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Standard Operating Procedure

Research Ethics Committee:
Human Research (Humanities)

Implementation date: 1 January 2012

The Secretary of the Research Ethics Committee (Human Research: Humanities) is seated in the Division for Research Development, Stellenbosch University.

Currently, the Secretary is Mr. Sidney Engelbrecht.

Please contact him for any queries about application forms, submissions, and any matter related to the results of ethics reviews of applications (including any responses of the researcher to the review).

His contact details are: E-mail: sidney@sun.ac.za
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The Research Ethics Committee (REC) normally meets on the last Thursday of every month, except in December and June. The deadlines for submissions are published on the website of the Division for Research Development, and are normally about 14 days before the meeting of the REC.

Words/concepts that are underlined and indicated with an asterisk are defined in the Glossary.
This Standard Operational Procedure (SOP) is currently written in English. As soon as it is finalized, it will also be made available in Afrikaans.

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1. OBJECTIVE

The overarching objective of this Standard Operating Procedure (SOP) is to promote and ensure a culture of ethically responsible research at Stellenbosch University in the social, behavioural, economic and educational sciences, in short the Humanities.

The specific objective of this SOP is to contribute to the promotion of quality and consistency in reviewing the ethical aspects related to social, behavioural, economic and educational research conducted at Stellenbosch University.

2. THE PURPOSE OF THE RESEARCH ETHICS COMMITTEE: HUMAN RESEARCH (HUMANITIES)

The purpose of this Research Ethics Committee (REC) in reviewing research is to contribute to safeguarding the dignity, rights, safety, and well-being of all actual or potential participants in social, behavioural, economic and educational research conducted at Stellenbosch University, balancing it with the innately intrusive nature of scientific research.

The Research Ethics Committee provides independent, competent, and timely reviews of the ethical risks related to research proposals, and can recommend measures aimed at avoiding or minimizing these risks – acknowledging that the ethical dimensions of research can never be fully separated from the scientific dimensions of research (that include, amongst others, methodological, theoretical and institutional aspects). The Research Ethics Committee can also require that certain measures be taken by the researcher to minimise or avoid potential ethical risks.

The Research Ethics Committee is responsible for carrying out the review of proposed research before the commencement of the research, and to ensure that there is regular monitoring and evaluation of the ethical risks related to on-going studies that received a positive decision from the Research Ethics Committee – particularly in research that entail high ethical risk*. The responsibility to submit research proposals with medium and high ethical risks* to the Research Ethics Committee for review lies with the individual researcher, the academic department(s) and faculties within which this research will be conducted.

The Research Ethics Committee is responsible for acting in the full interest of potential research participants and affected communities, taking into account the interests and needs of the researchers, and having due regard for the requirements of applicable professional bodies and academic societies, relevant regulatory agencies, applicable laws, and relevant institutional requirements.

The Research Ethics Committee will maintain a record of all the research proposals and protocols that have been considered in ethical terms, including those:

- approved by ethics committees of other institutions that were submitted to the Research Ethics Committee for commentary, ratification or endorsement;

- subjected to the process of departmental or faculty screening, as described below in Sections 7.3.1.1 and 12.

The Research Ethics Committee may create processes on departmental or faculty levels to screen research proposals with a view to differentiate between low, medium or high ethical risk research, but retains the overall responsibility and accountability for the ethics review process. As will be stipulated below in more detail, those involved in departmental or faculty processes will be informed about the importance of their tasks, and they will be furnished with standardised documentation, and where appropriate, with training to ensure conformity and high standards in the execution of their tasks.

3. SCOPE OF THE RESEARCH ETHICS COMMITTEE

Research proposals of Stellenbosch University researchers that contain medium or high ethical risks* related to its impact on human subjects, organisations, institutions, and communities, or any other ethical risk as is stipulated in the Framework Policy for the Assurance and Promotion of Ethically Accountable Research at Stellenbosch University, will be reviewed by the Research Ethics Committee.

Research proposals will be subjected to a screening process on departmental or faculty level, and the documentation related to this screening process, must be submitted to the Secretariat of the Research Ethics Committee for the purposes of monitoring and filing, as stipulated in Section 12 below.

Any research involving students, staff or alumni of Stellenbosch University must also be submitted for review by the Research Ethics Committee, irrespective of the level of ethical risk involved.

When reviewing research proposals, special attention will be given to research that includes certain individuals or categories of participants who may be vulnerable* to undue influence, e.g. the poor and the marginalised, pregnant women, children, people with disabilities, people in prison, refugees, the elderly, people in hospital, people attending a clinic, etc.

Health research* is generally excluded from the scope of this Research Ethics Committee. Health research is reviewed by the Research Ethics Committee (Human Research: Health).

The responsibility to submit research proposals with ethical risks of a medium or high level to the Research Ethics Committee lies with the researcher, supervisor and departmental chair, and where relevant, the faculty in which the research originates.

4. RESPONSIBILITIES OF THE RESEARCHER

The responsibility to conduct ethically responsible research lies in the first place with the researcher, supervisor and departmental chair. The Research Ethics Committee does not assume this responsibility.

In particular, researchers are required to develop an ethical orientation and internalisation of ethical principles and practices in research, rather than defer this responsibility to the Research Ethics Committee. This internalised ethical orientation should guide the researcher in every step of the research, instead of following a mechanistic, checklist or blueprint approach to the ethics of research.

In addition, researchers are required to familiarise themselves with the ethical codes, guidelines and practices appropriate to their disciplines or fields of study.

Researchers are furthermore alerted to the need to act ethically throughout the research process, and not assume that their responsibility has been fulfilled by a once-off ethics review. The technical processes to ensure compliance with the requirements of the Research Ethics Committee should not be a substitute for the scrutiny of questions of ethical practice that can emerge during any stage of the research process.

Researchers should note that complex and often unanticipated issues related to ethically responsible research may emerge during the course of research in contested, highly diverse and fluid situations, and that there are seldom straightforward ethical guidelines that the researcher can refer to in order to determine what the "right thing" is to do under such circumstances. Researchers should also note that uncertainty may exist about ethical risk in research, and that the nature or levels of risk can change during the research process, something that is often not predictable at the onset of the research.

However, the expertise and experience of the Research Ethics Committee are always available to researchers as a sounding board to help think through any uncertainty related to an ethical matter that may emerge during the course of research with a view to arrive at an appropriate response.

Where institutional permission is a strict requirement, for example from a Provincial Department of Education when research is done in a provincial school, or a Provincial Department of Health when research is done at a provincial clinic or hospital, it is expected that researchers apply for this permission in a timely fashion prior to applying for ethical clearance, so as not to delay the review process, and thus the research itself. Where these strict institutional requirements are in place, the Research Ethics Committee cannot approve a research proposal if this institutional permission is still outstanding. This clearly does not apply to research done on public institutions where the information that will be accessed is readily available in the public domain*. However, the

requirement of institutional permission does apply in cases where private records or archives have to be accessed for research purposes. In these cases, the explicit permission of the curator of the archive, or the owner of the private records must be obtained.

Researchers should not obtain consent from prospective participants prior to applying for ethical clearance, since this denies the Research Ethics Committee an opportunity to comment on the material and information that will be conveyed in the informed consent process. Rather provide the Research Ethics Committee with an example of the material that will be used to obtain and record informed consent. While it is not an absolute requirement to make use of the Stellenbosch University template for informed consent, any more informal information sheet and consent form must convey the substantive content of the Stellenbosch University template for informed consent.

Furthermore, researchers must make sure to use the latest versions of documents and forms available on the website of the Division for Research Development.

Researchers must indicate in a note to the Research Ethics Committee for exactly what they wish to obtain ethics clearance.

5. CONSTITUTING THE RESEARCH ETHICS COMMITTEE

The Research Ethics Committee has been constituted in terms of the Framework Policy for the Assurance and Promotion of Ethically Accountable Research at Stellenbosch University that was adopted by Senate on 20 March 2009.

