NELSON MANDELA UNIVERSITY

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

- Ethical and regulatory requirements for human research
- Activities that may not require ethics approval
- Definitions of terminology used in the ethics approval process

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All Standard Operating Procedures (SOPs) and associated documentation must only be accessed through the Nelson Mandela University Research Ethics (Human) website at https://rd.mandela.ac.za/Research-Ethics/Research-Ethics-Committee-Human-(REC-H) to ensure that the correct and most recent version is being used. It is the responsibility of the user of the documentation to ensure that the current version of the SOPs and associated documentation is being used.

Acknowledgement is given to the following institutions for access to documents on their Standard Operating Procedures which supported the development of this document:

- University of Cape Town [1]
- University of Stellenbosch [2]
- University of Free State [3]

1 VERSION HISTORY LOG

Version	Date	Reason for change	Implementation Plan
1.1	February 2022	Updated following National Health Research Ethics Council (NHREC) Quality Assurance Audit Report (July 2018)	Administrative support staff will receive training regarding the new SOPs. All users to be notified of the revised SOPs. Current version of SOPs to be available on REC-H website.

2 SYNOPSIS OF POLICY AND PURPOSE OF GUIDING PRINCIPLES CONTAINED WITHIN THE STANDARD OPERATING PROCEDURE (SOP)

1. Policy: Any activity, defined as research that involves human participants, planned and conducted by staff and/or students of Nelson Mandela University and affiliated institutions or on its premises, is subject to prior approval by REC-H.
2. The purpose of these guidelines is to define
   a. those activities that constitute human research and fall under the jurisdiction of REC-H;
   b. the terminology used in the context of the application, review and approval of research involving human participants; and
   c. the REC-H SOP documents relating to tasks and practices associated with the functions of REC-H, review and approval of research involving human participants, requirements for conducting and managing research involving human participants and continuing review of such research.

3 WRITING, REVISING AND MANAGING STANDARD OPERATING PROCEDURE (SOP)

This SOP will be written, revised, and managed as indicated in the table below.

SOP Title	Standard Operating Procedure Research Ethics Committee Human (REC-H)
Field of application	All staff and students engaged in research activities, Research Associates, External Researchers
Person(s) responsible for implementation	Research project leaders, study leaders, promoters, HODs, Deans, Directors, Research Development, DVC:RII
Person(s) responsible for drafting, review and revision	REC-H Chairperson Director: Research Development REC-H Secretariat
Status	Revised
Approval route	REC-H
Approving authority	Research and Engagement Committee
Relevant related policies	Policy on Research Ethics Code of Conduct for Researchers Whistleblowing Policy and Procedure Supply Chain Management
Stakeholder consultation	Research and Engagement Committees, Research Ethics Committees, Senate
SOP owner	DVC: RII, Director: Research Development, REC-H Chairperson
Approval date	Date Month 2022

4 ETHICAL AND REGULATORY REQUIREMENTS FOR HUMAN RESEARCH

1. Nelson Mandela University sets itself the aim of conducting research with:
   a. scholarly integrity and excellence,
   b. social sensitivity and responsibility,
   c. respect for the dignity and self-esteem of the individual and for basic human rights,
   d. reference to clearly specified standards of conduct and procedures that ensure proper accountability.
2. In the pursuit of this ideal, the University subscribes to the interdependent principles of scholarly responsibility, integrity and honesty, of human dignity and of academic freedom and openness. In the research context, these principles manifest in the relationships between the researcher and the research community and its ethos, research participants, society as a whole, and funders of research.
3. Mandela University therefore affirms the requirement that all research involving human participants be subject to prior ethics review, according to faculty and institutional guidelines, in order to ensure that harm to research participants is prevented or minimized and balanced against the likelihood of benefit. The Nelson Mandela University Research Ethics Committee (Human) (REC-H) is responsible for *inter alia* reviewing, approving and monitoring research involving humans.
4. REC-H does so by following ethical guidelines for research as stated by
   a. The Belmont Report 1979
   b. the World Medical Association Declaration of Helsinki[5]

