GETTING ETHICS APPROVAL FOR YOUR RESEARCH PROJECT

Research Ethics Committee: Humanities (including Departmental Ethics Screening Committees – DESCs)

MARCH 2015

Lyn Horn, Clarissa Graham, Heidi Prozesky, Callie Theron

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This guideline was written by Lyn Horn, Clarissa Graham, Heidi Prozesky and Callie Theron, with valuable insights provided by Maléne Fouché and other REC members.

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Please contact the REC: Humanities office at 021 808 9183 or cgraham@sun.ac.za for additional information or assistance

Webpage: http://wwwo.sun.ac.za/research/research-integrity-and-ethics/human-research-humanities-ethics-1.html

Please note that as of August 2015, only applications submitted electronically on the E-application form will be accepted for an ethics review. Link to E-application form and manuals: http://wwwo.sun.ac.za/research/research-integrity-and-ethics/human-research-humanities-ethics-1/electronic-application-process.html

TABLE OF CONTENTS

1 RESEARCH ETHICS COMMITTEE (REC) AND DEPARTMENTAL ETHICS SCREENING COMMITTEE (DESC) STRUCTURE AND PROCESSES

The REC: Humanities is a central research ethics committee that has been mandated by the Senate REC to review and approve all research involving human participants and organisations. This excludes biomedical research, which is reviewed and approved by the Health RECs of the Faculty of Medicine and Health Sciences. (For more information on the Health RECs, visit http://www.sun.ac.za/english/faculty/healthsciences/rdsd/health-research-ethics)

The primary purpose of reviewing the ethics of research is to ensure that the rights, interests, privacy and dignity of research participants are protected.

The REC for Humanities has approximately 16 members, representing most of the faculties that conduct research involving human participants. Members generally serve a three-year term but may elect to serve more than one term. Members are officially appointed by the Senate Research Ethics Committee.

The REC meets once a month, currently on the last Thursday of every month. More details and submission deadlines can be found at http://wwwo.sun.ac.za/research/research-integrity-and-ethics.html

The REC primarily reviews projects that are considered medium- or high risk by the applicant and supervisor or DESC (Departmental Ethics Screening Committee). DESCs are usually convened by the head of a department and consist of one or two members of that department, usually on a rotation basis. This enables members of departments to both share the review load and to develop ethics review capacity. Low-risk projects can be directly approved by DESCs and do not need to be submitted to the REC. Once a DESC has approved a project, the applicant may start data collection. (The DESC process is discussed in more detail in Section 7 on pages 18 and 19).

2 RESEARCH ETHICS: BASIC PRINCIPLES AND BENCHMARKS

Many human rights abuses have occurred in the name of research in the twentieth century. Some examples are the experiments conducted by the Nazis in the concentration camps during World War II, the Tuskegee and Guatemalan Syphilis experiments, radiation experiments conducted on soldiers in the USA and Stanley Milgram's 'submission to authority' experiments. While most of this research was conducted in a biomedical context, many of the lessons learnt are equally relevant to all research involving human participants.

In 1976 The National Commission for the Protection of Human Subjects was signed into Law in the USA. The purpose of the Commission was to investigate the exploitation of human research participants. On April 18, 1979 this commission published the Belmont Report, which identified three principles for ethical research involving humans:

Respect - by recognising people's autonomy and upholding rules of informed consent, respecting privacy and confidentiality.

Beneficence - the researcher's obligation to first do no harm and then to aim at providing some benefit.

Justice – an obligation to ensure that the benefits and burdens of research are fairly distributed. For example, vulnerable groups should not be unjustifiably targeted as research participants simply because they are easily accessible. This is particularly important when the direct benefit of the research to participants is likely to be small, or when there will be no direct benefit.

A more recent framework of benchmarks for ethical research[1] has been developed and adapted for human research (outside of a biomedical context) by Wassenaar and Mamotte[2]:

BENCHMARK	EXPLANATION
Collaborative partnership	This benchmark is not applicable to all research studies and may well not be applicable to most student research. However, when research is community-based, or involves particular groups within a community, researchers are encouraged to attempt to consult and collaborate with stakeholders who may be able to provide valuable insights into community context and practices. This may also add value to the research and assist with resolving challenges. In some instances community

[1] Emmanuel E, Wendler D, Kilen J, Grady C. What makes clinical research in developing countries ethical? The benchmarks of ethical research. Journal of Infectious Disease 2004; 189 (1 March):930-936.