In executing its duties the Research Ethics Committee and its sub-committees will ensure that it is free from bias and influence that could affect its independence. In its structure and functioning, and in the execution of its duties, the Research Ethics Committee and its sub-committees will follow the principles and guidelines stipulated in:

- The Framework Policy for the Assurance and Promotion of Ethically Accountable Research at Stellenbosch University that was adopted by Senate on 20 March 2009
- The National Health Research Ethics Council in so far as it is relevant to research in the social sciences and humanities
- The provisions of the National Health Act, no 61 (2003) and its amendments in so far as they are relevant to research in the social sciences and humanities
- Any relevant legislation, regulations and guidelines, including international guidelines and standards in so far as they are applicable to research in the social sciences and humanities
- Official documents of professional bodies and scientific organisations, in so far as they are relevant to research in the social sciences and humanities.

5.1 COMPOSITION

5.1.1 Research Ethics Committee

- The Research Ethics Committee consists of the following members:
  - At least two representatives of the Faculty of Arts and Social Sciences
  - At least two representatives of the Faculty of Economic and Management Sciences
  - At least two representatives of the Faculty of Education
  - At least one representatives of the Faculty of Law (which should be a person with a degree in law)
  - At least one representative of the Faculty of Theology
  - At least one representative of the Faculty of Military Sciences
  - Two representatives of the broader community who are not staff members of SU
  - At least one person with competence in providing care to people (which may be one of the persons listed above)
  - A representative of the Division for Research Development
- After consultation with the respective Faculties, the representatives of faculties are appointed to the Research Ethics Committee by the respective Deans of the Faculties
- The representatives of the broader community are appointed by the Senior Director: Research of Stellenbosch University, taking into account that it may be difficult to determine what "the broader community" is, or who may be a "representative" of it
- In certain cases, the Research Ethics Committee may require researchers to help 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 period of three years, subject to consultation with the respective Faculties by the respective Deans
- Members of the Research Ethics Committee can be appointed for more than one period of three years, subject to consultation with the respective Faculties by the respective Deans
- The Research Ethics Committee must be representative of the research communities it serves and, increasingly, reflect the demographic profile of the population of South Africa
- The Research Ethics Committee must include members of both genders, although not more than 70% should be either male or female
- The Research Ethics Committee must have at least nine members, including the Chairperson with 50% plus one constituting a quorum [The NHREC currently stipulates that 60% of the members constitute a quorum, but this is expected to change soon to coincide with what is reflected here.]
- 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.

5.1.2 Research Ethics Screening Sub-committees

- The Screening Sub-committee has two functions:
    - To prepare review reports for discussion at the Research Ethics Committee meetings
    - To assist the Chairperson with the process of expedited reviews
- The Screening Sub-committee will consist of at least two members of the Research Ethics Committee
- Appointment of the members of the Screening Sub-committee is done on an ad hoc basis to make provision for the screening of a particular research proposal
- Appointment of the members of the Screening Sub-committee will be at the discretion of the Chairperson of the Research Ethics Committee
- The Chairperson of the Research Ethics Committee has the prerogative to appoint any additional person to the Screening Sub-committee that he/she deems necessary for the screening of a particular research proposal.

5.2 MEMBER PARTICIPATION

5.2.1 Appointment and functioning of members of the Research Ethics Committee

- The duration of appointment to the Research Ethics Committee will be three years
- Reappointment is subject to approval by the relevant Faculty, and a motivation for reappointment that is accepted by the relevant Faculty
- The Chairperson and Deputy-chairperson 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
- 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 any other member of the Research Ethics Committee, and must be in writing
- Upon appointment to the Research Ethics Committee, new members must sign applicable confidentiality agreements
- At each meeting of the Research Ethics Committee, and at each appointment of a Screening Sub-committee, members have to 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) – that will provide a Secretariat and archive to the Research Ethics Committee.

5.2.2 Independent consultants

The Research Ethics Committee may call upon independent 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.

5.3 ROLES AND RESPONSIBILITIES

5.3.1 Research Ethics Committee

- The Research Ethics Committee will function according to the set of Standard Operational Procedures (SOP) formulated in this document
- The Research Ethics Committee 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 under paragraph 7 of this SOP, and to monitor the implementation of these decisions
- 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 may review protocols for projects of other organisations that collaborate with Stellenbosch University
- 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)
- The Research Ethics Committee has to notify researchers in writing regarding their decisions.

5.3.2 Research Ethics Committee Screening Sub-committees

The Screening Sub-committees of the Research Ethics Committee:

- Provide initial written reports on research proposals for the consideration of the Research Ethics Committee

- Recommend to the Research Ethics Committee when research proposals should be subjected to a full review (which is a review conducted by all of the members of the Research Ethics Committee at a meeting of the Research Ethics Committee)
- Assist the Chairperson in the process of expedited reviews.

6. APPLICATION REQUIREMENTS FOR RESEARCH ETHICS COMMITTEE REVIEW

Requirements for submitting an application to the Research Ethics Committee are available to prospective applicants on the website of the Division for Research Development, and include the following aspects:

6.1 DOCUMENTATION REQUIRED

If the Departmental Ethics Screening Committee (DESC) (see Sections 7.3.1.1 and 12, as well as Addendum 2) has referred an application to the Research Ethics Committee for review, the following documentation is required:

- A fully completed Application Form, dated and signed by the researcher, supervisor (if applicable) and departmental chair (available on the website of the Division for Research Development)
- An approved research proposal (clearly identified and dated, with an indication who approved it), together with supporting documents and annexes
- The Application Form should include:
    - A summary (as far as possible in non-technical language), synopsis, or diagrammatic representation ('flowchart') of the research process (i.e. a description of who will do what, when, where, how and for how long, to obtain data from whom)
    - A description (usually also included in the proposal) of the ethical considerations involved in the research, and the measures that are proposed to avoid or minimize any ethical risks that have been identified at the outset of the research
    - Interview schedules, questionnaires and observation schedules intended for research participants and, when required, should be translated into other languages relevant to the research
    - When translations into other languages than Afrikaans and English are to be used, convincing evidence that the translation is an accurate and complete representation of the original document is required. (This evidence can include a statement by a certified language practitioner or equivalent.)
- The curriculum vitae (signed, and dated) of any of the investigators conducting the research should be submitted on request of the Research Ethics Committee
- An overview of the process that will be used to recruit potential participants, when applicable (i.e. how, where and by whom will prospective participants be approached?)
- Material to be used (including advertisements) for the recruitment of potential research participants, when applicable

- A description of the process to be used to obtain and document free and informed consent (required when human research participants, institutions or organisations are involved), taking into account that:
    - 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 alert the Research Ethics Committee about the process of consent that is appropriate to, and will be followed in the research that is submitted for review. The stipulations below should therefore be used when applicable
    - Separate documents in appropriate language should be submitted for the consent of adults, and the assent of minors (under 18 years or age) to participate in research
    - This includes examples of the letter in which parents/guardians are asked to give permission by name for their children to participate in research (where applicable)
    - This includes examples of letters in which permission for access to participants is asked from relevant authorities, for example a Provincial Education Department, the principal of a school, a Provincial Health Department, the head of a hospital or a clinic, etc. – except in cases of accountability research*, in which case the nature of the research and the reason to waive this requirement are pointed out to the Research Ethics Committee
    - This includes a list of all of the authorities or institutions from which permission for the research will have to be obtained – particularly in cases where these permissions are not available at the time of the application, but have been requested, or will be obtained on an on-going basis during the research
    - The relevant letters of institutional or organisational permission where they already have been acquired must be submitted with the application. These letters of permission must be on an official letter head which is current and duly signed. Otherwise, it must be indicated clearly that these letters of institutional or organisational permission have been requested and will be submitted to the Research Ethics Committee as soon as they are available
- Written and other forms of information for potential research participants (clearly identified and dated) in the language(s) understood by the potential research participants and, when relevant, in other languages
- Informed Consent Form[1] (clearly identified and dated) in the language(s) appropriate to the potential research participants and, when relevant, in other languages

[1] Usually the Stellenbosch University template for Informed Consent, available on the website of the Division for Research Development is used for this purpose. However, more informal Informed Consent Forms or Information Sheets can be used if the prospective participants require it. In such cases, however, all of the information of the template must be reflected with a view to ensure that prospective participants are adequately informed about the nature of the research, the undertakings provided to safeguard their rights as participants, enabling them to make an informed choice whether to participate in the research or not.

