported to him / her.

16.11. Following completion of this process, the applicable Secretariat / administrator officer will be informed of the incident / adverse event by receiving a hard and/or electronic copy of all the required documentation related to the reporting and management of the incident / adverse event.

16.12. The Secretariat / administrator officer will place the incident / adverse event on the agenda of the next HREC (Non-Medical) meeting, during which the Chairperson / Co-Chairperson will give a very brief description of the incident / adverse event and the manner in which it was dealt with.
16.13. Should any Wits personnel or infrastructure be threatened / hurt / damaged within the boundaries of the Republic of South Africa they should immediately contact the Chairperson / Co-Chairperson for facilitation of this emergency situation.

17. DOCUMENTATION AND ARCHIVING

17.1. The following guidelines will apply to the documentation and archiving of submissions and applications, and the decisions of the HREC (Non-Medical):

17.1.1. The Secretariat of the HREC (Non-Medical) which resides in the Research Office is responsible for all documentation with regard to submissions and applications, as well as the archiving of reports and decisions of the HREC (Non-Medical).

17.1.2. All documentation and communications of the HREC (Non-Medical) will be dated, filed, and archived according to standard procedures applicable to the administration of HREC (Non-Medical).

17.1.3. The documentation and archive of the HREC (Non-Medical) is administered and governed according to the standard procedures and policies of the University, as applicable; i.e., submit documentation to the Registry Office, 4th Floor in Solomon Mahlangu House.

17.1.4. Records of the HREC (Non-Medical) will normally be archived for a minimum period of 15 (fifteen) years following the completion of the project—depending on the University policies, the Promotion of Access to Information Act, 2 of 2000, the Protection of Personal Information Act 4 of 2014 (also plays a role in this regard) and any other legislation that may be applicable.

17.1.5. Online submissions will be stored directly on the database of the online submissions system and via email archiving.

17.2. Documents that should be filed and archived include, but are not limited to:
17.2.1. The Research Integrity Policy, written terms of reference and standard operating procedures of the HREC (Non-Medical), and regular (annual) reports;

17.2.2. The published guidelines for submission established by the HREC (Non-Medical);

17.2.3. The agendas of the HREC (Non-Medical) meetings;

17.2.4. The minutes of the HREC (Non-Medical) meetings;

17.2.5. One (1) copy of all materials submitted by an applicant to the HREC (Non-Medical);

17.2.6. The correspondence by HREC (Non-Medical) members with applicants or concerned parties regarding an application, the decision on it, and follow-up;

17.2.7. A copy of the decision and any advice or requirements sent to an applicant by the Secretariat or the HREC (Non-Medical);

17.2.8. All written documentation or correspondence received during the processing of the application;

17.2.9. The notification of the completion, premature suspension, or premature termination of a study;

17.2.10. Annual reports;

17.2.11. The final summary or final ethics report on the study.

18. ADOPTION OF, AND CHANGES TO, THIS STANDARD OPERATING PROCEDURE

18.1. Changes to this Standard Operating Procedure can be made at any ordinary meeting of the HREC (Non-Medical) and any such changes must be noted by the URC. The HREC (Non-Medical) must assess the efficacy of its Standard Operating Procedure at least once a year, and minute the results of this assessment at one (1) of its ordinary meetings.
19. **AUDITING AND ACCREDITATION OF THE HREC (NON-MEDICAL)**

19.1. The HREC (Non-Medical) will be registered with the National Health Research Ethics Council ("NHREC"). It will be regularly audited by the NHREC. The University Research Committee and / or Research Office may be entitled to carry out check audits at any point in time without prior notification.

