HUMAN SCIENCES RESEARCH COUNCIL (HSRC)

RESEARCH ETHICS COMMITTEE (REC)

STANDARD OPERATING PROCEDURES (SOP)

DATE: OCTOBER 2023

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1. Preamble

The Human Sciences Research Council (HSRC) Research Ethics Committee (hereafter referred to as HSRC REC or REC) was established by the governing body of the HSRC in August 2002. The HSRC REC is mandated to fulfil its function by the Board of the HSRC, to which it reports on an annual basis.
The function of this committee is to promote research ethics in the organisation, and will primarily fulfil this function through independent, prospective, and ongoing ethics review of all social and human science research projects undertaken by members of staff of the HSRC.
No retrospective (*ex post facto*) ethics approval can or will be granted.
The REC will also review applications from researchers external to the HSRC where required and provide ongoing research ethics training to researchers and REC members.

2. Governance

Governance of the REC draws from relevant laws and HSRC policies. While research at the HSRC extends beyond the purview of health, most of the research reviewed by the HSRC REC falls under the definition of the National Health Act's (No. 61 of 2003) health research, which is:

"any research which contributes to knowledge of (a) the biological, clinical, psychological or social processes in human beings; (b) improved methods for the provision of health services; (c) human pathology; (d) the causes of disease; (e) the effects of the environment on the human body; (f) the development or new application of pharmaceuticals, medicines and (g) the development of new applications of health technology"

S72(7) defines clinical trials as "a systematic study, involving human subjects that aims to answer specific questions about the safety or efficacy of a medicine or method of treatment."

S73 of the Act makes it mandatory for all health research to be reviewed and approved by a REC registered with the National Health Research Ethics Council (NHREC).

3. Research ethics committee

3.1 Membership of the research ethics committee

Members of the REC are appointed through a transparent process. External members are appointed by the chief executive officer (CEO) of the HSRC following a formal recruitment and selection process. Invitation for nominations is publicised externally and to stakeholders. The chairperson of the committee is external and is assisted by two deputy-chairpersons, one external and one internal to the HSRC. Internal members are selected as follows: One researcher from each research unit is nominated by the Group Executives or head of the unit to be a member, with the possibility of nominating one or more alternates from each research unit to share the load of reviewing protocols and attending meetings. Of the unit representatives, one must be a research specialist, while the others should be experienced researchers at any level.

The CEO ensures that representation across the units provides coverage of the disciplines and methodologies of the human and social sciences, and that the REC is broadly represented. The list of appointed REC members is submitted to the HSRC Board for ratification.

The total number of REC members should be no less than 10. At least 40% and a minimum of 5 members of the REC should be external to the HSRC. Members of the REC are appointed to serve on the committee for a period of a three-year term, which is renewable twice.
REC membership should include appropriate expertise in line with the South African National

Department of Health (2015) *Ethics in health research: Principles, processes and structures*[1], hereafter referred to as DoH, 2015 as well as the United States Department of Health and Human Services (DHHS) in its 45 Code of Federal Regulations part 46 (45CFR46)[2] as follows:

- At least one layperson (e.g., a community representative with an informed interest in the social sciences).
- At least one member with knowledge of, and current experience in, the professional care, counselling, or health-related treatment of people (e.g., a registered medical practitioner, psychologist, social worker, or nurse).
- At least one member with professional training and experience in qualitative research methodologies.
- Members with professional training and experience in quantitative research methodologies.
- A member with expertise in biostatistics.
- A member with expertise in research ethics.
- At least one member who is legally qualified (which may include persons with broad expertise in human rights, including the rights of children, women, the elderly and other vulnerable groups.)

REC membership should include young academics (between 25-35) with Masters Degrees and who may be working towards their PhDs to allow for succession planning.

Members need to provide the REC's administrative office with an abbreviated CV and proof of research ethics training at the beginning of their term.

Members need to have continuous personal development in research ethics. Proof of assessed training should be submitted to the REC office on an annual basis.

The membership and composition of the REC as of 31 August 2022 are provided in Annexure A.

3.2. Conflicts of interest

Members of the REC should make decisions and conduct their oversight responsibilities in an independent manner, free from bias and undue influence.

REC members whose applications are being discussed, or who have a conflict of interest related to any research protocols that are to be considered, must declare their interests in such applications. These members should recuse themselves for that part of a meeting or, by invitation of the committee, may remain present to provide points of clarification, but will not be part of the decision making.

In the event that a conflict of interest involves the chairperson, the same conditions will be upheld. Should it be agreed that the chairperson should recuse him or herself, one of the vice-chairpersons (or any other REC member chosen by the remaining REC members for this particular purpose) will be acting chairperson, for the remainder of the discussion of the item in question. This will be reflected in the minutes.

[1] https://www.ul.ac.za/research/application/downloads/DoH%202015%20Ethics%20in%20Health%20Research%20Guidelines.pdf

[2] https://www.ecfr.gov/cgibin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1107

3.3. Confidentiality

REC members sign a standard confidentiality and non-disclosure agreement on appointment. The chairperson reminds members about this condition at every meeting.

3.4. Responsibilities of the REC members:

The responsibilities of members, chairperson, and deputy – chairpersons are delineated below.

3.4.1. General responsibilities of all members:

- Attending meetings on a regular basis and not leaving until meetings are adjourned.
- All REC members should have documented proof of research ethics training, refreshed at least annually.
- REC members who review clinical trial proposals should have good clinical practice (GCP) training, evidenced by a certificate issued not more than 2 years previously.
- Taking part in research ethics-related continuing education.
- Keeping up to date with national and international research ethics and regulatory guidance.
- Taking part in reviewing all protocols received for the month.
- Maintaining strict confidentiality regarding protocol information, reviews and decisions and all matters discussed at committee meetings.
- Disclosing conflicting of interests and, where a conflict does exist with respect to a study, not reviewing the protocol and leaving the room during discussion if required and not voting on the protocol.
- Deciding independently whether the design and conduct of proposed studies will protect participants' safety, rights and welfare.
- Remaining impartial and objective when reviewing protocols.
- Respecting all committee members' views and the deliberative process.
- Responding timeously to email and correspondence regarding HSRC REC-related matters between meetings. 72 hours is considered a reasonable time period for responding to communication.

3.4.2. Additional responsibilities of the chairperson:

- Chairing monthly meetings.
- Promoting the courteous treatment of all researchers attending the meeting.
- Reviewing amendments, serious adverse event (SAE, adverse event (AE) reports, protocol deviations, protocol violations, responding to general, non-administrative queries from researchers as well as renewals between meetings as required.
- Assigning tasks to members regarding REC-related matters between meetings.
- Performing expedited reviews of minimal risk research.
- Participate in non-compliance investigations.
- Participate in subcommittee meetings with researchers.
- Assisting the administrative officer in ensuring that suitable and proportionate review teams are set up.
- Representing the HSRC REC at DoH National Health Research Ethics Council (NHREC) meetings.
- Signing approval letters and minutes and authorising proxy signature where required.
- Reviewing and signing annual reports to the NHREC and the HSRC Board.
- Ensuring these SoPs are reviewed and updated annually
- Initiating research ethics training for researchers and REC members.

3.4.3. Additional responsibilities of the deputy - chairpersons:

- Chairing of meetings in absentia of the chairperson.
- Performing functions delegated by the chairperson, including expedited review.
- Participate in non-compliance investigations.
- Representing the HSRC REC at NHREC meetings.

An administrative officer is assigned to support the work of the REC.

3.4.4. The role of the administration officer is:

- Communicating the meeting schedule for the year ahead.
- Receiving applications and assigning REC numbers to protocols.
- Checking that applications are complete and signed.
- Compiling and distributing agenda packs, including applications and supporting documents, to be received at least one week before each meeting.
- Attending the monthly REC meetings and compiling detailed minutes of the discussions and evaluation of applications.
- Providing written feedback to applicants within two weeks of each REC meeting.
- Being in frequent contact with the chairperson regarding the assignment of protocols to members for reviewing, following-up on revisions to applications, applications for expedited review, applications that qualify for exemption from ethics review, and related matters.
- Providing feedback to applicants on the approval process.
- Administering requests for renewals and amendments by referring them to the chairperson.
- Informing the REC Chair of protocol deviations and violations within 24 hours of these being submitted.
- Assisting the chairperson with the annual REC report.
- Administering HSRC REC accreditation with the NHREC and US Office for Human Research Protections (OHRP).
- Keeping records: Ensuring that all REC documentation is dated, filed and archived. All records (electronic and hard copies) are stored securely to safeguard the information and ensure confidentiality. Administrative office staff are appropriately trained to ensure optimal record-keeping, retrieval, and confidentiality.

