RESEARCH ETHICS COMMITTEE: SOCIAL, BEHAVIOURAL AND EDUCATION RESEARCH (REC: SBE)

TERMS OF REFERENCE AND STANDARD OPERATING PROCEDURES

Purpose	Management of Research Ethics review processes concerning social, behavioural and education research at Stellenbosch University
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Contents

1. TERMS OF REFERENCE

Stellenbosch University (SU) is committed to the highest standards of ethical research and complies with all relevant legislation, guidelines and procedures governing human research.

The Research Ethics Committee: Social, Behavioural and Education Research (REC: SBE) is constituted in terms of the Policy for Responsible Research Conduct of Stellenbosch University that was approved by Senate on 24 June 2013.

The REC: SBE is mandated to review and provide oversight over the ethical aspects of non-medical, human research and the processing of personal information for the purpose of research.

The REC: SBE is registered with the National Health Research Ethics Council (NHREC) (Registration number: REC-050411-032). The REC: SBE reports to the Senate Research Ethics Committee (SREC) and NHREC at least annually in writing.

Research that involve patients, the review of medical or patient records, or clinical research are excluded from the scope of the REC: SBE. Health research in the narrow definition must be reviewed by the Health Research Ethics Committees (HREC1 or HREC2) of Stellenbosch University. The following research are deemed to be beyond the scope of the REC: SBE: biomedical, clinical and pharmaceutical research;

- biomechanical research, or research that involve the use of biomedical technology and applications, or the testing of mobility aids;
- research where blood or tissue samples will be collected or analysed;
- research targeting persons diagnosed with a medical, psychiatric or physical condition, where the purpose of the research is to study the condition itself and/or test interventions that could improve the condition or the quality of life of the participant;
- research that involves interaction with or the observation of patients in hospitals or other healthcare settings;

- research that involve the participation of healthy adults or children in physical or exercise activities that could result in injury[1];
- research that involves the testing and consumption of products, drinks or food stuffs by human panel members which have been enhanced by additives, not usually found in the food product
- the retrospective review and analysis of identifiable patient and/or other medical records.

The REC: SBE's role in reviewing research is to safeguard the dignity, rights, safety, welfare and well-being of human participants in research, having due regard for the requirements of applicable professional bodies and academic societies, relevant regulatory agencies, applicable laws, and relevant institutional requirements.

The REC can recommend measures aimed at minimising or avoiding potential or actual risks of harm – acknowledging that ethical considerations in the conduct of social science research can never be fully separated from its scientific dimensions.

The REC: SBE will fulfil its function by providing **independent**, **prospective**, and **ongoing** review of all social, behavioural and education research projects undertaken by members of staff, registered students and research-affiliates of Stellenbosch University.

The REC: SBE does not accept proposals submitted by researchers or students who do not have a formal research-affiliation with Stellenbosch University.

Ethics approval must be obtained before any recruitment and data collection from participants or their personal information commences. The REC will not consider projects for approval if it is apparent that empirical work involving human participants has already been conducted.

The REC: SBE will evaluate research according to the three broad ethics principles that underlie the conduct of behavioural research involving human subjects, as defined in the Belmont Report (1979)[2] and the eight key norms and standards as defined in Chapter Two

[1] University of Virginia: https://research.virginia.edu/human-research-protection-program/which-irb-should-i-submit

[2] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report. 1979. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html (Accessed 25 October 2019)

and Three of the Department of Health Guidelines (2015), but specifically adapted for research in the Social Sciences, Arts and Humanities as proposed by Wassenaar and Mamotte (2012)[3]. The REC: SBE will evaluate research according to these principles, norms and standards REGARDLESS of the applicant's level of study, their position at the institution or their level of seniority. Any sub-committees of the REC: SBE must evaluate research according to the same principles, norms and standards.

The Chairperson of the REC: SBE has the authority to appoint a standing or ad hoc subcommittee or co-opt expert reviewers to investigate or finalise certain matters under its jurisdiction, in compliance with applicable norms, rules and regulations, as prescribed in this SOP.

The REC: SBE may delegate its review, screening and provisional approval of low risk research to registered sub-committees. These sub-committees, once registered, will function as formal sub-committees of the REC: SBE and must operate under the same principles, and standards as discussed in this Standard Operating Procedures.

The REC normally meets on a monthly basis, except in December. The REC: SBE has the prerogative to change its annual submission and meeting dates when it is deemed necessary. The deadlines for submissions and meeting dates will be published on the website of the Division for Research Development (www.sun.ac.za/research).

2. ETHICAL AND REGULATORY REQUIREMENTS FOR RESEARCH INVOLVING HUMANS

Stellenbosch University (SU) is committed to applying the values of respect, compassion, equity, accountability and excellence in all its activities. This includes, by definition, all the research conducted at the University.

SU is of the view that good science assumes ethical responsibility according to internationally acceptable norms and that the responsibility for this lies with every person conducting research under the auspices of SU.

[3] Wassenaar, D. & Mamotte, N. (2012). Ethical Issues and Ethics Reviews in Social Science Research. In *The Oxford Handbook of International Psychological Ethics*. Oxford University Press.

2.1. Statutory Requirements for Human Research

The REC: SBE must comply with statutory obligations relating to human research ethics committees as set out in the National Health Act No. 61 of 2003 and as guided by the National Health Research Ethics Council.

The REC: SBE functions within the framework of all relevant promulgated Acts of Parliament and international treaties and conventions where South Africa is a signatory of, interpreted in a manner appropriate to research in the humanities, (i.e. the social, behavioural, economic and education sciences). Examples of relevant Acts, treaties and conventions include, but are not limited to:

- The Constitution of South Africa, Act 108 of 1996
- National Health Act, No 61 of 2003
- The Children's Act, Act 38 of 2005
- Human Tissue Act, Act 65 of 1983
- Promotion of Access to Information Act, Act 2 of 2000
- Protection of Personal Information Act of 2013
- United Nations Convention on the Rights of Persons with Disabilities and Optional Protocol 2006
- Stellenbosch University's Policy on Responsible Research Conduct

The Research Ethics Committee: SBER is therefore committed to the ethical principles laid out in the:

- Belmont Report 1979
- Declaration of Helsinki 2013
- Ethics in Health Research: Principles, Processes and Structures 2nd Edition, Department of Health, Republic of South Africa, 2015.
- Global Code of Conduct for Research in Resource-Poor Settings, 2019
- Singapore Statement on Research Integrity

More specifically, the REC: SBE is committed to the following broad ethical principles and key norms and standard as set by the Department of Health for the ethics review in all disciplines of research proposals involving human participants. These are discussed in Chapters 2 and 3 of the Department of Health guidelines 2015. Researchers and REC

reviewers are expected to familiarize themselves with these principles, norms and standards before embarking on research or reviewing a proposal for ethics approval.

2.2. Policies and Guidelines

In addition to the regulatory framework, the Research Ethics Committee functions within the framework of the following documents:

- Policy for Responsible Research Conduct at Stellenbosch University, 2013
- Stellenbosch University's procedure for the investigation of allegations of breach of research norms and standards, 2014
- The Universal Declaration of Human Rights (1948)

Furthermore, the REC is guided by the guidelines of professional bodies and scientific societies including, but not limited to:

- **Statement of Ethical Practice for the British Sociological Association:** https://www.britsoc.co.uk/ethics (Sociology and Social Anthropology)
- **Ethical guidelines and principles of conduct for anthropologists:** https://www.asnahome.org/about-the-asna/ethical-guidelines (Sociology and Social Anthropology)
- **The Health Professional Council of South Africa (HPCSA), Professional Board for Psychology.** Rules of Conduct Pertaining Specifically to Psychology. (Psychology and Educational Psychology): (http://www.psyssa.com/aboutus/codeofconduct.asp; http://www.hpcsa.co.za/downloads/conduct_ethics/rules/ethical_rules_psychology.pdf)
- **South African Council for Social Service Professions.** Policy Guidelines for Course of Conduct, Codes of Ethics, and the Rules for Social Workers. (Social Work)
- **American Sociological Association** Code of Ethics (2018) and the ASA Statement on the Importance of Collecting Data and Doing Social Scientific Research on Race (2002)

2.3. Roles and responsibilities of the principal investigator

For the purpose of this SOP, the principal investigator (PI) is a qualified scientist who undertakes scientific and ethical responsibility, either on his/her own behalf or on behalf of an organization/firm, for the ethical and scientific integrity of a research project at a specific site or group of sites. In some instances, a coordinating or principal investigator may be appointed as the responsible leader of a team of sub investigators. The PI is ultimately responsible for the conduct of a research project, and is also obligated to ensure the project is conducted in compliance with applicable laws and regulations and institutional policy governing the conduct of the REC-approved research. [4]

The principal investigator is responsible for submitting their proposed research for prospective ethics review if their research involves the participation of or interaction with human participants or involves the collection of personal information from/of human participants (individuals, members of a group).

Failure to apply for ethics clearance for non-exempt research may be reported to the Research Integrity Officer as research misconduct.

The application for ethics review must be reviewed and formally approved by the REC or pre-approved as low risk by a (registered) sub-committee of the REC (subject to REC ratification) before participant recruitment, data collection activities, planned research encounters. Retrospective review and approval or clearance is not permitted.[5]

Researchers must complete the relevant application form available on the system used by the REC for the purpose of ethics review. Applications are submitted through an electronic review management system provided by the Division for Research Development. A link to the electronic platform and instructions on how to navigate this platform will be available on the DRD website (www.sun.ac.za/research).

The REC: SBE in consultation with the DRD reserves the right to update or amend the ethics application forms at regular intervals to remove or add questions and criteria in order to

[4] University of Massachusetts, 2020: https://www.umass.edu/research/policy/pi-and-co-pi-roles-and-responsibilities

[5] Department of Health Guidelines, 2015, section 1.6.9 on page 12.

ensure compliance with national and international statutory requirements, norms and standards.

The REC: SBE will only accept applications submitted by SU staff members, SU-affiliated researchers, and registered SU-students who will conduct research under supervision for degree-purposes.

Students registered with the SU International Office as research-affiliate students may submit applications to the REC: SBE provided these students are under direct supervision of an SU-academic. The SU supervisor will essentially be responsible for ALL correspondence and reporting to the REC: SBE.

The REC: SBE does not review applications submitted by applicants who are not formally affiliated to Stellenbosch University, as described above.

SU staff members registered for a research degree at another university must either apply for ethics clearance from both universities. If the ethics committee at the other institution is registered with the NHREC, reciprocal review may be possible.

Research proposals submitted for review must be complete and fully developed and, in the case of student-applicants, in consultation with the supervisor. Proposals that are incomplete, under development or pending approval from the supervisor will not be considered for review.

Applicants are required to download and read relevant sections of this SOP or the **Researcher's Guidelines to getting ethics approval** to familiarise themselves with the research ethics review process and the requirements thereof before submitting an application to the REC or its sub-committees.

It remains the applicant's responsibility to ensure that their application to the REC is complete and submitted timeously, to track the progress of their application, and to respond to feedback from the committee and submit their revised applications timeously to the REC: SBE. It is also the researcher's responsibility to notify the REC office of potential delays or technical issues preventing them from submitting their application timeously.

Once formal approval is obtained from the REC or one of its sub-committees, the principal investigator (PI) is responsible for the following:

Conducting the Research: The PI is responsible for making sure that the research is conducted according to the REC approved research protocol. The PI is jointly responsible for the conduct of co-investigators and research staff involved with this research. The PI must ensure that the research is conducted within the recognised standards of their research field/discipline and according to the principles and standards of ethical research and responsible research conduct.

Participant Enrolment: The PI may not recruit or enrol participants unless the protocol for recruitment is approved by the REC. Recruitment and data collection must cease after the expiration date of REC approval. All recruitment materials for any form of media must be approved by the REC prior to their use.

Informed Consent: The PI is responsible for obtaining and documenting effective informed consent using **only** the REC-approved consent documents/process, and for ensuring that no participants are involved in research prior to obtaining their affirmative informed consent. The PI must give all participants copies of the signed informed consent documents, where required. The PI must keep the originals in a secured, REC-approved location for at least five (5) years after the research is complete.

Continuing Review: The REC must review and approve all REC-approved research proposals at intervals appropriate to the degree of risk but not less than once per year. There is **no grace period.** Prior to the date on which the REC approval of the research expires, **it is the PI's responsibility to submit the progress report in a timely fashion to ensure a lapse in REC approval does not occur.** If REC approval of your research lapses, all research activities must cease, and contact must be made with the REC immediately.

Amendments and Changes: Any planned changes to any aspect of the research (such as research design, procedures, participant population, informed consent document, instruments, surveys or recruiting material, etc.), must be submitted to the REC for review approval for planned implementation. Amendments may not be initiated without first obtaining written REC review and approval. The **only exception** is when it is necessary to eliminate apparent immediate hazards to participants and the REC should be immediately informed of this necessity.

Adverse or Unanticipated Events: Any serious adverse events, participant complaints, and all unanticipated problems that involve risks to participants or others, as well as any research related injuries, occurring at this institution or at other performance sites must be reported to the REC within **five (5) days** of discovery of the incident. The PI must also report any instances of serious or continuing problems, or non-compliance with the RECs requirements for protecting human research participants.

Research Record Keeping. The PI must keep the following research related records, at a minimum, in a secure location for a minimum of five years: the REC approved research proposal and all amendments; all informed consent documents; recruiting materials; continuing review reports; adverse or unanticipated events; and all correspondence and approvals from the REC.

Provision of Counselling or emergency support. When a dedicated counsellor or psychologist provides support to a participant without prior REC review and approval, to the extent permitted by law, such activities will not be recognised as research nor the data used in support of research. Such cases should be indicated in the progress report or final report.

Final reports. When the research is completed (no further participant enrolment, interactions or interventions), the PI must submit a Final Report to the REC to close the study.

On-Site Evaluations, Inspections, or Audits. If the researcher is notified that the research will be reviewed or audited by the sponsor or any other external agency or any internal group, the PI must inform the REC immediately of the impending audit/evaluation.

3. REC MEMBERSHIP, APPOINTMENT AND RESPONSIBILITIES

In executing its duties, the REC: SBE and its sub-committees will ensure that it is **free from bias and influence that could affect its independence**.

3.1. REC Composition

The Research Ethics Committee must consist of at least 15 members, including the Chairperson.[6]

The Research Ethics Committee should consist of academic staff from at least the following faculties[7]:

- Faculty of Arts and Social Sciences
- Faculty of Economic and Management Sciences
- Faculty of Education
- Faculty of Theology
- Faculty of Military Sciences
- Faculty of Engineering

The composition of the REC: SBE must meet the minimum standards and requirements, as set out in the Department of Health (2015) Ethics in Health research: Principles, Structures and Processes.[8]

In consideration of the specific expertise necessary for relevant review of Social Science, Behavioural and Education research, the REC membership must include:

- at least one member who is legally qualified (which may be one of the persons listed above)
- at least one representative of the broader community who is not a staff member of Stellenbosch University (which may be a representative of the SU student community)
- a representative with expertise in sampling within Social Science research (which may be one of the persons listed above)
- at least one person with expertise in research involving minors (which may be one of the persons listed above)

[6] The minimum number of members may be amended in consultation with the Senate Research Ethics Committee, considering the number of submissions for ethics review and the number of applications received from a specific faculty over a three-year period.

[7] Faculty representation and the number of members required per faculty should be proportionate to the number of submissions received from the faculty. The REC will consult with the Senate Research Ethics Committee and Deans, if amendments are required in terms of composition by faculty.

[8] Department of Health guidelines, 2015, pages 59

- at least one member with knowledge of, and current experience in, the professional care or counselling of people. Such a member might be a psychologist, social worker or nurse (which may be one of the persons listed above)
- at least one person with current experience in quantitative research methodologies (which may be one of the persons listed above)
- at least one person with current experience in qualitative research methodologies (which may be one of the persons listed above)
- at least one member with expertise in research ethics (which may be one of the persons listed above)

The Chairperson of the Research Ethics Committee can consult with or co-opt any expert that he/she deems necessary for the appraisal of a particular research proposal. A person with experience and knowledge of working with prisoners, must be co-opted when research involving the participation of prisoners, inmates, or persons under the jurisdiction of the Department of Correctional Services is to be reviewed.

Ideally, the REC should include ethnically and culturally diverse members with an appropriate mix of males and females.

3.2. Appointment of members

The representatives of faculties are appointed to the Research Ethics Committee by the respective Deans of the Faculties. It is the duty of respective Deans to identify and recruit academic staff to the REC, in consultation with the REC: SBE, taking into consideration the expertise required by the Department of Health.[9]

Any academic staff member(s) may also volunteer to serve on the REC: SBE with formal approval from their Dean or Head of Department.

The representative(s) of the broader community are appointed by the Director: Research Integrity and National Grants, within the Division for Research Development of Stellenbosch University, taking into account what "the broader community" is, and who may be a "representative" of it. In certain cases, the REC may require researchers to help

[9] The membership and composition of the REC will be continuously monitored to ensure appropriate representation. When a member resigns from the REC, the choice of a replacement takes into account the overall balance of the committee and specific expertise required.

identify a particular person representing a particular community in which the research will take place, research participants, or special interest groups, to be co-opted on an ad hoc basis to the Research Ethics Committee by the Chairperson of the Research Ethics Committee for the purposes of reviewing that particular research proposal.

Members of the Research Ethics Committee are appointed for a term of three years, subject to consultation with the respective Dean of the Faculty. Reappointment is subject to approval by the relevant Faculty.

Members are required to recruit an alternate member who will stand in for them in the event of their absence from a meeting.

The Chairperson and two deputy-chairpersons of the Research Ethics Committee are elected at a meeting of the Research Ethics Committee, and their respective identities are reported to the Senate Research Ethics Committee once they are appointed.

If a member is absent from a meeting for two consecutive meetings without an apology, his or her absence will be addressed by the Chairperson verbally and in writing to the specific member, after which the Chairperson can make a recommendation to the relevant Faculty which, in this context, has the authority to remove a member reported as non-attending from the Research Ethics Committee and appoint another representative for the remainder of the disqualified member's term.

Disengagement from the Research Ethics Committee can be initiated by the Chairperson or the member of the Research Ethics Committee and must be in writing. The disengaging members must inform his/her Dean of his/her decision and the Dean must appoint an alternative member within one month after receiving such notice. In these cases, the alternate member may replace the disengaged member.

Upon appointment and upon re-appointment to the Research Ethics Committee, members must sign applicable non-disclosure agreements.

Members will receive a letter of appointment from the SREC soon after their appointment is confirmed. Letters of appointment are kept on record by the REC: SBE Secretariat.

Stellenbosch University obtains professional liability insurance to cover both affiliated and non-affiliated members when carrying out any professional duties under the auspices of the REC: SBE.

At each meeting of the Research Ethics Committee, and at each assignment of a review, members must declare any conflicts of interest

To carry out its responsibilities, the Research Ethics Committee will be administratively supported by the Division for Research Development (DRD) who will provide a Secretariat, a review management system and an archive to the Research Ethics Committee.

The documentation and archive of the Research Ethics Committee is administered and governed according to the standard procedures and policies of SU, where applicable

Documents that should be archived include, but are not limited to,

- The Research Ethics Policy, written standard operating procedures of the Research Ethics Committee, and annual reports
- The agendas of the Research Ethics Committee meetings
- The minutes of the Research Ethics Committee meetings
- One electronic copy of all materials submitted by an applicant to the Research Ethics Committee
- The correspondence by Research Ethics Committee members with applicants or concerned parties regarding an application, the decision on it, and follow-up
- The notification of the completion, premature suspension, or premature termination of a study
- The final summary or final ethics report on the study.

Records of the Research Ethics Committee will normally be archived for a minimum period of 15 years following the completion of a review. Expired Research Ethics Committee documents will be disposed of using the standard procedure of Stellenbosch University for the safe disposal of confidential documents.

3.2.1. Expert reviewers and consultants

The Research Ethics Committee may call upon independent expert reviewer or consultants who may provide special expertise to the Research Ethics Committee on

proposed research protocols. These consultants may be specialists in ethical, scientific or legal aspects, or they may be representatives of communities, research participants, or special interest groups. The terms of reference for independent consultants will be stipulated by the Chairperson of the Research Ethics Committee in consultation with the Division for Research Development. Independent consultants may be invited to attend a meeting or meetings of the Research Ethics Committee, or be requested to provide written comments, subject to applicable confidentiality agreements.

3.2.2. Roles and responsibilities of REC members

The Research Ethics Committee will function according to Terms of Reference and Standard Operational Procedures (SOP) formulated in this document

The Research Ethics Committee member must ensure that it is adequately informed on all aspects of a research protocol, including its scientific validity, that are relevant to deciding whether the protocol is both acceptable on ethical grounds and conforms to the principles of this document

The Research Ethics Committee will have the responsibility to ensure that research conducted in the social, behavioural, economic and educational sciences at Stellenbosch University is in accordance with National and International guidelines and standards for ethically responsible research

The Research Ethics Committee has the responsibility to make decisions on applications for ethical clearance as defined in this SOP, and to monitor the implementation of these decisions in the case of high-risk research. The execution and implementation of the decisions of the research as approved by the REC, is the responsibility of the researcher.

In making these decisions the Research Ethics Committee focuses in particular on:

- actual or potential ethical risks related to research proposals, and
- measures to avoid or minimize these risks

The Research Ethics Committee will be available to render researchers, upon formal request, with expert opinion regarding research ethics (advice regarding application

procedures will be addressed on an informal and ad hoc basis by the Division for Research Development)

3.3. REC Code of Conduct for Members[10]

The Chairperson of the REC: SBE is expected to:

- Be knowledgeable in relevant legislation and national and international research ethics principles, guidelines and regulations, as well as institutional policies.
- Facilitate and direct discussion at convened meetings. This includes the ability to foster open and collegial discussion among all REC members whilst maintaining focus on the issues at hand (i.e. enabling the systematic review of proposals).
- Have respect for committee members from diverse backgrounds, perspectives and sources of expertise, which include the contributions of non-scientists.
- Be able to promote a culture of respect within the research community for the Research Ethics Committee process and for research ethics in general.
- Have the courage and confidence to uphold Human Research Ethics Committee judgements that may not be popular with investigators, the research community or University officials.
- Pursue continuing education in research ethics.

The Chairperson's responsibilities are to:

- Conduct monthly Research Ethics Committee meetings.
- Conduct expedited reviews or delegate this task to suitably qualified individuals who may or may not be committee members.
- Advise and consult with researchers on research ethics-related issues, or delegate this task to suitably qualified committee members
- Participate in non-compliance investigations
- Contribute to the development of Research Ethics Committee: SBE policies and procedures.
- Advise the Research Ethics Committee: SBE coordinators on general discussion items that should be added to the committee's agenda and sign off on the minutes after meetings.
- Consult with Chairs from research ethics committees across the campuses of Stellenbosch University to encourage and facilitate cross-disciplinary research.

[10] This Code of Conduct for REC: SBER members is based on the UCT SOP, 2018, which outline the Code of Conduct for its members.