c. the Department of Health of South Africa[4]
d. as well as other relevant declarations and statements in the area of research ethics, but not limited to the following documents and guidelines, to ensure compliance with national and international practices, including POPIA[6-26], through the Terms of Reference, relevant Standard Operating Procedures (SOPs), the Code of Conduct for Researchers and the Research Ethics Policy functions. The documentation related to ethical and regulatory requirements for human research can be accessed at https://rd.mandela.ac.za/Research-Ethics/Research-Ethics-Committee-Human-(REC-H).

5. REC-H is committed to the following ethical requirements.
   a. Social value
   b. Scientific merit
      i. It aims to protect the rights and welfare of research participants and researchers by adhering to the principles of beneficence, justice and respect for people, especially vulnerable populations. In so doing, it assesses the ethical implications of the **study design and research methodology.**
   c. Respect for persons
   d. Respect for vulnerable persons
   e. Privacy and confidentiality
   f. Fair participant and community selection
   g. Favourable balance of benefits and harms
   h. Collaborative partnerships
      i. To ensure that research is relevant and acceptable, researchers should engage key stakeholders such as community representatives and policy makers in designing the protocol, conducting the research and distributing the findings.
      ii. Moreover, community participation could include input into a suitable informed consent process, appropriate risk reduction interventions and decisions regarding treatment and care linked to the research. Collaborative partnerships should allow community members to become genuine, active partners in the research process. This requires sustainable forums for regular communication and problem solving.
      iii. Similarly, in international multi-centre research, collaborative partnerships between researchers and sponsors from developed countries and researchers and communities in the host country are likely to reduce exploitation, facilitate the negotiation of fair benefits and show awareness of and respect for cultural differences.
   i. Ethical review
   j. Professional competence
6. Prior authorisation
   a. Some research activities are so high risk that the Information Regulator must be approached for prior authorisation before the activity commences or continues. This is to allow the Information Regulator to determine whether there are satisfactory safeguards in place to protect the personal information i.e., assessing the security of the information.
   b. Nelson Mandela University REC-H notes that the application for exemption from section 57(1) of POPIA on public interest grounds is in progress on behalf of all universities via the USAF Code of Conduct (CoC) for Universities 2020. As the CoC has not been approved by February 2022, it means that in order to comply, Mandela University REC-H has to -
      i. identify which projects are affected,
      ii. apply for prior authorisation from the Information Regulator, and
      iii. suspend processing until authorization is received or the statutory periods of four weeks and 17 weeks expire.

7. Insurance coverage
    a. The university has insurance coverage for research related injuries for participants and/or researchers. In the event of a research activity having known risk of such incidents, full details are to be provided of such risks prior to approval. In the case of an unexpected adverse event occurring, it is the researchers' responsibility to immediately log a record of such an event with REC-H.