4. Meetings

The REC holds at least 11 meetings a year. The REC meets every month, except December.
Meetings are held face-to-face or virtually. The REC meetings are held every third week of the month and a schedule of the meeting dates for the year is available from the HSRC Research Ethics Office and on the HSRC website.

4.1. Number of members and quorum

If the REC consists of more than 15 members, the quorum shall be 33% with at least one internal member and at least one external member present.[3]

[3] The current number of members is 17. Hence a quorum is 33% of 17, namely 6.

If the REC consists of 15 members or less, the quorum shall be 50% +1 (rounded up when necessary to achieve a simple majority).

4.2. Attendance and participation

At the discretion of the chairperson, and subject to the applicant observing the confidentiality of the meeting, applicants may attend the meeting to clarify points of issue but applicants are not part of the decision making. Where this is not possible, a subcommittee meeting to include the reviewers, chair, administrator and research team is to be set up.

On invitation or request and at the discretion of the Chair, HSRC REC meetings may be attended by *bona fide* research interns, researchers and other interested parties as non-voting observers. Attendance is subject to the signing and submission of a confidentiality form to the REC administrative officer prior to attending the meeting.

4.3. Decisions

The REC will make its decisions at scheduled meetings at which a quorum of members is present. Decisions will be determined by consensus (general agreement). In situations where consensus cannot be achieved, the decision will be arrived at by vote. Where a meeting proceeds without a quorum, discussions and recommendations will be minuted, but decisions will be deferred to a subsequent quorate meeting.

The REC has powers to consult with external individuals or HSRC researchers with specialised knowledge if the expertise of the standing committee is considered to be lacking specialised experience for a given task. Consultation with such individuals is only acceptable if they are not conflicted in relation to the study under consideration and subject to confidentiality assurances. The REC may also consider involving an advocate for special interest groups of participants proposed for particular research, should such involvement be deemed as adding value to the review process for informed responsible decision making in that context.

The HSRC REC may also consult with other RECs if appropriate and provided that confidentiality agreements are in-place.

5. Protocol Application for Approval by the REC

5.1. Submission procedure

The Research Ethics Office sends out monthly reminders to all the HSRC staff members reminding them about the next REC meeting and makes available a comprehensive checklist to guide the researchers when making submissions.
For external applicants, the REC meeting dates are available on the website.

All documentation must be submitted to the Research Ethics Office **NO LATER** than the dates scheduled on the REC's yearly calendar. Late submissions will not be accepted unless non-review may jeopardize participants' safety and well-being.

5.1.1. Protocol submissions: Protocols submitted for REC review will include the following document/s: (See also DoH, 2015)

- Current REC application form(s)
- Study protocol(s)

- Written informed consent form(s)
- Information sheet(s)
- Questionnaires / survey instruments
- Participant recruitment procedures (e.g., advertisements)
- Data preservation and sharing plan
- CV of Principal Investigator(s)
- Dissemination plan: The researcher must state in the protocol how the results (positive or negative) will be disseminated.
- Proof of ethics training (e.g., TRREE[4] training - http://elearning.trree.org/) for all researchers involved in the study.
- Any other documents that the REC may need to fulfil its responsibilities.
- In terms of s2.3.8 of the NHREC Guidelines, "Researchers must be suitably qualified and technically competent to carry out the proposed research. The principal investigator (PI) or research leader has the primary responsibility to ensure the safety and well-being of participants, the scientific integrity of the protocol, and the responsible implementation of that protocol. For international multi-center research, at least one (co-) PI must be South Africa-based."
- For all postgraduate studies being conducted in South Africa a co-supervisor from a recognised tertiary institution in South Africa is necessary.
- In the case of external applications, proof of payment must accompany the application.

5.2. Principles of ethics review

The overarching ethics guidance for the HSRC REC will be DoH 2015. Hereafter, where relevant, major international guidelines (including, but not restricted to: The Declaration of Helsinki, [current version]; The Belmont Report; and the Council for International Organizations of Medical Sciences [CIOMS] Guidelines) will apply. When strict compliance with the letter of a particular requirement of these declarations and codes is not possible, the HSRC REC will ensure that the proposed research is nonetheless in keeping with the spirit of the declarations and codes.

The following National Legislations are applicable:

- Constitution of the Republic South African, 1996
- National Health Act, Act No. 61 of 2003
- Human Sciences Research Council Act, Act 17 of 2008.

The National Health Act (Act No. 61 of 2003) proposes the following functions for a REC:

- Review of research proposals and protocols to ensure that research will be conducted in the spirit of endeavouring to promote health, and to prevent or cure disability and disease.
- Ensuring that humans involved in research are treated with dignity and that their well-being is not compromised.
- Ensuring that informed consent is obtained in the case of human participants.
- Granting approval in instances where research proposals and protocols meet ethical standards.

Noting that this section should be read in conjunction with the Department of Health (2015) guideline.

5.2.1. The REC reviews protocols in the spirit of the eight ethical benchmarks for ethical research as proposed by Emanuel et.al (JID 2004:189) and adapted to social science research by Wassenaar & Mamotte (2012). The following principles apply:

[4] Training and Resources in Research Ethics Evaluation

Collaborative partnerships: Emanuel et al. (2004) encourage researchers to develop partnerships with stakeholders and relevant communities to help them become partners in the research enterprise and also to ensure that research is acceptable and responsive to the community's actual health problems and provides worthwhile benefits to the community.

Social value: The research should be socially valuable and benefits be equally shared. Researchers should assess the importance of health problems being investigated and the prospective value of the research to beneficiaries. The research must be worth doing, and be relevant to the broad health and development needs of South Africa and to the individual needs of those who suffer from the conditions under study.

Scientific validity: The research methodology, sampling and study design should be sound and yield results which are reliable and valid according to accepted principles of research practices. Researchers should ensure that the scientific design of the research realizes social value for the host community (Emanuel et al., 2004). The research proposal must be well designed, ethically sound and scientifically acceptable. There must be evidence of a theoretical grounding, relevant review of the literature, and that the study will contribute to advancement of knowledge.

Fair selection of study participants: The recruitment, selection, as well as the exclusion and inclusion criteria of research participants should be fair, just and based on scientific and ethical principles (Emanuel et al., 2004). Researchers should explain where potential participants will be recruited, together with any activities and/or consultations with the target population of this study that have preceded or will precede data collection. It should be clear whether participants are asked to volunteer or whether they will be selected. The recruitment and selection process, including who will do the recruitment, must be specified, considering factors which may increase the vulnerability of participants or increase their susceptibility to harm, detailing measures to offset these.

Favourable risk-benefit ratio: Potential risks of harm should be outweighed by the benefits to participants or the community where data will be collected (Emanuel et al., 2004). Researchers should specify the potential risks of emotional, psychological, social, legal or physical harm associated with each intervention or procedure in the research as well as measures to be taken to minimise potential harms. In addition, researchers should specify the expected benefits of the research intervention(s) or procedure(s), as well as steps to be taken to maximise benefits to participants.

Independent review: Independent review is vital to ensure public accountability and is mandated by the law and regulations. The REC should protect research participants and the researchers and improve the quality of the research (Wassenaar & Mamotte, 2012). The REC's decisions and resolutions are made independently; no pressure from outside the REC may be exerted on the REC or its members to effect a particular resolution. Resolutions may not be overturned or overruled by an office bearer of the host organisation or other party.

Informed consent: Informed consent requires disclosure of complete, accurate, and adequate information to participants (Tsoka-Gwegweni & Wassenaar, 2014) and the researcher should be culturally sensitive when communicating information about the study. The method used to obtain informed consent must be ethically and legally acceptable (individual and community consent where applicable). Appropriate documentation of this process needs to be submitted and described in full. An age-appropriate assent document for children between the ages of 7 and 18 years is necessary if minors are involved in the research.