- A statement describing any compensation for participation in the research (including expenses and access to medical, psychological or other care/support) to be given to research participants, when applicable
- A description of the arrangements for indemnity of researchers or support staff, when applicable
- A description of the arrangements for insurance coverage for research participants, when applicable
- A statement of agreement to comply with ethical principles set out in relevant guidelines (provided at the end of the application form for the principal investigator; if other researchers or research assistants are involved, separate declarations should be submitted for each one)
- All significant previous decisions about the proposed study (e.g., those leading to a negative decision or modified protocols*) by other Research Ethics Committees or regulatory authorities (whether at Stellenbosch University, in South Africa, or elsewhere) and an indication of modification(s) to the protocol made on that account. The reasons for previous negative decisions should be provided, if applicable.
- Financial contracts and payment of researchers must be declared, if applicable.
- In the case of contract research, a copy of the relevant sections pertaining to ethical matters, as well as a confirmation of the contract number as approved by the Division for Intellectual Property of Stellenbosch University and INNOVUS
- A statement, duly dated and signed, by a departmental or faculty research committee that the research proposal is scientifically sound and has been approved
- In cases where students, staff or alumni of Stellenbosch University will be participating in the research, a statement that an application for institutional permission has been, or will be submitted to the Senior Director: Institutional Research and Planning of Stellenbosch University
- A description of the arrangements to ensure confidentiality of research data during the research process, as well as in reporting on it
- A description of the arrangements to ensure that there will be no unauthorised access to research data (how will the data be kept safe?)
- A description of what will happen to the data after completion of the research (will it be destroyed; will it be entered into a data base; will it be entered into an archive?).

6.2 SUBMISSION AND PROCESSING OF APPLICATIONS

The following guidelines apply to the submission and processing of applications:

- An application for review of the ethics of proposed research should be submitted by a qualified researcher, or a researcher in training supported by a qualified supervisor responsible for the ethical and scientific conduct of the research
- The application must be approved by the relevant departmental chair
- The proposal must be submitted in hard copy format – until such time that a system for the electronic submission of applications is in place
- The proposal can be submitted in Afrikaans or English

- The application form has to be completed in full, and must be signed by all relevant parties (usually the researcher, supervisor, and Departmental Chair)
- The submission must reach the Secretariat 14 days before the next meeting date of the Research Ethics Committee
- The meeting dates of the Research Ethics Committee will be published on the website of the Division for Research Development
- Receipt of the application will be acknowledged by the Secretariat within one working day
- Researchers will be notified in writing about the outcome of the evaluation of the protocol, usually within 14 days after the regular meeting of the Research Ethics Committee has taken place
- The procedure and requirements for any amendments required to the research proposal/protocol, the recruitment material, the potential research participant information, or the consent form will be made available in writing to the applicant(s)
- Any amendments that should be effected by the researcher should be submitted to the Research Ethics Committee as soon as possible, but normally within 30 days, so as not to unduly delay the review process as well as the research process
- The responses from researchers to the Research Ethics Committee will normally be processed within 14 days of receipt.

7. RESEARCH ETHICS COMMITTEE FULL REVIEW

7.1 MEETINGS

- Meetings will be scheduled to be held on a monthly basis, unless decided otherwise by the Chair of the Research Ethics Committee
- At the last meeting of the current year members will be notified of the scheduled dates of meetings for the following year
- The meetings of the Research Ethics Committee will be minuted
- Minutes of meetings will be included in the agenda of the next meeting of the Research Ethics Committee for approval and to deal with matters arising
- Minutes of meetings will be circulated to members within 14 days after the meeting.
- The agenda and documentation for scheduled meetings will be circulated to members at least 7 days prior to the meeting.

7.2 ATTENDANCE OF RESEARCHERS

The researcher, supervisor or Head/Chair of Department may be invited to present the research proposal or elaborate on specific issues at a meeting of the Research Ethics Committee or, if applicable, at a special meeting of the RESEARCH ETHICS COMMITTEE, or at a meeting of the Research Ethics Screening Sub-committee.

7.3 ELEMENTS OF THE REVIEW

7.3.1 Review process

7.3.1.1 The screening of research proposals in departments

See also Section 12 of this SOP

Screening of research proposals with a view to differentiate between research with minimal,* low,* medium* and high ethical risk* takes place within the context of departments and faculties.

The screening process is initiated by the researcher that completes the Departmental Ethics Checklist (see Addendum 2) and submits it to the Departmental Chair for further processing.

Departments are required to appoint an ad-hoc Departmental Ethics Screening Committee (DESC) for each research proposal consisting of the Chair of the department and at least one other member of the department (or a colleague from a cognate department) not directly involved with the supervision or the conceptualization of the research proposal, with a view to make a joint decision about the research proposal. (The same process can be replicated on faculty level where a Vice-Dean can take the responsibility of the Departmental Chair as described above. In cases where the departmental chair or the Vice Dean is directly involved with the research, another member of the department or faculty should stand in for him/her, following the usual procedures within departments of faculties to address conflicts of interest.)

It is the responsibility of departments and faculties to submit all research with medium and high ethical risk to the Research Ethics Committee for review, and to ensure that the documentation related to the screening of research with low ethical risk is adequately processed to comply with the principles and guidelines applicable to ethically responsible research, and submitted to the Secretariat of the Research Ethics Committee for the purpose of monitoring and filing.

Departments are required to keep the final records of the screening process and the outcomes of it for auditing purposes. Records must be kept for at least 10 years.

7.3.1.2 Review by the Research Ethics Screening Sub-Committee

The primary task of the Research Ethics Screening Sub-Committee lies in the preliminary review of research proposals linked with medium or high ethical risk.

7.3.1.3 Review by the Research Ethics Committee

The primary task of the Research Ethics Committee lies in the review of research proposals with medium and high ethical risk. In this review, the Application Form and research proposal, as well as all supporting documents are considered, with special attention given to the recruitment of potential participants, the status and characteristics of participants (e.g. whether they are vulnerable or not), the informed consent process, documentation provided to research participants, and the suitability and feasibility of the research protocol. The Research Ethics Committee takes into account prior scientific reviews, if any, guidelines provided by professional bodies and scientific organizations, as well as the requirements of applicable laws and regulations. The following is considered in particular in the ethics review, as applicable:

- Scientific design and conduct of the study
- Approval of the scientific design and scientific validity of the research proposal by the relevant department, centre or faculty, prior to submission to the Research Ethics Committee
- The risk-benefit profile of the proposed research
- The normative evaluation criteria that are specific to the ethical dimensions of research in the social sciences and humanities
- Criteria for withdrawing research participants before completion of the research
- The measures of support provided to participants if they need it during or after the research
- Criteria for suspending or terminating the research in its entirety
- The adequacy of provisions made for monitoring and auditing the conduct of the research, including considerations related to data safety, and what happens to the data upon completion of the research
- The adequacy of the research site (when applicable), including the supporting staff, available facilities, and emergency procedures
- The manner in which the results of the research will be reported and published.

7.3.2 Recruitment of Research Participants

In the assessment of the recruitment of research participants the following will be considered, as applicable:

- The characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, and ethnicity). Special attention will be given to vulnerable individuals and groups*
- The means by which initial contact and recruitment is to be conducted
- The means by which full information about research aims and procedures is to be conveyed to potential research participants or their representatives
- Inclusion criteria for research participants
- Exclusion criteria for research participants.