[2] Wassenaar D, Mamotte N. Ethical issues and ethics review in social science research. In Ferrero A, Korkut Y, Lesch M, Lindsay G, Stevens M (Eds.) The Oxford Handbook of International Psychological Ethics. 2013 Oxford University Press.

	research priorities can be ascertained.
Social value	Wherever possible a research project should contribute in some way (even if very small) to generalizable knowledge that could have some value to society, or at least improve understanding of social processes. The social value of a project should be considered in the overall risk-benefit assessment of the project. If the potential social value of a project is evaluated as very low, then the cost (for example time and inconvenience) and risks of the project to participants also need to be low in order for such a project to be ethically admissible.
Scientific validity	A methodologically flawed research project is generally not ethical because it is likely to waste the time and resources of both the researcher and the research participants. It may also produce erroneous or misleading results.
Fair selection of participants	The research question being investigated should be directly relevant to the population selected as research participants. Recruitment of participants merely because they are easily accessible should be avoided except where this can be explicitly justified. Vulnerable groups should never be used in research if the research question can be answered by using a less

	vulnerable group. For example, do not include persons with a mental disability unless the research question is directly relevant to such people, and cannot be answered by using people without mental disability. Vulnerable research persons are "those who are relatively or absolutely incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength or other attributes needed to protect their own interests..."[3] Hence, the inability to provide independent and/or valid informed consent is the key issue when considering whether or not a person or group is vulnerable in a research context. Examples of groups that are generally (although not necessarily) considered vulnerable are children, people living with mental disability, prisoners, people living in poverty, people with low levels of education/literacy, members of stigmatised groups (for example, sex workers, immigrants, people living with HIV, refugees, and gay and lesbian groups - especially in parts of Africa).
Favourable risk/cost-benefit	Ideally research projects should have a favourable or neutral risk/cost-benefit assessment. This means that when the potential

[3] Council for International Organizations of Medical Sciences (CIOMS), World Health Organization. Guideline 13. 2002.

assessment	risks/costs of the project to participants and others are realistically evaluated and weighed against the potential benefits of the project to individual participants or to society, the balance of this equation is assessed by both the researcher and the REC as acceptable.
Independent ethics review	The primary purpose of an ethics review is to ensure that the interests and rights of research participants are maximally protected during the research process. Researchers can become 'too close' to their own research projects during the development phase, and hence overlook certain ethical aspects or potential concerns.
Informed consent	In the past, informed consent has been seen as the only necessary criteria for ethical research but, as illustrated in this framework, it is only one of eight elements. Informed consent is a process, not merely a form. This process should be described in some detail in the research proposal. The following aspects are critical to the informed consent process: • Participants must be competent to give both their legal and mental consent. • Participants must give their consent voluntarily, i.e. without any undue influence or incentive. • The researcher must fully disclosure information about the research (For example, if you were to participate in

	your own research, what would you reasonably want to know about the project?) • Participants must sufficiently understand all the information provided in order to make an informed decision. Consent forms must be written in simple language and should address the participant directly. (For example, I would like to invite <u>you</u> to participate…) The reading level of consent documents should generally not be higher than Grade 7-8 and any technical language must be explained in layman's terms or avoided. <u>Written versus verbal informed consent</u>: Informed consent can be obtained in a written (preferably) or verbal form, if the latter is more appropriate in the context, for example, if the signed informed consent form is the only document that records the identity of the research participant. In certain research contexts this may be undesirable (for example, research involving participants who may be vulnerable to criminal prosecution, such as illegal immigrants or sex workers). Where necessary, a request for approval of waiver of written informed consent can be motivated for and will be considered by the REC. However, according to South African law, written informed consent is mandatory for all health research.
On-going	It is essential that researchers show respect to all