Respect for recruited participants and study communities: the REC must ensure that researchers understand that they have an obligation to participants and the host community to maintain confidentiality of information (Emanuel et al., 2004). This principle requires that procedures be put in place to protect the confidentiality of research participants. Anonymous, aggregated results should be disseminated to participants as well as the larger community in an appropriate format/medium. Researchers should also uphold the principles of respect for human dignity and personal integrity. All efforts should be made to safeguard participants' privacy, both in terms of study procedures and storage of data, in line with the stipulations of the Protection of Personal Information Act (ACT NO. 4 OF 2013)

5.3. Research proposal

To ensure the protection of the rights, safety and well-being of research participants, as well as that of their communities, the following elements of the research proposal are to be reviewed:

5.3.1. Study design

The rationale for the research, its primary aims and objectives, the selected methodology, sample size, data analysis plan, and anticipated outcomes must be clearly stated.
The research proposal must be complete, ethically sound and scientifically acceptable. The chosen methodology should be justified. There must be evidence of a theoretical grounding, literature review and that the study will contribute to advancement of knowledge.

5.3.2. Participants

Fair selection of participants: researchers should explain where potential participants will be recruited; any activities and/or consultations with the target population of the study that have preceded or will precede data collection: whether participants will be asked to volunteer or whether they will be selected; details of the recruitment and selection process including who will do the recruitment; the factors which may increase the vulnerability of participants or increase their susceptibility to harm and measures to offset these.

In addition, information should be provided about the age range and demographic profile of the participants, and whether gender has been carefully considered.

If minors are to be involved in research, the researcher should explain how the research problem is relevant to minors, how informed consent and assent will be obtained, specifically if consent will be obtained from parental substitutes or, whether independent consent by older minors is justifiable. See DoH 2015 guideline in this regard.

The fairness of inclusion of participants has ethical implications in terms of distributive justice. Researchers should avoid practices that lead to particular groups of participants bearing more than a fair share of the burdens regarding research participation. Unfair exclusions (e.g., pregnant women) should also be avoided. The risk-benefit ratio for proposed participants, as well as future benefits to society, must be evaluated.

Certain individuals or communities may be considered vulnerable in the research context and will require careful consideration, e.g. minors (<18 years of age), adults with incapacity to provide informed consent, persons highly dependent on medical care, incarcerated persons and other vulnerable groups. Particular caution should be exercised before undertaking research involving participants in vulnerable communities and the proposal should demonstrate why inclusion of such

groups is essential to the research and how vulnerability would be managed. Where the proposed study population includes participants from vulnerable groups, consult DoH 2015, for more information and guidance.

5.3.3. Reimbursement / Fair Compensation

The recruitment of participants must be free of coercion and the level of compensation (if any) must be fair (Time, Inconvenience and Expenses method to be used- (https://www.sahpra.org.za/documents/523beceb2.51_CT_TIE_Compensation_Model_May18_v1.pdf) and properly discussed in the proposal.

Participants should not incur expenses to participate in the research. Note that compensation for time and inconvenience, and reimbursement for expenses such as travel, are not considered research benefits. The researcher should indicate whether participants will be reimbursed for costs associated with participation. If participants will be reimbursed, the researcher should submit a reimbursement plan to the REC, which includes the nature of the cost to be reimbursed, the amount/method/value of the reimbursement, as well as a justification for the amounts proposed. The proposed reimbursement plan will be reviewed against the risk level of the study.

For prospective studies, the researcher should also indicate whether reimbursement will be *pro rata*. In other words, the researcher should explain how they will deal with situations where research participation is terminated before the anticipated end of the study. This information should be indicated in the research proposal and the informed consent documents.

Where minors are the participants, their accompanying parent or guardian should also receive reimbursement for travel costs and refreshments.

Researchers should note the distinction between reimbursement and incentives in research. Researchers should explain whether incentives will be offered to facilitate participant recruitment. All inducements should be clearly and convincingly justified to the REC. The inducement should not unduly influence an informed choice about participation and should not undermine a potential participant's assessment of the potential of harm.

5.3.4. Risk-benefit ratio

Researchers should specify the potential risks of emotional, psychological, social, legal or physical harm associated with each intervention or procedure in the research as well as measures to be taken to minimize potential harms. In addition, researchers should specify expected benefits of research intervention(s) or procedure(s), steps to be taken to maximize benefit to participants and how feedback on study results will be made available to participants.

5.3.5. Referral pathways

Researchers should provide the REC with proof of appropriate engagement with role-players such as child rights and childcare organisations who may assist researchers to make appropriate and meaningful referrals when needed. Examples include local NGOs, psychologists and social workers who could assist in mitigating social, emotional, or psychological harm.

5.3.6. Confidentiality

The degree of and method of ensuring confidentiality must be appropriate. How data (written, audio or visual) will be kept confidential and for how long it will be stored must be discussed in the

proposal under “ethical considerations”. Where focus group discussions are planned, participants must be informed of the limits of confidentiality inherent in such research. It should be explained where paper-based information will be stored and who will have access to it while the documents are being worked on and also after the initial analysis is completed.

5.4. Mandatory Reporting Obligations

Research is often undertaken with vulnerable groups in society. In certain circumstances due to the vulnerability of such participants there may be mandatory reporting obligations on certain or all members of the research team. These are legal duties to report suspected abuse, maltreatment and neglect to the authorities in order to trigger interventions to address the vulnerability.

Researchers who conduct studies which have mandatory reporting obligations should submit a document detailing their SOP for dealing with such cases to the REC. Researchers involved in multi-country studies have the responsibility to familiarise themselves with each country’s legal framework in this regard and submit country-specific SOPs to the REC.

5.4.1. Crimes

According to DoH 2015, there is no general obligation to report either the commission of or the intention to commit a crime. However, if a researcher has information indicating that direct harm to another person may occur as a result of the intention to commit harm (e.g. a participant says ‘I’m going to kill her…’), then there may be an obligation to act, especially when the third person is known to the researcher.

5.4.2. Children – physical or sexual abuse and neglect

The Children’s Act requires anyone who reasonably believes a child to be suffering physical abuse causing injury, deliberate neglect and sexual abuse to report this to a child protection agency such as Child Welfare, the provincial Department of Social Development, or to a police official. Depending on the nature of a study, researchers need to inform children and parents or legal guardians in the assent and consent documents respectively of researchers’ obligations to report in these circumstances. Based on this information, parents and minors may choose not to take part in a study. Note that arrangements and negotiations e.g. with Childline South Africa or other agencies, should be made in advance of the application for ethics review so that partnerships have been formed to support participants where needed. The applicant should be able to provide the REC with documented assurance of such referral arrangements.

5.4.3. Children – under-age consensual sex

In terms of the Sexual Offences and Related Matters Act, the age of consent to sex is 16 for both heterosexual and homosexual sex.

Disclosures of nonconsensual sex, at any age with a child (birth – 18), is the crime of rape and should be reported to the police.

Disclosures of consensual sex with children birth – 12 should be dealt with in the following way:

Sex below the age of 12, even with consent is the crime of rape and should be reported to the

police.

Disclosures of consensual sex with children 12 – 15 with other 12 – 15 year olds or those who are 16 and 17 should be dealt with in the following way:

There should be no reporting of this sexual activity as it is peer sex and is not illegal if there is less than a two year age gap between the sexual partners. Even if there is a slightly larger age gap there should be no reporting but there should be referral to counselling and support services.

Disclosures of consensual sex with children 12 – 15 with adults should be dealt with in the following way:

There should be a careful intervention to establish if this is an exploitative relationship, for example, a school girl with a teacher at the school. If it is exploitative, the relationship should be reported to the police. Advice on this type of situation should be sought from experts such as Childline if there is any uncertainty in this situation.

Disclosures of consensual sex by 16 year olds with persons older than them should be dealt with in the following way:

If the child is 16 there is no need to report this activity as they may lawfully have sex with any person older than them.

If there is uncertainty, the interviewer should consult with the Principal Investigator or seek advice from the REC chairperson. For more details please see DoH 2015, section 3.2.2.5 (page 26-27).

The REC should be copied when cases are reported to the relevant authorities.

5.4.4. Domestic or family violence

There is no legal obligation to report domestic or physical violence unless it involves a child, see above.