7.3.3 Care and Protection of Research Participants

The following will be considered with respect to the protection of research participants, as applicable, taking into account that a wide variety of types of research are conducted within the humanities:

- The suitability of the investigator(s)'s qualifications and experience for the proposed study
- 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
- The adequacy of supervision of researchers in training
- Steps to be taken if research participants voluntarily withdraw during the course of the research
- Steps to be taken if research participants withdraw from the study because of an adverse event*
- Steps to be taken if researchers have to 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.

7.3.4 Protection of Research Participant Confidentiality

The following will be considered with respect to the protection of research participant confidentiality, as applicable:

- A description of the persons who will have access to personal data of the research participants [including medical records and biological data, or 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).

7.3.5 Informed Consent Process

The following will be considered with respect to the informed consent process, as applicable:

- 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 course of 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 the course of 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.

7.3.6 Institutional permission

The following will be considered with respect to obtaining institutional permission:

- 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 institutional 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

7.3.7 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, 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
- The relationship between researchers and 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.

7.4 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
- Proposed community consultation during the course of the research
- 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.

8. DECISION-MAKING WITHIN THE RESEARCH ETHICS COMMITTEE

8.1 Research Ethics Committee Process

In making decisions on applications for the ethics review of research, the Research Ethics Committee will make use of the following procedures and considerations:

- A member should withdraw from the meeting for the decision procedure concerning an application where there arises a conflict of interest. The conflict of interest should be indicated to the Chairperson prior to the review of the application and recorded in the minutes
- The principal investigator and/or supervisor and/or departmental chair may be allowed to present the research proposal/protocol to the Research Ethics Committee after which the Research Ethics Committee will discuss the research proposal/protocol in the absence of the aforementioned
- Decisions should only be made at meetings where a quorum is present
- The documents required for a full review of the application should be complete and the relevant elements mentioned above (see Section 6 and 7) should be considered before a decision is made.
- Decisions at meetings of the Research Ethics Committee are arrived at through consensus, where possible. When a consensus appears unlikely, it is recommended that the Research Ethics Committee vote. If there is a stay of votes, the Chairperson of the Research Ethics Committee can cast a deciding vote
- Advice that is non-binding may be appended to the decision of the Research Ethics Committee

- In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified
- A negative decision on an application must be supported by clearly stated reasons and suggestions to amend the application and/or supporting documents
- An approval is only valid for one year from the date of the clearance letter. If a research project stretches over more than one year, it is the responsibility of the researcher to apply for an extension of the approval before the validity of the approval has lapsed. If there are no fundamental changes to the research project, this application can be in the format of a short letter, supported by a short report on the ethical aspects of the research, stating whether any new or unforeseen ethical issues were encountered during the previous year, and how they were addressed. If there are substantive changes to the research project, a full application will have to be submitted again.

8.2 **Decisions that the Research Ethics Committee can make, include:**

The Research Ethics Committee can make the following decisions, including but not limited to:

- The approval of a research proposal
- Approval with stipulations
- Modifications required before approval (without the need for the response to come back to the full research ethics committee)
- Deferred (major modifications are required that must be discussed again by the Research Ethics Committee)
- Rejected.

In addition to the above, the Research Ethics Committee can, after due consideration and consultation, take the following actions, including but not limited to:

- Monitor research
- Inspect a research site
- Request an immediate report on the ethical aspects of a research project
- Temporarily suspend a research project
- Suspend a research project
- Investigate a case of a breach of ethics in research.

9. COMMUNICATING A DECISION

The decision of the Research Ethics Committee after reviewing an application will be communicated in writing to the applicant, normally within 14 days of the 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 exact title of the research proposal reviewed

- The clear identification of the research proposal/protocol of the proposed research or amendment, date and version number (if applicable) on which the decision is based
- The names and (where possible) specific identification numbers (version numbers/dates) of the documents reviewed, including the potential Research Participant Information Sheet/material and Consent Form
- The name and title of the applicant
- The name of the site(s) at which the research will be conducted
- The date and place of the decision
- The name of the Research Ethics Committee
- A clear statement of the decision reached
- Any advice by the Research Ethics Committee
- In the case of a conditional decision, any requirements by the Research Ethics Committee, including suggestions for revision and the procedure for having the application re-reviewed
- In the case of a positive decision, 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 protocol amendments (other than amendments involving only logistical or administrative aspects of the study); the need to notify the Research Ethics Committee in the case of amendments to the recruitment material, the potential research participant information sheet, the Consent Form; the need to report serious and unexpected adverse events related to the conduct of the study; the need to report unforeseen circumstances, for example the 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
- In the case of a negative decision, clearly stated reason(s) for the negative decision
- Signature (dated) of the Chairperson (or other authorised person) of the Research Ethics Committee.

10. MONITORING OF RESEARCH IN PROGRESS

The Research Ethics Committee can establish a monitoring procedure for following the progress of all studies for which a positive decision has been reached, from the time the decision was taken until the finalisation of the research. This will apply in particular to cases of high ethical risk 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

11. EXPEDITED REVIEWS

As an extraordinary measure, applications for ethics review can be processed following an expedited review procedure.

All applications for an expedited review must be thoroughly motivated in writing by the researcher or supervisor, and approved by the Departmental Chair (or his/her representative). Where an academic department is not involved in the research, a Dean, a Vice Dean or an appropriate Director of SU can motivate the application for an expedited review.

The expedited review process entails the following:

- The application is screened by a Screening Sub-committee, whose review report is submitted to the Chair of the Research Ethics Committee
- The Chairperson of the Research Ethics Committee approves the review report of the Screening Sub-committee and issues an instruction to the Secretariat of the Research

Ethics Committee to issue a clearance letter, subject to any amendments or requirements that in his/her view should be added to the review report

- The Review Report and the decision of the Research Ethics Committee about the expedited review are ratified at the next regular meeting of the Research Ethics Committee
- The researcher may continue with the research upon receipt of the clearance letter while awaiting the ratification of the expedited review
- If any changes to the decision of the Chairperson are made at the ratification of an expedited review, the researcher, supervisor and departmental chair will immediately be informed
- Normally an expedited review will not take longer than seven calendar days to complete.

12. SCREENING ON DEPARTMENTAL LEVEL

See also Section 7.3.1.1.

Researchers, supervisors and departmental chairs have the primary responsibility to ensure that research conducted in their respective disciplines is characterised by methodological rigour and complies with the guidelines of relevant professional bodies and scientific organizations, as well as relevant legislation, institutional, national and international ethics guidelines.

All research in which humans, institutions, organisations or communities/groups are involved, must be screened by Departments and/or Faculties following the procedures described below. In cases of research with minimal* or low ethical risk*, the assessment, decision, conditions and stipulations of the Department/Faculty must be recorded on the Departmental Ethics Checklist (see Addendum 2), a signed copy of which must be submitted to the Secretariat of the Research Ethics Committee. All research proposals posing medium or high ethical risk must be submitted to the Research Ethics Committee for review.

The Departmental and/or Faculty processes for the ethics screening of research proposals should be integrated with the process of approving research proposals in terms of their scientific integrity and rigour. This means that the Departmental Ethics Checklist for the ethics screening of a research project can be considered in the same process as the approval of the research proposal.

Besides assessing the ethical risk profile of the proposed research project as low, medium or high (see Glossary), the responsibility for ensuring that low ethical risk complies with the principles and guidelines of this document lies primarily within departments with researchers, supervisors and departmental chairs.

To record that all research proposals in which humans, institutions, organizations or communities/groups are involved, have been screened for ethical risks on Departmental and/or

Faculty level, the Departmental Ethics Checklist in Addendum 2 must be completed, and all of the documentation used, together with the Checklist, must be kept on record by the department for at least 10 years. In all cases, a copy of the completed Checklist must be sent to the Secretariat of the Research Ethics Committee.