5 ACTIVITIES THAT MAY NOT REQUIRE REC-H APPROVAL

1. The implications of engaging in research activities that require prior REC-H review without obtaining such review and approval are grave. The use and/or publishing of results obtained from unapproved research activities is in violation of national and international norms and standards, University policy and the NDoH Ethics in Health Research Guidelines (2024)[7]. Further, such data should not be included in a thesis or dissertation. Researchers are encouraged to consult a journal's publishing policies before initiating unapproved studies since many journal editors require evidence of REC approval as a condition of publication of research involving human participants. Even if the study involving human participants is for audit and/or quality improvement purposes or record reviews, if any publication and/or academic qualification could possibly arise from the findings, prior ethical approval is required. REC-H does NOT give retrospective approval for completed audits and/or record reviews, nor for any research study involving human participants. Prior ethical approval is a requirement.
2. Researchers who regularly collect data and/or biological samples from human participants for non-research purposes are encouraged to register such databases and/or repositories with REC-H which will facilitate the use of these repositories for research purposes at some future date.
3. Scholarship of Teaching of Learning (SoTL) involves staff (sometimes in partnership with their students) undertaking systematic inquiry about student learning. This is informed by prior scholarship on teaching and learning and could involve sharing the results with the public. SoTL studies require approval from REC-H.
4. A list of activities that may not require REC-H approval includes but is not limited to (refer to the REC-H website for further guidance):
    a. Research that makes use exclusively of documents and/or data that is accessible in the public domain i.e., secondary data or accessible through legislation or regulation usually need not undergo formal ethics review.
    b. Research that relies exclusively on secondary use of anonymous information or anonymous human biological materials usually need not undergo formal ethics review, provided that no identifiable information is generated.
    c. Research involving observation of people in public spaces and natural environments usually need not undergo formal ethics review provided that
        - the researcher does not interact directly with individuals or groups
        - the researcher does not stage any intervention
        - the individual or groups do not have a reasonable expectation of privacy
        - dissemination of research findings does not identify individuals or groups
    d. Quality assurance and quality improvement studies (audits), programme evaluation activities and performance reviews usually do not constitute research and thus usually do not undergo formal ethics review. However, if there is any potential for these activities to be published in any form external to the local University context, it is prudent to obtain ethics approval prior to commencing the study. Retrospective approval for studies is not possible.
    e. Certain undergraduate course related activities such as assignments which involves human participants that are not vulnerable groups should be exempt from ethics review, provided that the work will not be published, and that the relevant faculty takes responsibility to issue a letter for that

particular course related activity which covers any institutional risk. However, this course assignment activity must be differentiated from the undergraduate 4th year Research projects.

5. In the case of any doubt, it is advised to err on the side of caution and apply for ethics approval. In such cases it is also advised to liaise directly with the REC-H Chairperson for guidance.

6 DEFINITION OF TERMINOLOGY USED IN THE REVIEW AND APPROVAL OF REC-H APPLICATIONS

1. REC-H uses the following definitions in its processes.

TERM	***EXPLANATION***	***DOCUMENT REFERENCE***
Adverse event	An undesirable experience on the part of a participant.	Progress Report (RECH-004)
Advisory recommendations	Those recommendations which the PI/PRP are advised to note but which are not subject to approval.	Application Form (RECH-001)
Amendment	A minor change or addition with the aim of improving the data collection procedure.	Progress Report (RECH-004)
Anonymity	A situation where any data collected does not have any identifying information or direct link to any individual participant or group of participants.	Application Form (RECH-001); Application Form Sub-study (RECH-003S)
Approved with major modifications	Application in current form requires review in terms of the identified human ethics deficiencies.	Application Review Feedback Form (received by PI/PRP upon review of the application submission)
Approved with minor modifications	Application in current form requires review in terms of the identified deficiencies – generally sufficient consideration has been given to human ethics matters.	Application Review Feedback Form (received by PI/PRP upon review of the application submission)
Approved with no corrections	Application approved and approval letter is issued.	Application Review Feedback Form (received by PI/PRP upon review of the application submission)
Assent	Any record of agreement for a minor/child to participate in the data collection process. Parents/guardians are required to give consent for researchers to approach minors/children to participate in any data collection activities and minors are required to give assent. Consent from a parent/guardian does not automatically imply	Application Form (RECH-001); Application Form Sub-study (RECH-003S)