- Represent the REC: SBE at national forums relating to Research Ethics and Governance, particularly the National Health Research Ethics Council
- Consult with Chairs from other human research ethics committees through-out the country in order to:
    - Improve participants' welfare and safety, particularly in multi-institution research projects.
    - Develop and promote best practices in research ethics oversight.
- Consult with, or co-opt any expert that he/she deems necessary for the appraisal of a research proposal
- Represent the REC: SBE on the Senate Research Ethics Committee

The Deputy-Chairpersons of the REC: SBE are expected to:

- Be knowledgeable in relevant legislation and national and international research ethics principles, guidelines and regulations, as well as institutional policies.
- Have respect for committee members from diverse backgrounds, perspectives and sources of expertise, which include the contributions of non-scientists.
- Be able to promote a culture of respect within the research community for the Research Ethics Committee process and for research ethics in general.
- Pursue continuing education in research ethics.

The deputy chairpersons' responsibilities include:

- Performing functions delegated by the Chair, including expedited review.
- Assume the role and responsibilities of the Chairperson, when required.
- Advise and consult with researchers on research ethics-related issues.
- Participate in non-compliance investigations.
- Contribute to the development of Research Ethics Committee: SBE policies and procedures.
- General responsibilities, which accompany committee membership.

General REC: SBE Member responsibilities include

- All REC members should have documented proof of research ethics training, refreshed at least once within the period of appointment.
- Attending meetings on a regular basis and not leaving until meetings are adjourned.
- Informing the REC secretariat at least two weeks in advance, should the member not be able to attend a meeting.

- Maintaining strict confidentiality regarding proposal information, reviews and decisions and all matters discussed at committee meetings.
- Disclosing conflicting interests and where a conflict does exist with respect to a study, not reviewing the protocol or leaving the room during discussion of and voting on the protocol.
- Members must indicate with a tick on the attendance register that they will maintain confidentiality of all proceedings and declare any conflicts of interest.
- Respecting each other's views and the deliberative process.
- Deciding independently if the design and conduct of proposed studies will protect participants' safety, rights and welfare.
- Remaining impartial and objective when reviewing protocols.
- Serving as main reviewers for research in their areas of expertise.
- Serving as general reviewers of all research discussed at full committee meetings.
- Deciding by vote or consensus, whether to approve, require revisions, not approve or defer studies following deliberation at full committee meetings.
- Performing expedited audits of projects pre-approved as low risk by DESCs.
- Keeping up to date with national and international research ethics and regulatory guidance.
- Taking part in research ethics-related continuing education.

3.3.1.1. Expert reviewers and consultants

The REC: SBE may use consultants or ad hoc reviewers where additional or specialised expertise is needed to review specific protocols. Consultants may be asked to review an individual protocol or attend a meeting to provide education on any issue of general interest. Consultants do not count as part of a quorum or vote.

The Chair/Deputy Chairs may invite consultants from inside or outside the university who have special expertise to act as consultants or ad hoc reviewers of human research. Reasons for seeking additional or special competence may include but are not limited to the need for:

- Additional scientific, methodological or scholarly expertise.
- Knowledge about potentially vulnerable populations.
- Broader understanding of gender or cultural issues.
- Greater sensitivity to community perceptions.
- A statistical opinion.

These expert reviewers and consultants:

- Must have access to all documents submitted to the Research Ethics Committee SBE relevant to the specific study under review.
- May take part in deliberations and may make recommendations concerning a study but they may not vote.
- Must affirm that they have no conflict of interest with respect to the specific studies they are invited to review.
- Must maintain strict confidentiality with respect to the specific protocol and the meeting's proceedings.
- May provide information about a specific study by written report, attending the meeting, or both.

3.3.1.2. Observers and Guests

Observers and guests may attend a full Research Ethics Committee: SBE meeting at the Chair's discretion or invitation. Guests and observers are individuals with an interest in research ethics and the review process and may or may not attend regularly. Guests and observers:

- Do not count as part of the quorum.
- Must maintain confidentiality with respect to protocols and proceedings during the meeting and sign a non-disclosure agreement before the meeting proceeds.
- May not observe the final discussion and vote for any protocols in which they have a potential or actual interest.

Observers with a special interest or expertise in research ethics and who regularly attend monthly meetings may be invited to join the Committee as alternate members as vacancies arise. Observers can also put themselves forward for membership. In this way, the Committee will serve a capacity- building and mentorship role in research ethics more generally. In turn, the Committee will be able to appoint new members with experience of the review process and a demonstrated commitment to encouraging ethical research in the university.

3.3.1.3. Ex-officio Members

Ex-officio member means an individual is an automatic Committee member by virtue of the individual's status within the institution. Ex officio members:

- May take part in the Committee's deliberations to provide information and expertise.
- May vote on any Committee decision

- Must comply with the Committee's conflict of interest requirements.

Permanent ex-officio representatives on the Research Ethics Committee: SBE may include the:

- Director: Research Integrity and National Grants
- Division for Information Governance
- Library and Information Services, specifically the Research Data Manager
- Information Technology
- Equality Unit

3.3.2. Confidentiality

Confidential Information shall mean certain proprietary, personal, or protocol-specific information which the REC member acknowledges to be confidential. Such information includes all protocols relating to research with human participants and associated documentation. The Confidential Information may be conveyed in written, graphic, oral or physical form including (but not limited to) scientific knowledge, skills, processes, inventions, techniques, formulae, products, business operations, designs, sketches, photographs, drawings, specifications, reports, studies, findings, data, plans or other records, and/or software.

All REC members, expert consultants, ex-officio members, observers and guests shall sign a standard confidentiality and non-disclosure agreement on appointment to REC.[11]

3.3.3. Conflict of Interest: Research Ethics Committee: SBE Members[12]

REC members (including sub-committee reviewers, community members, expert consultants and ad hoc reviewers) are expected to make decisions and conduct their oversight responsibilities in an independent manner, free from bias and undue influence.

REC members are required to disclose any relationship, interest or other circumstances that could reasonably be perceived as creating a conflict of interest with respect to the REC's review of the protocol. At each meeting of the REC, and at each appointment of a sub-

[11] Stellenbosch University HREC SOP, 2015, 11-12

[12] The conflict of interest policy is based on the HREC SOP of 2015, specifically pages 10-11

committee, members must declare any conflicts of interest and recuse themselves from the appraisal of the application.

REC members must disclose any relationship, interest or other circumstances, which could reasonably be perceived as creating a conflict of interest, including the following:

Personal Relationship: The REC member has a personal relationship with the principal investigator or key personnel of a research protocol under review by the REC

Relationship to the research study: The REC member (his/her spouse or immediate family member) is the principal investigator or co-investigator of the research protocol under review by the REC.

Business relationship or Affiliation: The REC member serves as a trustee, director, officer, owner or partner of a for-profit entity that could be affected by the outcome of the research protocol under review by the REC.

Financial Interest: The REC member has a financial interest that could be affected by the outcome of the research protocol under review by the REC. Included in the definition of financial interest are equity interests e.g. stock, stock options or other ownership interests, payment or expectation of payment derived from intellectual property rights (e.g. patent royalties); and payments received from a for-profit entity for consulting or other services.

Other examples of conflicting interests include but are not limited to the following:

The REC member has an interest that he or she believes conflicts with the his or her ability to review a project objectively.

The REC member is in direct competition with the investigators for limited resources, funding, sponsorship or research participants, or the REC member is considered a personal or professional adversary of the investigators. Since such situations may depend on the circumstances, the REC member should raise such a situation as soon as possible with the Chair. The standard used by the Chair is whether an independent observer could reasonably question whether the individual's actions or decisions would be based on factors other than the rights, welfare and safety of participants.

3.3.4. Procedure for handling conflicting interest:

REC members are required to disclose only those interests that may be affected by the research, which is the subject of the research proposal and that might otherwise reasonably be perceived to affect their independent unbiased judgment with respect to the REC's review of the protocol or related matters.

REC members should make disclosures to the chairperson. The chairperson and committee shall determine whether a conflict exists. The determination of whether a conflict exists shall be reflected in the minutes.

The chairperson may similarly become involved in a situation of potential conflict of interest. In this case he/she should discuss the matter with the Committee, or the Chairperson of the Senate Research Ethics Committee, whichever is seen to be most appropriate.

Recusal

REC members who have a conflict of interest related to any research protocols that the REC is about to consider will refrain from participating in any discussion of the protocol or related matters, except to the extent necessary to provide relevant factual information requested by the chair.

Unless requested by the chair to provide such information to the REC, the REC member with a conflict of interest will leave the meeting during the discussion and voting process. The outcome of the committee decision in the absence of the recused member will NOT be discussed upon return of the member concerned but may be conveyed after closure of the meeting.

REC members assigned as a primary or secondary reviewer for a protocol or related matters, with respect to which a conflict of interest has been identified, must notify the chair and Secretariat so that the protocol can be reassigned.

If the conflict of interest involves the chairperson, he or she will appoint the deputy-chairperson, or another member as acting chairperson (with approval of the committee). The acting chairperson will conduct the meeting, for the remainder of the discussion, of the item in question.

4. REC REVIEW PROCEDURES

The REC: SBE can review applications for ethics clearance according to these predefined review procedures:

- Exemption from ethics review
- Faculty/Departmental Ethics Screening review (DESC/FESC) for exemptions and low risk projects)
- Expedited review process
- Reciprocal review process
- Convened (Full) meeting (for medium and high-risk projects and for applications from environments that do not have a functioning and registered DESC/FESC)
- Expert review process
- Continuing review process
-

4.1. Exemption from ethics review

Certain types of research may be exempt from research ethics review. This means that the research does not require formal ethics review from an REC. This does not mean that researchers may forego consideration and reflection of ethical issues such as authorship, copyright, intellectual property rights, representation, etc. are irrelevant to the research.

Research is considered exempt from ethics review, if the project relies **exclusively** on:

- accessing and using information that is deemed public domain and are not subject to any copyright laws or licensing;
- information accessible through legislation or regulation
- secondary use of anonymous information of human participants, provided that no identifiable information is generated, and the researchers cannot link the information back to an individual. In these cases, researchers are expected to provide the REC with a sample of the dataset to confirm anonymity.
- the collection of non-human data i.e. annual reports, market or trade data, etc.
- the observation of people in public spaces and natural environments provided the following criteria are met: 1) the researcher does not interact directly with these individuals or groups, 2) the researcher does not stage any intervention, 3) individuals or groups being observed in

these public spaces do not have a reasonable expectation of privacy, and, 4) the dissemination of findings will not identify these individuals or groups.

Apart from the projects described above, the following activities do not require formal ethics review, unless there is an intention or prospect to share/ present the findings to the public:

- Course-related activities (with no intention or prospect to share the data gathered with third parties or present the findings to the public)
- Quality assurance audits or service surveys (with no intention or prospect to share the data gathered with third parties or present the findings to the public)
- Data collected for internal University administrative purposes, i.e. teaching evaluations or customer service surveys.

In general, exempt research does not require a formal submission to the REC for review. However, in cases where it is anticipated that a journal editor, sponsor or funder could request proof of ethics exemption, a formal application for exemption must be submitted and reviewed by the REC **before** such confirmation may be confirmed.

The researcher (and the supervisor in cases of degree-research) takes full responsibility for ethical and responsible conduct in research which is confirmed as exempt. **An exemption from formal ethics review procedures do not imply an exemption from the researcher's ethical responsibility with reference to authorship, research integrity, respect for persons, groups and the community, and representation of findings.**

Where exempt research holds the potential to harm or hold negative consequences for certain individuals, groups, or juristic persons, researchers are expected to immediately consult with the REC for advice on how to ensure that such risks or negative consequences are mitigated.

4.2. Faculty and Departmental Ethics Screening Committees (ESCs)

Faculties, Departments or Research Centres may register with the REC: SBE to establish a formal sub-committee of the REC: SBE, called an Ethics Screening Committee (ESC).

Only ESCs which are formally registered and recognised by the REC: SBE have the delegated authority to review and provisionally approve projects deemed exempt or low risk according to the REC's project risk classification system.

As sub-committees of the REC: SBE, ESCs are expected to review exempt and/or low risk proposals using the same criteria as discussed in these Standard Operating Procedures.

ESCs are required to submit a complete review report as per the requirement set forth by the REC for each proposal it reviews and approves. Proposals that do not include a complete review report will not be audited or ratified by the REC. SBER.

Once registered, an ESC may be granted a status as a Level 1 or Level 2 ESC depending on specific criteria as set by the REC.

A registered Level 1 DESC/FESC has the mandate to **review and provisionally approve** low risk research from their environments according to the REC: SBE's review criteria. Formal approval will only be confirmed after a member of the REC: SBE has audited the application and the ESC's review report/decision.

A registered Level 2 DESC/FESC has the mandate to **review and formally approve low risk** research from their environments according to the REC: SBE's review criteria. The decision of the ESC is ratified immediately after the submission of the application and the ESC review report.

4.2.1. Composition of the ESC

The membership and composition of an ESC is determined by the Faculty Dean or Head of Department.

Department ESCs are convened by the head of a department or their delegate and consist of at least two academic staff members or vetted technical staff with relevant experience (research, sampling, etc.). At least one of these members must have REC experience or training.

Faculty ESCs are convened by the Dean or Vice-Dean: Research of the Faculty or their delegate and consist of at least two academic representatives or vetted technical staff with relevant experience (research, sampling, etc.). At least one of these members must have REC experience or training.

ESC members must be an academic member of the department or faculty who has experience in conducting research involving human participants or research that involves access to personal information/data.

ESC members may not review proposals for which they are directly involved in the supervision or the conceptualisation of the research proposal to avoid potential conflict of interest. In cases where an ESC member is directly involved with the research, another member of the department or faculty should be assigned to review the proposal, following the usual procedures within departments or faculties to address potential conflicts of interest.

The ESC must assign an administrator to manage the ESC review process. This administrator may be an academic staff member, technical staff member or a support staff member. This person will be responsible for managing the online ethics review management process for their ESC.

ESC members should have previous training or experience in Research Ethics or should have attended a Research Ethics Training session prior to being appointed. Such training may be offered by an experienced ESC member or by the Research Ethics office or be gained by attending at least three consecutive meetings of the REC: SBE. ESC members are required to complete a certified online research ethics training module of which certificates of completion must be kept on record by the ESC administrator.

The term of membership, appointment and termination from the ESC is determined by the relevant department or faculty.

4.2.2. DESCs/FESC duties and responsibilities

The primary purpose of the ESC is to conduct a scientific and ethics review and provisional approval of research projects that are deemed exempt or considered low risk, according to the REC project risk classification system.

ESCs cannot pre-approve projects that are deemed medium or high risk. Medium and high-risk research must be immediately referred to the REC: SBE for review at a convened meeting. ESCs should ensure the completeness of applications referred to the REC: SBE.

The ESC determines the risk level of the proposed research according to guidelines provided by the REC: SBE. Uncertainty on risk categories or ethics issues must be referred to the REC: SBE for advice.

The ESC must ensure that the screening of research deemed low risk is done according to the standard ethical requirements and the proposal review requirements as described in these

Standard Operating Procedures. The emphasis of the review should be on an honest and critical reflection on, and deliberation about, the potential risks and benefits of the study and its potential impact on research participants and/or communities. These considerations and reflections must be recorded in the ESC review report for audit purposes.

The ESC may request the applicant to make changes to the project or informed consent form, etc., and should ensure that these changes are made prior to the implementation of the project.

Meeting frequency, location, procedures, quorum and any other logistical arrangements to facilitate the ESC review process are determined by the ESC. These procedures must be reported to the REC: SBE for its records and must be accessible to students and staff for their planning purposes.

ESCs must ensure a reasonable turn-around time in the processing and review of applications, following a time schedule that is well-coordinated with the submission deadlines for applications to the Research Ethics Committee that are published annually on the DRD website. A review conducted by the ESC should be done within a maximum of 15 business days.

It is the responsibility of the DESC/FESC to communicate its review decisions to the applicant.

4.2.2.1. Level 1 DESC/FESC audit process

All low-risk projects that are approved at Level 1 DESC/FESCs are subject to REC: SBE audit. Level 1 DESC/FESCs must submit low risk projects to the REC: SBE office via the review management system for a formal ethics clearance letter to be issued. The audit will only commence once the DESC/FESC sends to the REC: SBE office the application form with all accompanied documents and a detailed DESC/FESC review report motivating the risk level.

A REC: SBE audit differs from a review in its depth. Where a full review examines the application in detail, an audit confirms that the essential elements of ethical research are covered by the applicant, and adequately addressed as per the recommendations made by the ESC.

These applications will be submitted on a rolling basis and will be allocated to one REC: SBE member for audit.

The REC: SBE member assigned to audit the DESC/FESC-approved project must confirm audit within ten business days from the day of receipt.

An audit is confirmed via the online review management system. REC: SBE members assigned to audit the project must confirm the risk level as low and where required highlight any additional stipulations, which may apply.

In the case of a misclassified or problematic project, the REC: SBE reviewer may refer the application to the REC: SBE Chairperson for review at a convened meeting of the REC: SBE. If the REC: SBE Chairperson agrees with the REC: SBE members' decision to refer the application for full review, that REC: SBE member will be asked to review the application as primary reviewer. The REC: SBE Chairperson will assign a second reviewer to the project for discussion at the meeting. In this case, the REC Secretariat will notify the researcher to cease all recruitment and data collection activities, taking into consideration any negative impact this may have on enrolled participants.

The REC: SBE Chairperson may at his/her discretion co-opt expert reviewers, or former REC: SBE members to assist with the audit of a particular project, particularly when specific expertise is required or during peak application periods.

The REC: SBE reserves the right to attend a DESC/FESC meeting and observe meetings.

4.2.2.2. Level 2 DESC/FESC ratification process

A sample of low-risk projects that are approved at Level 2 DESC/FESCs level are subject to REC: SBE ratification. Level 2 DESC/FESCs must send low risk projects to the REC: SBE office via the review management system. Ratification will only commence once the Level 2 DESC/FESC sends to the REC: SBE office the application form with all accompanied documents and a detailed DESC/FESC review report motivating the risk level.

A REC: SBE ratification differs from an audit in its depth. Where an audit examines the essential elements of the application, a ratification merely confirms the risk assessment.

These applications will be submitted on a rolling basis and a sample will be allocated to one REC: SBE member for ratification. Ratification is confirmed via the online review

management system. REC: SBE members assigned to ratify the project must confirm the risk level as low and where required highlight any additional stipulations, which may apply.

The sample to be audited by the REC and the schedule of these audits are negotiated and agreed-upon by the REC Executive Committee and ESC at the time of registration as a Level 2 ESC.

In the case of a misclassified project or whether essential elements of ethical considerations are not addressed, the REC: SBE reviewer may refer the application and ESC review report to the REC Chairperson for consideration. If the REC: SBE Chairperson agrees with the REC: SBE members' decision to refer the application, the REC Chairperson may request a meeting with the ESC Chairperson and members to evaluate the review. The REC Chairperson may at his/her discretion request the REC to reconsider the registration level of the DESC. The REC: SBE reserves the right to investigate the DESC's/FESC's review and approval process for low risk applications or any concerns raised that the DESC/FESC is not following due process in reviewing low risk applications, and to provide departments/faculties with feedback on it if necessary. DESC/FESC registration can be put under review.

The REC: SBE Chairperson may at his/her discretion co-opt expert reviewers, or former REC: SBE members to assist with the ratification of a sample of projects, particularly when specific expertise is required or during peak application periods.

The REC: SBE reserves the right to attend a DESC/FESC meeting and observe meetings.

4.2.2.3. Registration process for determining a Level 1 and Level 2 ESC

All ESCs must register with the REC: SBE in order to operate as a sub-committee of the REC: SBE. Details on how to register are published on the Division for Research Development's webpage.

The registration process would entail completing an online registration form which provides details on the name of the ESC, its membership (which includes the expertise and training of the members on research ethics and/or social science research), structure and frequency of meetings (online or standard convened meeting), how they will handle potential conflict of interest and confidentiality within the meeting, identification of the

coordinator/administrator of the DESC; rotation schedule of members, number of applications reviewed annually, expected time of high volume of submissions to ESC, specific review criteria or processes in line with the REC procedures for review, etc.

Once application for registration is submitted, the REC Executive Committee may consider the registration at an ad-hoc meeting or refer the registration to a convened meeting of the REC for their consideration. The REC Executive Committee or REC may request that the REC office provide additional information such as a record of submissions supplied by the REC office, if deemed necessary. The REC will determine the level and arrange a meeting with the DESC to discuss the assessment and their recommendations.

The registration level of an ESC is not permanent. Level 1 ESCs may apply for registration as a Level 2 ESC. All ESCs are required renew their registration with the REC at annual intervals.

Criteria which may earn ESCs a Level 2 registration:

- One-third of the ESC's current membership should have served on the REC: SBE for one full term.
- The ESC is currently represented by at least one ESC member serving on the REC: SBE for one full term.
- All ESC reviewers have undergone certified research ethics training as per Department of Health requirements
- ESC reviews are thorough and consistent and are done according to the criteria set out in these Standard Operating Procedures.
- Applications approved by the ESC as low risk always include a comprehensive review report and are complete i.e. all documents and information are attached to the application.
- Project risk levels are classified with consistent accuracy according to the REC: SBE's project risk level system. The ESC initiates prior consultation with the REC where there are uncertainties around a project's risk classification.

Criteria which may earn ESCs a Level 1 registration:

- All ESCs are registered as Level 1 ESCs upon first registration with the REC.
- Applications approved by the ESC as low risk include a comprehensive review report and the application is complete i.e. all documents and information are attached to the application as far as possible
- At lease of the ESC reviewers have undergone certified research ethics training as per Department of Health requirements or have prior REC review experience
- ESC reviews are done according to the criteria set out in these Standard Operating Procedures.

- Project risk levels are classified according to the REC: SBE's project risk level system. The ESC initiates prior consultation with the REC where there are uncertainties around a project's risk classification.

4.3. Expedited review

There may be circumstances where the REC may consider a review of an ethics proposal through expedited review procedures.

A request for expedited review would apply only for the first submission to the REC.

Researchers are expected to contact the REC office to alert the REC of their impending request for expedited review prior to submitting their application.

The Chairperson or Vice-Chairperson(s) have the final prerogative in determining whether a submission is eligible for expedited review. The Chairperson or Vice-Chairperson(s) must be allowed a minimum 1 business day to consider the request for expedited review.

Once a request for expedited review is confirmed, the Chairperson or Vice-Chairperson(s) may designate one or more REC members to perform an expedited review of the application. No member with a conflict of interest may serve as a reviewer for any expedited item.

An expedited review will be finalised within **10 business days after the application has been assigned to a REC member for review.** Researchers are expected to ensure that the application is complete enough to facilitate a review of the proposal according to the REC's proposal review criteria as described in this Standard Operating Procedure.

Applications for ethics review are eligible for expedited review under extraordinary and extenuating circumstances, if:

- The researchers can provide written proof that the project was commissioned within an extremely limited timeframe (please refer to Addendum 2 on the considerations for commissioned research). Researchers are expected to provide the REC with a timeline of when the call for the research was issued and when the intended start-date of the project is, as set by the project owner, funder or sponsor.
- The request for an expedited review is adequately motivated in writing by the applicant or their supervisor (in the case of student research).

Failure by the lack of adequate planning and preparation on part of the researcher, or failure to timeously apply for ethics clearance will not be accepted as a motivation for expedited review.

Researchers or a Faculty/Department Screening Committees who experience technical difficulties with submitting their application timeously must report the matter to the REC helpdesk office immediately for resolution. Technical difficulties resulting from user incompetence (i.e. not following the current instruction guides provided by the REC office) will not be accepted as motivation for expedited review.