The departmental chair, in consultation with at least one other independent member of that department (or one colleague from a cognate department) jointly forms the Departmental Ethics Screening Committee (DESC). The members of the DESC assess a research proposal and the Departmental Ethics Checklist with a view to determine the risk category of the proposed research, and to decide, in the case of minimal and low risk research, whether the measures are adequate to address any ethical risks, and in the case of medium or high ethical risk research, to submit an application for review to the Research Ethics Committee.

The second member of the DESC is appointed by the departmental chair, and can also be someone from a cognate department. When the departmental chair is involved with the research that is to be screened, his duties must be fulfilled by another member of the department (or a colleague from a cognate department).

The departmental chair can delegate his/her role as chair of the DESC to another senior staff member in the department – who is not also a member of the Research Ethics Committee. Departments are encouraged to spread membership of the DESC on a rotational basis across the members of the department.

The Research Ethics Committee reserves the right to inspect any of the check lists and/or documents submitted or kept on record by departments with regards to minimal and low ethical risk research, and to provide departments/faculties with feedback on it if necessary.

Training will be made available by the Division for Research Development on a regular basis to DESC members.

Process notes:

- All submissions to the Research Ethics Committee must be accompanied by a fully completed Departmental Ethics Checklist. The departmental screening process is where the ethics review process starts.
- When medium or high ethical risk research is referred to the Research Ethics Committee for review, it is important to share the DESC's assessment, experience and wisdom about avoiding or mitigating ethical risks with the Research Ethics Committee. Please record which ethical risks are related to the medium or high ethical risk research, and what should be done to avoid or mitigate these ethical risks on the last page of the Departmental Ethics Checklist, or on a

separate page, and indicate in a note to the Research Ethics Committee exactly for what ethics clearance is requested.

- Departments should have a short turn-around time in the processing of Departmental Ethics Checklists, following a time schedule that is well-coordinated with the submission of applications to the Research Ethics Committee.
- Departments are encouraged to involve researchers, supervisors and promotors in the deliberations and/or feedback of the DESC with a view to promote awareness, insight, and opportunities for the discussion of ethical issues related to research.

13. REVIEWS OF RESEARCH PROPOSALS OF RESEARCHERS NOT FROM STELLENBOSCH UNIVERSITY

The Research Ethics Committee can review research proposals of researchers that are not affiliated to Stellenbosch University, but working in partnership with Stellenbosch University, or wishing to obtain the inputs of the Research Ethics Committee about research that is done in or around Stellenbosch. In such cases, the Research Ethics Committee will take the following into consideration:

- The general point of departure is that research proposals should be reviewed at the institution where academic quality control will take place. A copy of all of the documentation, as well as the result of the review done by that institution should then be submitted to the Research Ethics Committee if a researcher not affiliated with Stellenbosch University wishes to obtain the commentary of the Research Ethics Committee.
- The Research Ethics Committee reserves the right to form its own opinion on the submissions received from a researcher not affiliated with Stellenbosch University.
- A researcher not affiliated with Stellenbosch University who wishes to do research on students, staff or alumni of Stellenbosch University, must obtain institutional permission for the research from the Senior Director: Institutional Research and Planning of Stellenbosch University, and submit a full application for ethics review to the Research Ethics Committee. A copy of all of the documentation, as well as the result of the ethics review done by the researcher's home institution should be submitted with the application, together with a note indicating exactly what ethics clearance is applied for. In cases where researchers do not have a system of ethics review, the researcher should supply a letter from a supervisor or departmental chair (or equivalent) stating that the research project is scientifically sound, and supported by the supervisor/departmental chair.

14. 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.

15. DOCUMENTATION AND ARCHIVING

The following guidelines will apply to the documentation and archiving of submissions and applications, and the decisions of the Research Ethics Committee:

- The Secretariat of the Research Ethics Committee, which resides in the SU Division for Research Development (DRD) office is responsible for all documentation with regard to submissions and applications, as well as the archiving of reports and decisions of the Research Ethics Committee
- All documentation and communications of the Research Ethics Committee will be dated, filed, and archived according to standard procedures applicable to the administration of Research Ethics Committees. These procedures are available in writing to researchers on the website of the DRD
- The documentation and archive of the Research Ethics Committee is administered and governed according to the standard procedures and policies of SU, as applicable
- Records of the Research Ethics Committee will normally be archived for a minimum period of 15 years following the completion of a review.

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

- The Research Ethics policy, written standard operating procedures of the Research Ethics Committee , and regular (annual) reports
- The published guidelines for submission established by the Research Ethics Committee

- The agendas of the Research Ethics Committee meetings
- The minutes of the Research Ethics Committee meetings
- One 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
- A copy of the decision and any advice or requirements sent to an applicant
- All written documentation received during the 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.

Expired Research Ethics Committee documents will be disposed of using the standard procedure of Stellenbosch University for the safe disposal of confidential documents. Expired DESC documents will be treated in the same manner.

16. REPORTING TO THE SENATE RESEARCH ETHICS COMMITTEE

The Research Ethics Committee submits, on a regular basis, a report to Senate Research Ethics Committee. The report could include, but are not limited to matters such as:

- The number and types of projects approved
- Details of studies monitored
- Details of studies not approved
- Adverse events
- Any complaints or grievances regarding research, or decisions of the Research Ethics Committee
- Any reports or press releases regarding studies that have been subjected to ethics review
- Administrative or other difficulties being experienced
- Requirements for staff training on research ethics, or details about such training
- Research Ethics Committee membership.

17. 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, after faculties have been given a reasonable time to comment on the Standard Operating Procedures.

Changes to this Standard Operating Procedure can be made at any ordinary meeting or workshop of the Research Ethics Committee, and any such changes must be approved by the Senate Research Ethics Committee, after faculties have been given a reasonable time to comment on these changes.

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.

18. AUDITING AND ACCREDITATION OF THE RESEARCH ETHICS COMMITTEE

The Research Ethics Committee is provisionally registered with the National Health Research Ethics Council (NHREC). Its registration number is REC 050411-032, and it will be regularly audited by the NHREC.

19. APPLICABLE DOCUMENTS

The list and examples of documents forming the basis of ethics review in the social sciences and humanities are available on the website of the Division for Research Development of Stellenbosch University.

19.1 REGULATORY FRAMEWORK

This Research Ethics Committee 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 educational sciences). Examples of relevant Acts, treaties and conventions include, but are not limited to:

- The Constitution of South Africa, Act 108 of 1996
- The Children's Act, Act 38 of 2005
- National Health Act, Act 61 of 2003
- Human Tissue Act, Act 65 of 1983
- Promotion of Access to Information Act, Act 2 of 2000

19.2 POLICIES AND GUIDELINES

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

- Framework Policy for the Assurance and Promotion of Ethically Accountable Research at Stellenbosch University that was adopted by Senate on 20 March 2009
- SU guideline document on scientific misconduct
- National Department of Health (DoH) (2004), *Ethics in Health Research: Principles, structures and processes*.

- Guidelines on Ethics for Medical Research: General Principles, Medical Research Council (MRC)
- The Universal Declaration of Human Rights (1948)

Furthermore, the RESEARCH ETHICS COMMITTEE 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**
  http://www.britsoc.co.uk/equality/Statement+Ethical+Practice.htm
  (March 2002, updated May 2004) (Sociology and Social Anthropology)

- **Ethical guidelines and principles of conduct for anthropologists**
  (*Anthropology Southern Africa.* 2005, 28(3&4):142-3) (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)

Faculties and Departments can add to this list on an ongoing basis.