respect for participants and study communities	the participants throughout the project by: • Accepting voluntary withdrawal at any point, even without explanation. In some instances this may also require the withdrawal of a participant's data from the study. When children are involved, researchers need to be particularly sensitive to any indication that the child no longer wishes to participate (for example, changes in behaviour or non-verbal communication), and then respond appropriately by withdrawing the child. • Ensuring that confidential information is adequately protected (for example, by keeping electronic data password-protected, keeping paper data securely locked away in an office (rather than at home) and avoiding the direct linkage of identifiers with data (for example, name, ID or student number). This can be done by using study-specific codes. If necessary, identifying information linked to the codes can be kept separately. • Maintaining confidentiality of information. This may be challenging in qualitative research that makes use of focus groups, but should be carefully considered during the research development phase. • Keeping the identity of communities confidential to avoid the risk of stigmatisation. For example, a study investigating the social contributors of Foetal Alcohol Syndrome in a

	community in the Western Cape should not identify a specific community but rather broadly refer to a community in the Western Cape.

Particular care is needed to ensure that the ethical aspects of the research project have been thoroughly considered when children and vulnerable groups or communities are included as research participants. There are several internationally recognised guidelines or codes that provide additional in-depth information on the ethics of human research. (See the list of resources in Section 9.) Furthermore, researchers who undertake such research within a health-related context should familiarise themselves with the South African health research ethics and regulatory framework.

3 THE SOUTH AFRICAN RESEARCH REGULATORY ENVIRONMENT: WHAT YOU NEED TO KNOW

Currently there is no overarching legislation that governs research involving human participants in South Africa (SA). However, there are several pieces of legislation that are relevant to researchers, depending on the nature of the research project. These are briefly introduced below. If a researcher believes certain legislation may directly impact on his or her research, the onus is on the researcher to obtain clarity in this regard, either from the REC or from the Stellenbosch University Legal Services division or the Division for Institutional Research and Planning (regarding POPI and PAIA).

3.1 National Health Act. No.61. 2003 (NHA) and Regulations relating to research involving human participants.

The NHA was the first piece of legislation in SA that specifically regulates health research involving both human and animal participants. All research-related aspects of this legislation were finally signed into law in March 2012, although certain aspects of this legislation remain controversial. The definition of health research used in the

legislation is very broad and includes any research which contributes to knowledge of "... (a) the biological, clinical, psychological or social processes in human beings; ..." This could be interpreted to mean that most research done in the humanities falls under the legal jurisdiction of the NHA!

However, Stellenbosch University has obtained an external legal opinion on this matter. This legal opinion is that there are reasonable grounds for interpreting the definition narrowly, i.e. that 'health research' is 'biomedical' in nature. The Senate Research Ethics Committee (SREC) has accepted this opinion, hence only research that is directly related to the understanding or prevention of illness or the promotion of health through avoidance of risk- related behaviours should be considered to fall directly under the NHA.

Another contentious aspect of the NHA is Section 71 which has also now been signed into law. This section has three specific requirements:

i. Written consent for all health research is mandatory.
ii. Parental consent for all health research involving minors is mandatory.
iii. Ministerial consent for all non-therapeutic research (no direct benefit to individual participants anticipated) is mandatory, BUT the Minister of Health has now formally delegated this function to all registered and audited RECs (which includes the REC: Humanities), giving them the authority to approve all non-therapeutic research involving minors, thus effectively

removing this requirement. This delegation is in acknowledgement of the fact that much of this research is low-risk research and involves observation, questionnaires or interviews, i.e. it is not experimental research.

The NHA is framework legislation and thus a set of more detailed regulations governing health research involving humans were signed into law by the Minister of Health in May 2013 - REGULATIONS RELATING TO RESEARCH ON HUMAN SUBJECTS. These regulations provide a set of norms and standards for research involving human participants. Legally they apply specifically to 'health research' but nevertheless document an ethical standard that is applicable to most research involving human participants.

3.2 National Health Research Ethics Council (NHREC)

The NHREC was established in terms of the NHA for the purposes of determining guidelines for the functioning of health research ethics committees; registration and auditing of health RECs and to adjudicate complaints about the functioning of health research ethics. The NHREC also has the legal mandate to institute disciplinary action against any person found to be in violation of any norms and standards, or guidelines set for the conducting of research, and deal with any complaints by researchers who believe that they may have been discriminated against by a health research ethics committee.

The NHREC has encouraged all RECs reviewing research involving human participants, including those reviewing primarily social science research, to register with this body. The rationale for this is that the definition of health research contained in the NHA is very broad, and that a significant proportion of social science research is loosely health-related.