5.4.5. Elderly persons

Older persons are women over 60 and men over 65. Disclosures or awareness of abuse against an older person or their need for care and protection must be reported to the Department of Social Development in terms of the Older Persons Act.

5.4.6. Users or sellers of drugs

There is no general duty to report people who use or sell drugs. However, professional persons who are under a legal obligation to maintain confidentiality (for example, doctors, psychologists and nurses) may report such information to the police in terms of the Drugs and Drugs Trafficking Act. This means that only certain people in the research team would need to exercise their discretion regarding reporting this information.

5.5. Informed consent

The method used to obtain informed consent must be ethically and legally acceptable (individual

and community consent where applicable). Appropriate documentation of this process needs to be submitted and described in full. The Informed Consent Document must contain all the necessary elements (see section 5.4). An age-appropriate assent document for children between the ages of 7 and 18 years is necessary if minors are involved in the research. Waivers of written consent can be applied for under specific extraordinary circumstances.

5.6. Investigators

The investigator must have the appropriate qualifications, experience, research ethics training and facilities to conduct the specific research in an ethical manner.

5.7. Dissemination

The dissemination of research results must be discussed in the proposal, e.g., publications, conferences, feedback to communities, etc.

5.8. REC review process

Complete applications are submitted to the Research Ethics Office in the form of one unbound hard copy plus an electronic copy.
The administrative officer circulates the electronic version (and hard copies where necessary) of applications to the REC members and assigns protocols to members who are experts in that field. Members are not restricted to review only applications which are assigned to them.
Members complete a review sheet (Appendix B) and make additional comments as needed.

5.9. Scheduled REC meetings

The meeting proceeds as follows:

- The chairperson opens the meeting.
- A quorum, as described earlier (3.1), must be present for all decision making.
- If not quorate, the meeting will proceed. Discussions and recommendations will be minuted, but decisions will be deferred to a subsequent meeting that is quorate.
- The administrative officer records those present and also notes apologies.
- The minutes of the previous main REC meeting are corrected and accepted.

New Agenda Items are generally discussed in the following order, but this may be subject to change depending on the volume and type of items received at each meeting:

- Pre-discussion items
- Matters arising from the previous meeting
- Protocols standing over
- New applications; Exemptions; Amendments and Renewals
- Serious adverse events (SAEs).

5.10. Exemption from ethics review

The REC may grant exemption from ethical review for research which does not involve human participants and carries no risk for the well-being of individuals or groups of individuals (e.g. research which is restricted to the secondary analysis of data sources which are in the public domain). Applicants may submit motivated requests for their protocols to be exempted from ethics review. These requests will be considered by the REC chairperson. A certificate of exemption will be issued for studies which meet the requirements.

Only research which is deemed to involve **no more than minimal risk** (DoH, 2015, p. 78) and falls in one of the following categories (DoH, 2015, p. 8-9) may qualify for exemption from ethics review:

- Research that relies exclusively on publicly available information or accessible through legislation or regulation.
- Research involving observation of people in public spaces and natural environments, provided that:
  - The researcher does not interact directly with individuals or groups;
  - The researcher does not stage any intervention;
  - The individuals or groups do not have a reasonable expectation of privacy;
  - Dissemination of research findings does not identify individuals or groups.
- Quality assurance and quality improvement studies (audits), programme evaluation activities and performance reviews. **Importantly**, it should be noted that if publication of such studies is panned, ethics approval should be obtained before the audit begins.

5.11. Expedited review process

Only research which is deemed to involve **no more than minimal risk** (DoH, 2015, p. 78) may qualify for expedited review.
Minimal risk research is defined as "where probability and magnitude of possible harms implied by participation are no greater than those posed by daily life in a stable society or routine medical, dental, educational or psychological tests or examinations" (DoH, 2015, p54).

The HSRC REC may use the expedited review procedure in the following circumstances:

- All of the categories listed above under 4.10 but which are intended for publication.
- Research involving observation of people in natural environments, provided that:
  - The intended participants are not particularly vulnerable;
  - The researcher does not stage any intervention;
  - The individuals or groups do not have a reasonable expectation of privacy;
  - Dissemination of research findings does not identify individuals or groups.
- To approve minor administrative changes in previously approved research during the period for which approval is already authorized.
- For studies using existing or archived material collected for clinical or diagnostic purposes, including waste and surplus samples, the following will be taken into consideration:
  - Whether subsequent usage was envisaged in the previously approved proposal.
  - Whether the scope of the current proposal is different from the previously approved proposal.
  - Whether samples are anonymous.
  - Whether the results of research might place any individual, family or community at social, psychological, legal or economic risk of harm.
  - Whether the link to identifiers exists.
  - The person who holds the code or link should sign an explicit written agreement not to release the identifiers to the research team. This agreement should accompany the submission to the REC.
  - If the samples can be linked to identifiers, the REC must decide on a case-by-case basis whether expedited or full review is necessary.

Under an expedited review procedure, the review may be carried out by the REC chairperson, assisted where necessary by one or more experienced REC members designated by the chairperson. Decisions arising from an expedited review process, other than outright rejection, may be confirmed by the chairperson between scheduled REC meetings. When processing the reviews,

the chairperson will exercise all the authority of the REC except that the research may not be disapproved. An expedited application may only be disapproved after confirmation at a full REC meeting.

Applications for expedited review can be submitted to the REC administrative officer at any time. At the end of each week, all such applications will be sent to the chairperson and one or more suitable and available members for review. This subcommittee will have 10 working days in which to review the application.

A list of all protocols that have been approved using the expedited review process since the last REC meeting will be included in the subsequent REC meeting agenda for noting and record keeping (Adapted from: 45 CFR 46 110(b); BREC, 2010).

5.12. Full committee review

The review process for protocols categorised by the chairperson, on their risk profile, as requiring full committee review will be as follows:

- Protocols received at least 15 days prior to a scheduled REC committee meeting will be tabled at the next committee meeting.
- Each application and protocol will be reviewed in advance of a convened REC meeting by the REC chairperson and designated REC members. One external and one internal reviewer per unit, and where necessary an expert reviewer, will be allocated in advance to review each such application.
- Each protocol will be discussed at a convened quorate REC meeting.
- At the REC meeting, the chairperson facilitates the review process by asking assigned reviewers to provide their comments.
- The reviewers and expert reviewer (where applicable) provide an evaluation of the strengths and weaknesses of the proposed research. They also judge the study's risk level using standard definitions of research risk (see DoH, 2015, p. 78) and their rationale for that judgement. Subsequently, other REC members present at the meeting are afforded an opportunity to provide their evaluations.
- The opinions of all members of the REC are taken into account.
- The chairperson adds additional points for consideration and proposes a risk level, decision and way forward.
- Decisions are reached either by consensus or by a vote.
- The REC must document its decisions in writing, clearly identifying the study, the documents reviewed, and the dates for the following:
    - Approval.
    - Provisionally approved (require amendments).
    - Not approved (require resubmission).
    - Rejection.
    - Termination or suspension of any prior approval.
- Written feedback on the REC's conclusions will be provided to the Principal Investigator (PI) within 15 working days of the REC meeting.
- Reasons for provisional approval, resubmission and rejection will be furnished to the PI in a manner that is clear to the PI.
- The PI should submit a detailed response letter which addresses all points raised by the REC, together with amended application forms and study documents (as appropriate) with all changes clearly marked by tracked changes or by using a different colour.

- Proposals that have been provisionally approved may be recommended for approval outside the meeting by a subcommittee comprising of the chairperson or deputy-chairperson, with additional reviewers where necessary. This recommended approval must be ratified at the next full REC meeting.
- Proposals requiring resubmission are resubmitted to the full committee for consideration at a subsequent meeting.

The Research Ethics Office provides the PI with a response letter and the following information is included in each letter:

- Protocol reference number.
- Title of study.
- If commercially sponsored, the version date of the protocol and consent forms.
- The REC's decision: approved, revisions required, not approved, deferred.
- Date of meeting.
- If approved, the duration of approval and date of re-review.
- If revisions are required, a list of conditions with reasons, and a statement that the study may not begin until the researcher receives formal notification of REC approval after review of the response to the revisions.
- If disapproved, the basis for the decision.
- If deferred, the reasons why the study has to stand over until the next meeting.