Expedited reviews, according to the Department of Health Guidelines (2015) may only apply, in principle, to research that poses no more than minimal risk of harm. Projects that are deemed medium and pose a high probability of harm to participants are to be reviewed by the REC at a convened meeting and will not be accepted for expedited review unless **evidence is presented that the project is commissioned to be done in an extremely limited timeframe**. The REC Executive Committee (comprised of the REC Chairperson and Vice-Chairpersons) will determine whether the request for an expedited review is accepted.

All applications that are reviewed through expedited procedures during a REC cycle will be listed in the REC agenda and minutes of the upcoming REC meeting.

The REC review reports, and the decision of the expedited review are ratified at the upcoming meeting of the Research Ethics Committee

If the application is formally approved without conditions or requirements, the researcher may continue with the research upon receipt of the clearance letter while awaiting the ratification of the expedited review at a convened REC meeting

If any changes to the decision of the Chairperson and sub-committee are made at the ratification of an expedited review, the applicant will immediately be informed and will be required to adhere to or respond to the additional conditions discussed at the meeting

4.4. Reciprocal review process

Reciprocal recognition means that two or more RECs registered with the National Health Research Ethics Council (NHREC) decide to recognize each other's prior review.

The REC may at its own discretion, recognise the prior review and approval of a research proposal by another NHREC-registered REC to avoid duplication of effort. Researchers may consult the National Health Research Ethics Council's website for a list of NHREC-registered Human RECs: http://nhrec.health.gov.za/

The REC will recognize prior review and determine the nature of the documents to be filed locally. The researcher must provide a copy of the official approval letter and the proposal documents that were approved by the other NHREC-registered REC (including consent documents, data collection instruments and/or any recruitment material to be used).

RECs that recognise prior review in this manner may revise their decision to do so if justifying circumstances arise. The reasoning supporting a reversal of recognition will be documented.

A reciprocal review is done by the REC Chairperson, Vice-Chairperson or another designated REC member within **15 business days** after receipt of the application.

4.5. Convened REC review

Projects classified as medium or high risk and which do not qualify for expedited review will be reviewed at a convened meeting of the REC.

Meetings will be scheduled to be held on a monthly basis, unless decided otherwise by the Chair of the Research Ethics Committee.

New submissions must be received by the REC office by the published agenda closing date (usually three weeks prior to the upcoming REC meeting) in order to be considered for the agenda of that meeting.

At least 50 percent (plus 1) of voting members (if the REC has less than 15 members) must be present at the meeting to reach a quorum. If the REC consists of more than 15 members, a third of membership make a quorum.

At least one member whose primary concerns are non-scientific must be present at the meeting.

At least one of the reviewers assigned to a project must be present at the meeting for discussion of the proposal.

Each committee member must have access to a copy of the complete documentation for each application under review.

The meetings of the Research Ethics Committee will be minuted.

4.5.1. Pre-meeting process

The REC administration office checks the application submitted for review for completeness and may request additional information from the applicant.

Each application submitted for convened meeting review is allocated to two members of the committee, at least two weeks prior to the meeting for review.

The Secretariat will send an assignment list with the projects included in the agenda and their assigned reviewers at least two weeks before the meeting date.

Reviewers must notify the REC Secretariat and/or REC Chairperson immediately if they are unable to attend the meeting.

The chairperson may, at her/his discretion, co-opt an external consultant or expert reviewer for a project, if s/he feels the committee does not have the necessary expertise to adequately evaluate all aspects of a particular research application.

REC members are required to submit their completed review reports to the Secretariat at least 5 days prior to the meeting date.

The REC coordinator collates all the available reviews into the meeting agenda and distributes the agenda to the REC at least 2 days prior to the meeting.

4.5.2. REC Convened Committee Review process

The REC Chairperson or designated person opens the meeting.

A quorum, as described earlier must be present for all decision making. Where the number of voting members are more than 15, the quorum may be 33% (as stipulated in the DoH

guidelines (2015), provided at least one member whose primary concerns are not scientific is present at the meeting.

The Director: Research Integrity and National Grants shall serve as an alternate member when needed to meet quorum.

The REC Chairperson may allow academic staff members or members of FESCs/DESCs to observe the meeting, subject to signature of a non-disclosure agreement. Observers and guests may not vote on applications under review.

The REC Secretary records those present and notes apologies. Every effort will be made to ensure that at least one of the reviewers assigned to review a project are present at the meeting to present feedback. Should this not be possible the Chairperson will present the review reports to the REC for discussion.

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:

- Minutes of the previous REC meeting are corrected and accepted.
- Matters arising from the previous meeting
- General items
- New applications
- Resubmission of deferred projects
- Discussion and review of projects forwarded to the full committee after expedited review or ratification

New applications are introduced by the chairperson. The primary reviewer presents a summary and review of the study to the committee. The second reviewer adds comments where required. Discussion is then opened to the full committee for questions or comments.

If one of the REC members is an investigator, co-investigator or supervisor involved in the project, he/she must inform the REC Chairperson of the potential conflict of interest at the start of the meeting and should voluntarily recuse her/himself prior to discussion and decision-making. This recusal will be recorded in the minutes. The recusal of the member will not affect the quorum of the REC.

Investigators will not attend the meeting routinely unless requested to do so by the chairperson. The chairperson facilitates discussion and summarises the perceived viewpoint of the committee. Investigators may only attend the meeting for the discussion of their application and must leave the discussion prior to decision-making or voting by the REC. Investigators and their supervisor may not be part of the decision-making process of the REC.

Decision making will generally be by consensus. If consensus is not reached, then the REC: SBE will vote on a proposal, and this will be recorded in the minutes. Voting will be recorded as the number for, against and those abstaining. Decisions should only be made at meetings where a quorum is present.

4.5.3. Preparation of the agenda and minutes

Minutes must reflect the agenda of each meeting and must record the discussion and action taken on each agenda item.

The draft minutes of the previous meeting as prepared by the REC administrative staff are sent to members of the REC at least 7 days before the upcoming meeting for their review. A call for corrections or comments can be made prior to or at the convened meeting. If none is made, a motion to approve the minutes is made and the minutes of the previous meeting is signed by the REC Chairperson and another voting member of the REC.

Written minutes of the REC meeting will be recorded in sufficient detail to:

- Meeting logistics: start and end time, date and location
- Review and approval of minutes from the previous meeting
- Identify all individuals attending the meeting: administrative staff, REC members and alternates, consultants, guests and observers and researchers (if invited to present their proposal)
- The minutes will reflect when an alternate member substitutes for a regular member and for whom the alternate is substituting.
- The minutes will document when a member is recused from discussion and voting due to a conflict of interest. The minutes will also indicate whether prior to recusing him or herself the member remained in the room to provide information at the committee's request.
- For all applications under review at the meeting, the minutes must reflect:
    - The project ID number, principal investigator and study title.

- Deliberations, actions and votes (if applicable) on each study undergoing initial or continuing review, and each amendment or revision requiring full-committee review.
- The REC's decision or action taken on the application and the reasons for the decision
- If a proposal is approved conditionally (i.e. revisions are required before approval), the minutes must state whether the committee determines that the revisions and/or recommendations are to be reviewed by the Chair, a designee or by the assigned reviewers.
- The minutes may include a summary of the discussion of controversial issues and resolutions. Minutes shall be written impersonally, and opinions expressed by members shall not be attributed to them.
- In order to encourage open and frank discussion at committee meetings, minutes will not normally be made available to others outside the University administration unless otherwise required by law or regulation.
- The minutes will include a summary of expedited approvals, and any other business relevant to the REC: SBE meeting.

REC agenda:

The agenda will include a list of new applications submitted for REC full review. All projects reviewed under ESC procedures, expedited or continuing review procedures will be listed in the agenda for acknowledgement by the REC.

All adverse events reported in previously approved studies, general and policy matters; and/or allegations of misconduct in research or other complaints will be included in the agenda for discussion and/or acknowledgement at the convened meeting.

The REC agenda will be distributed to members of the committee at least 2 days prior to the meeting.

4.6. Expert review process

The Chairperson of the REC and/or the Director: Research Integrity and National Grants can consult with or co-opt any expert that he/she deems necessary for the appraisal of a research proposal.

These independent consultants may provide special expertise to the REC on proposed research protocols. These consultants may be specialists in research ethics, scientific, or

legal aspects, or they may be representatives of communities, research participants, or special interest groups.

The terms of reference for independent consultants will be negotiated and agreed-upon by the Chairperson of the Research Ethics Committee in consultation with the Division for Research Development.

Independent consultants may be invited to attend a meeting or meetings of the Research Ethics Committee, or be requested to provide written comments, subject to applicable confidentiality agreements.

If an application is referred to an expert reviewer, the assigned review will be asked to conduct the review within **10 business days** after acceptance of the request for expert review.

4.7. Continuing review process

4.7.1. Annual Progress Reports for renewal of ethics clearance

Ethics approval is valid for a limited period depending on the level of risk of the project as confirmed by the REC.

A progress report for the renewal or reapproval of the project must be submitted to the REC a **minimum of 2 months** before the expiration of ethics approval, so that the submission can be reviewed, and the project re-approved prior to the expiry date.

The REC: SBE Annual Progress report should be used for the purposes of renewal of ethics approval.

The progress report should contain sufficient information to allow the reviewer(s) to conduct a substantive and meaningful review of the progress of the project, including any challenges or problems encountered.

An updated, complete protocol, incorporating all approved amendments should be attached to the submission.

For medium and high-risk research, progress reports are required annually until such time as the investigator submits a final study report or a notice of termination of the study.

Research activities may not continue after the protocol approval period has expired. The researcher must obtain renewal of ethics approval before data collection and participant recruitment may commence. If a continuing review of an active, study is not approved prior to the expiry date, the REC approval will automatically end, and the study will be suspended.

It is the responsibility of principal investigators to monitor approval periods and to ensure that continuing review reports are submitted in time to allow for expedited or full committee review.

4.7.2. Final reports for completion of a study

A study is considered active or ongoing (and therefore subject to the submission of annual progress reports) until such time that the date of approval lapses, a final report is submitted by the applicant and accepted by the REC or the project is closed through an historical closure of the record (due to expiration of the approval period).

The principal investigator can voluntarily close a study when it is completed (e.g. when all participant accrual is completed and/or all data (including study follow-up data) pertaining to participants have been collected and when no further interaction with participants is planned for research purposes.)

Applicants must submit a final report to confirm the project as complete which will be reviewed and approved by expedited review procedures. In the case of medium or high risk research, if a study is not closed by the researcher but is allowed to expire as a lapse in approval, an administrative suspension letter will be sent to the principal investigator.

Researchers are required to keep track of the proposal approval period and ensure that they notify the REC as to whether the study will continue or whether it is completed. If the researcher fails to submit a final report by the protocol expiration date, an administrative suspension letter will be issued until such time that the researcher notifies the REC of their intention to either continue with the study or confirm completion of the study.

If a researcher terminates employment with SU, they must either submit a final report to the REC to close the study or submit an amendment to transfer the project to another principal investigator. The researcher must notify the REC of the transfer via a major amendment.

This amendment must be approved by the REC before the project will be transferred. If the PI is unwilling or unable to provide such an amendment, the REC may choose to administratively close the study.

4.7.3. Amendments

Amendments are changes to an active study, made in advance of the planned date of implementation.

Amendments may be classified as minor or major (substantive). All amendments must be reviewed and approved by the REC or a sub-committee before implementation. The proposed amendments must include a justification or rationale for the proposed change(s).

Substantive changes that alter the overall purpose, research question or objectives of a study may require a new submission to the REC. Researchers must consult the REC office to determine whether the proposed changes may be accepted as a minor or major amendment, or whether the proposed changes necessitates a new application.

Minor amendments for projects that were initially approved by the ESC as low risk may be submitted to the ESC for consideration and approval. ESCs are required to notify the REC of all approved amendments by submitting a review report and the approved amendment to the REC via the online review management system. All minor amendments that are approved by the DESC must be recorded on the online review management system for audit and recordkeeping purposes. The ESC may only review and approve minor amendments as defined below. Major amendments must be referred to the REC for review and approval. ESCs that are uncertain about whether an amendment qualifies as minor or major is advised to consult with the REC office immediately before proceeding with the review of the amendment.

Minor amendments are changes to the proposed research and or supporting documents that are considered negligible or non-substantial that it would not alter the risk-benefit assessment of the study or increase the potential risk of harm to participants. These may include:

- Negligible changes to the study title

- Small format/typographical/editorial changes to the informed consent documentation, questionnaires or recruitment flyers
- Changes regarding the inclusion of a small number of additional questions provided they do not change the meaning or tone of the questionnaire
- Changes that do not affect the study design, study outcomes and/or the risk level of the project
- Changes regarding a new site for the research, provided it is not distinctly different from the other research sites
- Extension of the period over which the research is to be conducted
- Minor administrative changes (i.e. contact information of the applicant and/or co-investigators)
- An increase or decrease in the proposed number of participants supported by a statistical justification
- Changes regarding the inclusion of additional participants or informants provided they are from the same population group as previously agreed to

Major amendments are changes to the proposed research and or supporting documents that are deemed substantial enough to potentially result in an alteration of the risk-benefit assessment of the study or increase the potential risk of harm to participants. These may include:

- Changes in the study design or research methods
- Changes to how data will be analysed
- Adding another research activity, study procedure or including another phase of research
- Changes to study population (i.e. the type of participants required for the research or adding a population group that is exposed to key vulnerabilities in the context of research or requiring specific attention by the REC)
- Changes regarding a new site if the new location is abroad or distinctly different from the previously agreed-upon research sites
- Major changes to the documentation to be used during the research including a substantial revision of the informed consent documents, a questionnaire or interview schedule
- Significant changes to the inclusion or exclusion criteria
- Change in the principal investigator whilst the project is still active

Researchers may not implement minor or major amendments until approval of the amendment is confirmed by the REC or its sub-committees in writing.

Amendments are generally reviewed via expedited review procedures within **seven business days** from the date of receipt.

It is possible that a substantial or major amendment could require the research to be suspended until it is considered by the REC at a convened meeting, particularly where such an amendment might increase the risk of harm to participants or introduce an additional harm to the study. In the event of such a decision by the REC, the REC office will notify the researcher to suspend research activities in a timeous fashion.

4.7.4. Protocol deviations

A protocol deviation is a "once-off", unplanned occurrence when, for a well-motivated reason, the proposal as approved by the ESC or REC is not followed due to unanticipated circumstances which require immediate decision making by the researcher or fieldworker, in order to eliminate an immediate risk, or inconvenience to the research participant.

Protocol deviations differ from amendments because they usually apply to a single incident or participant and are not intended or planned at the time.

A deviation must be reported to the REC immediately or soon after the event has occurred, but generally **within seven calendar days after the occurrence or discovery of the deviation.**

Deviations may be sent to the primary reviewer of the study and the Chairperson for their expedited review and advice.

4.7.5. Adverse or harmful events and unintended consequences or unanticipated incidents

An occurrence of an adverse or harmful event in SBER research is rare but not impossible.

An adverse event in SBER research is defined as any untoward, harmful or unfavourable event or incident experienced by a participant as a direct result of taking part in the research activity or procedure.

An adverse event has a causal relationship with the identified or known risks associated with the research.

An unanticipated incident is defined as an untoward, harmful or unfavourable incident experienced by a participant, or a member of the research team which might not be as a direct result of taking part in the research activity or procedure.

An unanticipated incident may or may not necessarily have a causal relationship with the research or any identified or known risks associated with the research.

Examples of such incidents may include but are not limited to: a spouse physically abused by their partner for taking part in the study; a child-participant reporting abuse to a researcher, or where the researcher suspects possible abuse; sexual assault or any harassment experienced by the participant or members of the research team; inadvertent disclosure or loss of confidential information or a device on which such information is stored, or any event or experience that has a negative impact on participants or members of the research team, etc.

Such events must be reported to the REC as soon as it has occurred but no later than five calendar days after the investigator first learns of this occurrence.

The REC may call an ad-hoc meeting with the researcher to discuss the matter. Depending on the nature and severity of an event, advice may be sought from the SU Legal Office, a registered psychologist or counsellor, or another professional whose advice will assist the researcher in mitigating or responding to the event.

4.8. Recommended turnaround time for review and decision-making

Type of review	**Recommended deadline for submissions**	**Recommended time allowed for administrative checks/review AND/OR consideration of the request for expedited/expert review**	**Recommended turnaround time for reviewers to review a submission**	**Recommended time allowed for feedback to be sent to applicant after completion of review**	**Total time elapsed (counted in weeks from date of submission)**
Exemption and DESC/FESC review	Can be submitted on a rolling-basis or upon the proposed deadline as set by the ESC	To be determined by the ESC	**A maximum of fifteen business days** upon receipt of the complete application as submitted by the DESC/FESC	To be determined by the ESC	3-4 weeks
REC Audit of a DESC/FESC-approved study	Submitted by ESC on rolling-basis	2 business days after receipt of submission from the ESC	**Ten business days** upon receipt of a complete application	Two business days after decision is confirmed by the reviewers	3 weeks
REC expedited review	Submitted on date as agreed-upon or confirmed by the REC Chairperson	1 business day after receipt of submission	**Ten business days after expedited request is accepted**	Two business days after receipt of all reviewer reports and Chair confirmation	+/- 2 weeks
REC reciprocal review	Upon the agenda closing date as published by the REC	1 business day after receipt of submission	**Fifteen business days** upon receipt of a	Two business days after receipt of all reviewer reports	3-4 weeks

			complete application	and Chair confirmation	
Convened meeting review	Upon the agenda closing date as published by the REC - in cases where an ESC-review is required before submission, the ESC undertakes to submit the medium and/or high-risk study to the REC upon the closing date.	**2 business days after receipt of submission**	**2-3 weeks** prior to date of convened meeting	Seven business days after the convened meeting has taken place	4-5 weeks
Expert review	REC Chairperson may request an expert review of any submission at his/her discretion	Not applicable	**Ten business days** once expert reviewer accepts the review assignment	Two business days after receipt of all reviewer reports and Chair confirmation	+/- 2 weeks
Progress/final reports	2 months before the expiration of ethics approval on or before the REC agenda closing date	**2 business days after receipt of submission**	**Ten business days** upon receipt of a complete application	Two business days after receipt of all reviewer reports and Chair confirmation	+/- 2 weeks
Amendments	Rolling-basis or upon an agreed upon date as communicated to the REC office or as arranged with the REC	**2 business days after receipt of submission**	**Seven business days** upon receipt of a complete application	One business day after receipt of all reviewer reports and Chair confirmation	1-2 weeks
Deviations	Immediately or within seven calendar days after the deviation occurred/discovered	**Not applicable**	**Seven business days** upon receipt of a complete application	Two business days after receipt of all reviewer reports and Chair confirmation	1-2 weeks
Harmful occurrences/events	Immediately or within seven calendar days after the event has occurred	**Not applicable**	**Five business days** upon receipt of a	One business day after receipt of all reviewer reports	1 -2 weeks

			complete application	and Chair confirmation	

Please note that during the REC's peak season of submissions (normally April-October), expected turnaround times may increase by **1-2** additional week(s) depending on the volume of submissions received in the review cycle and availability of REC members to review these submissions.

These expected turnaround times apply to research applications that are scientifically and ethically sound. It may take considerably longer to finalise review decisions for research applications that are scientifically and/or ethically problematic or flawed. Review time is also subject to DESC/FESC or REC capacity, and the timing of the application.

Researchers are expected to plan their research, accordingly, taking into consideration the time required for ethics review.

4.9. Project risk classification: criteria and guidance

The concept of 'risk' applies primarily to potential risk to a human research participant or the community in which the research will be conducted. However, certain research projects can involve potential risk to the researcher or members of the research team. Such risks must also be taken into consideration when determining the overall risk level of a project.

Researchers putting themselves or their research team members in a situation or position of potential harm are required to reflect on their safety and well-being during the study.

Researchers (and supervisors in the case of student projects) must conduct a reasonable risk-benefit assessment of the project. Such a risk assessment must take into consideration the research question, aims and objectives, the topic to be investigated, the participants to be recruited or information to be accessed, the methods to be used to collect data, circumstantial or contextual factors which may place the

participants or research team members at risk of harm, expectations of privacy and confidentiality, as well as potential risks and benefits that are likely for those participating in or affected by the research. Researchers need to reflect on and discuss the potential social value of their research and are expected to consider how the findings of the research may be translated into the local context. Researcher should reflect on and discuss in their research proposals plans for disseminating the findings or recommendations to the participants/groups or communities involved in the research, any planned interventions or social impact projects which may be done after the research is complete, etc.

The REC: SBE's project risk classification system is used in a manner to categorise projects that may be reviewed and pre-approved by a sub-committee of the REC i.e. an Ethics Screening Committee and those projects that must be reviewed and approved by the REC: SBE at a convened meeting. This classification should be considered according to the assessment of ethical risk and the type of research, rather than other criteria such as level of degree, position or seniority of the applicant.

Given the time limitations for many postgraduate students (specifically undergraduate, Honours and Masters degree students), it is recommended that postgraduate students either:

- Pursue research that fall into the low risk classification as described below. This research can be reviewed using the Departmental/ Faculty Ethics Screening process, which generally offers a shorter turnaround time by the REC; or
- Pursue research that fall into the medium or high-risk classification, but plan for this in advance, and submit to the REC: SBE with plenty of time for adequate convened (full) meeting review prior to the expected research start date.

4.9.1. Types of harm in SBE research:

The following risks should be considered in the context of Social Science, Behavioural and Education Research.

Psychological Risks: Psychological risks may be experienced during participation in the research and/or afterwards as a result of participating in the research. These risks include anxiety, stress, fear, confusion, embarrassment, depression, guilt, shock, loss of self-esteem, and/or altered

behaviour.

Social/Economic Risks: Economic risks include alterations in relationships with others that are to the disadvantage of the subject, and may involve embarrassment, loss of respect of others, labelling with negative consequences or diminishing the subject's opportunities and status in relation to others. These risks include payment by participants for procedures, loss of wages or income, and/or damage to employability or insurability.

Legal Risks: Legal risks include risk of criminal prosecution or civil lawsuit when research methods reveal that the subject has or will engage in conduct for which the subject or others may be criminally liable.

Loss of privacy and/or confidentiality: Confidentiality is presumed and must be maintained unless the investigator obtains the express permission of the subject to do otherwise. Risks from breach of confidentiality include invasion of privacy, as well as the social, economic and legal risks outlined above. Loss of confidentiality is the most common type of risk encountered in social and behavioural science research.

(University of Chicago, Social & Behavioral Sciences IRB & Investigator Manual, 2009:12)

RISK CATEGORY	DEFINITION	EXAMPLES
HIGH RISK	Research in which there is a real and foreseeable risk of harm, which may lead to an adverse event, if not managed in a responsible manner. In these cases, the magnitude of harm and severity of its consequences to the participant, community and or the researcher is high.	• Research investigating illegal activities which might place either the participant or the researcher at risk of harm; • Research in which information may be revealed that requires action on the part of the researcher where such information could place the researcher or members of the research team, the participant or others at risk e.g. research involving child victims of physical or sexual abuse, victims of domestic violence, etc.