TERM	***EXPLANATION***	***DOCUMENT REFERENCE***
	that the affected minor(s)/child(ren) are obligated to assent to participate in the data collection procedure.	
Benefit	Any possible direct positive effect of any data collection activity on the welfare of a participant over and above what would be expected from such a participant as a result of routine daily tasks.	Application Form (RECH-001); Application Form Sub-study (RECH-003S); Progress Report (RECH-004)
Child / minor	'Child' is defined the POPIA 2013 as 'a natural person under the age of 18 years who is not legally competent, without the assistance of a competent person, to take action or to make decisions in respect of any matter concerning him- or herself'	
Compliance audit	The audit of the conduct and records of the approved research to verify compliance with REC-H requirements and conditions.	Standard Operating Procedures
Collaborative research	Research involving coordination between the researchers, institutions, organizations, and/or communities.	
Conflict of interest	A compromised situation as regards ethical conduct of research as a result of conflicting duties, responsibilities or interests (personal, professional or otherwise) on the part of the PI and/or PRP and/or participant recruiter and/or gatekeeper and/or sponsor of the study.	Application Form (RECH-001); Application Form Sub-study (RECH-003S); Application Form Umbrella (RECH-003U); Progress Report (RECH-004); Request for Access to Staff and Students (RECH-011)
Consent	Any record of **voluntary, specific and informed** expression of will in terms of which permission is given for the participation in the data collection process, and for the processing of personal information. Consent must be specific to be valid. The consent must always relate to a specific processing purpose. A blanket consent to the processing of personal information will not be valid. If the consent relates to multiple processing purposes, separate consent should be obtained for each processing purpose. In other words, the consent must be granular. Consent must be informed. Prior to consenting in this manner, data subjects must be given information about the consent before they make their decision, e.g. participants must have received information on the study	Application Form (RECH-001); Application Form Sub-study (RECH-003S)

TERM	***EXPLANATION***	***DOCUMENT REFERENCE***
	and what would be required from them as well as been given the opportunity to engage with the researcher regarding the study, giving rise to informed consent, a legal requirement. The consent must be drafted in clear, plain language and for this the institution must take the kind of audience the consent is aimed at into account. Consent must be explicit. The consent must be explicit. This means that consent has to be given through a clear, unambiguous, affirmative act. Silence or inactivity cannot be taken as consent which is why the use of pre-ticked opt-in boxes is not allowed. Data subjects must be free to withdraw consent without undue effort. It is considered best practice for the withdrawal of consent to be possible through the same channel that consent was obtained.	
Data analysis	The process of systematically applying statistical and / or logical techniques to describe and illustrate, condense and recap, and evaluate data. Analysis transforms the data into insights.	Application Form (RECH-001); Application Form Sub-study (RECH-003S)
Data collection instruments	Research methods / techniques used for the collection of data from human subjects (e.g. survey, questionnaire, interview schedule, etc.).	Application Form (RECH-001); Application Form Sub-study (RECH-003S)
Data collection procedure/process	The systematic process by which observations or measurements are collected, using research methods/techniques, on targeted variables in an established system, which enables one to answer relevant questions and evaluate outcomes.	Application Form (RECH-001) Application Form Sub-study (RECH-003S)
Data processing (referring to personal information)	‘‘**processing’’** means any operation or activity or any set of operations, whether or not by automatic means, concerning personal information, including— (a) the collection, receipt, recording, organisation, collation, storage, updating or modification, retrieval, alteration, consultation or use; (b) dissemination by means of transmission, distribution or making available in any other form; or (c) merging, linking, as well as restriction, degradation, erasure or destruction of information;	POPIA 2013
Data record	**‘‘record’’** means any recorded information— (a) regardless of form or medium, including any of the following: (i) Writing on any material; (ii) information produced, recorded or stored by means of any tape-recorder, computer equipment, whether hardware or software or both, or other device, and any material	POPIA 2013