5.13. Special requirements for protocols that are deemed to be clinical trials

A clinical trial is a research study or investigation intended to test safety (not harmful or dangerous to human health), quality (ingredients are of good quality), effectiveness (working to diagnose, treat, prevent or cure a disease condition) and efficacy (better/ best when compared with other treatment or medicine for a similar condition) of new and/or existing or old medicines, medical devices and/or treatment options, using human participants. The word "medicine" includes medicines that are used to treat diseases (therapeutic medicines), to prevent diseases (prophylactic medicines, e.g. vaccines), and medicines that are used in special investigations (diagnostic medicines, e.g. medicines used during special X-ray examinations to map out kidneys).
Reference: (http://www.sanctr.gov.za/Resources/Whatisaclinicaltrial/tabid/175/Default.aspx)

Institutional registration is in place to meet the statutory requirement to register clinical trials with the South African National Clinical Trials Registry (SANCTR), (see www.sanctr.gov.za). The HSRC REC administrative officer serves as central contact point. Applicants are therefore not required to register on the SANCTR website but simply to log in, using a general username and password. That can be obtained from the REC administrative officer.

Steps in the registration process of a clinical trial are as follows:

- Finalise contract negotiations and project planning.
- Complete the national trials register application form. Do not register as a new user, simply log in as HSRC user at www.ethicsapp.co.za, the username is hsrc, password rehsrc. A unique application number will be generated by the NHREC system.
- If the clinical trial involves an unregistered medicine, device or product or if the trial investigates a new indication for or application of an existing medicine, device or product, an application should be made to the South African Health Products Regulatory Authority (SAHPRA)[5] and proof of such approval should be submitted to the HSRC REC.

[5] SAHPRA oversees the regulation of "health products which includes medicines, medical devices,

- Apply for ethics clearance with HSRC REC. Submit a print-out of the form completed at www.ethicsapp.co.za and the unique application number as generated, together with all other documents required for HSRC research ethics application.
- Once clearance has been obtained from the HSRC REC, a unique HSRC reference number will be provided by the HSRC REC administrative officer.
- Using the NHREC application number, as well as the HSRC ethics reference number, the trial can now be registered on the SANCTR.
- The National Department of Health will then issue a National Register Number.
- This number must be forwarded to the HSRC REC administrative officer for reference.

5.14. Special considerations for social media research

The fundamental principles of conducting ethical social research remain the same and mandate consideration of participant autonomy, confidentiality, vulnerability, as well as potential risks and harms. There are also aspects that require special consideration, most notably the necessity and processes of obtaining informed consent and respect for privacy (especially in the context of social media users' perceived expectation of privacy). In addition, issues such as intrusiveness, power, social justice, inequality, bias, and cultural pluralism need to be reflected upon (Samuel & Buchanan, 2020 . Researchers should be aware that ethical concerns may emerge during all steps of the research process.

While recognising that these considerations will depend on the context of the study, which is influenced by many factors such as the particular group of participants, the sensitivity of the topic, the methods used and the discipline in which the research is being conducted, the REC will specifically consider the following aspects (as outlined by Samuel & Buchanan, 2020), of the proposal:

- Respect for the autonomy, privacy and dignity of individuals and the community:
    - Public/ private distinction – the extent to which potential data derived from online sources should be considered in the public or private domain.
    - Confidentiality – level of risk to the confidentiality of participants' data and how to minimise and/or inform participants of these risks.
    - Copyright – copyright issues and data ownership and when permission should be obtained to use potential data sources.
    - Valid consent – the process of how robust, traceable and valid consent procedures will be implemented.
    - Withdrawal – how robust procedures which allow participants to act on their rights to withdraw data will be implemented.
    - Debriefing - how robust procedures which maximise the likelihood of participants receiving appropriate debrief information will be implemented.
- Scientific integrity:
    - Levels of control – how reduced levels of control may affect the scientific value of a study, and how best to maximise levels of control where appropriate and feasible.

in-vitro diagnostic tests and devices, radiation emitting products and devices used in health care and industry".
(https://www.mm3admin.co.za/documents/docmanager/editor/9400/UserFiles/who%20is%20sahpra.pdf)

- Social responsibility:
    - Disruption of social structures – the extent to which the proposed research study procedures and dissemination practices might disrupt or harm social groups.
- Maximising benefits and minimising harm:
    - Maximising benefits – assessment of how each of the issues mentioned above might act to reduce the benefits of the proposed research and which procedures will be put in place to maximise benefits.
    - Minimising harm – assessment of how each of the issues mentioned above might lead to potential harm and which procedures will be put in place to minimise such harms.

5.15. Rapid review of studies

Rapid review and approval apply only to emergency research or an emergency amendment to previously approved research. It includes interventional and non-interventional research and is applicable to studies in all risk categories. It applies to studies that qualify for expedited review as well as those in need of full committee review.

A rapid review should be at least as thorough as would pertain ordinarily even though performed much quicker. The benefit-risk-ratio should be high. This procedure should be interpreted alongside DoH, 2015, sections 3.4.1 and 3.2.4, specifically 3.2.4.3, 3.2.4.4 and 3.2.4.6.

The following definitions and criteria apply:

- Emergency research: Emergency research comprises research that should be conducted as a matter of urgency in an emergency. An emergency for purposes of this SOP is a situation that poses an immediate risk to the health or lives of people, and for which urgent research is required to prevent a worsening of the situation or reduce its negative impact. Examples are the emergence of an epidemic, or pandemic, or a natural disaster.

- Emergency amendment: For the purposes of this SOP this is a situation in which an amendment should be reviewed and approved as an emergency because a delay in doing so may put research participants at risk of harm.

Whether a study or amendment is suitable for emergency review is at the discretion of the chairperson of the REC, guided by this SOP.

Procedures for studies that qualify for expedited review:

- The researcher will submit an application to the REC administrator and attach all documents related to the study.
- The researcher will request by e-mail to the REC administrator that a specific study be processed under a rapid review procedure.
- Once an application is accepted for emergency review, and is deemed to meet the criteria for expedited review (refer section 4.11), the submission will be fast-tracked via the chairperson or a deputy-chairperson, assigning the study to a sub-committee consisting of at least one additional REC member who is suitable and available to perform the review, with an option to obtain a review from or consult with an expert in the field who is not a member of the REC.
- Reviews will be returned by reviewers in less than four working days of requesting them to do the reviews.
- Reviewer comments will be collated within 72 hours of receipt and these will be sent to the researcher for responses and modifications.

- The chairperson will consider the researcher's responses to the reviewers' comments within 72 hours of receiving these (with the same provisions for a Friday and Public Holidays as above) and consult further with the reviewers should it be considered essential.
- In deliberating about emergency applications, the REC members may communicate with each other using any suitable media in their deliberations, including face-to-face meetings, e-mails, and e-conferencing. Written records should be maintained of the process and decisions.
- If the researcher has satisfactorily addressed all the reviewers' comments, the chairperson will issue an emergency approval certificate.
- A list of all protocols that met the criteria for expedited review and have been approved using the rapid review process since the last REC meeting, will be included in the subsequent REC meeting agenda for noting and record keeping.

Procedures for studies in need of full committee review:

- The researcher will submit an application to the REC administrator and attach all documents related to the study.
- The researcher will request by e-mail to the REC administrator that a specific study be processed under a rapid review procedure.
- Once an application is accepted for emergency review, the submission will be fast-tracked via the chairperson or a deputy-chairperson, assigning the study to a sub-committee consisting of a minimum of two additional REC members who are suitable and available to perform the review, with an option to obtain a review from or consult with an expert in the field who is not a member of the REC.
- Reviews will be returned by reviewers in less than four calendar days of requesting them to do the reviews. The exception is applications submitted on a Friday or Public Holiday, in which case the next working day will be taken as day 1.
- Reviewer comments will be collated within 72 hours of receipt and these will be sent to the researcher for responses and modifications.
- The chairperson will consider the researcher's responses to the reviewers' comments within 72 hours of receiving these and consult further with the reviewers should it be considered essential.
- In deliberating about emergency applications, the REC members may communicate with each other using any suitable media in their deliberations, including face-to-face meetings, e-mails, and e-conferencing. Written records should be maintained of the process and decisions.
- These deliberations, together with a recommendation regarding approval, modification or rejection, will be sent to all the REC members via email. REC members will have 48 hours to respond in writing. Members should send an email to the REC administrator clearly stating whether they agree, disagree or request the imposition of further requirements or instructions upon the study, together with justification for such a decision. Late responses will not be considered.
- Final decisions will be based on a simple majority of what constitutes a quorum. In other words, if the quorum is 6, a simple majority would be 4.
- A list of all protocols that have been approved using the rapid review process since the last REC meeting, will be included in the subsequent REC meeting agenda for noting and record keeping.