	This project requires review by the REC: SBE at a convened meeting. **Certain High-Risk studies may be subject to monitoring and audits by the REC: SBE**	• The research will actively recruit persons who have experienced or might be experiencing a traumatic or stressful life event • Research that may require immediate follow-up and monitoring of a participant's well-being.
MEDIUM RISK	Research in which **potential harm is likely**, but appropriate steps can be put in place to mitigate or reduce the probability of harm or risk and its impact on participants. **This project requires review by the REC: SBE at a convened meeting.**	• Research in which the type of information collected (e.g. personal or sensitive information that a person would reasonably expect to remain private and confidential), in combination with the collection of personal identifiers may put the participant at risk of identification if such confidential data is breached (name, student number, address etc.) • Research which involves the collection of personal information classified in the Protection of Personal Information Act (2013) as special personal information • Research in which an individual or group is exposed to key sources of vulnerability (social, psychological, economic, legal) in the context of the research project • The research involves the participation of minors (persons under the age of 18) • Participants are required to commit an act, or answer questions which might diminish their self-respect or cause them to experience embarrassment, shame or regret • Participants are exposed to questions which may be experienced as stressful or upsetting, or to procedures and activities which may evoke unpleasant or harmful responses or reactions • The use of stimuli, tasks or procedures may be experienced as distressing, noxious or unpleasant

		• Research involving inmates at correctional facilities, persons with limited freedom of movement, or people functioning in unequal power relationships, for example work environments, churches and schools, community projects where beneficiaries are recruited by the staff of community organisations or service providers. • The research involves persons living with intellectual disabilit(ies) and/or mental illness (which may affect their factual capacity to consent or whom may be unduly coerced into research) • Research involving deception of participants or withholding of information from participants • The researcher requires access to classified or confidential information without the prior, informed consent of participants (explicit motivation is required for waiver of consent, dependent on the type of information sought; researchers may be required to conduct a privacy impact assessment) • Research involving participants who are illegal and/or undocumented immigrants or migrants
LOW RISK	Research in which the likelihood of harm or discomfort anticipated is low **This project may be reviewed and provisionally approved by a Faculty or Department Ethics Screening Committee.**	• The research **will not** involve the participation of any individuals or groups who may be exposed to key sources of vulnerability (as discussed in the section on vulnerability in research) e.g. minors, prisoners, persons who do not have the factual capacity to consent. • The research will collect information such as opinions and attitudes rather than information that a participant may regard as private, confidential or sensitive. • The information can be collected without personal identifiers.

The examples outlined in this section are not exhaustive as the REC: SBE and its registered sub-committees must review each proposal on a case-by-case basis.

The examples and types of risk identified here do not exclude any other potential risks of harm not listed in this section. Researchers and the REC are expected to apply their mind to potential risks and benefits of research to participants and communities, adopting an approach that reflects on the ethics of responsibility

The REC: SBE maintains the ultimate decision as to the appropriate risk level assigned to a specific project.

4.10. REC Decision-making

The REC has the authority to make one of the following decisions on a proposal submitted for its review.

Approved: The proposed plan of research and supporting documents submitted for REC review is approved in its current form, with no changes required.

Conditional approval: The proposed research is approved with minor alterations and/or conditions to be met prior to the commencement of enrolment of research participants and data collection. It is the responsibility of the researcher to ensure that these conditions are met before recruitment and/or any data collection activities. The applicant must resubmit the revised application and requested documentation with a covering letter responding to the points raised. All requested protocol and consent changes must be clearly marked. A response to a study approved with conditions must be finalised and resubmitted to the REC within three months after the feedback letter is issued. If a response is not received within three months of the date of issue, without explanation by the researcher, the REC will suspend the approval of the study until a response is submitted by the researcher.

Modifications required: The proposed research has some significant concerns and several clarifications or methodological changes are required before approval may be confirmed. The applicant must resubmit the revised application and requested documentation with a covering letter responding to the points raised. All requested protocol and consent changes must be clearly marked. The review can be finalised by an expedited review process (**10 business days**) i.e. without having to serve before the full committee again. A response to a request for modifications must be finalised and resubmitted to the REC within three months after the feedback letter is issued. If a response is not received within three months of the date of issue, without explanation by the researcher, the REC will withdraw the application.

Deferred: The proposed research has major methodological issues with ethical implications and/or ethical concerns and requires considerable revision. The applicant must resubmit a revised application and requested documentation with a covering letter responding to the points raised. All requested protocol and ICF changes must be clearly marked. **The**

application must be reviewed at a convened meeting of the REC: SBE and cannot be reviewed via expedited review procedures. A response to a request for modifications must be finalised and resubmitted to the REC within three months after the feedback letter is issued. If a response is not received within three months of the date of issue, without explanation by the researcher, the REC will withdraw the application.

Rejected: The project cannot be approved or resubmitted for REC consideration in its current form. An outright rejection should be avoided if a researcher can be advised to improve the proposal before resubmission to the REC.

Suspension or termination research

The REC has the authority to suspend or terminate approval of research where circumstances indicate that a project is non-compliant with the approved protocol and the interests of participants are at risk of harm. A suspension or termination of Committee approval of research may occur at any time during the period for which Committee approval has already been given, after due process is followed (see section 10 of this SOP)

The REC may suspend or terminate a study based on a report or allegation of:

- Unanticipated problems involving risks to participants or others
- Serious or continuing non-compliance
- Findings in the continuing review or monitoring process

PI-initiated suspension or termination: In the case where a research project is prematurely suspended or terminated by the principal investigator/researcher, the investigator/researcher must notify the REC in writing of the reasons for suspension or termination and give a summary of the results obtained in a study thus far. The REC may request any additional information in order to make an independent determination.

REC-initiated suspension: A suspension by the REC occurs when the REC or Chairperson places a temporary hold on research that has been previously approved so that no new participants may be recruited, and no research activities may occur unless necessary for currently enrolled participants' safety and well-being, and no-follow up may be conducted unless it is in the best interest of participants and approved by the REC.

REC-initiated termination: Termination of a previously approved project occurs when REC withdraws approval and stops all research activity **permanently, usually due to evidence of an extreme breach of the norms and standards of ethical research**. 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.

The REC Chairperson will notify the principal investigator of the suspension or termination in writing, providing reasons. The Chair will inform the investigator of steps to be taken as a result of the suspension or termination of the research.

Such steps may include, but not limited to:

- Drafting a plan to withdraw participants which protects their safety and wellbeing.
- Notifying current participants, by phone, email or in person, that the study has been suspended or terminated and providing reasons for the action.
- Notifying participants of any follow-up procedures, assessments or referrals which are necessary and permitted by the REC for their safety and well-being. This may require a gradual withdrawal, if an abrupt discontinuation is likely to put participants at risk.
- Reporting any adverse events or outcomes to the REC which happen during follow-up.

All written communication from the investigator to participants requires REC approval prior to distribution.

The principal investigator may appeal against a decision to suspend or terminate a study within seven calendar days of receiving written notification. The written appeal to the REC must include a plan for ensuring that the rights and welfare of currently enrolled participants are protected and a plan to ensure that future participants will be protected if the study receives Committee approval to continue.

4.11. Duration of ethics approval

Ethics approval for projects approved as low risk by an ESC or REC will be granted approval for a period of three years only from the date of approval.

Projects that are deemed medium or high risk will be granted approval for one year from the date of approval.

Circumstances of a research project can change several times over its duration. The Department of Health guidelines require that the ethics committees conduct substantive and meaningful continuing review of all approved research at least annually and more frequently if the level of risk warrants this.

Researchers must therefore note that ethics approval is granted for the specific research plan, and for a specific period as outlined in the initial application to the REC: SBE. Any amendment, deviation, unanticipated event or request for renewal of ethics approval or request for study closure must be timeously reported to the REC.

4.12. Historical Closure of a REC approved study

If a continuing review of an active study is not submitted and approved prior to the expiration date, the REC's approval of the study will automatically end, and the study will be suspended.

The REC office will issue a letter notifying the principal investigator or supervisor (in the case of student research) of a suspension for lapse of approval.

Whilst the REC office will try to notify the principal investigators of the upcoming expiration of the approved protocol. It is the responsibility of principal investigators to monitor approval periods and to ensure that continuing review reports are filed in time to allow expedited or full committee review.

4.13. REC feedback to applicants

The decision of the Research Ethics Committee after reviewing an application or submission for continuing review will be communicated in writing to the applicant, normally within 7 business days after the convened meeting at which the decision was made.

The content of the communication will be generated from the details provided in the application, but will at least, include the following:

- The project ID as generated by the REC office
- The exact title of the study as provided in the application form
- The name and title of the applicant, supervisor and/or co-investigators identified in the application form(s)

- The name of the Research Ethics Committee who reviewed the application
- A clear statement of the decision reached
- Any advice, comments or recommendations made by the Research Ethics Committee
- In the case of a conditional approval, any requirements by the Research Ethics Committee, including comments or suggestions for revision and the procedure for having the application re-reviewed
- In the case of a positive decision, the feedback letter will include a statement of the responsibilities of the applicant, for example, confirmation of the acceptance of any requirements imposed by the Research Ethics Committee; submission of progress report(s); the need to notify the Research Ethics Committee in cases of amendments to the protocol; the need to report harmful occurrences or unexpected events/deviations related to the conduct of the study; the need to report unforeseen circumstances, for example the suspension or termination of the study, or significant decisions by another Research Ethics Committee; the information the Research Ethics Committee expects to receive in order to perform on-going review; dates for interim reports, final summaries or final reports, when applicable
- The schedule/plan of on-going review by the Research Ethics Committee (passive or active monitoring), if applicable
- In the case of a negative decision, clearly stated reason(s) for the negative decision
- Advice that is non-binding may be appended to the decision of the Research Ethics Committee

5. PROPOSAL REQUIREMENTS FOR ETHICS REVIEW[13]

This section outlines the required information and documents to facilitate the ethics review of a project submitted to the REC: SBE or any of their registered sub-committees.

Researchers and ESC/REC reviewers are expected to familiarize themselves with below requirements and considerations to ensure a thorough and relevant review of the project.

The application form should be completed in simple, non-technical language which can be readily understood by lay members or non-experts on the REC. A submission to the REC must be written in English, in order to make the submission accessible for any internal or

[13] This section is drawn from criteria as set forth in the DoH guidelines, Chapter 2 and 3
REC: SBE Standard Operating Procedures, 2019, version 1.5

external auditors. Exceptions for other languages can be made according to the capacity on the REC.

The proposal submitted for ethics review should not be longer than 15-20 pages but should include enough detail for the REC to be able to assess the ethical acceptability and implications of the study. If the proposal is longer than 20 pages, the REC may request an executive summary/synopsis.

According to the Department of Health's guidelines (2015), Chapters 2 and 3, a REC must consider the following criteria during ethics review:

- **Relevance, value and scientific integrity with specific consideration of the research design, aims and objectives**
- **Fair selection of participants with consideration of the recruitment process**
- **Research procedures (which include a review of activities for participation, and data to be collected from participants)**
- **Risk of harm and likelihood of benefit**
- **Reimbursements and inducements for participants**
- **Ongoing respect for dignity of participants, including their privacy and confidentiality interests**
- **Process of obtaining informed consent**

5.1. Scientific design, aims and objectives

The ethical acceptability and implications of the chosen methodology and the design must be assessed.

Sound and valid scientific methods must be evidenced or confirmed by prior scientific review by the relevant department or its DESC, a faculty or its FESC, or an external reviewer who has expertise in the field, prior to submission to the REC. To this end, researchers should provide clear evidence of previous scholarly assessments of the proposed design where appropriate in the literature reviewed and/or research methodology section). The REC may request confirmation of prior scholarly review, where deemed necessary.

In the case where prior scientific review is not provided, the REC must engage specifically in scientific review that shows not only whether the selected design and methodology are sound but also that the stated aims and objectives are achievable and will likely produce

valid outcomes, or in the case of qualitative research, the theoretical paradigm and methodology chosen is suitable in light of the stated aims and objectives.

DoH guidelines (2015) states that even if scientific review has occurred, the REC must assess how the research will be conducted, whether the researchers are suitably qualified, that adequate monitoring and safety measures are in place and achievable, that the study is suitably resourced, and so forth. The REC may request a researcher and/or supervisor's CV to confirm this.

Note that risk of harm is unlikely to be justifiable if the research lacks scientific or scholarly merit.

5.2. Participant recruitment and selection processes

The selection of participants must be appropriate for the research question.

Researchers must provide the REC with a clear processes or steps to recruit and select participants. Researchers should, if their design allows, describe the groups or communities who will be selected and justify, based on the research question, aims and objectives, why the specific groups/community was selected for the study.

In the case of emergent or iterative research designs, it might not be possible for researchers to identify specific groups in advance. Researcher must therefore provide the REC with the proposed approach and timeframe for initial engagement with the communities or groups and must undertake to update the REC of the selected groups as the research unfolds. Researchers using emergent or iterative research designs must then outline the specific theoretical or pragmatic approach that will be used to make decisions on the selection of potential participants/groups.

The rationale for the planned number of participants to be selected or recruited must be reasonable in light of the aims and objectives and proposed methodologies. Underpowered studies may be futile. An explanation of how the sample size is to be determined should be provided. For qualitative research, the method for sample selection and recruitment must be clear and complete. The rationale for the inclusion and exclusion criteria must be clear, explicit and reasonable.

If vulnerable participants are to be included, an adequate justification should be provided; protective safeguards and measures should be explained. Exclusion criteria should be based on sound reasons. Inclusion and exclusion criteria have ethical implications (e.g. fairness of selection) and are not just of scientific relevance.

The principle of distributive justice requires that particular groups or categories of persons should not bear more than a fair share of the burden of research participation. But, equally, groups or categories of persons should not be deprived of a fair opportunity to participate in research. In other words, all persons should be able to contribute to the advancement of knowledge that research aims to achieve. The REC should assess whether the selected study population that will bear the risks associated with participation is likely to benefit from the research, if not immediately, then at least in the foreseeable future or, at least, whether the group represented by the participants is likely to benefit from the research. In other words, the risk-benefit ratio can include that risk of harm to participants might be offset against likelihood of benefit to others, in some circumstances.

Recruitment strategies should be neutral, and should describe the purpose of the research, the anticipated risks of harm and potential benefit of participation and other relevant details. Recruitment methods should be properly described in the proposal and the recruitment materials should be included with the proposal e.g. posters, flyers, and advertisements. Recruitment and enrolment processes should endeavour to avoid perceptions of selection bias. The location, context and timing of recruitment and enrolment should be appropriate for protection of privacy and confidentiality interests. If potential participants are in a dependent relationship with the researchers or recruiter, e.g. student/lecturer, patient /doctor, employee/employer, the proposal should explain the measures that ensure that the potential participant's ability to make a voluntary choice is unrestricted. Where the researcher will recruit personally, the possibility of perceptions of undue influence or possible therapeutic misconception must be managed. The REC may also enquire whether the selected sample group has been or is currently involved in previously approved research so as to assess the possibility of excessive burden or risk exposure.

5.2.1. The use of socially constructed categories, such as race, ethnicity and gender:

The RECs of Stellenbosch University recognize that human categories such as race, ethnicity and gender are social constructs;

The use of socially constructed categories, such as race, ethnicity and gender in research must be adequately justified;

The onus is on the research applicant to adequately justify to the REC: SBE the value and meaning of the use of such categories, inclusive of how it will be documented and reported on for the purposes of the study;

The researcher(s) must have the necessary expertise/ background to carefully navigate the contours of these complex constructs, and evidence of such expertise and/or support must be provided to REC: SBE;

Participants must retain the right to self-identification and preference not to answer;

Research proposing the use of socially constructed categories will warrant review by two reviewers and be discussed at a convened meeting of the REC: SBE. The discussion will be documented in REC meeting minutes;

When reviewing research proposals where human categories are included in the fabric of the study (e.g. in the aim, methodology, research instrument(s), ICF and or recruitment strategies), REC reviewers must carefully consider the rationale, justification and evidence of the careful unpacking of intricacies as provided by the researcher(s) for the inclusion of such variables(s) for data collection, analysis or reporting;

The REC: SBE follows a structured and disciplined process as outlined by the SA Constitution, international and national guidelines, for example the NDOH guidelines (2015) that explicitly states that:

- It must be necessary to collect this data: “Information about a person’s race or ethnic origin must be necessary (s 29(a)) or for affirmative action purposes (s 29(b))”; and that
- Nobody may be excluded based on race, gender, etc.: “Persons should not be excluded unreasonably or unfairly on the basis of any of the prohibited grounds for discrimination: race, age, sex, sexual orientation, disability, education, religious belief, pregnancy, marital status, ethnic or social origin, conscience, belief or language (s 8 of the Constitution); or

- Nobody may be unfairly targeted based on race, gender, etc.: “Similarly, persons should not be unfairly targeted for research merely on the basis of one or other of these grounds.”

5.3. Research procedures and activities

The research procedures should be described in a manner that ensures the rationale and details are clear to the REC. The researcher should identify all the activities that participants will be involved in and why these specific activities were chosen (i.e. are the activities appropriate for the chosen design).

Where researchers use emergent methodologies or their research will be conducted in phases, researchers must endeavor to provide the REC with a clear description or discussion of their research approach and design. Researchers must make it explicit that their research procedures are emergent and must provide the REC with a detailed plan for continuing review submissions and processes to inform the REC of up-to-date activities and procedures. Researchers should consult the section 6 of this SOP regarding informed consent.

Procedures or activities that are deemed standard practice in a specific context (i.e. evaluations, class activities, assessments or tests) should be differentiated from procedures necessary only for research purposes, to assist with weighing the risk of harm against the likelihood of benefit.

In the case of education, psychometric or psychological research where the researcher is using screening tools or diagnostic instruments, the proposal should explain whether specific results will be made known to participants or whether the researcher will refer special cases for further intervention.

Research conducted in health facilities, schools and other education institutions should not adversely affect routine activities or the functioning of these facilities.

In the case of research conducted in any other settings, care should be exercised not to disrupt routine practices without the parties involved having been consulted or having made prior arrangements. See the section on gatekeeper permission and negotiating access in

The appropriate expertise and qualifications of researchers, study and project leaders to perform procedures should be assured, e.g. survey design and methods training. Researchers who are not trained or experienced in conducting Social Science, Behavioural or Education research must be supervised by or consult with someone with the appropriate expertise and qualifications.

5.4. Risk of harm and likelihood of benefit

The ratio of risk of harm to likelihood of benefit should be favourable, i.e. the likelihood of benefit, at least to the category of person involved, should outweigh the risk of harm to the participants as well as to the community or society as a whole. In weighing risk of harm against likelihood of benefit, the analysis is concerned not only with the participants themselves but also with community or societal interests. The ratio may be analysed by considering whether:

- the harms and benefits are adequately identified, evaluated and described;
- the harms stated in the proposal match those stated in the informed consent documentation;
- the risk of harm is reasonable in relation to anticipated benefit;
- the risk of harm is reasonable in relation to the importance of the anticipated knowledge to be gained;
- counselling and support services will be made available, if appropriate
- anticipated harms will be minimised by preventing occurrence as far as possible and by implementing appropriate interventions should the harm occur.

Researchers who use emergent methodologies might not be able to anticipate potential risks, but should, to the best of their abilities reflect on and discuss the potential consequences or impact of their proposed research process on the participant and/or community.

The nature of harms will vary in accordance with the type of research under consideration. Potential harms usually considered in SBER may include psychological, legal, physical, social (including stigma) and economic risks/harms. The researcher is expected to reflect on and anticipate potential harms and devise plans and interventions to address the harm should these occur or to mitigate potential impact on the participant/community.

Researchers and the REC should also assess the possibility of harm to the researcher, study or project personnel e.g. safety concerns. Researchers who work in contexts where their

or their project personnel's safety and well-being may be of concern, should provide the REC with a detailed plan or protocol to ensure their safety and well-being (physical, psychological, legal, social and financial).

5.4.1. Care and Protection of Research Participants

The following will be considered with respect to the protection of research participants, as applicable, considering that there is a wide variety of types of research:

- The suitability of the investigator(s)'s qualifications and experience for the proposed study (the less experienced and qualified the researcher in conducting the research, the higher the potential risk of harm to participants)
- Any plans to withdraw or withhold standard therapies, remedies, supervision, services, support or interventions etc. (if applicable) for the purpose of the research, and the justification for such action
- The adequacy of psychological or other care to be provided to research participants during and after the course of the research, if applicable. Researchers are expected to show evidence of consultation and arrangements with appropriate counsellors and/or centres that provide care and assistance to participants.
- The adequacy of supervision of researchers in training
- Steps to be taken if research participants voluntarily withdraw during the research
- Steps to be taken if research participants withdraw from the study because of an adverse event*
- Steps to be taken if researchers must withdraw a research participant from the study for emergency or other reasons
- The criteria for extended access to, the emergency use of, and/or the compassionate use of services, material or facilities used during the research
- The arrangements, if appropriate, for informing the research participant's general support network (for example a parent, a teacher, a social worker), including procedures for seeking the participant's consent to do so)
- Description of any plans to make the results of the study available to the research participants following the research
- A description of any financial costs to research participants
- The rewards and compensations for research participants (including money, services, and/or gifts)

- The provisions for compensation/treatment in the case of the injury/disability/death of a research participant attributable to participation in the research
- Insurance and indemnity arrangements for research participants.

5.4.2. Protection of Researchers, Research Partners and Research Assistants

The following will be considered with respect to the protection of researchers, research partners and research assistants:

- The ethical risks that researchers, research partners and research assistants are exposed to in the course of the research, and the question whether appropriate and adequate measures are put in place to avoid or minimize these risks
- Measures that are put in place to support research assistants should they experience emotional upheavals during or after the research process, e.g. debriefing sessions
- Insurance and indemnity arrangements for researchers, research partners and research assistants, where applicable and relevant
- The relationship between researchers and research partners and/or research assistants, with a view to ensure that due recognition is given to the contribution that each makes to the research, in particular, but not limited to publications
- Where necessary, measures to protect researchers from interference by powerful individuals or institutions.

5.4.3. Community considerations

The following will be considered with respect to the impact of research on communities, as applicable:

- The "community" may not be characterised by social coherence and stability, but by contestation, conflict, imbalances in power relations, inequality and injustice – pointing to the question, if applicable, whether these characteristics are appropriately acknowledged and responded to in the research design with a view to minimise ethical risks
- The impact and relevance of the research on the local community, or groupings within it, and on the concerned communities from which the research participants are drawn
- The steps taken to obtain permission, when relevant and appropriate, from the community, or groupings within it, in which the research will be conducted
- The steps taken to consult with the concerned communities, or groupings within it, during the course of designing the research, as well as during the process of conducting the research
- The influence of the community, or groupings within it, on the consent of individuals

- The extent to which the research contributes to capacity building, such as the enhancement of local processes and structures, and the ability to respond to public needs
- A description of the availability and affordability of any successful study result to the concerned communities, or groupings within communities, following the research
- The manner in which the results of the research will be made available to the research participants and the concerned communities, or groupings within them.

5.5. Reimbursements and inducements for participants

Participants should not have to incur expenses to take part in research. Consequently, researchers should budget to reimburse expenses incurred by participants for travel, refreshments and for inconvenience, depending on the circumstances. If no travel or other expenses are incurred, reimbursement is not required unless an inconvenience reimbursement is justifiable.