TERM	***EXPLANATION***	***DOCUMENT REFERENCE***
	subsequently derived from information so produced, recorded or stored; (iii) label, marking or other writing that identifies or describes anything of which it forms part, or to which it is attached by any means; (iv) book, map, plan, graph or drawing; (v) photograph, film, negative, tape or other device in which one or more visual images are embodied so as to be capable, with or without the aid of some other equipment, of being reproduced; (b) in the possession or under the control of a responsible party; (c) whether or not it was created by a responsible party; and (d) regardless of when it came into existence;	
Data reporting	The process of collecting and submitting data which gives rise to accurate analyses of the facts. Data reporting is the step that translates raw data into information i.e. the step before data analyses.	Application Form (RECH-001); Application Form Sub-study (RECH-003S)
Data re-use	The use of data collected and entrusted to researchers in the context of the current study for other research purposes. The publication of research manuscripts as a result of the current study is not classified as re-use of data.	Application Form (RECH-001); Application Form Sub-study (RECH-003S)
Data storage	The manner in which data is stored for short and long term, with due consideration given to the protection of privacy and anonymity of the data. Personal data to be stored in line with the POPI Act, whereby personal information may be processed with the consent of the data subject or a competent person where the data subject is a child, if the data subject or a competent person where the data subject is a child, consents to the processing, then the processing of personal information is justified.	Application Form (RECH-001) Universities South Africa. 2020. POPIA Industry Code of Conduct: Public Universities (the code) [25] POPIA 2013
Date of commencement of data collection	The date upon which data collection for the study will commence. This date must occur after the anticipated date of ethics approval and at least 6 weeks after the date of submission of the application for review.	Application Form (RECH-001); Application Form Sub-study (RECH-003S); Application Form Umbrella (RECH-003U)
De-identify / de-identified (referring to personal information)	‘‘**de-identify**’’, in relation to personal information of a data subject, means to delete any information that— (a) identifies the data subject; (b) can be used or manipulated by a reasonably foreseeable method to identify the data subject; or (c) can be linked by a reasonably foreseeable method to other information that identifies the data subject.	POPIA 2013

TERM	***EXPLANATION***	***DOCUMENT REFERENCE***
Deviation	That process that falls outside the approved set of processes.	Progress Report (RECH-004)
Discontinuation	Discontinuation of a study refers to an investigator-initiated voluntary suspension or termination, whereby an investigator may choose to voluntarily suspend or terminate some or all activities of an approved protocol.	
Duration of data collection	The anticipated maximum period (in months) of the PI/PRP/research assistants' direct interaction with human subjects from date of commencement of data collection. This period shall not exceed 12 months. Should the approved data collection procedure require a period exceeding 12 months, the PI/PRP shall apply for an extension of the data collection procedure after 10 months of the approved period of 12 months has passed and submit such extension application together with an annual report of the data collection activities to date for review and approval.	Application Form (RECH-001) Application Form Sub-study (RECH-003S)
Enrolment	The methods/techniques used by researchers to screen, and select participants from those who have volunteered to participate in the study. Evidence must be provided of a fair identification, screening and selection process.	Application Form (RECH-001); Application Form Sub-study (RECH-003S)
Exception	That occurrence that is inconsistent with an anticipated outcome.	Progress Report (RECH-004)
Exclusion criteria	That set of characteristics that excludes volunteers (i.e. those individuals who have been recruited and have indicated a willingness to participate) from contributing to the data collection procedure. Unless there are good reasons for deception, exclusion criteria must be made available in writing at the point of recruitment.	Application Form (RECH-001); Application Form Sub-study (RECH-003S); Progress Report (RECH-004)
Extension\renewal	The extension of the period for data collection activities, which is for one year, to a maximum of three years.	Progress Report (RECH-004); Extension (RECH-005)
Feedback	The sharing of findings from the data collection procedure with the original source (i.e. participants) and possibly other sources (e.g. sponsors, gatekeepers, community, etc.). It is preferred that participants, at least, be the recipients of some form of summarised feedback. Should feedback be given to other sources (e.g. sponsors, gatekeepers, community, etc.), the intention to do so should be shared at point of recruitment.	Application Form (RECH-001); Application Form Sub-study (RECH-003S)
Gatekeeper	A person(s) who control(s) access to the participant population. A gatekeeper shall not also fulfil the role of participant recruiter.	Application Form (RECH-001); Application Form Sub-study (RECH-003S)