This SOP for rapid review of studies will be in force until DoH 2015 is revised or if suitable alternative guidelines emerge.

5.16. Review of external applications

Provided there is no more suitable or eligible REC in South Africa the HSRC REC will, at the discretion of the chairperson, and at a prescribed fee to cover administrative costs, accept review of research protocols submitted to it by researchers from other institutions who are not HSRC staff members or affiliates. Upon acceptance, the same process for expedited or full review will be implemented, as described in sections 4.8 to 4.12.

5.17. Reciprocal recognition of protocols reviewed and approved elsewhere

The REC will, where applicable and on request, consider reciprocal approval of protocols that have been approved by RECs that are registered with the NHREC. Such protocols may qualify for expedited review as described in section 4.11. If the protocol raises significant ethical or logistical issues as judged by the chairperson or deputy-chairperson, it will have to be reviewed by the full REC.

Protocols that had been reviewed and approved by recognised RECs in other countries still require REC review in South Africa.

5.18. Continuing review procedures

5.18.1. Recertification and continuing review

REC approval is valid for one year. Should an approved study not be completed within the validity period, an application for recertification / renewal must be submitted for consideration by the REC chairperson.

Annual recertification will only be given for the study to continue on receipt of a satisfactory Annual Passive Monitoring of an Approved Study document (https://hsrc.ac.za/who-we-are/our-standards/).

All serious adverse events (SAEs) that occurred during the study period should have been reported to the REC as required and should be referred to in the recertification form.

A request for recertification/ renewal must reach the REC at least two months before the expiration of the current approval. It is the responsibility of the PI to ensure that renewal is granted before the current ethics approval expires.

Recommendations for recertification for non-expedited studies must be tabled at a full committee meeting for ratification.

Recommendations for recertification of expedited studies can be approved by the chairperson in-between meetings and then be noted at the next full committee meeting.

Should any changes in the approved protocol (beyond changes of planned dates) be made, this is no longer deemed to be a request for recertification and an amendment should be submitted as described in section 4.18.1.

At the end of the study, a final close-out report must be submitted to the REC.

5.18.2. Protocol amendments

An amendment is a change that is administrative in nature or has an impact on the safety or integrity of the participants, alters scientific value of the research or interpretation of the results, affects validity of data, the design of the study, planned statistical analyses or significantly alters other aspects of the research. Changes in the PI also constitute amendments, and applications for

such amendment should include information on the role and tasks of the persons involved with the required certifications.

All requests for protocol amendments are submitted in writing and accompanied by the required completed form (https://hsrc.ac.za/who-we-are/our-standards/).

If the REC administrative officer, in consultation with the REC chairperson, designates it as a minor amendment, it will be reviewed by the REC chairperson in consultation with one deputy chairperson or other REC member if necessary, and will be duly included in the agenda of the next REC meeting.

Recommendations for approval of protocol amendments to non-expedited studies must be tabled at a full committee meeting for ratification.

Recommendations for approval of protocol amendments to expedited studies can be approved by the chairperson in-between meetings and then be noted at the next full committee meeting.

Administrative amendments may be approved by the chairperson in-between meetings and will be tabled as part of the agenda for ratification by the full REC.

If it is a major amendment, the application will be submitted for full review at a forthcoming meeting of the REC. Unless urgently required to protect the safety of participants, all amendments to research protocols (including changes to key study personnel/supervisors, etc.) require prior written approval from the REC.

Minor amendments do not change the risk benefit profile of the study in any way. Examples of typical minor amendments are:

- Additional investigators or study sites.
- Small changes in the consent process.
- Change in background information or update of literature review.
- Extension of period of study.
- Other changes that do not affect the study design and will not affect the study outcomes or results.
- Administrative changes.
- Stricter inclusion or exclusion criteria.

Major amendments require a change(s) to the study methodology or procedure that may result in an alteration of the risk-benefit profile of the study. Examples include:

- Change in study aims, objectives or design.
- Resulting changes to consent documents.
- Additional study procedures.
- Easing of inclusion or exclusion criteria (http://www.doh.gov.za/nhrec/).

The following documentation should be submitted to the HSRC REC:

- Cover letter explaining the nature of and reason for the amendment.
- Application form that includes a justification for each amendment.
- Revised protocol with tracked changes.
- Revised informed consent document with tracked changes.
- Any other relevant documents that were revised with the amendment.

5.18.3. Adverse events

Reports on adverse events (AEs) and serious adverse events (SAEs) should be reported in writing to the REC, the study sponsors, HSRC line management and any regulatory authority (where appropriate), within seven working days of the occurrence.

An AE is defined as:
Any negative or untoward occurrence that may present during the study intervention, but which does not necessarily have a causal relationship with the research undertaken.

An SAE is defined as any negative or untoward occurrence that:

- Results in death.
- Is life-threatening.
- Requires participant hospitalisation or prolongation of existing hospitalisation.
- Results in persistent or significant disability/incapacity (social harm for displacement from the home).
- Any other experience that suggests a significant hazard, contraindication, side-effect, or precaution that may require medical or surgical intervention to prevent one of the outcomes listed above.

In all instances, the researcher has to indicate whether the SAE is related or unrelated to the study.

5.18.4. Protocol violations and protocol deviations

Protocol violations and deviations shall be reported in the same manner as adverse events.

Deviation
Any alteration or modification to the approved research without prospective REC approval. This includes all REC-approved materials and documents including the detailed protocol, REC application, consent form, recruitment materials, questionnaires/data collection forms, and any other information relating to the research study.

Deviations are categorised into minor and major

Minor Deviation
A minor or administrative deviation is one that does not have the potential to negatively impact the rights, safety, or welfare of participants or others or the scientific validity of the study.

Major Deviation
A major deviation is one that does have the potential to negatively impact the rights, safety, or welfare of participants or others or the scientific validity of the study.

Protocol Violations

Protocol violations are any unapproved changes, deviations or departures from the study design or procedures of a research project that are under the investigator's control and that have not been reviewed and approved by the REC. The violation is willful on the part of the investigator(s). It involves serious or continuing noncompliance with REC and / or NHREC policies.

5.18.5. Suspension or termination of approval

The REC may suspend or terminate approval of a study that is not being conducted in accordance with prevailing REC or South African Department of Health ethical requirements. The primary

justification for suspension or termination of approval should be the safety of participants. Such suspension or termination of approval must be authorised by the REC chairperson in consultation with a REC subcommittee and/or other co-opted parties as soon as possible, but not more than seven days after receipt of relevant information by the chairperson. All such discussions should be fully minuted. Such action must be reported to the REC at the next quorate meeting, and to the HSRC Deputy CEO for Research.

Should a research study be prematurely suspended or terminated, the PI must notify the REC. A summary must be communicated regarding the reasons for the suspension or termination, before the anticipated date of termination.

6. Participant information and informed consent requirements

The following guidance by the Department of Health (2015) should be followed: "Research details must be provided in a clear, simple and culturally appropriate manner. If a participant lacks capacity to exercise an informed choice to participate, an appropriate person to make the choice for them must be identified by the investigator. A participant is free at any time to withdraw consent to further involvement in the research, without having to face any unfair negative consequence or disadvantage".

6.1. Language of the participant informed consent document

Informed consent is a vital requirement of the ethical conduct of research and is valid only when it is obtained without deceit or misrepresentation. The informed consent requirements are not intended to pre-empt the laws of the country, which may require that additional information be provided to participants. The REC recognizes that obtaining informed consent in a multilingual society is complex and the process should be considered on a case-by-case basis.

Researchers are encouraged to use readily available tools for the objective assessments of language difficulty for instance the Flesch Reading Ease and Flesch-Kincaid Grade Level.