A fair rate of reimbursement should be calculated using the Time, Inconvenience and Expenses (TIE) method to determine the cost to participants for time expended, inconvenience and refreshments associated with research participation. This method costs expenses at the current hourly rate for unskilled labour in the marketplace, regardless of whether the participant is employed.

Researchers must submit planned payment schedules and amounts together with a justification to the REC when making application for ethics review. The REC should exercise caution against taking an unreasonably paternalistic view of the rate of reimbursement. The proposal and the informed consent documentation should indicate whether reimbursements are pro rata if the participant does not complete the study; i.e. whether only some of the offered reimbursement is available if participation is stopped before the anticipated end of the study. Where minors are the participants, their accompanying parent or guardian should also receive reimbursement for travel costs and refreshments. Inducements encourage participation. They may be offered in some circumstances where e.g. recruitment is anticipated to be difficult. However, a justification for this tactic should be provided and the inducement should not unduly influence an informed choice about participation. An inducement should not undermine a potential participant's assessment of risk of harm. All inducements should be clearly explained and justified to the REC. Input

from community members on the REC or other role players is encouraged and may be constructive.

Researchers who wish to use lucky draws or competitions as inducement for participation in research, must ensure that the procedures for the lucky draw or competition are compliant with Section 36 of The Consumer Protection Act, also read with The Consumer Protection Act Regulations published under GN R293 in GG34180 of 1 April 2011, Regulation 11. The procedures for the lucky draw or competition must be discussed in detail in all informed consent documentation. Researchers may consult the Division for Information Governance's memo discussing these considerations (see Addenum 3 of this SOP).

5.6. Protection of Research Participants' privacy and confidentiality interests

The principle of respect for persons requires careful attention to privacy and confidentiality interests. Privacy describes the person's interest in controlling access to their personal information. Confidentiality is about whether and how research data might be disclosed, whether carelessly or inadvertently, thus revealing the participant's identity or category, making him vulnerable to harm.

The proposal should explain how data records and consent forms (written, audio or visual) are to be secured, the length of time they will be retained and who will be responsible for storage and/or final disposal. The proposal should explain why particular identifying information is required for the study that purports to collect data anonymously.

RECs should assess whether notifiable activities might occur amongst participants, e.g. abuse of minors or notifiable diseases and, consequently, whether appropriate measures are in place and are explained in the research proposal. Furthermore, the REC must ensure that the required notification or reporting and its management are explained in the consent documents. Where focus groups are planned, RECs should check that the information for participants explains clearly that researchers cannot guarantee confidentiality because members of the focus group may disclose information outside the research setting, despite agreeing not to do so. For this reason, consent documentation should advise potential focus group participants not to disclose personally sensitive information, as the researcher

cannot guarantee confidentiality, even if other participants are urged to respect confidentiality.

The Protection of Personal Information Act 4 of 2013 was assented to on 19 November 2013. This Act provides guidance on how the right to privacy regarding personal information is protected. It stipulates that the right to privacy includes 'protection against unlawful collection, retention, dissemination and use of personal information' (Preamble to Act).

Research activities are a legitimate purpose, provided that protective measures are adhered to. Thus, researchers and RECs should pay careful attention to measures that will protect privacy and confidentiality interests. In general terms, a person should know what information is being collected, why it is being collected, what will happen to it, how long it will be retained, whether it will identify the person, whether it will be shared with others and why, whether it will be sent outside South Africa and why. The person should agree to these terms.

Researchers should include the following in their proposals:

- A description of the persons who will have access to personal data of the research participants [including any other records of a confidential nature], where applicable
- The measures taken to ensure the confidentiality and security of personal information concerning research participants
- A description of the measures taken to keep the data (in electronic, hard-copy, or any other format) in safe storage, and to prevent any unauthorised access to it
- A description of the length of time that the data will be kept in storage, when it will be destroyed (if applicable), and if it will not be destroyed, where it will be stored, for what purpose
- A description of the measures taken to set up a data-basis or archive that will continue to exist after completion of the research (including permission from research participants to have data about them stored in this manner, where the data will be stored, who the curator of the data will be, and how access to that data will be regulated).

5.7. Process for obtaining informed consent

A description of the process to be used to obtain and document free and informed consent (required when human research participants, are involved), should be addressed in the proposal, considering that:

- A wide spectrum of processes to gain and record consent exists, including but not limited to verbal consent, tick-box consent, written consent, ticking a box on the cover page of an on-line questionnaire, once off events of giving consent, and extended processes over time gaining and maintaining trust (typically applicable to ethnographic research)
- Special care should be taken to obtain and record consent (or where applicable, assent) in cases where research is done on vulnerable individuals or groups
- Researchers should provide a description of the process of consent that is appropriate to and will be followed in the research that is submitted for review.
- A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent, as it is relevant and appropriate to the research
- The adequacy, completeness, and comprehensibility of written and oral information to be conveyed to prospective research participants, and, when appropriate, their legally acceptable representative(s)
- Clear justification of the intention to include in the research individuals who cannot give consent, and a full account of the arrangements for obtaining consent or authorisation for the participation of such individuals
- A clear description of the measures taken to obtain permission (i.e. consent) from parents/guardians for their children to participate in research
- A clear description of the measures taken to obtain assent from minors (younger than 18 years of age) to participate in research
- A clear description of reasons for any request to waive consent or assent
- A clear indication of the assurances given to research participants prior to commencing with the research that their rights, safety, dignity and well-being will be protected
- A clear indication that research participants will receive information that becomes available during the research relevant to their participation (including information about their rights, safety, and well-being)
- The provisions made for receiving and responding to queries and complaints from research participants or their representatives during a research project

- A full description of how research results will be made available to research participants and where applicable, the community/communities/groups in communities in which the research was done
- A clear description of reasons for not making research results available to participants or the community/communities in which the research was done.

6. CONSIDERATIONS FOR OBTAINING INFORMED CONSENT

Informed consent is a constitutional right and ethical requirement for participation in research.[14] The National Health Act of South Africa requires that research or experimentation on a living person may only be conducted with the written consent of the person after he or she has been informed of the objects of the research or experimentation and any possible positive or negative consequences on his or her health.[15]

The REC: SBE views informed consent as a conversation which must allow for interactive communication between the researcher and the potential participant, and not a singular event such as the signature of an informed consent form.[16] The informed consent process must therefore take place before any research encounter and must be affirmed throughout the research, as part of a **commitment to an ongoing consent process**.

The REC: SBE or a sub-committee must review and approve the process for informed consent, and associated forms to be used to document informed consent before participants are invited to take part in any research activities or encounters.

Adults, i.e. persons over the age of 18 years, may make independent decisions. However, they may first wish to consult with family members or others in keeping with personal preference or cultural practices. Consequently, the process should permit enough time for consultation between recruitment and the point of decision-making. No person should be required to make an immediate decision.[17]

The REC and its sub-committees are required by the Department of Health to assess the proposed process for obtaining informed consent as well as the information that potential

[14] Section 12(2) of the South African Constitution
[15] Section 71 (1b) of the National Health Act
[16] UCT SOP, 2018, page 114
[17] Department of Health Guidelines, 2015, page 24

participants will be given and the measures that will be used to facilitate and confirm understanding. An important element of making an informed choice is the nature and quality of information made available to the potential participant.

Below are expectations as set forth by the Department of Health regarding information disclosure to facilitate voluntary informed consent.

Researchers must ensure that the setting in which informed consent will be obtained will **minimise the possibility of undue influence or coercion**, that the setting is **sufficiently private and appropriate**, according to the expectation of the individual, and that the **person who will conduct the process will be appropriately trained, independent and bias-free,** and there are **no unequal power relations between the person obtaining consent and the potential participant.**

The text of all informed consent and assent forms or information sheets must be

- written in plain language and appropriate to the participants' level of understanding[18],
- free of scientific jargon and unexplained acronyms,
- clear and explain technical terminology e.g. randomisation, anonymity, confidentiality
- translated into language(s) appropriate to the population group or context,
- include a measure or plan to probe understanding and comprehension of the information and how it will be done especially for very vulnerable potential participants

Researchers must check all consent/assent documents with a first-language speaker, preferably from the selected community or population group, to confirm the appropriateness of the language used. Researchers are encouraged to pilot the informed consent form with a member of the community to confirm that the document is appropriately worded or translated, and that the information is easy to understand and accurately represented.

The REC provides templates for informed consent and assent forms on the Division for Research Development's website: www.sun.ac.za/research

[18] The Flesch-Kinkaid readability tool should be used to assess the complexity of text. This tool is built into MS Word's spelling & grammar check tool as 'readability statistics'. No more than Grade 8 equivalency should be the target complexity level.

Researchers must use the REC templates for informed consent and assent as these templates have been designed and are regularly updated to ensure compliance with the Department of Health expectations for informed consent and other important legislative or regulatory requirements.

If the researcher cannot, **for a well-motivated reason**, use the REC's templates for informed consent/assent, the researcher must ensure that the informed consent form and assent form contains the basic elements for informed consent/assent as required by the Department of Health.

Researchers who work with vulnerable populations groups may employ other creative methods of conveying information, for example, videotapes, photographs or diagrams of research procedures, group discussions, web sites, or comics that explain the nature of the research.[19] These alternative methods must be approved by the REC before it may be used and should contain the basic elements of informed consent as recommended by the DoH guidelines (2015). Researchers who recruit persons with factual incapacity to consent, should consult section 3.2.4 of the DoH guidelines.

Researchers should be prepared to accommodate potential participants with disabilities to ensure equal access to participate in research. For example, visually impaired people may benefit from documentation with large font and high contrast. Hearing-impaired people may need sign language interpreters. [20]

Below are the basic elements of consent/assent as set forth by the Department of Health. Below elements must be addressed in the informed consent/assent process or documents. The informed consent process must:

- Make it explicit that the person is being asked to participate in research
- that the choice whether to participate is voluntary
- that refusal to participate will not be penalized or hold any negative consequence
- that choosing to participate can be reversed, i.e. the person may decide to withdraw or terminate participation at any time without explanation or prejudice; also confirming what will happen to the person's information and data once they withdraw

[19] UCT SOP, 2018, page 115

[20] UCT SOP, 2018, page 115; Article 9 and 12, UN Convention on the Rights of Persons with Disabilities and Optional Protocol

- who the researchers are and the nature of their expertise
- explain in plain language the purpose and nature of the research process and the activities that the participant is being asked to consent to
- the expected duration of participation
- any recording of the activities whether visual or audio, as well confirming the purpose of the recording
- the nature of the participant's responsibilities
- the nature of the researcher's responsibilities
- the anticipated risks of harm or discomfort and the measures to minimise risk of harm
- the potential benefits, if any, for participants, both during and after the research
- the extent to which confidentiality is possible
- potential future use of a participant's information and data
- information about how access to data will be secured and how it will be stored
- whether reimbursement for expenses is available
- whether sponsors of the research and regulatory authorities may inspect research records
- that the research may be terminated early in particular circumstances
- that the research has been approved by a registered REC (include identifying details)
- states that participants may contact the REC at the contact details provided if they have queries or complaints about their rights and welfare as research participants,
- states that participants may contact the researcher at the contact details provided if they have queries about the research project.

6.1. Verbal consent consideration and requirements

The National Health Act of South Africa requires that research or experimentation on a living person may only be conducted with the **written consent** of the person after he or she has been informed of the objects of the research or experimentation and any possible positive or negative consequences on his or her health.[21]

The REC may only waive this legal requirement for written (signed) informed consent if it is **ethically justifiable for the specific circumstances or context of research**.[22] Researchers

[21] Section 71 (1b) of the National Health Act

[22] Department of Health 2019, Aide Memoire, Meeting of the National Health Research Ethics Council (NHREC), Human Research Ethics Committees (HRECS), Animal Research Ethics Committees (ARECS) and other Interested Parties, 16 May 2019.

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are therefore required to describe the specific circumstances that would necessitate a waiver of the legal requirement to obtain written consent. For example, an ethically acceptable justification for the waiver of written informed consent may be in the context where signed informed consent form might be the only identifiable link between the participant and the research, and where identification might place the participant at an increased risk of harm. The REC will consider such requests on a case-by-case basis.[23]

Verbal consent may also be appropriate in specific community or cultural contexts where the signature of an informed consent form might be perceived as mistrust between the researcher and participant. Researchers are required to describe specific contexts in which written informed consent would be disruptive or inappropriate.

Researchers who apply to obtain verbal consent must therefore provide the REC with motivation or justification for using a verbal consent process and must include the script that will be used to obtain consent. The researcher should also outline how and when verbal informed consent will be facilitated.

6.2. Emergent or iterative research designs and informed consent:

In the case where the research design is emergent or iterative, a 'once-off', isolated informed consent process/encounter may not be appropriate or possible given the research design. Given the nature of emergent research, it might not always be possible for researchers and the REC to confirm or balance the benefit-to-risk ratio in advance. [24]

The REC therefore recommends that process or phased consent be obtained in cases where research is emergent. Process consent or phased consent means that consent will be obtained on an ongoing basis as the research unfolds. Such an approach to consent would be dependent on an ongoing relationship with the persons or communities selected for participation in the research, and is predicated on respectful, honest and transparent engagement with the participant and/or communities.

[23] UCT Faculty of Health Sciences (2018) Human Research Ethics Committee, Manual of Standard Operating Procedures, page 116

[24] Cutcliffe, J. R., & Ramcharan, P. (2002). Leveling the playing field? Exploring the merits of the ethics-as-process approach for judging qualitative research proposals. Qualitative Health Research, 12(7), 1000–1010.

Researchers who use emergent or iterative research designs generally obtain consent verbally, however it is not unlikely in specific circumstances for researchers to obtain ongoing written informed consent. Whichever way consent is obtained, the researcher must ensure that the sufficient information is shared with the participant and or group prior to each research encounter.

Cutcliffe and Ramcharan (2002: 1008) suggests an "*initial attempt to gain consent, where the purpose and procedure of the research are described to the participant. The potential risks and benefits, as they are known at that point in time, are also explained, and the emergent nature of the design is made clear, which is an important component of informed consent. With this, the possibility of unforeseen risks and benefits emerging during the course of the research is highlighted. Along with such explanation is the reassurance that matters of consent will be raised again during the research process, particularly as hitherto unknown risks or benefits become clear or, indeed, whenever the participant feels the need to raise matters of consent. Finally, the consent to represent a person in a particular way might be handled through member checks; this would provide the final vindication of the researcher's work from the interviewee's point of view*."

Researchers who use emergent or iterative designs must provide the REC with a clear description (in as much detail as possible) of how process or phased consent will be done in the context of the research, the principles and values that will underline engagement with potential and actual participants.

6.3. Social media and online research

Researchers using social media platforms to recruit participants or collect data, should reflect on and familiarise themselves with the specific ethical issues this type of research creates and how general principles of ethical research will be interpreted and applied.

The British Psychological Society notes in its guidelines for internet-mediated research that "*the extent to which the research can be thought of as occurring within a private or public domain, given that those boundaries are often blurred online, may be difficult to decide. It*

is not always easy to determine which online spaces people perceive as 'private' or 'public' or under which circumstances they might be happy to be observed, or otherwise."[25]

The REC recommends that researchers use below checklist as developed by Gelinas, Pierce, Winkler, Glenn Cohen, Fernandez Lynch & Bierer (2017) for reflecting on and developing a proposal which involve the use of internet-mediated platforms or social media networks:[26]

- Describe the proposed social media recruitment techniques, including: a list of the sites to be used, a description of whether recruitment will be passive and/or active. In the case of using active recruitment, a description of how potential participants will be identified and approached, and their privacy maintained.
- Ensure that the social media recruitment strategy complies with applicable laws and regulations governing communication and privacy.
- Provide the REC with a statement confirming that the research and proposed use of listed social media platforms are compliant (or non-compliant) with the policies and terms of use of relevant websites, OR if proposed techniques conflict with relevant website policies and terms of use, seek an exception from the website to its terms of use and provide the REC with written documentation of the exception, if granted. In compelling circumstances, case can be made to the REC to consider whether the recruitment strategy should be allowed to proceed in the absence of an exception from the site.
- Ensure that the proposed recruitment strategy respects all relevant ethical norms, including: Proposed recruitment does not involve deception or fabrication of online identities. Proposed recruitment does not involve members of research team "lurking" or "creeping" social media sites in ways members are unaware of. Recruitment will not involve advancements or contact that could embarrass or stigmatize potential participants.
- If the research team intends to recruit from the online networks of current or potential study participants: Provide the REC with a statement explaining this approach and describing plans to obtain consent and documentation of consent from participants before approaching members of their online networks or to invite the individual themselves to approach members of their network on the research team's behalf.

[25] British Psychological Society (2017). Ethics Guidelines for Internet-mediated Research. INF206/04.2017. Leicester: Author. Available from: https://www.bps.org.uk/psychologists/standards-and-guidelines/ethical-enquiries (pages 4, 7)

[26] Luke Gelinas, Robin Pierce, Sabune Winkler, I. Glenn Cohen, Holly Fernandez Lynch & Barbara E. Bierer (2017) Using Social Media as a Research Recruitment Tool: Ethical Issues and Recommendations, The American Journal of Bioethics, 17:3, 3-14, DOI: 10.1080/15265161.2016.1276644

- Consider whether a formal communication plan is needed for managing social media activities among participants (e.g. WhatsApp/Facebook groups), including: Steps to educate participants about the importance of confidentiality and how certain communications can jeopardize the scientific validity of a study (e.g., a section in the orientation or consent form).
- Triggers for intervention from the research team (e.g., misinformation or speculation among participants on social media that could lead to a breach in confidentiality). Interventions from the research team (e.g., corrections of misinformation or reminders about importance of confidentiality and respectful engagement on social media).

6.4. Gatekeeper permission: Negotiating access to participants and/or data

Researchers should engage key role players at various stages of planning and conducting research to improve the quality and rigour of the research, to increase its acceptability to the key role players, to harness role player expertise where possible, and to offset power differentials where these exist. Engagement efforts may comprise of various activities, including awareness-raising initiatives for role players, including but not limited to participating communities.[27]

All institutions and organisations have an autonomous right to permit or deny access to their information, space, personnel and clients and/or service users for research purposes, unless such information is already published in the public domain.[28] Institutions and organisations might have formal processes and requirements with respect to accessing affiliated persons or their information. Researchers must confirm with these organisations and institutions what procedures should be followed to gain access to participants or information.

Researchers who conduct their research in less formal settings or require access to persons who form part of collectivities, closed communities or groups, may also be required to negotiate access with legitimate authorities and/or legitimate gatekeepers prior to conducting research in these settings. [29]

[27] Department of Health Guidelines, 2015, page 16
[28] Singh & Wassenaar, 2016, 42
[29] Singh & Wassenaar, 2016. Pages 42; Department of Health Guidelines, 2015, page 40

All negotiations to access must be predicated on respectful, transparent and prior engagement with legitimate gatekeepers. Such negotiations to access should preferably take place during the development of the research proposal, to fulfil the ethical standard of role player engagement. Such prior engagement could assist the researcher in developing a context-specific approach to accessing participants and conducting research.

The following will be considered with respect to obtaining institutional permission for the purpose of ethics review:

- If a central authority (or authorities) are involved, copies of the institutional permission that was obtained, or, if such institutional permission is still outstanding at the time of submitting the application, proof that permission was requested
- If the institutions at which the research will be conducted are identified during the research process, when, for instance, snowball sampling is used, it is only required to describe the general process that will be used, together with the material that will be used in the process – in which case the institutional permissions will be kept on record and in safe-keeping by the researcher.

6.5. Focus groups and participant observation[30]

In the context of focus groups, the informed consent document must include a statement indicating that the researcher cannot guarantee that participants' confidentiality will be maintained as other participants in the group may disclose what was discussed with persons outside the group. The researcher can request that focus group members respect each other's confidentiality by not speaking to others about matters raised in the group.

In the context of participant observation, the researcher should:

- Ensure that participants are aware of the researcher's identity and purpose among the group.
- Disclose and disseminate as broadly as possible through general announcements or other informal means the researcher's purpose, research topic, and data gathering methods. Participants should be aware that any of their interactions with the researcher may constitute some form of data gathering.
- Obtain permission from group leaders or spokespersons, where appropriate, but especially if they can help communicate to a community the researcher's identity, purpose and methods.

[30] This section is taken directly from the UCT SOP, 2018 pages 127-128
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At the same time, researchers must be careful to avoid situations where such public endorsements or announcements to the community create pressure to participate. Participants must remain free to avoid all interaction with the researcher.

- To the extent possible, the researcher must try to obtain informed consent from each individual participant with whom the researcher interacts.

6.6. Research involving deception and withholding information

The Department of Health sets forth the following consideration for research that involves some form of deception or withholding information from participants: [31]

Sometimes, to ensure validity of research, researchers withhold certain information in the consent process. This may take the form of **withholding information about the purpose of specific procedures**. In such cases, the researcher should ask prospective participants whether they are willing to consent to remain uninformed as to the purpose of some procedures until the research is completed. After conclusion of the study, the researcher must provide participants with the omitted information. In other cases, participants are not told that some information is being withheld until the research has been completed.

In all research where some form of deception or withholding of information is necessary for the validity of the research, the researcher must obtain explicit approval from the REC at a convened meeting of the REC.

Active deception of participants is considerably more controversial than simply withholding certain information. **Deception is not permitted where the deception itself would disguise the possibility of a participant being exposed to more than minimal risk.**

Researchers must provide the REC with sufficient justification that the deception is indispensable; that no other research method would suffice; that significant advances could result from the research; and that nothing has been withheld that, if divulged, would cause a reasonable person to decline to participate.

[31] Department of Health guidelines, 2015: section 3.4.5, pages 48-49
REC: SBE Standard Operating Procedures, 2019, version 1.5

The REC should also be given enough information in order to consider the consequences for the participant of being deceived, and whether and how deceived participants should be informed of the deception upon completion of the research.

Participants who disapprove of having been deceived should be offered the opportunity to request that their information be excluded from the research.

7. RESEARCH INVOLVING MINORS

The Department of Health requires researchers and the REC to consider the following conditions when developing a proposal involving the participation of minors or when reviewing a proposal that involves the participation of minors.

This section is therefore taken directly from the Department of Health guidelines 2015, Chapter 3, section 3.2.2 to ensure that these minimum standards are adhered to whilst conduct research involving minors. The REC: SBE has however included additional considerations which apply to the involvement of children in Social, Behavioural and Education research.

Researchers are expected to familiarize themselves with the Department of Health Guidelines as it applies to research involving minors.

7.1. Consideration set forth by the Department of Health

Below the age of majority, the law protects young people from their own emotional, cognitive and physical immaturity and limited life experience through the legal status of minority. In other words, minors, i.e. persons under 18 years of age,[32] are legally incapable of performing legal transactions without assistance from a parent or guardian. In the research context, this means that, in principle, anyone under the age of 18 years may not choose independently whether to participate in research; a parent or guardian must give permission for the minor to choose. This is because young persons' understanding of key aspects of the research initiative may be compromised and, consequently, they may be exposed to increased risk of harm from particular research procedures. Exceptions to the

[32] Section 28 of the Constitution; and Section 17 of the Children's Act 38 of 2005

requirement for parental permission are discussed in the section addressing minor's independent consent.

Tension exists between the views that, in general, children and adolescents should not bear the burden of research unnecessarily, on the one hand, and that children and adolescents are entitled to improved health care and services based on findings drawn from rigorous research conducted in the child population of South Africa, on the other. The solution lies in the approach that minors should participate in research only where their participation is indispensable to the research; i.e. the research cannot deliver the desired outcomes if adult participants were to be used instead.