20. **REGULATORY FRAMEWORK**

20.1. This HREC (Non-Medical) functions within the framework of all relevant promulgated Acts legislation of Parliament and international treaties and conventions to which the Republic of South Africa is a signatory, interpreted in a manner appropriate to research in the humanities, (i.e. the social, behavioural, economic and educational sciences). Examples of relevant Acts, treaties and conventions include, but are not limited to:


20.1.2. The Children's Act, Act 38 of 2005;

20.1.3. National Health Act, Act 61 of 2003;

20.1.4. Promotion of Access to Information Act, Act 2 of 2000; and


21. **POLICIES AND GUIDELINES**

21.1. In addition to the regulatory framework, the HREC (Non-Medical) functions within the framework of the following documents:

21.1.1. Department of Health, Ethics in Health Research: Principles, Processes and Structures, 2nd ed. 2015; and

22. DEFINITIONS

Unless the context clearly indicates otherwise, the following terms will bear the following meanings:

22.1. “Applicant” any student or staff of the University or any third party undertaking any research involving human subjects (i.e. human participants)

22.2. “Confidentiality” While confidentiality may be desirable, it cannot be guaranteed in, for example, focus groups, or ethnographic observation. Similarly anonymity should be preserved in questionnaires, but cannot be offered in workshop methodologies, focus group research. Participants should have the right to remain anonymous in the final report, and this must be respected in handling of all data relating to them. Participants need to be informed about these issues.

22.3. “Consent” Consent in social science and humanities research involving human participants:

Consent in social science and humanities research involving human participants:

Where informal ethnographic or participant observation methods are used, or where signed Consent Forms are not possible, or for research involving group contexts (focus group, Participant Rapid Assessment, Rapid Rural Appraisal, public performance, workshops) state how the quality of informed consent will be assured. It is essential that participants in research be fully informed and agree, on this basis, to participate in the research.
22.4. “Conflict of Interest”

Incompatibility of duties, responsibilities or interests (personal or professional) of a person or an institution as regards ethical conduct of research so that one cannot be fulfilled without compromising another.

22.5. “Data”

‘Raw’ or "Unprocessed Data," especially where the identity or personal data of research participants is included, must be safeguarded and preserved from unauthorised access. Data may be destroyed after use, but preservation in an archive or personal collection may also be appropriate, desirable or even essential. For instance, data sets that contain historically important information or information that relates to national heritage must be preserved and should be placed in a public archive where possible and appropriate.

All data should be preserved in a way that respects the nature of the original participants’ consent.

22.6. “Days / days”

Refers to working days i.e. any day which is not a Saturday, Sunday or official public holiday in the Republic of South Africa.

22.7. “Ethics”

are defined as the rules of conduct recognised in respect to a particular class of human actions or a particular group, and are concerned with how morally accepted outcomes can be achieved in specific situations.
22.8. “Participants requiring additional attention” means "participants who fall into one or more of the following categories:
- Minors: Children and adolescents;
- Women: Women and Pregnancy;
- Persons with mental disabilities;
- Persons with substance abuse related disorders;
- Persons in dependent or subservient relationships (e.g., students where the investigator is directly involved in their training; employees where the investigator has line authority over them);
- Prisoners;
- Persons highly dependent on medical care:
  - Intensive care;
  - Neonatal intensive care;
  - Terminal care;
  - Persons with impaired capacity to communicate;
- Unconscious persons;
- Specific social collectives;
- Persons in indigenous medical systems;
- Emergency care research;
- Innovative therapy or intervention;

22.9. “Permission” Obtaining permission is necessary when conducting research within the premises of a particular site such as ethnography of the functioning of a supermarket or a school, or the way teachers interacts with learners in a school environment.
22.10. "Risk Levels of Research"

Risk levels of research are given in the document available for download from the HREC (Non-Medical) website.

22.11. "School Sub-committees of the HREC (Non-Medical) / Sub-committees"

Research Ethics Committees at Departmental, School or Faculty level, constituted as Sub-Committees of the HREC (Non-Medical), which review protocols for ethics clearance purposes. These Sub-Committees shall only review protocols from undergraduates, Honours students, and Masters by Coursework and Research Report students. All Masters by Dissertation, Doctoral, and non-degree protocols should be referred to the HREC (Non-Medical).

22.12. "Vulnerable Categories"

The term 'vulnerable categories' includes, among others, children under 18 (eighteen) years old, orphans, prisoners, persons with cognitive or communication disorders, people who are traumatised or currently in traumatic situations. Where necessary, include details of steps to be taken to facilitate data collection across language barriers (e.g. interpretation or translation).