6.2. The following essential elements must be understood and valued before a participant is capable of giving informed consent:

- Study description
  - Statement that this is research and thus experimental.
  - Purpose of the study.
  - Expected duration of participation.
  - Procedures that will be specific to the research.
  - Distinction between routine and experimental procedures.
- Responsibilities
  - Of the researchers.
  - Of the participant.
- Foreseeable risks and discomforts
  - The nature of the risks (physical, psychological, social, etc.).
  - Reasonable estimates of the magnitude of possible harm.
  - Measures to minimise risk of harm.
- Benefits
  - Description of the potential benefits to the participants or to others, both during and after the research.
- Disclosure of alternative procedures/treatments
- Confidentiality of records

- The extent that confidentiality of the data will be maintained.
- Who has/needs to have access to the data?
- Any mandatory reporting responsibilities.

- Reimbursement
  - Whether reimbursement for time, inconvenience and expenses is available.
  - For prospective studies, the informed consent document should indicate whether reimbursement is pro rata if the participant does not complete the study i.e. what proportion of the offered reimbursement will be available if the participant does not complete the study.
- Compensation and treatment for research-related injury for research involving more than minimal risk:
  - Explanation of compensation or medical treatment provided (if any).
  - If there is a risk that some of the treatment may not be covered by insurance.
  - Payment responsibilities.
  - Where further information may be obtained.
- Contact Information
  - Whom to contact for:
    Questions about the research.
    Participant's rights.
    Research-related injury, complaints, or other issues.
- Voluntary Participation
  - Refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.
  - Confirmation that informed consent is an ongoing process; participants can withdraw at any time.
- Additional elements
  - Some risks are currently unforeseeable.
  - Investigators may terminate participation if deemed in the best interest of the participant.
  - Additional costs.
  - Consequences of participant's withdrawal.
  - If and when significant new findings will be communicated to participants.
  - Number of participants.
  - That the research has been approved by a registered REC.
  - Contact details of REC representatives.
  - Statement that participants' data may be added to databases of journals/funders/researchers/sponsors. Participants may decline consent for data sharing.

6.3. SA GCP Guidelines (2020) require the following information/explanations in consent documents to be used in clinical trials:

- That the trial involves research.
- The purpose of the trial.
- The trial treatment(s) and the probability for random assignment to each treatment, where appropriate.
- The trial procedures to be followed, including all invasive procedures.
- The participant's responsibilities.
- Participation in the trial is voluntary and refusal to participate or withdraw from the trial will not prejudice the ongoing care of the person in any way.
- Those aspects of the trial that are not experimental.
- The foreseeable risks of harm or inconveniences to the participant and, when applicable,

to an embryo, foetus, or nursing infant.

- The expected benefits. When there is no clinical benefit to the participant, the participant must be made aware of this.
- The alternative procedure(s) or course(s) of treatment that may be available to the participant and their potential benefits and risks.
- The compensation and/or treatment available to the participant in the event of trial-related injury.
- The anticipated payment, if any, to the participant in the trial.
- The anticipated expenses, if any, to the participant for taking part in the trial.
- Allow access of sponsor, SAHPRA, National Health Research Ethics Council, relevant research ethics committees and/or other regulatory authority to participant records.
- Provide a contact name and number for the principal investigator and directly responsible investigator.
- The identity of the sponsor and any potential conflict of interests.
- The requirement to preserve the participant's confidentiality.
- Expected duration of participant's participation.
- Foreseeable circumstances and/or other reasons under which the participant's involvement in the trial may be terminated.
- Approximate number of participants in the trial.

7. The REC requires the following information on the informed consent process with each new application:

- A description of the process for obtaining informed consent, including the process for ascertaining understanding and appreciation of the information provided.
- Assurances that research participants will receive information that becomes available during the course of the research relevant to their participation.
- The provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.
- In all instances, verbal and written informed consent should be obtained, unless acceptable exemptions apply.
- For minor participants under the age of 18 years, consent from the parent or legal guardian must be sought, unless acceptable exemptions apply.
- In addition to the consent of the parent or legal guardian, informed assent must also be obtained from the minor participant if the minor is capable of understanding. Maturity, psychological state of mind and age should be taken into account. Assent is generally appropriate from the age of seven years and special care should be taken to create an informed assent document that will be understandable to minors. The protocol must provide sufficient information outlining the steps that will be taken to obtain the child's assent and how it will be documented.
- Following approval of original English versions, all translations with authenticity certificates (or other method used to confirm accuracy) must be submitted to the REC for notification.

For more information, refer to the Ethics in Health Research: Principles, Processes and Structures. Second Edition. Department of Health, Republic of South Africa, 2015

For clinical trials information should be provided about insurance against research related bodily injuries. See SA GCP Guidelines 2020, the MCC/SAHPRA Clinical Trials Compensation Guidelines and Venter v Roche Products (Pty) Ltd et al (12285/08) [2013] WCHC 7 May 2013 and on appeal (A11/2014) 22 October 2014.

8. Vulnerable participants

8.1. The Committee must pay special attention to protecting the welfare of certain classes of participants who may be regarded as vulnerable. These include, but are not limited to:

- Minors.
- Persons in dependent relationships.
- People whose first language is not English.
- Elderly or aged patients.
- Minorities.
- Students.
- Employees.
- Persons with intellectual or mental impairment.
- Traumatised and comatose patients.
- Persons highly dependent on medical care.
- Persons with physical disabilities.
- Terminally ill patients.
- Persons in correctional facilities.

The REC may impose additional measures to protect the welfare of these participants, especially with regard to informed consent.

9. Research with minors

Children should participate in research only where such research poses acceptable risks of harm. That is, research involving minors should be approved only if:

- The research, including observational research, is not contrary to the best interest of the minor.
- The research, including observational research, places the minor at no more than minimal risk of harm (i.e., the 'everyday risks standard' which means the risk of harm is commensurate with daily life in a stable society or routine medical, dental, educational or psychological tests or examinations – referred to as 'negligible risk' in some guidelines); or
- The research, including observational research, involves greater than minimal risk of harm, with no prospect of direct benefit to the minor, but has a high probability of providing significant generalizable knowledge. The degree of risk of harm should be justified by the risk-knowledge ratio.
- Greater than minimal risk of harm should represent no more than a minor increase over minimal risk.
- Where appropriate, the minor will assent to participation.

Research involving children must be reviewed appropriately. The National Health Act distinguishes research with children as 'therapeutic' and 'non-therapeutic' research. The intention is to ensure RECs give due consideration to the degree of risk of harm posed by a proposal and the likelihood of benefit to the child-participant.

Therapeutic research entails research that includes interventions that may hold out the prospect of direct health-related benefit for the participant. Non-therapeutic research entails research that includes interventions that will not hold out the prospect of direct health-related benefit for the participant but may produce results that contribute to generalizable knowledge.

According to Section 71(3)(a)(ii) of the National Health Act 'non-therapeutic' health research with minors, may only be conducted when the following four criteria are met: (i) in such

manner and on such conditions as may be prescribed; (ii) with the consent of the Minister; (iii) with the consent of the parent or guardian of the minor; and (iv) if the minor is capable of understanding, the consent of the minor.

The Minister may delegate authority, in terms of s 92(a), to any person in the employ of the state, a council, board or committee established in terms of the Act to give this consent. The Minister has delegated authority to provide Ministerial Consent for 'non-therapeutic' health research with minors to RECs that have been found to be compliant with the audit and have achieved full registration with the NHREC. Correspondence in this regard was sent to relevant RECs on 14 October 2014.

Regulations for research with human participants, published on 19 September 2014 (R 719) contain Form A that sets out the four criteria to be met for the additional review of 'non-therapeutic' health research with minors.https://hsrc.ac.za/who-we-are/our-standards/ .

9.1. Complaints or appeals by investigators

The HSRC REC is an independently functioning body. This means:

- Its decisions and resolutions are made independently;
- No pressure from outside the REC may be exerted on the REC or its members to effect a particular resolution;
- Resolutions may not be overturned or overruled by an office bearer of the HSRC or other party;
- Investigators should seek to resolve complaints with REC procedures or decisions through the chairperson in the first instance. Such complaints or appeals must be submitted via the office of the REC administrative officer. The chairperson may refer the matter to independent external advisors before responding to the complaint, also in writing.