Because of their status of legal incapacity, in principle, minors may not choose independently whether to participate in research. A parent or guardian must give permission for the minor to choose. It should be noted that the parent or guardian does not choose for the minor who is capable of choosing;[33] rather, the parent or guardian gives permission for the minor to choose. Where a minor is very young or is factually incapable of exercising a choice, then the parent or guardian chooses whether the minor should participate.

The best interest of a child should be paramount in decisions that affect the child. [34]This principle is difficult to apply in the research context because research participation is unlikely to be in the best interest of a minor. Good research design does not accommodate a best interest analysis easily. Rather, the design draws on aggregates of information. This means that, in the research context, the best interest principle should be understood to mean that participation in the research should not be *contrary* to the individual minor's best interest. Further, the research should investigate a problem of relevance to minors.

Where research can be done with consenting adults but nevertheless proposes also to include minors, the researchers must provide strong justification for the inclusion of minors. The REC cannot make assumptions on behalf of the researchers. The REC requires all relevant information to be provided by the researchers.

[33] Section 10 of the Children's Act 38 of 2005. Note that a caregiver, a foster parent and a schoolteacher or principal are not guardians. Note that legal incapacity is not the same as factual incapacity. Minority is a legal incapacity status.

[34] See also s 9 of the Children's Act 38 of 2005.

For purposes of this SOP, the following definitions apply:

'**Adolescent**' means a child between the ages of 12 and 17 years of age (ICH Topic E 11 Clinical Investigation of Medicinal Products in the Paediatric Population. 2000 https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use_en-30.pdf

'Assent' means a minor's affirmative agreement to participate in research. Mere failure to object should not be interpreted as assent.[35]

'**Caregiver**' means a person who factually cares for a child (s 1 Children's Act, 38 of 2005; a caregiver is obliged (in terms of s 32(1)) to safeguard the child's health, well-being and development; and to protect the child from abuse and other harms. Further a caregiver may exercise the parental right to consent to *medical examination or treatment* of the child (in terms of s 32(2))

'**Child**' means a person under the age of 18 years (s 28 Constitution; s 1 Children's Act 38 of 2005)

'**Child-headed household'** means a household per s 137 Children's Act 38 of 2005

'**Guardian**' means a person appointed by a court to look after the financial and welfare interests of a minor, or a person appointed by a parent with sole responsibility for the minor in terms of the parent's Will

'**Harm**' means physical, emotional, psychological, social or legal harm

'**Minor**' means a person (child) less than 18 years (s 17 Children's Act 38 of 2005)

'**Orphan**' means a child who has no surviving parent caring for him or her (s 1 Children's Act 38 of 2005)

'**Parent**' includes an adoptive parent (s 1 Children's Act 38 of 2005)

'**Therapeutic research**' means research that includes interventions that may hold out the prospect of direct health-related benefit for the participant (Regulation 135)

[35] UCT SOP, 2018, page 161

'**Non-therapeutic research**' means 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 generalisable knowledge (Regulation 135)

7.2. Minimum conditions for research involving minors

a) Children should participate in research when their participation is scientifically indispensable to the research. Research should investigate a problem of relevance to children. The protocol should provide sufficient information to justify clearly why children should be included as participants.
b) Children should participate in research only where such research poses acceptable risks of harm. That is, research involving minors should be approved only if:
    i. The research, including observational research, is not contrary to the best interest of the minor;
    ii. 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
    iii. The research involves greater than minimal risk of harm but provides the prospect of direct benefit for the minor. The degree of risk of harm should be justified by the potential benefit; or
    iv. 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.
    v. Greater than minimal risk of harm should represent no more than a minor increase over minimal risk.
    vi. Where appropriate, the minor will assent to participation.
c) 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 place special emphasis on deliberation by the REC about the degree of risk of harm posed by a proposal and the likelihood of benefit to the child-participant. This distinction is of little practical import since most research involves a mix of 'therapeutic' and 'non-therapeutic' interventions or components and reviewers usually assess the proposal as a whole.
d) The degree of risk of harm should be evaluated against the likelihood of benefit to the child-participant as outlined in b) above. Furthermore, the REC: SBE has written permission to exercise the Minister's delegated power to approve research with children that includes non-therapeutic components must ensure that their deliberations on these components are properly minuted and recorded as required by the Regulations. The REC must ensure that it includes members with appropriate experience in research involving children. Hence all research that involves the

participation of minors must be reviewed by the REC: SBE at a convened meeting.

e) Children should participate in research only where the proper written permissions have been obtained. The general principle is that minors cannot agree to research participation without assistance of a parent or guardian (exceptions to the general principle are discussed in the section on minor's independent consent). This principle holds notwithstanding the exceptions created in the Children's Act 38 of 2005 for consent to medical treatment and surgical operations (s 129); consent to HIV-testing (s 130); and the exception for female minors created in the Choice on Termination of Pregnancy Act 92 of 1996 (s 5(2)). Consequently, in principle, the consent process for a minor's participation in research requires
    - Permission in writing from parents or legal guardian for the minor to be approached and invited to participate (in accordance with s 10 of the Children's Act 38 of 2005);
    - Assent from the minor in writing (i.e. agreement to participate) if he or she chooses to participate.

Note *that an unmarried minor mother may not agree to the participation of her child in research without assistance. Her guardian (usually her parent) is also the guardian of her child while she is a minor and must consent to the child's participation. In other words, pregnancy and childbirth do not change the legal status of the minor mother. When the mother reaches the age of majority (18 years), she may consent to her child's participation in research.*

f) Children should participate in research that takes cognisance of their privacy interests. Although children are legally dependent, they have significant privacy interests.

g) When parents or a guardian give permission for their minor child to choose whether to participate in research, this permission is given based on a detailed description of all activities and interventions that will affect the child in the study. However, this does not mean that parents are entitled to know the outcome of all diagnostic and therapeutic interventions, especially as regards older minors (adolescents). The informed consent documentation must explain whether results of tests will be made known to child-participants and their parents. Whether this happens, depends to an extent on the socio-cultural context and the best interest standard.

h) The minor's interest in confidentiality, i.e. being identified or identifiable without permission of the minor **and** her parent or guardian must be respected.

i) Research involving children must respect their evolving capacity to give consent. Minors who turn 18 years old during the course of a study should be approached at the time of their birthday to re-consent. This is because they must now provide independent consent to continue to be a participant. In cases where minors are permitted to decide independently whether to participate, [36]the consent process should address how re-consent will be managed when they change status from minority to majority. Similarly, in

[36] See section on minor's independent consent

the case of large and longitudinal studies, attention must be given to how the change from minority to majority will be managed. Where a study is no longer in active interaction with participants, re-consent procedures may be less important.

j) Researchers must familiarise themselves with the legal obligations to report child abuse and neglect. See section on mandatory reporting obligations.

k) Researchers must ensure the safety of children who are involved in their research and ensure that all research team members or those who will interact with the child for the purpose of research are vetted and qualified to do so.

7.3. Parental permission

The Children's Act 38 of 2005 emphasises the right of a child to participate in any matter concerning that child, provided he or she has sufficient maturity to participate appropriately and meaningfully (s 10), notwithstanding legal incapacity. This means that parents or guardians may not decide whether their minor child should participate in research without the minor's contribution to the decision. The choice of whether to participate is not a legal decision but rather a factual choice. Consequently, the process should be that the parent or guardian is requested to give permission for the minor to be approached to be invited to participate in the study. The factual decision whether to participate is the minor's and not the parent's.

Parental permission and minor's decision must be consistent, i.e. if the minor decides not to participate, the parent may not override this decision. If the parent is reluctant for the minor to participate but the minor wants to do so, the matter must be managed carefully to establish what the concerns are and whether they may be resolved. The minor cannot choose to participate if the parent withholds permission for that minor to choose. Researchers are unlikely to be able to intervene where the suspicion is that the parent is withholding permission unreasonably, since a best interest analysis in this context is irrelevant.

7.4. Permission for situational research or classroom observations

The Department of Health advises the following in the case of education situational research, where the focus of research is on a teacher's performance but necessarily the learners in the class are indirectly involved although not as participants. Researchers are expected to explain carefully to the REC, the school, the parents and the learners (to the extent of

practical feasibility) what is intended with these observations, how it is to be achieved, whether any recordings will be made, the purpose of the recordings, who will have access to these recordings and where it will be stored, what will happen to the recordings after completion the research, how learners' confidentiality will be maintained, etc. Further it is important that the researcher spend time familiarizing the class to his or her presence to avoid unnecessary interference with teaching and learning activities.[37] Parents and learners must be given enough time to consider the purpose of the activities, and should be given enough time to contact the researcher should they have questions, concerns or specific requests.

7.5. Orphans without guardians

i. Introduction

Many minors in South Africa do not have parents and very few have court-appointed guardians. These minors are often described as 'orphans and vulnerable children' or OVC. The absence of a legally appropriate parental substitute poses a problem for researchers because of the lack of clear guidance as to an acceptable substitute in the informed consent process for *research* participation. (Note that for treatment purposes, substituted consent occurs on the basis of necessity, which is not applicable to the research context.)

ii. Justification

Important research that seeks to understand and improve psychosocial, economic and educational conditions for orphans and vulnerable children to improve their future wellbeing generally involves no more than minimal risk of harm. Other research that may involve a minor increase over minimal risk of harm may also be justified on the basis that it would be unjustifiable to exclude a significant segment of the child population from research on the basis of their legal status. Consequently, it is ethical and reasonable to designate parental substitutes in these circumstances.

iii. Pragmatic parental substitutes[38]

In the interest of fostering consistency as well as compliance with the spirit of the legal provisions that protect minors' interests, especially the Constitution and the Children's Act, pragmatic guidance is provided here to deal with situations where no

[37] Department of Health 2019, Aide Memoire, Meeting of the National Health Research Ethics Council (NHREC), Human Research Ethics Committees (HRECS), Animal Research Ethics Committees (ARECS) and other Interested Parties, 16 May 2019.

[38] This pragmatic guidance is provided to temper the chilling effect of a literal interpretation of s 71 of the National Health Act 61 of 2003, which otherwise might prevent important ethical research.

biological parent or legal guardian exists. The permissible level of risk is limited (see 3.2.2.1).

***Note** this guidance does not permit expedient substitution e.g. where a parent is temporarily unavailable.*

This guidance takes its lead from the Constitution, the Children's Act, the National Health Act, the Criminal Law (Sexual Offences) Amendment Act; the South African Good Clinical Practice Guidelines (2006) available at www.doh.gov.za/docs/factsheets/guidelines/clinical/2006/index.html.

The guidance is premised on **three conditions, all of which must be satisfied**:

1. The risk standards set out in 3.2.2.1 b) must be adhered to; and
2. It is not possible to do the research with adult participants; and
3. The research proposes to investigate a problem of relevance to minors.

***Note** that if the proposed research holds out more than a minimal risk of harm, there must be a compelling justification for why orphans should be included as participants, e.g. the research focus has particular relevance for OVC and cannot be studied without their enrolment.*

The parental substitutes should be used in *descending order*, as listed.

i. The minor chooses whether to participate and thus expresses her will **AFTER**
ii. The parent gives assistance with understanding (so the minor makes an informed choice)
iii. If no parent, then guardian: either court-appointed OR as indicated by the parent in a Will (s 27 Children's Act)
iv. If no guardian, then foster parent (per order of Children's Court) (Note that social workers should request that the authority to give permission should be included expressly in the court order authorising foster care)[39]
v. If no foster parent (per iv. above), then caregiver (s 1 Children's Act: defined as '…any person other than a parent or guardian, who factually cares for a child and includes – a) a foster parent; b) a person who cares for the child with the implied or express consent of a parent or guardian of the child; c) a person who cares for the child whilst the child is in temporary safe care; d) the person at the head of a child and youth care centre where a child has been placed; e) the person at the head of a shelter; f) a child and youth care worker who cares for a child who is without appropriate family care in the community; and g) the child at the head of a child- headed household')
vi. If minor is caregiver in child-headed household and no supervisory adult (s 137 Children's Act), then trusted adult nominated by minor, including but not limited to social worker, community worker or teacher.

[39] Note a caregiver, a foster parent and a schoolteacher or principal are not guardians.

7.6. Minors' independent consent

In particular circumstances, e.g. for reasons of sensitivity, like discussion about sexual activities, substance abuse etc., it may be desirable and ethically justifiable for minors (especially older minors i.e. 16 years and older) to choose independently i.e. without parental assistance, whether to participate in research. Generally, only minimal risk research is suitable for independent consent by minors. Reasons supporting the desirability of independent consent may include recruiting sufficient numbers of minors who otherwise would be unwilling to participate if they must tell their parents about the nature of the research in order to obtain parental permission.

An ethical justification for independent consent by minors may be made in the following manner:

- By prior engagement with participating community role players, the PI can request (and justify explicitly) REC approval of a waiver of the parental (or substitute) permission requirement. Engagement could include outreach to relevant role players such as canvassing the opinion of a representative body of parents e.g. via schools or school governing bodies.
- Factual evidence of such engagement must form part of the PI's justification in the protocol. Factual evidence may be in the form of a letter from a relevant role player (like a community leader, school principal or a CAB) that confirms the view that independent consent is acceptable to the parents.
- If the REC accepts the ethical justification and the factual evidence of parental support for independent choice by their minor children, then the REC may grant a waiver of the requirement of written parental permission and must document the process carefully.

7.7. Mandatory reporting obligations

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, especially when the third person is known to the researcher. For specifically designated persons, there are statutory reporting obligations. (See below section on mandatory reporting of abuse)

i. Reporting obligations for 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, the provincial social development department, or to a police official.

ii. Reporting obligations for under-age sexual activity

The age at which minors can lawfully consent to sexual activity is 16 years, in terms of the Criminal Law (Sexual Offences and Related Matters) Amendment Act 32 of 2007 (Sexual Offences Act). Anyone with knowledge of a sexual offence against a minor is required to report this to a police official. In effect, any adult or person >16 years who engages in sexual activity with a minor <16 years commits a crime and may be prosecuted. The Act describes a broad range of sexual offences, including rape, sexual assault, sexual grooming, sexual exploitation, and use of children in pornography including photographs. This means that the range of activities that may constitute a sexual offence is extensive.

The Sexual Offences Act differentiates between adolescents (12 - <16 years) and older minors (16 and 17 years). In the case of children younger than 12 years, sexual activity is unlawful even with consent. For adolescents, the situation is as follows. The *Teddy Bear Clinic* case[40] found criminalisation of consensual sexual acts between adolescents aged 12 – <16 years to be unconstitutional, on the basis that adolescents should not be subjected to criminal sanctions when they exercise their entitlement to determine their personal relationships in light of their rights to autonomy, dignity and privacy. The Constitutional Court imposed a moratorium on action against adolescents in terms of ss 15 and 16 of the Sexual Offences Act. This moratorium of 18 months is to give Parliament time to revise the offending legislative provisions by April 2015.[41]

Consensual sexual acts between adolescents aged 12 - <16 years are not criminal and are not reportable. Sexual acts with adolescents aged 12 - <16 years by an adult or a person >16 years, *even if consensual*, are criminal and reportable. Sexual acts with children <12 years are criminal and reportable.

iii. Sexual and reproductive health research with minors

Research with minors that focuses on their sexuality and reproductive health is likely to encounter instances of abuse and underage sexual activity. The dilemma for researchers is whether to ignore the strict letter of the law or to

[40] The Teddy Bear Clinic for Abused Children v Minister of Justice and Constitutional Development (CCT 12/13) [2013] ZACC 35; 2014 (2) SA 168 (CC); see also J v NDPP [2014] ZACC 13.

[41] See Draft Criminal Law (Sexual Offences & related matters) Amendment Act Amendment Bill [B-2014].

report as indicated in terms of the Sexual Offences Act and the Children's Act. The matter is not simple.

The clash of interests is obvious, e.g. using the law to protect the minor from abuse may have the unintended consequence of increased harm (physical and social) for that child. Further, thoughtless reporting may violate privacy and confidentiality interests of the minor e.g. in terms of the Choice on Termination of Pregnancy Act, the Children's Act and the Child Justice Act. Whether a researcher, who has but a research interest in the life of the child, but no further right of access or duty of intervention ought to take on the responsibility of a social worker is unclear. Consequently, researchers should think very carefully about the anticipated consequences of reporting in light of the legal context. The proposal submitted for ethics review should explain fully the approach to be adopted, and justify how reporting obligations will be managed, so that the REC can deliberate effectively. The consent documents should clearly inform the minor (and proxy consent providers where necessary) about when reporting obligations arise and how they will be addressed, so that an informed choice can be made about whether to participate. Appropriate engagement with role-players such as child rights and childcare organizations may assist researchers to make appropriate and meaningful referrals.

Researchers are advised to include the following wording to their informed consent and assent forms in the cases of child research:

Consent form

The researcher(s) may not be able to keep confidential, information about known or reasonably suspected incidents of deliberate neglect or physical, sexual or emotional abuse of a child. If a researcher is given such information, he or she may report it to the authorities such as child welfare or the police.

Assent form

We will not tell anyone what you tell us without your permission unless there is something that could cause harm to you or someone else. If you tell us that someone is or has been

hurting you, we may have to tell that to people who are responsible for protecting children so they can make sure you are safe.[42]

7.8. Mandatory reporting of abuse

How to respond adequately to the reporting requirement within a research context:

***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. The applicant should be able to assure the REC about the referral arrangements.*

1. Disclosure by any adolescent under 16 years of sexual or other abuse, or on whose behalf abuse is reported by a peer, caregiver, guardian or family member or other relevant person, should trigger an immediate termination of further interviews with the respondent and members of the household.
2. If there is a clear statement that the parties involved in the abuse include an adult (anyone 18 years or older) or anyone who is more than two years older than the adolescent (s 56(2)(b)), the interviewer should report the matter to Childline South Africa at toll free: 0800 055 555 [or another child protection agency]. Childline should contact a registered social worker in the area who should investigate and inform the South African Police Service (SAPS) accordingly. The interviewer should record details of the child's name, physical address and the name of the school the child attends. As proof of complying with the statutory reporting obligation, the interviewer should insist on a Childline reference number.
3. Any secondary reporting of abuse, e.g. where a child indicates that she has reported the abuse to a teacher or another adult but that no action has been taken, the matter should be brought to the attention of Childline, who should deal with the matter. Again, the interviewer should insist on a Childline reference number, as proof of reporting.

If there is uncertainty about whether to report, the interviewer should consult with the Principal Investigator. [*Insert conditions appropriate to the circumstances*]

Examples in practice	**Action by researcher**
A 14-year-old tells of having sex with her 17-year-old boyfriend	Childline > Police
A 12-year-old reports 'having sex' with 19-year-old neighbour	Childline > Police
An 11-year-old tells of a previously reported incident of 'bad touching' by adult aunt that went to court	No action; ask whether the child wants to talk to someone
A 15-year-old relates rape by father	Childline > Police
A 13-year-old boy relates anecdote of sex	Not over two years, so no action

[42] UCT SOP, 2018, pages 169
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with 15-year-old girlfriend	
A 13-year-old says she is 'having sex' but does not disclose who the partner is	No action
A 17-year-old brags that he has 'forced' many girls into having sex with him	No action
A 17-year-old learner speaks of having become pregnant by a school teacher who she does not identify	Ask whether she wants to speak to someone
An 18-year-old learner points out a female school teacher with whom he says he is 'sleeping'	Ask whether he wants to speak to someone

8. VULNERABILITY AND INCAPACITY IN RESEARCH

To define vulnerability in the context of research is complex as it is often situational, relational and multi-layered[43]. The REC: SBE accepts that vulnerability is not an absolute condition or position nor is it an innate characteristic of a person or group, but that there are contextual circumstances, whether in society or the research environment, which might render someone exposed to certain risks or harms if these are not carefully considered, and addressed by researchers.[44]

The REC therefore takes a layered and situational approach to vulnerability and incapacity in research.[45] The REC recognises that there are various sources of vulnerability and incapacity which can either stem from contextual circumstances (personal, social, psychological, political, economic, educational, etc.), or the research setting (power imbalance, unequal power relations infrastructural, etc.). The REC proceeds from the conceptual understanding that vulnerability and incapacity should be considered within the specific context.

The REC recognises two levels of vulnerability as discussed in existing policies and guidelines governing human research:

[43] Bracken-Roche et al. Health Research Policy and Systems (2017) 15:8
[44] Department of Health, 2015, page 26
[45] Lange, M.M, Rogers, W. & Dodds, S. (2013). Vulnerability in research ethics: A way forward. *Bioethics, 27*(6), 333-340.

Level 1: The first level of vulnerability stems from a person's capacity to consent. Persons who are legally or factually incapable of consenting to participate in research are considered vulnerable in the research setting as these persons are vulnerable to coercion. Such may also be vulnerable due to their inability to understand what they are consenting to, and the potential risks and benefits of research. In South Africa, minors (persons under 18 years of age) do not have the legal capacity to consent to participate in research without assistance or permission from a parent or guardian.[46] Adults who are factually incapable of giving informed consent should participate in research only where their participation is indispensable to the research. Persons living with a severe intellectual or mental disability are generally considered to be factually incapable of consenting to participate in research.

Level 2: The second level of vulnerability is more broadly defined and nuanced than the narrow consideration of whether someone is legally or factually capable of consenting or not. Where someone might have the legal and factual capacity to consent to participate in research, there might be personal or contextual circumstances, or key sources of vulnerability[47] that could render them vulnerable to the risks associated with research.[48] Such risks may be related to social, political or economic dimensions and/or may emerge in the research setting or through the process of the research. . The researcher should be sensitive to "emergent vulnerabilities" during the research process and they must work to manage any discomforts experienced by participants (van den Hoonard, 2019). [49] For example, adults who are economically disadvantaged have the legal and factual capacity to consent, but their economic status is a source of vulnerability which could expose them to potential coercion or undue influence. Similarly, persons who form part of stigmatised or marginalised groups, have factual and legal capacity to consent, but their participation in research might expose them to increased risk of stigmatisation if a researcher does not put in place adequate safeguards to ensure confidentiality and accurate and ethical representation of their experiences. Where factors usually associated with vulnerability are integral to the research, the proposal must demonstrate how vulnerability will be

[46] Department of Health guidelines, 2015, pages 27-33
[47] Bracken-Roche et al. Health Research Policy and Systems (2017) 15:8
[48] Bracken-Roche et al. Health Research Policy and Systems (2017) 15:8
[49] Van den Hoonaard, W.C. (2019). The vulnerability of Vulnerability: Why Social Science researchers should abandon the doctrine of vulnerability. Sage Handbook of Qualitative Research (pp. 305-321). Sage.

managed and what specific safeguards will be put in place to ensure that these sources of vulnerability are not exacerbated by virtue of their participation in the research process.

Apart from the aforementioned sources of vulnerability and incapacity, the Department of Health also identifies specific groups of participants which require REC consideration.[50] Research that involves the participation of the groups listed below are identified by the Department of Health as vulnerable; in addition, those individuals or groups whose participation might be affected by afore-mentioned sources of vulnerability, must be also referred to the REC for review at a convened meeting:

- **Minors (children and adolescents)**
- **Adults with incapacity to provide informed consent**
- **Persons in dependent relationships**
- **Persons highly dependent on medical care**
- **Prisoners**
- **Groups who have been historically oppressed on the basis of 'race'**[51]

Researchers and the REC should avoid patronising assumptions about a person or community's ability to make responsible decisions.[52] Researchers should be especially cautious and reflexive of their engagements with all participants and communities, and must assure participants, the communities and the REC that the research and the way the groups are represented will not lead to further stigmatisation or marginalisation.