TERM	***EXPLANATION***	***DOCUMENT REFERENCE***
Human participant	An individual about whom an investigator conducting research obtains data through intervention or interaction with individual or identifiable private information.	UCT REC-H SOP
Identifiable	The identity of an individual is or may be readily ascertained or associated with reported information.	Risk Assessment section in Application Form (RECH-001)
Incidental findings	Any unexpected discovery made during the course of data collection/analysis, these findings being outside the scope of the research. Cognisance to be given to relevant mandatory reporting procedures should such be relevant to the context of the study.	Application Form (RECH-001); Application Form Sub-study (RECH-003S)
Inclusion criteria	That set of characteristics that all participants must exhibit so as to be included in the data collection procedure. Unless there are good reasons for the deception, inclusion criteria must be made available in writing at the point of recruitment.	Application Form (RECH-001); Application Form Sub-study (RECH-003S); Progress Report (RECH-004)
Insurance	Refers to the insurance or indemnity covering the liability of the investigator in respect of claims made against them by the participants with respect to injury attributable to their participation in a research project.	Application Form (RECH-001); Progress Report (RECH-004)
Institutional environment	Institutions like hospitals, prisons, mental institutions, and so forth.	Application Form (RECH-001); Application Form Sub-study (RECH-003S)
Intervention/interaction	Includes physical procedures performed on an individual, manipulation, communication or interpersonal contact with an individual or manipulation of an individual's environment.	Risk Assessment section in Application Form (RECH-001)
Low risk study	A study where the only foreseeable risk is one of discomfort to the participants.	Application Form (RECH-001); Application Form Sub-study (RECH-003S); Application Form Umbrella (RECH-003U)
Minimum number of participants	The minimum number of participants required to make the study viable. It must be noted that it is as unethical to require too many participants than is actually necessary (wasting the time of participants) as it is to require too few participants (also wasting participants' time since the study would then not be viable).	Application Form (RECH-001); Application Form Sub-study (RECH-003S)
Negligible risk study	A study where the only foreseeable risk is one of inconvenience to the participants. Inconvenience is of a lower level of risk than discomfort.	Application Form (RECH-001); Application Form Sub-study (RECH-003S);

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		Application Form Umbrella (RECH-003U)
Non-compliance	The result of deviating from approved processes.	Standard Operating Procedures
Not approved application	Application in current form is rejected on human ethics grounds.	Application Review Feedback Form (received by PI/PRP upon review of the application submission)
Obligatory recommendations	Those recommendations that are required to be addressed as part of the response to the initial review.	Application Review Feedback Form (received by PI/PRP upon review of the application submission)
OHRP	US Office for Human Research Protections	US Department of Health and Human Services
Participant	A living individual (or group of living individuals) about whom a researcher conducting research obtains data through an intervention or interaction with the individual or identifiable private information. A participant is an individual who has indicated a willingness to participate and who has subsequently been selected for participation.	Application Form (RECH-001)
PI	Primary investigator. The person undertaking the study.	Application Form (RECH-001); Application Form Umbrella (RECH-003U); Progress Report (RECH-004); Request for Access to Staff and Students (RECH-011)
Personal information	'Personal information' means information relating to an identifiable, living, natural person, and where it is applicable, an identifiable, existing juristic person, including, but not limited to – (a) information relating to the race, gender, sex, pregnancy, marital status, national, ethnic or social origin, colour, sexual orientation, age, physical or mental health, well-being, disability, religion, conscience, belief, culture, language and birth of the person; (b) information relating to the education or the medical, financial, criminal or employment history of the	POPIA 2015. Universities South Africa. 2020. POPIA Industry Code of Conduct: Public Universities (the code) [25]