20. REFERENCES

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

- CSIR Research Ethics Policy.
- CSIR Research Ethics Committee: Standard Operational Procedures.
- Department of Health, Education, and Welfare, Office of the Secretary, Protection of Human Subjects. *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Report of the National Committee for the Protection of Human Subjects of Biomedical and Behavioural Research*. DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014. 18 April 1979.
- National Department of Health (DoH) (2004), Ethics in Health Research: Principles, structures and processes.
- World Medical Association, *Declaration of Helsinki: Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects*. Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964. Amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975; the 35th World Medical Assembly, Venice, Italy, October 1983; the 41st World Medical Assembly, Hong Kong, September 1989; and the 48th General Assembly, Somerset West, Republic of South Africa, October 1996, Helsinki, August 2008.
- World Medical Association, *Declaration of Lisbon on the Rights of the Patient*. Adopted by the 34th World Medical Assembly, Lisbon, Portugal, September/October 1981 and amended by the 47th General Assembly, Bali, Indonesia, September 1995.
- *Operational Guidelines for Ethics Committees Reviewing Biomedical Research*, WHO Geneva 2000

21. GLOSSARY

Most entries in this Glossary have been taken over verbatimly 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.

Accountability research*

> Research about the accountability of politicians, government departments, public officials, professionals, professional bodies, organizations, institutions, corporations, companies, or the providers of services or goods.

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.

Ethical 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.

High risk (research)

Research in which there is foreseeable risk of harm and discomfort, which may lead to a serious adverse event, if not managed in a responsible manner.

*Elaborated in terms more appropriate to social research**

Research in which potential exists for a level of emotional or psychological distress and/or social stigmatisation, prosecution or persecution where there is a likelihood that harm could be done to the well-being of the participant even if due care is taken and mitigation is provided for. *(See Addendum 3 for a classification of risk types.)*

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.)*

Minimal risk

The probability or magnitude of harm or discomfort anticipated in the research is not greater in itself than that ordinarily encountered in daily life.

*Elaborated in terms more appropriate to social research**

Research involving the analysis of existing statistics, as well as literature, documents, databases and information in the public domain, for example in public libraries, public archives, on websites, newspapers, or newsletters. Any anticipated harm or discomfort to third parties related to this research is no greater than ordinarily encountered in daily life. *(See Addendum 3 for a classification of risk types.)*

No risk research*

See *Minimal risk*.

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." Wikipedia

REC reference number

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 Ethics (health)

Reviews invasive types of research, e.g. intervention studies collecting blood or tissue, drug trials, using surgical procedures or chart reviews involving biomedical subject areas.

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: A FLOWCHART OF THE PROCESS OF ETHICS CLEARANCE

THE SCREENING PROCESS IN DEPARTMENTS	
1.	The researcher prepares the research proposal, and completes the Departmental Ethics Checklist and submits it to the supervisor/promotor and/or departmental chair for further assessment and decision-making by the Departmental Ethics Screening Committee (DESC).
2.	The departmental chair, in consultation with at least one other independent member of that department (or cognate department) assess and come to a decision about the Departmental Checklist after due consideration. This group of two persons are referred to as the Departmental Ethics Screening Committee (DESC). If the departmental chair is involved with the research, his/her duties must be delegated to another member of the department, or the chair of a cognate department.
3.	The departmental chair submits the following documentation to the Secretariat of the Research Ethics Committee. (a) In the case of minimal and low ethical risk research, a copy of the Departmental Ethics Checklist (keeping all the other documentation regarding the screening on record in the department). (b) In the case of medium and high risk research, a copy of the Departmental Ethics Checklist, with a note that the full application for ethics review will follow.

MONITORING THE DOCUMENTATION RELATED TO MINIMAL AND LOW ETHICAL RISK RESEARCH	
4.	The REC has the duty to monitor from time to time the documentation that was submitted to the department with regards to minimal and low ethical risk research, and to provide departments and faculties feedback on it if necessary.

THE PROCESS OF ETHICS REVIEW BY THE RESEARCH ETHICS COMMITTEE	
5.	The Agenda of the REC closes 14 days before the date of a regular meeting of the REC.
6.	The Chair of the REC appoints a screening sub-committee of at least two members of the Research Ethics Committee to do a preliminary review of a research proposal. In this preliminary review it is indicated whether the application should be subjected to a full review of the Research Ethics Committee or not.
7.	At a regular meeting of the Research Ethics Committee, the preliminary review reports are tabled and discussed, and decisions are made regarding the ethics approval of applications.
8.	After the meeting of the Research Ethics Committee, the first reader of the screening sub-committee has 7 days to finalize the review report and submit it to the Chair of the Research Ethics Committee.
9.	The Chair of the Research Ethics Committee ensures that everything is in order with the finalized review reports, and forwards them to the Secretariat of the Research Ethics Committee for further processing.
10.	The Secretariat of the Research Ethics Committee conveys the results of the ethics review to the researcher, supervisor and departmental chair normally within 14 days from the date of the meeting of the Research Ethics Committee.

RESPONSES OF RESEARCHERS TO THE REC	
11.	In cases where the Research Ethics Committee refers documents back to researchers for amendment, or have queries regarding aspects of the research proposal, researchers are requested to respond as soon as possible in writing to the Secretariat of the Research Ethics Committee – in conjunction with the supervisor and departmental chair.
12.	The response of the researcher is then submitted immediately to the screening sub-committee who has 14 days to report to the Research Ethics Committee whether the responses are in order or not.

EXPEDITED REVIEWS	
13.	In extraordinary cases, and only on the basis of an acceptable motivation approved by the departmental chair, an application for ethics review can be handled in an expedited manner.
14.	In an expedited review, the Chairperson of the REC appoints a reader to draw up a preliminary review of the application.
15.	The Chairperson of the REC makes sure that the review report is in order, and then submits the review report to the Secretariat to process further.
16.	An expedited review will be ratified at the next regular meeting of the Research Ethics Committee.
17.	A period of 7 days should be allowed for the completion of an expedited review.

Addendum 2

DEPARTMENTAL ETHICS SCREENING COMMITTEE (DESC)

CHECKLIST

Implementation date: 1 January 2012

Preamble to the Checklist

Researchers, supervisors and departmental chairs have the primary responsibility to ensure that research conducted in their respective disciplines is characterized by methodological rigour and comply with the guidelines of relevant professional bodies and scientific organizations, as well as relevant legislation, institutional, national and international ethics guidelines.

All research in which humans, institutions, organizations or communities/groups are involved must be screened by Departments. The departmental processes for the ethics screening of research proposals should be integrated with the process of approving research proposals in terms of their scientific integrity and rigour. This means that the Departmental Ethics Checklist for the ethics screening of a research project should be considered in the same process as the approval of the research proposal.

The checklist serves as a heuristic (i.e. a guideline) to assist the researcher in evaluating the potential ethical risks associated with the research. The emphasis should be primarily on an honest and critical reflection on, and deliberation about the risk of unjustifiably impacting negatively on the research participants and other stakeholders involved in the research, and not on the completion of the checklist as a mere bureaucratic necessity.

To record that all research proposals in which humans, institutions, organizations or communities/groups are involved have been screened in ethical terms, the Departmental Ethics Checklist must be completed in a manner that attests to the fact that the researcher (and, if applicable the Departmental Ethics Screening Committee (DESC)) has diligently reflected on the matter.

Process notes:

- All submissions to the Research Ethics Committee must be accompanied by a fully completed Departmental Ethics Checklist. The departmental screening process is where the ethics review process starts.
- When medium or high ethical risk research is referred to the Research Ethics Committee for review, it is important to share the DESC's assessment, experience and wisdom about avoiding or mitigating ethical risks with the Research Ethics Committee. Please record which ethical risks are related to the medium or high ethical risk research, and what should be done to avoid or mitigate these ethical risks on the last page of the Departmental Ethics Checklist, or on a separate page, and indicate in a note to the Research Ethics Committee exactly for what ethics clearance is requested.
- Departments should have a short turn-around time in the processing of Departmental Ethics Checklists, following a time schedule that is well-coordinated with the submission of applications to the Research Ethics Committee.
- Departments are encouraged to involve researchers, supervisors and promotors in the deliberations and/or feedback of the DESC with a view to promote awareness, insight, and opportunities for the discussion of ethical issues related to research.