The Department of Health guidelines (2015) advises that RECs should ensure the following when reviewing research that involves participants from vulnerable groups:

- That persons in these communities are not being involved in research merely because they are expediently accessible, while the research could be carried out in a less vulnerable community;
- That the research is relevant to the needs and priorities of the community in which it is to be carried out (the research holds social value or benefit to the community or society);

[50] Department of Health guidelines, 2015, pages 26-40

[51] Certain racial or other minority groups are susceptible to oppression, stigma and misrepresentation within a particular context

[52] Department of Health guidelines, 2015 page 27

- And that research participants know they will take part in research; and that the research will be carried out only with their consent, Particular attention should be given to the content, language(s) and procedures used to obtain informed consent. [53]
- That the potential benefits of participating in the research outweighs the potential risks or harms.

Researchers working with individuals or communities who may be exposed to sources of vulnerability or incapacity must provide information which identify the specific sources of vulnerability or incapacity, the specific safeguards and steps researchers will put in place to manage the specific sources of vulnerability in the research setting, so as not to increase or exacerbate this source of vulnerability. Researchers should also provide a detailed description of the specific actions or steps they will take to ensure that persons have equal capacity and opportunity to participate in research and that their research will not lead to further marginalisation or stigmatisation of the participant or communities.

Researchers must provide the REC with up-close knowledge of the groups they are researching.[54] Up-close knowledge highlights the need for some form of prior community interaction or engagement. Researchers are expected to consult with key persons or experts from the community about specific key sources of vulnerability and the best approach to address these in the context of research. Researchers are furthermore expected to take a reflexive approach whilst conducting the research and must reflect on and discuss their positionality in the study. The researcher should also provide the REC with a rich discussion of the research environment or setting and identify specific circumstances which may exacerbate or add additional layers of vulnerability e.g. trained staff and interpreters are unavailable or there are certain language or infrastructural barriers to equal participation in research.[55] Researchers should then consult with communities on what would be practical and acceptable ways of addressing these structural barriers to equal and voluntary participation.

[53] Department of Health Guidelines, 2015, page 26-27

[54] Peter, E. & Friedland, J. (2017). Recognizing risks and vulnerability in research ethics: Imagining the "what ifs?" Empirical Studies in research ethics, 12(2), 107-116.

[55] Kipnis, K., 2001. *Vulnerability in research subjects: A bioethical taxonomy. Ethical and policy issues in research involving human participants*. Volume II. Commissioned papers and staff analysis. Bethesda, MD: National Bioethics Advisory Commissions.

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9. MONITORING OF RESEARCH IN PROGRESS OF CERTAIN STUDIES OR HIGH-RISK RESEARCH

The Research Ethics Committee or Chairperson can establish a special monitoring procedure for following the progress of certain, usually high ethical risk studies for which a positive decision has been reached, from the time the decision was taken until the finalisation of the research.

The on-going lines of communication between the Research Ethics Committee and the applicant will be clearly specified in the communication of the review result to the applicant.

- The follow-up procedure will take the following into consideration:
- The requirements laid down for follow-up reviews, the review procedure, and the communication procedure may vary from the requirements and procedures for the initial decision on an application
- The follow-up review intervals are determined by the nature and the events expected in relation to particular research projects, though each research project should undergo a follow-up review at least once a year

The following instances or events require the follow-up review of a study:

- any protocol amendment likely to affect the rights, safety, and/or well-being of the research participants or the conduct of the study
- serious and unexpected adverse events related to the conduct of the study or study results, and the response taken by investigators, sponsors, and regulatory agencies, when applicable
- any event or new information that may affect the benefit/risk ratio of the study

A decision of a follow-up review will be issued and communicated to the applicant, indicating a modification, suspension, or termination of the Research Ethics Committee's original decision or confirmation that the decision is still valid

In the case of the premature suspension/termination of a research project that was approved by the DESC or the Research Ethics Committee, the applicant should notify the Research Ethics Committee immediately of the suspension/termination and the reasons for suspension/termination.

A summary of results obtained in a study prematurely suspended/terminated should be communicated immediately to the Research Ethics Committee

The Research Ethics Committee should receive notification from the applicant at the time of the completion of a study

10. PROCEDURES FOLLOWING SELF-REPORTING OR ALLEGATIONS OF NON-COMPLIANCE[56]

The primary responsibility of the REC: SBE is to protect the rights and welfare of human participants in research.

The principal investigator must conduct his or her research using specific materials, forms and procedures approved by the Committee. Committee approval letters also specify any special conditions that accompany approval and provide a time limit on the approval period.

The principal investigator and the study team are expected to comply with all ethical standards, regulations, laws and conditions placed on the conduct of the study. The Committee will investigate and address all reports or allegations of non-compliance.

Definitions:

Non-compliance: Any violation of any regulation governing human research or any deviation from the REC: SBE -approved protocol. Non-compliance varies in nature, severity and frequency.

Minor Non-compliance: A non-compliant incident that does not affect participants' safety, compromise data integrity, violate participants' rights or welfare or affect participants' willingness to participate in the research. Examples include a missed deadline for a continuing review, inadvertent errors due to inattention to detail, misunderstanding or an oversight.

Serious Non-compliance

[56] The REC: SBE adopts the non-compliance procedures as described in the UCT, SOP of 2018. Minor amendments have been made to ensure relevance to the SU context.
REC: SBE Standard Operating Procedures, 2019, version 1.5

Serious non-compliance is an activity that jeopardises participants' safety, rights or welfare, or the integrity of the data. Examples include:

- Conducting human research without REC: SBE approval.
- Research participants do not meet inclusion criteria but are still enrolled in a study, potentially or actually increasing risk and adversely affecting their rights and welfare as research participants.
- Not using the consent form approved by the REC: SBE
- Activities that compromise participants' privacy and confidentiality.
- Implementing substantive modifications to a REC-approved protocol without prior REC: SBE approval.
- Enrolment of research participants when REC: SBE-approval has lapsed.
- Inadequate training and supervision of research staff.

Continuing Non-compliance

Continuing non-compliance is defined as a series of more than one non-compliant event in reasonably close proximity that, if unaddressed, may compromise the integrity of the human research protection programme. The pattern may reflect a lack of knowledge or a lack of commitment on the part of the investigator and study team to protecting participants' safety and welfare in research.

Examples include:

- Repeated failure to follow REC: SBE policies and procedures particularly after the REC has informed the investigator of the problem(s) and that corrective action needs to be taken.
- An investigator has a record of non-compliance over a long period or in a number of existing or previously approved studies. In this case, the REC: SBE may refer continuing non-compliance to the Stellenbosch University's Compliance Officer or Research Integrity Officer.

Allegation of Non-compliance

Allegation of non-compliance is a report that represents an unproven assertion.

Finding of Non-compliance

Finding of non-compliance is a report of non-compliance that is substantiated by evidence

Reporting Non-compliance

Allegations, observations or evidence of non-compliance in human research must be reported to the REC: SBE Chair by:

- Principal investigators.
- Any member of the study team.
- REC: SBE members.
- Study monitors, auditors or sponsors directly, or through the principal investigator.

Research participants and others not directly involved with conducting or overseeing the research may also report incidents of non-compliance.

The REC: SBE will review all reports of non-compliance. The Chair may conduct the review alone, or with designated individuals, or delegate this task to a reviewing subcommittee of REC: SBE members or request an independent audit (See section on Monitoring of Research in Progress for further guidance).

The Chair or subcommittee will review written materials, interview knowledgeable sources and collect relevant documentation. The Chair or subcommittee will compile a factual and objective written report of findings and evidence. The Chair will inform the principal investigator about the progress of the review and investigation at the start and at the end of the process. Findings which in the opinion of the Chair, subcommittee or auditor(s) are supported by the preponderance of evidence will be considered findings of non-compliance.

REC: SBE Responsibilities

The REC: SBE is responsible for making a final determination as to whether serious or continuing non-compliance has taken place. This should occur as soon as possible which is usually at the next scheduled full-committee meeting. The Chair shall inform members about the actions taken thus far and advise regarding further actions to be taken.

In considering how to react to serious or continuing non-compliance, the REC: SBE aims to:

- Correct the non-compliance.
- Institute corrective measures to help ensure the non-compliance does not happen again, either with the investigator or protocol in question, or with any other investigator or protocol.
- Attempt to mitigate any adverse effects on participants.

Possible REC: SBE responses include:

- Suspend or terminate the study if participants' safety and welfare are being jeopardised.
- Place the study on administrative hold pending the outcome of the investigation.
- Require periodic independent audits.
- Modify the research proposal.
- Modify continuing review timetable to include more frequent Committee reviews.
- Require that the principal investigator and study team receive additional education or training in research ethics.
- Require oversight by a senior investigator.
  Advise the Faculty or Department to limit the research of the investigator (by number of active protocols or number of active participants). In this case, the final decision to support such a recommendation of the REC: SBE's remains with the Faculty or Department.
- Refer to other institutional entities if the non-compliance rises to the level of scientific or professional misconduct e.g. the Research Integrity officer, Compliance officer
- Require that participants currently or previously on the study be notified of the non-compliance when such information might affect their willingness to continue to take part in the research.
- Require that participants be re-consented.
- Monitor the informed consent process.
- Conclude that the investigation served as an educational tool and that, based on the principal investigator's response to the investigation (such as an audit), no further action is necessary.
- Recommend that an embargo be placed on publication/ access to the publications, in consultation with the Faculty and SU Library and Information Services

The REC: SBE is responsible for ensuring that changes and other mandates are carried out by the principal investigator. To this end, the REC: SBE may request appropriate documentation from the principal investigator and may perform confirmatory site visits.

Investigators' Responsibilities

Investigators:

- Must report non-compliance on their studies using the REC: SBE Deviation form
- May choose voluntarily to suspend or terminate a study until the potential issue is investigated and/or resolved.

- Are expected to cooperate with any fact-finding and subsequent investigation and to keep all records related to the investigation.
- Must respond promptly in writing to all issues and questions raised - this may include an explanation of the non-compliance and a plan of action to ensure that similar incidents will not occur in the future.
- Must comply with all recommendations resulting from the investigation.

The principal investigator may submit a written request asking the REC: SBE to reconsider its decision. The request should clearly indicate the facts or the interpretation in dispute and should provide supporting evidence where applicable. The REC: SBE will decide either by consensus or vote to leave the decision unchanged or to reopen the investigation.

- The final report shall include the following information:
- Title of research project and/or grant proposal in which the non-compliance occurred.
- Name of principal investigator on the protocol.
- REC: SBE reference number and reference numbers for any applicable federal funding.
- A detailed description of the non-compliance.
- Actions the institution is taking or plans to take to address the non-compliance.

A copy of the final report may be sent to the:

- Dean of the Faculty.
- Deputy-dean of Research in the Faculty.
- Principal investigator.
- Head of Department.
- Grants and Funding Office when research is funded by a grant or contract.

11. COMPLAINTS AND GRIEVANCES PROCEDURES

Researchers who have complaints or grievances regarding the decisions of the Research Ethics Committee, must follow the Generic Standard Operating Procedure for Appeals and Complaints of the Senate Research Ethics Committee (see Addendum 5). In terms of this Generic Standard Operating Procedure, researchers who wish to appeal to, or complain about, a decision of the Research Ethics Committee must first do so in writing to the Research Ethics Committee. The appeal must contain a clear motivation as to the reasons for the appeal. The following procedure will then be followed to address the appeal:

- The Chairperson of the Research Ethics Committee will take appropriate steps to (re)- evaluate the protocol and provide the Research Ethics Committee with a report and a recommendation. These steps can include a request that another Screening Sub-committee again look at the application and review the Research Ethics Committee's decision.
- The Research Ethics Committee will then reconsider the entire application, together with the report of the Chairperson or the Research Ethics Screening Sub-committee at a meeting following the one at which the appeal was tabled
- The new decision of the Research Ethics Committee will be communicated to the researcher in writing
- If the researcher is then still aggrieved, the second phase in the Standard Operating Procedure can then be activated by submitting a further appeal in writing to the Senate Research Ethics Committee (SREC).

If researchers have complaints or grievances regarding the decisions of the DESC, the matter must first be taken up with the departmental chair. If the matter is not resolved in that context, the matter can be taken up in writing with the Chairperson of the Research Ethics Committee.

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

The Standard Operating Procedure of the Research Ethics Committee is approved by the Senate Research Ethics Committee.

Changes to this Standard Operating Procedure can be made at any ordinary meeting or strategic workshop of the Research Ethics Committee, and any such changes must be approved by the Senate Research Ethics Committees.

The Research Ethics Committee must assess the efficacy of its Standard Operating Procedure at least once a year and minute the results of this assessment at one of its ordinary meetings.

The Glossary, Addendums and the entries to Section 19 of this SOP are exempted from the procedure described above.

13. REFERENCES

In the compilation of this Standard Operating Procedure the following documents were consulted:

- National Department of Health (DoH) (2015), Ethics in Health Research: Principles, structures and processes.
- UCT Faculty of Health Sciences Standard Operational Procedures
- Stellenbosch University HREC Standard Operational Procedure, 2015.

14. GLOSSARY

Most entries in this Glossary have been taken over verbatim from the Glossary of the National Health Research Ethics Council (NHREC) – as point of reference and with a view to further elaboration in some cases to convey the concept in terms more appropriate to research in the humanities. Definitions marked by an asterisk (*) do not appear in the Glossary of the NHREC. In using these definitions, please note that there is wide spectrum of kinds of research conducted in the humanities. A definition that may not be applicable to your own research, may well be applicable to research done in other departments and faculties in the humanities.

The definitions in this glossary serve as a guide to interpret the SOP. Where definitions in the list below differ from, or clash with definitions generally used in your field of research in the humanities, there is an obligation on researchers to bring the alternatives to the attention of the research ethics committee, and to make it explicit in their applications which definitions they use, if different from the entries in this glossary.

The Research Ethics Committee can update this Glossary on an on-going basis.

Adverse event

Any undesirable or unintended response or occurrence in a research participant, i.e. a clinical sign, symptom, condition, or psychological reaction, to a research intervention, which does not necessarily have a causal relationship with the intervention being researched.

*Elaborated in terms more appropriate to social research**

Any undesirable or unintended response or occurrence that emerges in research, which does not necessarily have a causal relationship with the research process, for example, a research participant disclosing unsolicited information that reveals an emergency situation.

Applicant

A qualified researcher undertaking the scientific and ethical responsibility for a research project, either on his/her own behalf or on behalf of an organization/firm, seeking a decision from an ethics committee through formal application.

Approval (in relation to the Research Ethics Committee)

The research Ethics Committee's affirmation that the research protocol has been reviewed and that the research may be conducted by the applicant according to the constraints set out by the ethics committee, the institution and legal requirements.

Approval conditions

Conditions to be met by the applicant prior to the start of the research. Approval conditions are issued by the Research Ethics Committee with the final letter confirming a favourable ethical opinion. (Note: Approval conditions are distinct from the further information or clarification requested from the applicant when issuing a provisional opinion.

Assent *

Permission to participate in research provided by a minor, or someone under legal guardianship.

Benefit

That which positively affects the interests or welfare of an individual or group, or the public generally.

Chair

The member of a Research Ethics Committee appointed to be Chair by the appointing authority. Where the Chair is unavailable for any reason, his/her duties may be performed by the vice-Chair /secundus.

Child

Subject to law in the relevant jurisdiction, a child is a minor who lacks the maturity and legal ability to make a decision whether or not to participate in research.

Confidentiality

The obligation of people not to use private information – whether private because of its content or the context of its communication – for any purpose other than that for which it was given to them.

Conflict of interest (research)

In the research context: where a person's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations in research; or where an institution's interests or responsibilities have the potential to influence the carrying out of its research obligation.

Conflict of interest (Research Ethics Committee)

A conflict of interest arises when a member (or members) of the Research Ethics Committee holds interests with respect to specific applications for review that may jeopardize his/her (their) ability to provide a free and independent evaluation of the research focused on the protection of the research participants. Conflicts of interests may arise when an Research Ethics Committee member has financial, material, institutional, or social ties to the research.

Consent

A person's or group's voluntary agreement based on adequate knowledge and understanding of relevant material, to participate in research. Informed consent is one possible result of informed choice, the other possibility is refusal.

Discomfort

A negative accompaniment or effects of research, less serious than harm.

Ethical/Unethical

Right or morally acceptable on one hand, wrong or morally unacceptable on the other. Conforming to the rationally acknowledged norms and standards of behaviour, or failure to conform to such norms and standards.

Ethics review

Review of research by a Research Ethics Committee or other body.

Ethical risk [in human research, non-medical] *

An action, procedure or method used in the research and in its reporting that can compromise the dignity, rights, safety, and well-being of participants in research, or those affected by that research.

Ethics

A branch of moral philosophy concerned with the rational evaluation of the concepts of right and wrong, justice and injustice, virtue and vice, good and bad, and activities to which these concepts apply.

Harm

That which adversely affects the interests or welfare of an individual or a group. Harm includes physical harm, anxiety, pain, psychological disturbance, devaluation of personal worth and social disadvantage.

Inconvenience

A minor negative accompaniment or effect of research, less serious than discomfort.

Individually identifiable data

Data from which the identity of a specific individual can reasonably be ascertained.

Integrity

Honesty and probity as qualities of character and behaviour.

Investigator

A qualified scientist who undertakes scientific and ethical responsibility, either on his/her own behalf or on behalf of an organization/firm, for the ethical and scientific integrity of a research project at a specific site or group of sites. In some instances a coordinating or

principal investigator may be appointed as the responsible leader of a team of sub investigators.

*Elaborated in terms more appropriate to social research**

The terms “investigator” and “researcher” can be used interchangeably; and it should be noted that research in the humanities may not be site-specific.

Low risk (research)

Research in which the only foreseeable risk is one of discomfort.

*Elaborated in terms more appropriate to social research**

Research in which the potential exists for minor emotional discomfort, e.g. the subject matter may have a low degree of personal, social or political sensitivity that could cause embarrassment to participants. This risk can be easily mitigated by a sensitive approach by the investigator. *(See Addendum 3 for a classification of risk types.)*

Monitoring (of research)

The process of verifying that the conduct of research conforms to the approved proposal.

Medium risk

Research in which there is a probable risk of harm or discomfort, but which can be fairly easily managed to pose the minimum risk to the participant.

*Elaborated in terms more appropriate to social research**

Research in which the potential exists for a level of emotional or psychological distress and/or social stigmatisation, prosecution or persecution that could be harmful to the participant if due care is not taken by the investigator, and could require mitigation, e.g. counselling or other forms of support. *(See Addendum 3 for a classification of risk types.)*

Personal information

Information by which individuals can be identified.

Privacy

Privacy implies a zone of exclusivity where individuals and collectivities are free from scrutiny of others. It may also include control over the extent, timing and circumstances of sharing oneself with others, whether physically, intellectually or in terms of behaviour.

Protocol

A document that provides the background, rationale and objectives of the research and describes its design, methodology, organisation and the conditions under which it is to be performed and managed.

Provisional clearance

Ethical approval is granted on condition that the researcher provides further information or clarification on specified issues, or submits outstanding documents, prior to the commencement of the research.

Public domain*

Generally, a zone of common, unrestricted access shared by individuals and collectives.

*Elaborated in terms more appropriate to intellectual property right on research instruments**

"Works are in the **public domain** if the intellectual property rights have expired, if the intellectual property rights are forfeited, or if they are not covered by intellectual property rights at all. In a general context, public domain may refer to ideas, information, and works that are "publicly available", but in the context of intellectual property law (which includes copyright, patents, and trademarks), public domain refers to works, ideas, and information which are intangible to private ownership and/or which are available for use by members of the public. This includes sources such as Wikipedia, but may or may not include information gathered from social media, i.e. Facebook or Twitter.

Project ID

Reference number uniquely assigned by the Research Ethics Committee accepting the application for review. This includes a specific project number and year.

Research

Includes at least an investigation undertaken to gain knowledge and understanding or to train researchers.

Research Ethics Committee (Research Ethics Committee)*

Body, which has been constituted by the Senate of Stellenbosch University, and has been authorised and registered by the NHREC, to carry out ethical review of research,.

Research misconduct

Includes fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research, and failure to declare or manage a serious conflict of interest. Also includes failure to follow research proposals approved by a research ethics committee, particularly where this failure may result in unreasonable risk or harm to humans, other animals or the environment. Also includes the wilful concealment or facilitation of research misconduct by others.

Requirements

In the context of decisions, requirements are binding elements that express ethical considerations whose implementation the ethics committee requires or views as obligatory in pursuing the research.

Revision of application

Any changes made to the terms of an application at the request of the Research Ethics Committee following the meeting or, following issue of an opinion, before the research has started. Revision is not permitted prior to the Research Ethics Committee meeting once the application has been validated.

Risk

The function of the magnitude of harm and the probability that it will occur. *(See Addendum 3 for a classification of risk types.)*

SOPs

The standard operating procedures issued by the Research Ethics Committee

Sponsor

An individual, company, institution or organization that takes responsibility for the initiation, management, and/or financing of research.

Voluntary participation

Participation that is free of coercion and pressure.

Vulnerable person / groups

Those whose willingness to volunteer in a research study may be unduly influenced by the expectation of benefits associated with participation.

*Elaborated in terms more appropriate to social research**

Individuals or categories of participants can be vulnerable *prior* to research, or rendered vulnerable *because* of research, due to factors including, but not limited to:

1. Reduced ability to make a voluntary decision, because of factors including, but not limited to age, mental disarray, subordinate position, and impoverished position.
2. Reduced ability to make an informed decision, because of factors including, but not limited to lack of familiarity with the scientific method, linguistic barriers, inability to read or write, reticence to ask questions about the research.
3. Breaching of confidentiality by the researcher in any stage of the research.
4. Exposing participants unfairly to the risks of the research, or bestowing on participants unfairly the benefits of the research.
5. Exposing participants, or third parties not directly involved in the research, to any complications that may be caused by the research.

(With thanks to the CSIR and Prof. Thad Metz.)

ADDENDUM 1: RESEARCH ETHICS COMMITTEES: APPEALS AND COMPLAINTS

Generic Standard Operating Procedure

Approved by the Senate Research Ethics Committee 9th February 2011

A. DEFINITIONS

Appeals arise because a Research Ethics Committee[57] (REC) rejects a research proposal, adjudges a protocol deviation or violation to be sufficiently serious to merit calling a halt to the research, or requires additional protections or conditions before approving a protocol and the Principal Investigator (PI) objects to the decision of the REC and wishes to appeal.

An appeal **must** be directed to the chairperson of the relevant REC. A researcher may not appeal directly to the Senate Research Ethics Committee (SREC).

Complaints arise because of alleged REC procedural irregularities, breach of researcher confidentiality, unacceptable delays or conflict of interest.

Complaints should be directed, in the first instance, to the chair of the relevant REC. However if the researcher deems the matter extremely serious and urgent, the complaint can be submitted directly, in writing, to the chairperson of the SREC.