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	person; (c) any identifying number, symbol, email address, physical address, telephone number, location information, online identifier or other particular assignment to the person; (d) the biometric information of the person; (e) the personal opinions, views or preferences of the person; (f) correspondence sent by the person that is implicitly or explicitly of a private or confidential nature or further correspondence that would reveal the contents of the original correspondence; (g) the views or opinions of another individual about the person; and (h) the name of the person if it appears with other personal information relating to the person or if the disclosure of the name itself would reveal information about the person. If the link between the information and the data subject can be severed, a process referred to as de-identification or anonymisation, the POPIA no longer applies, however, ethics approval would still apply.	
Power relationship	A situation where the PI and/or PRP and/or participant recruiter (a co-worker/gatekeeper or similar) might be in a position of authority when recruiting participants, thereby creating an effect of undue influence and compromising the voluntariness of the recruitment and enrolment processes.	Application Form (RECH-001); Application Form Sub-study (RECH-003S)
Privacy and confidentiality	A situation where the researchers have the responsibility to protect data collected and entrusted to them for research purposes from unauthorised access, use, disclosure, modification, loss, theft, and so forth. Private information includes information that an individual can reasonably expect will not be made public, and information about behaviour that an individual can reasonably expect will not be observed or recorded.	Application Form (RECH-001); Application Form Sub-study (RECH-003S)
Processing of information	'Processing' means any operation or activity or any set of operations, whether or not by automatic means, concerning personal information, including – (a) the collection, receipt, recording, organisation, collation, storage, updating or modification, retrieval, alteration, consultation or use; (b) dissemination by means of transmission, distribution or making available in any other form; or (c) merging, linking, as well as restriction, degradation, erasure or destruction of information.	POPIA 2015. Universities South Africa. 2020. POPIA Industry Code of Conduct: Public Universities (the code) [25]
PRP	Primary responsible person. This individual must be a fulltime member of permanent staff, or a research associate and professional associate, and usually the	Application Form (RECH-001); Application Form Umbrella (RECH-003U);

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	supervisor of the student in the case of the study being for the purposes of acquiring a qualification.	Progress Report (RECH-004); Request for Access to Staff and Students (RECH-011)
Recruitment	The process used by researchers to identify and approach individuals to volunteer to contribute to the data collection for a study (these individuals being referred to as "**volunteers**"). A reasonable period of time should elapse between recruitment of volunteers and enrolment of "**participants**" (those individuals who have indicated a willingness to participate and who have been subsequently selected for participation).	Application Form (RECH-001); Application Form Sub-study (RECH-003S); Progress Report (RECH-004)
Research	A systematic investigation, including research development, and testing and evaluation, designed to develop or contribute to generalizable knowledge.	
Researcher	Researchers may include academic staff, non-academic staff, post-doctoral fellows, graduate and undergraduate students and visiting scholars.	
Research Participant	A living individual (or group of living individuals) about whom a researcher conducting research obtains data through an intervention or interaction with the individual or identifiable private information. A participant is an individual who has indicated a willingness to participate and who has subsequently been selected for participation.	Application Form (RECH-001)
Research repository	Collection of information and/or human biological materials for research purposes which includes but is not limited to data from multiple sources, modified over time with access controlled via a gatekeeper. Data may or may not be anonymised.	Standard Operating Procedures
Researcher competence and expertise	All listed collaborators and personnel assisting with the research are expected to be appropriately qualified and competent to conduct the research component in which they are involved.	Application Form (RECH-001)
Resolution on formal review feedback form	**NOT APPROVED**: application in current form is rejected on human ethics grounds. **RESUBMISSION**: application in current form is rejected on human ethics grounds, but the researchers are invited to review extensively and resubmit for review. **APPROVED WITH MAJOR MODIFICATIONS**: application in current form requires review in terms of the identified human ethics deficiencies. **APPROVED WITH MINOR MODIFICATIONS**: application in current form requires review in terms of the identified	Application Review Feedback Form (received by PI/PRP upon review of the application submission)