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DEPARTMENTAL ETHICS SCREENING COMMITTEE (DESC) CHECKLIST (DATA COLLECTION) To be prepared by the researcher (student researcher in consultation with supervisor/promotor) and attached to the actual research proposal, and submitted to your Departmental Chair				
Name of researcher: Prof/Dr/Mr/Ms/Other				
Department of Researcher:				
Title of research project:				
If a registered SU student, degree programme:				
SU staff or student number:				
Supervisor/promotor (if applicable): Prof/Dr/Mr/Ms				
ETHICAL CONSIDERATIONS	**Yes**	**NS***	**No**	**ACTION REQUIRED**
1. Familiarity with ethical codes of conduct				
As researcher I have familiarised myself with the professional code(s) of ethics and guidelines for ethically responsible research relevant to my field of study as specified in the list herewith attached, AND the 'Framework policy for the assurance and promotion of ethically accountable research at Stellenbosch University'				If YES: Continue with the checklist. If NS/NO: Researcher must do so before proceeding.
2. The proposed research: (Go through the whole of Section 2)				
a) Involves gathering information directly from human subjects (individuals or groups) (e.g. by means of questionnaires, interviews, observation of subjects or working with personal data)	**Yes**	**NS**	**No****	If YES: Continue with the checklist. If NO: This checklist process does not apply to the proposed research, except if 2 (b) applies.
b) Involves gathering information directly from companies, corporations, organisations, NGOs, government departments etc. that is not available in the public domain				If YES: Continue with the checklist. If NO: This checklist process does not apply to the proposed research.
c) Is linked to or part of a bio-medical research project				If YES/NS: REC clearance may be required. DESC needs to decide.
d) Involves gathering of information without consent/assent, i.e. will be conducted without the knowledge of the subjects of/participants in the research				If YES/NS: REC clearance may be required. DESC needs to decide.
e) Involves collection of identifiable information about people from available records/archival material to be collected on individuals/groups/lists with personal information				If YES/NS: REC clearance may be required. DESC needs to decide.

* NS = Not sure/Don't know

** Please note: If the "No" option is selected it does not nullify the responsibility that rests on the researcher to ensure that ethical research practices are followed throughout the research process. The onus rests on the researcher to ensure that, should any ethical issues arise throughout the research process, the necessary steps are taken to minimise and report these risks to the supervisor/promotor of the study (where relevant), the Departmental Chair , and the REC. Furthermore: If the "No" option is chosen it does not absolve the researcher to seriously consider the possible risk that the research can in some way wrongfully disadvantage research participants and/or stakeholders or deny them fundamental rights.

3. The proposed research involves the gathering of information from people in the following categories:				
a) Minors (persons under 18 years of age)	**Yes**	**NS**	**No**	If YES/NS for any of these categories (a-f): REC clearance may be required. The DESC must screen the proposal/project and must refer it to the REC if the ethical risk is assessed as medium or high. Then continue with the checklist. If NO for all of these categories: Continue with the checklist.
b) People with disabilities				
c) People living with/affected by HIV/AIDS				
d) Prisoners				
e) Other category deemed vulnerable; SPECIFY here: [See Glossary of SOP for definitions.]				
f) Stellenbosch University staff, students or alumni	**Yes**	**NS**	**No**	If YES/NS: REC clearance must be obtained. Complete Checklist and submit to DESC. If NO: Continue with the checklist.
4. Assessment of risk of potential harm as result of research (tick ONE appropriate YES or NS box)				
a) **Minimal risk** (for a classification of risk types, and definition, see Glossary and Addendum 3 in REC SOP)	**Yes**	**NS**	**No**	If YES: Established ethical standards apply. Proceed to 5, 6 and 7 and completion of checklist. If NO/NS: Proceed to 4b).
b) **Low risk** (for a classification of risk types, and definition, see Glossary and Addendum 3 in REC SOP)	**Yes**	**NS**	**No**	If YES/NS: Established ethical standards apply; researcher/ supervisor/promotor must refer the project to the DESC for further guidance. Proceed to 5, 6 and 7 and completion of checklist. If NO: Continue with the checklist.
c) **Medium risk** (for a classification of risk types, and definition, see Glossary and Addendum 3 in REC SOP)	**Yes**	**NS**	**No**	If YES/NS: REC clearance must be obtained; the research project must be referred to the REC. Proceed to 5, 6 and 7 and completion of checklist. If NO: continue with the checklist.
d) **High risk** (for a classification of risk types, and definition, see Glossary and Addendum 3 in REC SOP)	**Yes**	**NS**	**No**	If YES/NS: REC clearance must be obtained; the research project must be referred to the REC. Proceed to 5, 6 and 7 and completion of checklist. If NO: Continue with the checklist.
5. The proposed research involves processes regarding the selection of participants in the following categories:				
a) Participants that are subordinate to the person doing the recruitment for the study	**Yes**	**NS**	**No**	If YES: REC clearance may be required. The DESC must assess and advise. If NO: Continue with the checklist.
b) Third parties are indirectly involved because of the person being studied (e.g. family members of HIV patients, parents or guardians of minors, friends)	**Yes**	**NS**	**No**	If YES: REC clearance may be required. The DESC must assess and advise. If NO: Continue with the checklist.

6. Steps to ensure established ethical standards are applied (regardless of risk assessment)				
a) **Informed consent**: Appropriate provision has been/will be made for this (either written or oral)	**Yes**	**NS**	**No**	If YES: Develop & apply protocols and clear with DESC. Continue with checklist. If NS/NO: Attach justification & refer proposal to DESC for further assessment and advice.
b) **Voluntary participation:** Respondents/informants will be informed, inter alia, they have the right to refuse to answer questions and to withdraw from participation at any time				
c) **Privacy**: Steps will be taken to ensure personal data of informants will be secured from improper access				
d) **Confidentiality and anonymity:** Confidentiality of information and anonymity of respondents/informants will be maintained unless explicitly waived by respondent.				
e) **Training:** research assistants/ fieldworkers will be used to collect data, and ethics awareness will be included in their training				
f) **Mitigation of potential risk**: Likelihood that mitigation of risk of harm to participants is required is medium/high, and appropriate steps have been/will be taken (e.g. referral for counselling)	**Yes**	**NS**	**No**	If YES/NS: Develop protocols for submission to DESC. Continue with checklist. If NO: Proceed with checklist.
g) **Access:** Institutional permission is required to gain access to participants and has been/will be secured. Specify here from whom: [If the permission letter required is available, submit it to the DESC. If it is not available, apply for it immediately and indicate to the DESC when it will be expected.]	**Yes**	**NS**	**No**	If YES: Develop application for authorisation, clear with DESC & apply. Continue with checklist. If NS: Refer proposal to DESC for assessment and advice. Continue to 6 (h). If NO: Proceed to 6 (h).
h) **Accountability research***: Institutional permission to gain access to participants poses an obstacle to conduct the research.	**Yes**	**NS**	**No**	If YES/NS: Refer proposal to DESC for assessment and advice. Continue with checklist. If NO: continue with checklist.
i) **Public availability of instruments to gather data**: [When applicable] Are the instruments that will be used to gather data available in the public domain?	**Yes**	**NS**	**No**	If YES or not applicable: proceed with checklist. If NS/NO: Obtain permission to use the instrument(s) and submit letters of permission with the proposal to DESC for assessment and advice Continue with checklist..
j) **Use of psychological tests**: [When applicable] Are the instruments that will be used to gather data classified by law as psychological tests?	**Yes**	**NS**	**No**	If YES/NS: Indicate who will administer these tests, and whether they are appropriately registered and adequately trained to do so. Provide registration number and professional body. Continue with checklist. If NO or not applicable: Proceed with checklist.
k) **Protecting data from unauthorised access**: Are appropriate measures in place to protect data from unauthorized access? If yes, specify what the measures are:	**Yes**	**NS**	**No**	If YES: Specify and proceed with checklist. If NO/NS: Develop and put in place appropriate measures. Continue with checklist.