B. APPEAL PROCESS

The process described below may be a two stage process involving first the REC against which the appeal has been lodged. If the REC agrees or prefers, the matter can be referred to the Senate Research Ethics Committee to be finalised. However, in order to retain the decisional integrity and independence of a REC within its own institution, PI's may not appeal directly to the SREC. The researcher retains the right to appeal or complain to the National Health Research Ethics Council, if the research falls under the jurisdiction of this council i.e. fulfils the definition of Health Research as defined in the National health Act No.61.2003.

[57] Health Research Ethics Committee (REC) 1 and 2, Non-medical REC; Animal Care and Use REC; Biosafety REC

B1. APPEAL PROCESS (REC LEVEL)

1. Where a PI is dissatisfied with a REC decision, he or she has the right to obtain from the REC written reasons for its decision and should exercise this right before launching an appeal.

2. Each committee is expected to have a mechanism whereby a PI may appeal the REC's decision. The chairperson of the REC must appoint a subcommittee to revisit the substance of the application together with any additional information put forward by the PI. The subcommittee must obtain at least one independent, external, expert review of the research project and the substance of the appeal. Additional reviews should be obtained if deemed appropriate. The subcommittee may have the same powers as the REC, if so constituted by the REC concerned.

3. The appeal is usually considered on the grounds of written submission only. However the chairperson of the appeal subcommittee may invite the PI to provide an additional oral submission to the subcommittee and answer questions.

4. After deliberation of all the information placed before it, the subcommittee must either

a. Uphold the appeal

b. Reject the appeal

c. Refer the matter to the Senate REC.

5. In the event of an (a) or (b) outcome, the decision of the REC (or REC-subcommittee) is final.

6. If the REC or REC-subcommittee refers the matter to the Senate Research Ethics Committee (SREC) it undertakes to adhere to any decision taken by the SREC, regarding the matter.

7. Researchers conducting 'health research' retain the right to complain or appeal to the National Health Research Ethics Council in the event that they remain dissatisfied with the outcome of the appeal[58].

B2. APPEAL PROCESS (SENATE RESEARCH ETHICS COMMITTEE LEVEL)

1. Notice in writing of the intention to refer the matter must be given by the chair of the research ethics committee (REC) to the chair of the Senate Research Ethics Committee. The PI must also be notified of this decision. The chair of the SREC must notify the Vice-Rector Research of the receipt of the appeal.

2. The basis of the appeal and all the relevant documentation must be submitted in writing to the chair of the Senate REC within seven (7) days of the notice in 1) above.

3. The matter is usually heard on the basis of written submissions only, that is, no oral evidence is led. It is therefore important that the chair of the REC ensure that all the information that is relevant is before the Appeal Panel of the Senate REC. The PI, the REC and other interested parties may make submissions to augment the existing record, in accordance with the time lines set out by the Chair of Senate REC (see below under Appointment of Appeal Panel).

B2.1 Composition of Appeal Panel

The appeal will be heard by an independent panel made up of 3 – 5 members, who will ordinarily be members of the Senate REC, but may be other persons if deemed necessary by the Chair of the Senate REC.

The members of the panel must include one member from the Faculty concerned. The members of the panel must not be members of the REC.

In the case where special expertise might be needed to deal with technical aspects of the substance of the appeal, then such expertise should be sought without compromising the independence of the panel.

[58] The National Health Research Ethics Council has been given the mandate by the National Health Act No.61. 1983 (NHA) to investigate and manage complaints related to the review and approval of 'health research' as defined in the NHA, by research ethics committees.

B2.2 Appointment of Appeal Panel

The panel must be appointed by the Chair of the Senate REC who must draw up timelines for the submission of documentation, for the hearing of the appeal and for delivery of the panel's decision.

B2.3 Powers of Appeal Panel

The appeal panel is empowered

- to request further information if needed;
- to interview the parties; but if it does so, it must be in the presence of both parties, failing which, it must report to the other party the substance of the submissions or answers given and allow an opportunity to rebut;
- to require the parties to seek to resolve the matter through mediation or seek some other route as to a possible resolution of the dispute; and
- to recommend to the REC that the appeal be upheld; or
- to recommend to the REC that the appeal be dismissed.

As previously stated, researchers conducting 'health research' as defined by the SA National Health Act No.61.2003, retain the right to submit an appeal or complaint to the National Health Research Ethics Council if unsatisfied with the outcome of the process

C. COMPLAINTS PROCESS

1. All complaints against an REC, for matters as described above, should be submitted directly to the REC chairperson, who should make every effort to investigate the complaint thoroughly, resolve the issue and communicate the outcome of the investigation to the complainant.

2. Only complaints that cannot be resolved effectively by the REC chairperson, or that are deemed to be irresolvable by either the researcher or REC chairperson, should be submitted to the SREC.

3. The chairperson of the SREC shall notify the chairperson of the REC that a complaint has been made against the REC, inform him/her of the nature and substance of the complaint and request that he/she responds in writing to the complaint, providing sufficient detail.

4. The chairperson of the SREC shall appoint an ad-hoc committee to investigate the complaint and report back to the full SREC at a forthcoming meeting. Where necessary the subcommittee may need to interview the complainant, the chairperson and/or other persons.

5. The SREC shall compile a report of its findings and recommended action. The report shall be submitted to the Vice Rector: Research, the chairperson of the REC and other parties if deemed necessary by the SREC.

6. The PI shall be notified of the outcome of the SREC investigation.

ADDENDUM 2: Ethics in commissioned research

Guidelines for applicants on the ethical process

Version	Date	Author/Commentator
1	1 August 2019	Lara Skelly (Research Manager: USB)
2	20 August 2019	Included comments from Marius Ungerer (Professor: USB)
3	2 September 2019	Included comments from IT guys on RDM
4	3 September 2019	Included comments from USB DESC discussion & from John Morrison
5	16 September 2019	Comments from Angus Bowmaker-Falconer (Research Fellow: USB)
6	19 September 2019	Comments from John Morrison (Research Consultant: USB)
7	4 October 2019	Comments from Lisa le Roux (Director: Unit for Religion and Development Research)

What is commissioned research?

Commissioned research is any research that has been requested and paid for by an external[59] party.

The Policy for Responsible Research Conduct at Stellenbosch University[60] defines research as: "any systematic enquiry aimed at producing new and generalisable knowledge, new meaning or a deeper understanding of meaning". Commissioned research is not exempt from this definition. If the commissioned research includes (a) a systematic enquiry that (b1) is aimed at producing new knowledge or (b2) new or deeper meaning, then it would be considered research.

Not covered by this definition are occasions where research might be used to facilitate workshops. While workshops like this might offer new knowledge or understanding to the participants, it is not a systematic

[59] Although this is mostly likely to be an external party, commissioned research may also be commissioned from the institution itself. Trans-Disciplinary commissioned research may be an example here.

[60] http://www.sun.ac.za/english/research-innovation/Research-Development/Documents/Policies%20and%20Guidelines/ENGLISH/SU%20Research%20Ethics%20policy%20approved%20by%20Council_24%20June%202013.pdf

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enquiry on behalf of the facilitator. Workshops like this could be used as sources of research data, but they are not in themselves considered research. An example could be workshops used for case study development.

A useful way to think about this is to look at the dimensions of research[61]. All research contains four key components: the research question, the context, methods and a theoretical or conceptual framework. Should one or more of these elements be missing, it is not research. In commissioned research, the funder[62] typically dictates the research question (although the researcher might assist in articulating it in scientific terms) and the context.

According to the Policy, "At SU all research involving interaction with or observation of human subjects, or information linked to human subjects, or research involving groups of individuals, or organisations must go through a process of ethical screening and clearance". This includes commissioned research.

Researchers at SU might undertake research projects in their personal capacity. In such instances, the risk is born by the individual. A rule of thumb: if the SU Indirect Cost Recovery Rate is included in the funder expenses, then the project should be reviewed under the SU ethics system.

Ethical compliance of contract research

The policy states that all research involving human participants must comply with the following principles:

1. Be relevant to the needs and interests of the broader community. Furthermore, biomedical research should be directly relevant to the community in which the research is conducted
2. Have a valid scientific methodology
3. Ensure research participants are well informed about the purpose of the research and how the research results will be disseminated and have consented to participate, where applicable
4. Ensure research participants' rights to privacy and confidentiality are protected
5. Ensure the fair selection of research participants
6. Be preceded by a thorough risk-benefit analysis
7. Thorough care must be taken to ensure that research in communities is effectively coordinated and does not place an unwarranted burden on such communities

For commissioned research, ethical compliance is frequently simplified. Where research is commissioned by an organization to do research on that organization, it may be understood that the research will benefit that organization. Participants, typically from the organization, would be informed and their rights protected. Selection of participants could be dictated from the organization, which would ensure that there is not an unwarranted burden on these groups.

It remains the responsibility of the researcher to make certain that adequate participant protection is in place, and not to rely on the organization to ensure it. A discussion with the funder on the details of participant

[61] https://pubsonline.informs.org/doi/abs/10.1287/isre.13.4.416.71
[62] In this document, funder and commissioning party will be used interchangeably

protection is advised to confirm that the funder and the researcher have a shared understanding of what needs to be done in terms of ethical research.

Where the commissioned research is not done within the organization in question, the standard considerations for compliance apply.

Commissioned research could be a simple desktop study. In this case, the research would be exempt. It is still prudent to apply for ethical clearance in such instances, however, as the results of the research might introduce an element of risk that the Ethical Committees could advise on.

This guideline is focused on the issues around the ethical risk of the commissioned research. Legal issues in commissioned research, including copyright and intellectual property concerns, would be reviewed by the Division for Research Development's Research Contract's Office.

Components of a contract research proposal

Introduction/background and rational for the research

In this section, it is advisable to make it explicit that this is a proposal for commissioned research. This will assist in managing the expectations of the reviewer. There must be a clearly articulated purpose. Questions that could guide the applicant would be: For what purpose is this research done? What will be done with the findings of the research? For whose benefit is this research done? If the Terms of Reference includes this information, that can be submitted in the ethical application

Research questions, aims and objectives

Here too, it is prudent to make reference to the nature of the research: commissioned. Stating this clearly will assist the ethical reviewer in understanding the application. A research aim could be to provide answers to the funder. The sole purpose of research should not be an audit with the view of negatively affecting anyone. It should always have the purpose of creating knowledge and providing a benefit to the funder and other stakeholders. Restating this, the cost-benefit ratio of the research should be favourable.

Literature review that supports the above

In commissioned research this section can be brief. A thorough review of the literature is not necessary to develop the research question(s) as these arise from the funder. However, linking the commissioned research to other studies is advisable, particularly in the report to the funder.

Methodology

The chosen method should fit the purpose of the study, and be balance by the costs.

The method of data collection and analysis should be described in as much detail as possible, as this affects the validity of the study. It is often in the method where the risks of research lie. This section should depart from the typical student way of citing textbooks toward a clearly articulated logic of how the research is designed,

which scientific methods form part of the design, and most importantly, how the research will be carried out step by step. In this latter part, adherence to ethical principles[63] should be explained as part of the process

Data

Secondary data research types

a. Secondary data research using sources that are published, i.e. literature freely available on the internet, websites, expert forums, social media traffic, official statistics made available for public use (economic, population, demographic, business) – **EXEMPT**
b. Secondary data research based on data available for public consumption but needs some kind of subscription to a gatekeeper (e.g. IRESS, EBSCO Host, and other SU library resources). The question here is about whether the subscription covers private research done largely for consulting purposes and not for academic knowledge purposes (or for the purposes of obtaining an academic qualification). **Not necessarily EXEMPT**. The purpose and destiny of the research needs to be explained clearly and reconciled with the license agreements covering the subscriptions.
c. Secondary data research based on buying data or on obtaining data from the commissioning organisation. **Not EXEMPT**. Such research must be covered by gatekeeper permission that is clear on for what purpose the data are used, any exclusion criteria, as well as how the data will be accessed, managed, and returned after completion. Where possible, the researcher should verify permissions.

2. Primary data research types
   a. Expert opinions: People are selected as participants because of their standing in society and/or their recognised expertise in a field. Such participants may be paid or not for their time. The strength of the findings may also be dependent on openly declaring who these participants were. This again could be declared on aggregate basis, or by way of individual viewpoints. These participants may also be recruited based on their individual knowledge, or based on their affiliations. Depending on who the commissioner is, the principle of voluntary participation may also not be so clear. For example, in a consultancy project to improve work processes in a particular organisation, certain role players just have to take part. However, based on certain conditions in the organisation, certain expert persons may even be vulnerable
   The expert opinion category of data source therefore requires careful thinking about aspects of voluntariness, vulnerability, anonymity / confidentiality, and institutional permission, which therefore requires an explicit explanation in the application. Moreover, for the informed consent process, one cannot merely rely on standard documents. Dedicated documents will have to be drawn up.
   b. Other interview/surveys
   - This category would cover most of the primary data collection projects. In commissioned research, participants might be obligated to provide information by the funder (for example, when a company mandates that the employees participate in the research). This might result in a bias in the data. A reflection on these matters should be included.
   - Interviews and other surveys in commissioned research should be treated much like they are in other forms of research.

Data management and analysis

Stellenbosch University has several tools available with data management:

- https://redcap.sun.ac.za/ for collecting and/or storing data

[63] See Global Code of Conduct for Research in Resource-Poor Settings: http://www.globalcodeofconduct.org/wp-content/uploads/2018/05/Global-Code-of-Conduct-Brochure.pdf

- OneDrive for the storage of individual researchers' data (5 TB of storage space per SU researcher)
- MS Teams or Groups as a RDM collaboration space for research groups (25 TB; SU researchers and external collaborators)

Data should be stored for a minimum of 5 years. For data stored in perpetuity, SUNScholarData provides the ideal platform.

Limitation on the access of data should be clearly spelled out, as some funders expect the raw data. If the data (raw or in any other format) will be provided to the funder, this should be explicit in the consent letter. The ethics application should make it clear that there is agreement between the expectation laid out in the terms of reference and the other documents relating to the project.

The research must also describe the method of data analysis. Reference can be made to existing methods to save on time. Sage Research Methods Online is a good starting point to search for existing methods.

Ethical considerations

Most commissioned research for commercial purposes will be considered low risk. As such, they can be reviewed by the DESC.

The funder might introduce an element of risk, particularly if they unethically request that data or results are falsified. Some funders have expectations that cannot be met through ethical research[64]. Another element of risk is in the non-compliance from the funder requests. For example, if for some reason the research cannot continue, the funder might hold the University accountable. Include a short reflection on the risks that might arise from the funder. Research without any clear ethical basis and / or objectives should not be undertaken.

The funder might undertake some of the risk. It is important to remember that ethical clearance given by SU does not extend beyond SU. The researcher should ensure, as far as possible, that the role that the funder plays in the research is ethical.

Include here any steps that will be taken to mitigate risk. For example, should counselling be made available to the participants subsequent to the research, it should be stated in this section together with the details of the counsellor.

Limitations of research

All research includes limitations. Frequently, awareness of the limitations only arise through the process of research. As such they are more applicable at the delivery stage. If any limitations can be identified at the stage of ethical clearance application, they should be included here and reported to the funder.

In commissioned research the focus could rather be on delimitation, in other words, that the expectations of what will be included and what will be excluded be clearly set out. It may also be advisable to state our assumptions, and / or promises, of cooperation by the funder.

[64] For example, if the commissioned research is to "prove the efficacy of the intervention".

The underlying contract, and how it deals with mutual expectations, should form an important anchor in addressing the ethics of commissioned research.

Reporting of results

Commissioned research could be confidential, and only shared with the funder. In other cases, it could be embargoed, or it would be intended for publication in academic journals. Include details of where and when the results would be reported in this section.

Permissions

When research is done within an organization, permission for that research must be obtained. In the case of commissioned research, where the research is done within the funding organization, that permission is implicit in the commission. The ethical application should include proof of this, which could be the Terms of Reference or the contract. Where the commissioned research is done outside of the funding organization, the usual organizational permission requirements apply.

Timelines

In the contract or tender document, it is advisable that the research include a statement that the execution of the research is contingent on gaining ethical approval.

Commissioned research often works with tight deadlines. It is advisable for the researcher to consult with a member of the DESC or REC on the construction of the application to ensure that the review process is as smooth and speedy as possible. The ethical process can be done concurrently with the tender process to expedite the process.

Useful documents

Stellenbosch University, 2013. Policy for responsible research conducted at Stellenbosch University. http://www.sun.ac.za/english/research-innovation/Research-Development/Documents/Policies%20and%20Guidelines/ENGLISH/SU%20Research%20Ethics%20policy%20approved%20by%20Council_24%20June%202013.pdf

REC Humanities Templates and Guidelines: http://www.sun.ac.za/english/research-innovation/Research-Development/Pages/REC-Documents.aspx

ADDENDUM 3: Division for Information Governance memo on lucky draws and competitions as inducements

Lucky draw competitions as a means to induce participation in research.
23 July 2018
Compiled by: Ms Jerusha Naidoo (Division for Information Governance)

Background:

A trend amongst researchers is to engage with research participants and as a method of reward in some instances offer "entrance" into a competition (lucky draw) to win a prize, some prizes offered have been opportunity to win in some instances: an iPad; Takealot vouchers; a day at a spa etc. This brings the following questions to the fore:

1. Are such competitions legally permissible in terms of the Consumer Protection Act?
2. Value totals of the prizes are inconsistent, e.g. A voucher of R5000 versus a R500 voucher or less which cannot be exchanged for cash. Is there a reasonable standard in terms of law?
3. On whom is liability imposed if no prize is awarded or if nepotism occurs? In other words, whom is the risk owner?
4. Are there checks and balances in place?
5. What is the proposed solution?

Legislative Guidelines:

The Consumer Protection Act, Act 68 of 2008 is applicable to every transaction occurring within the Republic unless it is exempted. An argument can be made that the opportunity to be entered into a draw falls outside the scope of the Act as the research participant is not a consumer, no consideration is paid for the supply of goods or services no consumer agreement was reached and no transaction occurred. It appears that a lucky draw may also fall outside the scope of the Lotteries Act, Act 57 of 1997.

Section 36 of The Consumer Protection Act read with The Consumer Protection Act Regulations published under GN R293 in GG34180 of 1 April 2011 contain in Regulation 11 some interesting departure points for consideration bearing in mind that Regulation 11 deals with promotional competitions from a consumer protection perspective.

The person who conducts a promotional competition must for a period of at least three years, retain:

- full details of the promoter, including identity or registration numbers, addresses and contact numbers;
- the rules of the promotional competition;
- a copy of the offer to participate in a promotional competition;
- the names and identity numbers of the persons responsible for conducting the promotional competition;
- a full list of all the prizes offered in the promotional competition; a representative selection of materials marketing the promotional competition or an electronic copy thereof, but such copy must be easily accessible in a generally available format;
- a list of all instances when the promotional competition was marketed, including details on the dates, the medium used and places where the marketing took place;
- the names and identity numbers of the persons responsible for conducting the selection of prize winners in the promotional competition;
- an acknowledgment of receipt of the prize signed by the prize winner, or legal guardian where applicable, and his or her identity number, and the date of receipt of the prize, or where this is not possible, proof by the promoter that the prize was sent by post or other electronic means to the winner using his or her provided details;
- declarations by the persons responsible for conducting the competition made under oath or affirmation that the prize winners were to their best knowledge not directors, members, partners, employees, agents or consultants of or any other person who directly or indirectly controls or is controlled by the promoter or marketing service providers in respect of the promotional competition, or the spouses, life partners, business partners or immediate family members;
- the basis on which the prize winners were determined;
- the summary describing the proceedings to determine the winners, including the names of the persons participating in determining the prize winners, the date and place where that determination took place and whether those proceedings were open to the general public; whether an independent person oversaw the determination of the prize winners, and his or her name and identity number; the means by which the prize winners were announced and the frequency thereof;
- a list of the names and identity numbers of the prize winners;
- a list of the dates when the prizes were handed over or paid to the prize winners;
- in the event that a prize winner could not be contacted, the steps taken by the promoter to contact the winner or otherwise inform the winner of his or her winning a prize; and
- in the event that a prize winner did not receive or accept his or her prize, the reason for his or her not so receiving or accepting the prize, and the steps taken by the promoter to hand over or pay the prize to that prize winner.

A person must not directly or indirectly inform another person that a participant has won a

competition, if:

- no competition has in fact been conducted;
- the person has not in fact won the competition;
- the prize for that competition is subject to a previously undisclosed condition; or
- the person is required to offer further consideration for the prize, after the results of the competition have been announced.

Some important definitions for consideration are:

"participant" means a person who enters, competes in or is otherwise eligible to win a promotional competition;

"prize" includes a reward, gift, free good or service, price reduction or concession, enhancement of quantity or quality of goods or services, or other discounted or free thing;

"promoter" means a person who directly or indirectly promotes, sponsors, organises or conducts a promotional competition, or for whose benefit such a competition is promoted, sponsored, organised or conducted; and

"promotional competition" means any competition, game, scheme, arrangement, system, plan or device for distributing prizes by lot or chance if it is conducted in the ordinary course of business for the purpose of promoting a producer, distributor, supplier, or association of any such persons, or the sale of any goods or services; and any prize offered exceeds the threshold prescribed by the Minister irrespective of whether a participant is required to demonstrate any skill or ability before being awarded a prize.

If Guidelines are adopted strictly in line with the above, then the Primary Investigator will have to fully comply to requirements set out in the Promotion of Access to Information Act ("PAIA"), Act 2 of 2000 as well as the Protection of Personal Information Act, Act 4 of 2013.

Application of law to the facts:

1. Are such competitions legally permissible in terms of the Consumer Protection Act?

Argument can be made that the scope of research competitions falls outside the scope of the Act.

2. Value totals of the prizes are inconsistent, e.g. A voucher of R5000 versus a R500 voucher or less which cannot be exchanged for cash. Is there a reasonable standard in terms of law?

Currently, there does not appear to be a standard in terms of the law. According to Ethics in Health Research Guideline which states that, "Inducements encourage participation. They may be offered in some circumstances where e.g. recruitment,

especially of healthy participants, is anticipated to be difficult. However, a justification for this tactic should be provided and the inducement should not unduly influence an informed choice about participation. In particular, an inducement should not undermine a potential participant's assessment of risk of harm. All inducements should be clearly explained and justified to the REC. Input from community members on the REC or other role players may be constructive".[65]

3. On whom is liability imposed if no prize is awarded or if nepotism occurs? In other words, whom is the risk owner?

It is idealistic to envision that a perceived wrong party would hold only the Primary Investigator responsible and not join the Institution in a civil action, alternatively publish details on social media or report the matter to newspapers locally or nationally. Denny argues that there is no withdrawal of existing benefit, that there was "hope" in that a benefit may be acquired and that only in the instances of withdrawing an existing benefit or a right can legitimate expectation be argued.[66]

4. Are there checks and balances in place?

Currently, no checks and balances are in place to ensure that if a prize is awarded that the process and outcome was conducted in a fair manner. It is unclear whether there are resources available to conduct such checks.

5. What is the proposed solution?

Further investigation is required from the various RECs to determine risk exposure and mitigating steps into place which will not deter from ethical research gathering practices.

[65] Ethics in Health Research published on 1 March 2015.

[66] Denny A, [2003] "Procedural Fairness in Competitions", Judicial Review 8 p228.