TERM	***EXPLANATION***	***DOCUMENT REFERENCE***
	deficiencies – generally sufficient consideration has been given to human ethics matters. **APPROVED WITH NO CORRECTIONS**: application approved unconditionally.	
Resubmission of application invited	Application in current form is rejected on human ethics grounds, but the researchers are invited to review extensively and resubmit for review.	Application Review Feedback Form (received by PI/PRP upon review of the application submission)
Risk	Any possible negative effect of any data collection activity on the welfare of a participant over and above what would be expected from such a participant because of routine daily tasks.	Application Form (RECH-001); Application Form Sub-study (RECH-003S); Progress Report (RECH-004)
Safety of researchers	Any possible risk to the safety of the researchers during the data collection activity.	Application Form (RECH-001); Progress Report (RECH-004)
Secondary data	Documents and/or data that is accessible in the public domain.	
Societal and/or ethical value	Any possible benefit as a result of the study/data collection procedure that would be either temporarily or permanently transferred to the community from which participants are drawn.	Application Form (RECH-001); Application Form Sub-study (RECH-003S); Progress Report (RECH-004)
Study	The research project being conducted.	Application Form (RECH-001); Application Form Sub-study (RECH-003S); Application Form Umbrella (RECH-003U); Request for Access to Staff and Students (RECH-011)
Study closure	A suspension due to lapse of Committee approval will be referred to as an 'administrative closure' which will automatically occur when the Committee approval period expires.	
Sub-study	Any research projects being conducted as sub-projects of this study.	Progress Report (RECH-004)
Suspension	A suspension occurs when the REC-H Committee or Chair places a temporary hold on research that has been previously approved so that no new participants may be	

TERM	***EXPLANATION***	***DOCUMENT REFERENCE***
	accrued, no research interventions may occur unless necessary for currently enrolled participants' safety and welfare, and no follow-up may be conducted unless it is in the best interest of participants and approved by the Committee. Suspension describes suspensions as a result of the REC-H decision but can also describe suspensions that occur automatically due to a lapse of Committee approval. A suspension due to lapse of Committee approval will be referred to as an 'administrative closure' which will automatically occur when the Committee approval period expires. An investigator may choose to voluntarily suspend some or all activities of an approved protocol.	
Termination	Termination of a previously approved protocol occurs when the REC-H withdraws approval and stops all research activity permanently. No new participants may be enrolled, and no further research interventions can occur. Where indicated, follow-up visits may be conducted with Committee approval to monitor participants' safety and welfare. An investigator may choose to voluntarily terminate some or all activities of an approved protocol.	
Umbrella research project	A broad research project under which a number of smaller research projects fall. Typically, an umbrella research project is one in which a number of individual masters and doctoral students collaborate, with each individual masters and doctoral student conducting research to realise at least one objective of the umbrella research project. It is required that the individual masters and doctoral students submit independent ethics applications for their parts of the umbrella project. An umbrella research project is advised for groups of undergraduate and/or honours students undertaking small research projects. In this case, individual students are not required to submit independent ethics applications for as long as the data collection procedures and instruments are significantly similar.	Application Form (RECH-001) Application Form Sub-study (RECH-003S)
Violation	That occurrence/process that fails to comply with the data collection procedures for which approval was granted.	Progress Report (RECH-004)
Volunteers	Individuals approached during the recruitment process to volunteer to contribute to the data collection for a study.	Application Form (RECH-001)

TERM	***EXPLANATION***	***DOCUMENT REFERENCE***
Vulnerable group	The term is usually synonymous with "groups at risk". A group is generally considered vulnerable because there is good reason to suspect that the individuals in the group may have special difficulty giving free and informed consent to being the subjects of research. The vulnerability may be due to an inability to understand and give informed consent or to unequal power relationships that hinder basic rights. Although vulnerability is not an absolute condition certain groups of participants require careful consideration to ensure that, where appropriate, additional precautions are put into place. Vulnerable groups include minors (under 18 years of age), women, adults with factual incapacity to provide informed consent (e.g. mental impairment), persons in dependent relationships or comparable situations, persons highly dependent on medical care, persons with physical disabilities, prisoners, collectivities (persons participating in research as groups).	National Department of Health. 2024. Ethics in Health Research.[7] Department of Health. 2020. SA Good Clinical Practice: Clinical Trial Guidelines.[8]