22.13. "Vulnerable Communities"

means "communities which have some or all of the following characteristics:

• Limited economic development;
• Inadequate protection of human rights and discrimination on the basis of health status;
• Inadequate community or cultural experience with the understanding of scientific research;
• Limited availability of health care and treatment options;
• Limited ability of individuals in the community to provide informed consent;
• Culturally marginal groups
• Persons involved in illegal activities or livelihoods.” (SA DoH, 2004).

23. REFERENCES

23.1. Council for International Organizations of Medical Sciences (CIOMS) (2002);

23.2. International Ethical Guidelines for Biomedical Research involving Human Subjects. Geneva;


23.5. Human Sciences Research Council (HSRC) (n.d.). Research Ethics Committee Terms of Reference;

23.6. Medical Research Council: (2000). Guidelines on Ethics for Medical Research: General Principles. Cape Town; and

23.7. The North West University Research Ethics Committee

24. ACKNOWLEDGEMENTS

24.1. The following sources are acknowledged for their input into the development of this SOP:

24.1.1. North West University Research Ethics Committee; and

24.1.2. UCT
## 25. APPROVAL HISTORY OF THE SOP

<table>
<thead>
<tr>
<th>STRUCTURE CONSULTED</th>
<th>Target date for discussion**</th>
<th>Date approved/discussed#</th>
<th>Date noted#</th>
</tr>
</thead>
<tbody>
<tr>
<td>HREC (Non-Medical)</td>
<td>20 October 2017</td>
<td>20 October 2017</td>
<td>-</td>
</tr>
<tr>
<td>University Research Committee</td>
<td>09 November 2017</td>
<td>November 2018</td>
<td></td>
</tr>
<tr>
<td>University Research Committee</td>
<td>28 February 2020</td>
<td>28 February 2020</td>
<td></td>
</tr>
<tr>
<td>University Research Committee</td>
<td>29 January 2021</td>
<td>29 January 2021</td>
<td></td>
</tr>
</tbody>
</table>

* Outline which structures will be consulted on this issue, and in which order

** Indicate which meeting of each structure is being targeted.

# This date is only filled in when the specific body has dealt with the issue.

25.1. Submission Content

25.2. Proposal (Complete the sentence: This body is requested to approve the draft Standard Operating Procedures of the Human Research Ethics Committee Non-Medical ("HREC (Non-Medical)"):  

25.2.1. University Research Committee ("URC") is requested to approve new Terms of Reference and Standard Operating Procedures for the HREC (Non-Medical) at the University of the Witwatersrand, Johannesburg ("University" / "Wits").

25.3. Motivation (Please put down the reasons why this decision should be reached, that is, why this should be supported):
25.3.1. The proposed Terms of Reference and Standard Operating Procedures are designed to ensure that the Human Research Ethics Committee (NON-MEDICAL) HREC (Non-Medical) at the University of the Witwatersrand, Johannesburg is compliant with the requirements of the National Health Act 61 of 2003 (“National Health Act”) and the Department of Health, Ethics in Health Research: Principles, Processes and Structures, 2nd ed. 2015 (“National Guidelines 2015”). At the University, Johannesburg is compliant with the requirements of the National Health Act (Act 61 of 2003) and with the Department of Health Guidelines for Health Research (2004).

25.4. Financial Implications (Outline what it will cost)

25.4.1. Applicants with no affiliation to the University or are considered to be external applications to the University can approach any of the NHREC-registered RECs of the University to review and approve their research proposals, where such an REC may on a case-by-case basis decide whether it is the appropriate REC to deal with the matter and whether the REC is willing and has proper expertise and capacity to evaluate the application.

25.4.2. The HREC (Non-Medical) can review research proposals / Protocols / applications of Applicants that are not affiliated to University, or external applications subject to payment of a cost (“Review Fee”) levied for such service in the current amount of R15 000,00 (fifteen thousand Rand) plus VAT (currently at 15%) as per the Value Added Tax Act as amended from time to time, which Review Fee is payable upon submission. The Review Fee may change from time to time. The Review Fee is not for any Applicants within the University. The Review Fee is subject to the HREC (Non-Medical) Chairperson’s discretion, in consultation with the Secretariat and Research Office.