l) **Unexpected information**: If unexpected, unsolicited data is revealed during the process of research, data will be kept confidential and will only be revealed if required by law.	**Yes**	**NS**	**No**	If YES: Proceed with checklist. If NO/NS: Consult on this matter with DESC. Continue with checklist.
m) **Emergency situations**: If an unexpected emergency situation is revealed during the research, whether it is caused by my research or not, it will immediately be reported to my supervisor/promotor and Departmental Chair for further advice.	**Yes**	**NS**	**No**	If YES: Proceed with checklist. If NO/NS: Consult on this matter with DESC. Continue with checklist.
n) **Permission to use archival data**: [When applicable] Is permission granted from the custodian of the archive to use it.	**Yes**	**NS**	**No**	If YES: Proceed with checklist. If NO/NS: Consult on this matter with DESC. Continue with checklist.
o) **The archive itself does not pose problems**: [When applicable] The initial conditions under which the archive originated allow you as a third party researcher to use the material in the archive.	**Yes**	**NS**	**No**	If YES, proceed with checklist. If NO/NS: Consult on this matter with DESC. Continue with checklist.
7. Conflict of interest				
Is the researcher aware of any actual or potential conflict of interest in his/her proceeding with this research?	**Yes**	**NS**	**No**	If YES/NS: Identify concerns, attach details of steps to manage them, and refer to DESC for assessment and advice. If NO: No further action required, except signing the declaration and the checklist, and submitting it to the DESC with supporting documentation.

DECLARATION BY RESEARCHER:
I hereby declare that I will conduct my research in compliance with the professional code(s) of ethics and guidelines for ethically responsible research relevant to my field of study as specified in the list herewith attached, AND the 'Framework policy for the assurance and promotion of ethically accountable research at Stellenbosch University', even if my research poses minimal or low ethical risk.

Print name of Researcher	**Signature of Researcher**
Date	

Print name of Supervisor	**Signature of Supervisor**
Date	

DECISION OF DESC

Referral to Research Ethics Committee: Yes / No

[In the case of a referral to the RESEARCH ETHICS COMMITTEE, this checklist and its supporting documentation should be submitted, as well as the full application for ethics review, together with its supporting documentation, avoiding unnecessary duplication of documentation. Also list the ethical risks that are related to the research proposal that is submitted for review, together with the DESC's proposals to avoid or mitigate these ethical risks. Clearly indicate in a note exactly what ethical clearance is requested for.]]

If no referral is required, state any DESC conditions/stipulations subject to which the research may proceed (on separate page if space below is too limited): *[Or stretch table below if required]*

Any ethical issues that need to be highlighted?	Why are these issues important?	What must/could be done to minimize the ethical risk?

Print name of Departmental Chair	**Signature of Departmental Chair**
Date	

Print name of second member of DESC	**Signature of second member of DESC**
Date	

DOCUMENTS TO BE PROPERLY FILED IN THE DEPARTMENT AND (E-)COPIES SEND TO SU RESEARCH ETHICS COMMITTEE OFFICE. ON RECEIPT OF THIS COPY, THE RESEARCH ETHICS COMMITTEE SECRETARIAT WILL ISSUE A RESEARCH ETHICS COMMITTEE REGISTRATION NUMBER.

Note: Departments are requested to provide staff members and students with a list of professional Code(s) of ethics and guidelines for ethically responsible research relevant to their field of study on which they can indicate by signature that they have familiarised themselves with it. The last item in the list should be the 'Framework policy for the assurance and promotion of ethically accountable research at Stellenbosch University'.

With thanks to the Department of Sociology and Social Anthropology, Stellenbosch University of the initial concept.

ADDENDUM 3: CLASSIFICATION OF RISK TYPES

While economic risk is not mentioned in the list below, the following classifications of types of risk is useful in thinking about risk in social research:

CLASSIFICATION A:

"**Physical Risks**: These risks include physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research. These risks are not commonly encountered in social and behavioural science 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 subjects 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 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)

With thanks to the Department of Sociology and Social Anthropology, August 2011

CLASSIFICATION B:

Departments are invited to submit examples of classifications of risk types that can be added to this addendum.

ADDENDUM 4: EXAMPLES OF DIFFERENT KINDS OF RISK IN RESEARCH PROJECTS

1. Minimal risk

- Research involving the analysis of existing statistics, as well as literature, documents and information in the public domain, for example in public libraries, public archives, on websites, newspapers, or newsletters. Any anticipated harm or discomfort to third parties related to this research is no greater than ordinarily encountered in daily life. (Sociology and Social Anthropology)

2. Low risk

- A study of a social setting, a network, a set of activities, etc. that are not controversial and involve ethnographic methods (participant observation and interviews). A study of informal trade or of public life in a tourist destination could be examples. Much of the knowledge is of a public nature. (Sociology and Social Anthropology)

- Post-hoc analysis of large sample of student essays/exam papers where anonymity of students is assured; much standard socio-economic survey and interviewing work where standard protocols re informed consent, voluntary withdrawal and confidentiality are in place. (Sociology and Social Anthropology)

- Low risk research is research in which the investigation of largely uncontroversial topics is undertaken through interviews, surveys and participant observation. The participants in such research are typically adults or children who are unremarkable in terms of their social status, health status and/or development. As such, there is the little potential for discomfort or inconvenience on the part of participants; where such potential does exist, the predicted discomfort or inconvenience would be minor. (Department of General Linguistics)

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3. Medium risk

- A study of vulnerable social categories, e.g. relationships between children and adults as experienced by both these categories. A study of controversies about school discipline is an example. Some of the knowledge is private and is based on a relation of trust between researcher and participants. (Sociology and Social Anthropology)

- Dealing with potentially sensitive topics such as HIV, sexuality, rape, violence, but one cannot presume that sensitivity can be generalised across all cultural/social contexts. (Example: researchers in Uganda maintained that stigma re HIV not an issue there compared to SA, so very different context in which to make judgements re potential harm or discomfort.) (Sociology and Social Anthropology)

- Medium risk research is research in which there is an increased potential for emotional or psychological discomfort, due to either the topic investigated being controversial or connected to social stigma or the participants themselves being vulnerable. Such research could be harmful to the participant if not managed properly by the researcher. (Department of General Linguistics)

4. High risk

- Criminal activities that are linked to names, or ones in which victims of sexual abuse are asked questions about their abuse in ways that provoke flashbacks. (Sociology and Social Anthropology)

- A study involving vulnerable social categories where exploitation or severe personal loss is involved, e.g. research re sexual abuse, abortion, crime, drugs, witchcraft accusations, etc. The knowledge that is gained in this category of risk often involves intimate or secretive aspects. Information that is provided is often not meant to be published in detail. (Sociology and Social Anthropology)

- Research with/on political dissidents in a very repressive political environment; research on whistle-blowers. (Sociology and Social Anthropology)

- A study on bereavement. (Sociology and Social Anthropology)

- A study on children's access to pornography. (Sociology and Social Anthropology)

- High risk research is research in which there is a foreseeable risk of emotional or psychological discomfort or harm if not managed in a responsible manner. Such research involves intimate details of vulnerable participants, and highly sensitive topics. (Department of General Linguistics)

- A study on political refugees.

- A study on ex-criminals on the Cape Flats.

- Any study on prisoners.

- A study on cutting behaviour among adolescent girls, with a waiver of parental consent.

- A study of bereavement among adolescents in a high school setting.

ADDENDUM 5

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[2] (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.

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

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

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[3].

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).

[3] 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.

B2.1 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.

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.