If complaints remain unresolved, investigators may lodge a formal complaint (in writing) with the HSRC DCEO: Research. Should this not lead to a resolution, the complaint may be submitted directly to the NHREC at the National Department of Health (http://www.doh.gov.za/nhrec/).

10. Complaints/ third party – hotline

The HSRC Research Ethics Office has a complaints hotline, which is independently managed and operates 365 days a year, 24 hours a day. All calls are free of charge. All stakeholders are able to report unethical behaviour and any wrongdoing anonymously. Tip-offs policy - http://intranet.hsrc.ac.za/sites/default/files/documents/policies/Tip-Offs%2520Service.pdf.

10.1. Handling a tip-off

The REC administrative officer will receive an email from the service provider stating the complaint and will share the information with the chairperson. The PI will be contacted to remedy the situation. The administrative officer follows up until the matter is resolved.

11. Annual reports

The chairperson of the REC is responsible for an annual report to the NHREC. The REC administrative officer supports the REC chairperson with the compilation and submission of this report.

12. Research misconduct (HSRC policy on research integrity)

Research misconduct encompasses inter alia:

- Failure to submit a protocol for ethics approval in term of this document
- Fabrication, falsification, plagiarism in proposing, performing, reviewing or reporting of research
- Deviation from or failure to adhere to the approved protocol without prior formal approval from the HSRC REC
- Misrepresentation of data and/or interests and/or involvement
- Falsification of credentials
- Deception in the research proposal
- Non-approved deception in the carrying out of research
- Piracy of materials
- Failure to follow accepted procedures to exercise due care in avoiding unreasonable harm or discomfort to participants or research staff
- Failure to obtain voluntary and informed consent
- Breach of confidentiality
- Negligent management of data security.

Incidents of research misconduct will be reported to the HSRC Research Integrity Officer (RIO) at research.intergrity@hsrc.ac.za and managed in accordance with applicable HSRC policies and procedures. The identity of the individual who raises awareness of research misconduct will be protected.

13. Updates to the HSRC REC standard operating procedures or membership

This document is regarded as a living document that may be updated to reflect changes in practice or improved processes. Any changes to HSRC REC Standard Operating Procedures will need to be approved by the Research Subcommittee of the HSRC Board and submitted to the SA NHREC.

14. More information

HSRC REC administrative officer, research.ethics@hsrc.ac.za

HSRC website, http://www.hsrc.ac.za/en/about/research-ethics

Review and approval history

2008	JE Botha and D Wassenaar	Approved by HSRC REC
February 2020	K Sithole and T Rossouw	Approved by HSRC REC
August 2022	K Sithole and A Dhai	Approved by HSR REC

References

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2. Council for International Organisations of Medical Sciences (CIOMS). (2016). *International ethical guidelines for biomedical research involving human subjects*.
3. Emanuel EJ, Wendler D, Killen J, Grady C. What makes clinical research in developing countries ethical? The benchmarks of ethical research. Journal of Infectious Diseases 2004; 189:930-7.
4. Samuel, G., & Buchanan, E. (2020). Guest Editorial: Ethical Issues in Social Media Research. *Journal of Empirical Research on Human Research Ethics* 1(9). DOI: 10.1177/1556264619901215.
5. Wassenaar, D. R., & Mamotte, N. (2012). Ethical issues and ethics reviews in social science research.
6. Ferrero, Y. Korkut, M.M. Leach, G. Lindsay, & Stevens, M.J. (Eds.), *The Oxford handbook of international psychological ethics* (pp. 268-282). New York: Oxford University Press. DOI: 10.1093/oxfordhb/9780199739165.013.0019
7. Tsoka-Gwegweni, J., & Wassenaar, D.R. (2014). Using the Emanuel framework to examine ethical issues raised by a biomedical research ethics committee in South Africa. *Journal of Empirical Research on Human Research Ethics 9* (5), 36-45.
8. Ethics in Health Research: *Principles, Processes and Structures 2nd Edition*, Department of Health, Republic of South Africa, 2015.
9. Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa, 2020.
10. Human Sciences Research Council Act, Act 17 of 2008.
11. National Health Act 61 0f 2003.
12. South African Constitution, 1996 (Chapter 2 – Bill of Rights)
13. South African Medical Research Council Human Research Ethics Committee (2018) Standard Operating Procedures.

14. Stellenbosch University (2018) Standard Operating Procedures Research Ethics Committee: Human Research (Humanities).
15. University of Pretoria (2017) Standard Operating Procedures.
16. HRPP. Protocol Violation or Incident | Human Research Protection Program (HRPP) (ucsf.edu)

ANNEXURE A

REC Members Term of Office from 1 November 2021 until 31 October 2024

External HSRC members

Prof Ames Dhai – chairperson (Capacity – Biomedical, Social Science and Ethics)

Prof Peter Nyasulu (Capacity – Biomedical, Biostatistics, Public Health, Epidemiology, Ethics)

Dr Shenuka Singh (Capacity – Dentistry, Biomedical, Ethics)

Prof Ann Strode (Capacity – Legal, Children's Rights)

Prof Warren Freedman (Capacity – Law)

Ms Thandi Kekana (Capacity – Community Representative)

Ms Anisa Keshav (Capacity – Community Representative)

Dr Aslam Sathar (Capacity - Physiology and Microbiology)

Dr Rebone Maboa (Capacity - Health and medical field, clinical research, and occupational health medicine)

Dr Bongile Mabilane (Capacity – Biomedical, Public Health, Ethics)

REC Members Term of Office from 30 June 203 until 30 June 2026

Internal HSRC members

Centre for Science, Technology, and Innovation Indicators (CeSTII)
Dr Il-haam Petersen (Capacity – Sociology)
Dr Amy Khan (Capacity – Economics)

Equitable Education and Economies (EEE)
Dr Andrea Juan (Capacity – Policy and Development Studies)
Dr Adam Cooper (Capacity – Education Policy Studies, with Commonwealth Split-site)
Dr Bongiwe Mncwango (Capacity – Sociology)

Africa Institute of South Africa (AISA)
Dr Rodney Managa (Capacity – Agriculture, Horticultural Science)
Dr Nomcebo Ubisi (Capacity – Food Security, Agriculture and Climate change)

Public Health, Societies and Belonging (PHSB)
Prof Sibusiso Sifunda (Capacity – Epidemiology, Biostatics and Public Health)
Dr Allanise Cloete (Capacity – Anthropology focusing on stigma and discrimination)

Developmental, Capable and Ethical State (DCES)
Ms Diana Sanchez Betancourt (Capacity – Social Sciences, Peace and Conflict Studies)
Dr Mathias Alubafi (Capacity – Higher Education and Training)

Impact Center (IC)
Dr Mercy Ngungu (Capacity – Data Scientist, mathematical statistics, and technology)
Dr Lorenza Fluks (Capacity – Psychology)

ANNEXURE B

HSRC- REC report:
Protocol:
Applicant:

	Yes	No	Comment
Is there scientific basis for initiating this study?			
Is there equipoise in research?			
Research falls in national priority?			
Risk level:			
Minimal risk [6]			
Minor increase over minimal risk			
Moderate increase over minimal risk			
Major increase over minimal risk			

	N/A	Satisfactory	Requires clarification	Incomplete/ Missing	Unsatisfactory	Comment
Objectives clear and achievable						
Literature review						
Appropriateness of study design						
Methods and procedure appropriateness						
Study population						
Research participant selection appropriateness						
Data analysis approach appropriateness						
Incentive to participate						
Participants consent form/statement						
Process for preserving respondents' anonymity						

Recommendation - Select one only

1. Approve research as submitted

……

2. Approved research proposal with minor modification (specify)

……

3. Approve research proposal as submitted with the stipulation that the final research instruments be submitted for further review and approval prior to initiating the research

……

[6] Minimal risk research: "where probability and magnitude of possible harms implied by participation are no greater than those posed by daily life in a stable society or routine medical, dental, educational or psychological tests or examinations" (DoH, 2015, p54)

4. Approve research with the major revisions……

5. After amendments, return the proposal to the primary reviewer for further review…….

6. Reject the research proposal (Justify)……

Comments

Signature of reviewer: **Date:**