The REC for Humanities is registered with the NHREC, has been audited by them and is in good standing with this statutory body.

3.3 Promotion of Access to Information Act 2 of 2000 (PAIA)

The purpose of PAIA is to promote access to information held by the state, a public body or "another person and that is required for exercise or protection of rights". This can include information that is considered to be in the public's best interest or in the interest of the 'common good'. It is beyond the scope of this guideline to attempt to summarise the extent of the Act, but researchers need to be aware that in specific instances an external person or body may petition Stellenbosch University to release research-related information in the interests of the public good. Sections 36, 37 and 38 of the Act do provide for the mandatory protection of trade secrets, commercial information and personal confidential information. Researchers are advised to contact the REC office or the Division for Institutional Research and

Planning (021 808 3967) if they have any concerns about the implications of PAIA for their research.[4]

3.4 Protection of Personal Information Act (POPI)

POPI was signed into law on 26th November 2013 and is being phased in. It is expected that it will be fully implemented by April 2015.

POPI provides for the protection of personal information, especially if that information is held by third parties (e.g. the university, insurance companies, and local Municipalities, etc.) The Act sets requirements for the lawful processing of all personal information and the release of that information to other parties. The 'rule-of-thumb' principle is that the data subject – the person whose information is collected and maintained – must give their consent for the further processing of their information.

POPI does potentially have implications for researchers. For example, it may now be more difficult to get access to contact- or distribution lists from institutions or other

[4] Example: In 2013 SU researchers published the results of DNA analysis research indicating that meat products bought at various supermarkets in South Africa contained products and meat from animals (e.g. horse, water buffalo) that were not declared on the label. A consumer protection organization launched a formal petition requiring that SU disclose the identities of the stores where the meat samples had been purchased so that these stores could be publicly named. In terms of PAIA, SU was compelled to comply with this request.

bodies. From the perspective of Stellenbosch University, the implementation of POPI means that all requests to access information, including basic information such as student ID numbers or email addresses, MUST be made to the Division for Institutional Research and Planning (DIRP). Individual departments may no longer give permission for staff or student researchers to access information about students in their own departments. This approval must be given by the DIRP.

The conditions for the lawful processing of information are stipulated in Chapter 3 of the Act.

4 RESEARCH ETHICS AT STELLENBOSCH UNIVERSITY

Section 7.2 Social, Behavioural and Educational Research of the Policy for Responsible Research Conduct at Stellenbosch University (approved June 2013) states the following:

At SU all research involving interaction with or observation of human subjects, or information linked to human subjects, or research involving groups of individuals, or organisations must go through a process of ethical screening and clearance. Investigators are responsible for ensuring that they obtain ethics approval for their research where applicable. If an investigator (students included) is unsure if ethical approval is required for a specific project, it is the responsibility of that investigator to seek and obtain clarification from a reliable resource.

Section 7.3 then states:

All research involving human participants must comply with the following principles:

7.3.1 Relevant to the needs and interests of the community in which the research is conducted.

7.3.2 Have a valid scientific methodology.

7.3.3 Ensure research participants are well informed about the purpose of the research and how the research results will be disseminated and have consented to participate, where applicable.

7.3.4 Ensure research participants' rights to privacy and confidentiality are protected.

7.3.5 Ensure the fair selection of research participants.

7.3.6 Be preceded by a thorough risk-benefit analysis.

7.3.7 Thorough care must be taken to ensure that research in communities is effectively coordinated and does not place an unwarranted burden on such communities.

5 HOW TO DETERMINE IF YOUR PROJECT REQUIRES ETHICAL APPROVAL.

5.1 Is it research?

The first issue that needs to be decided is whether or not your project qualifies as research. There is often a grey area between research and an assignment which is primarily an educational exercise. The same applies to research and quality assurance, or programme evaluation.

'Research' is defined in the Stellenbosch University policy (referred to earlier) as "any systematic enquiry aimed at producing new and generalizable knowledge, new meaning or a deeper understanding of meaning". Generally a researcher intends to publish or present the results of the project at a conference, or submit them as a thesis, in order to fulfil the 'generalizable' criteria.

In certain degree programmes, particularly Honours programmes, it is conceivable that certain small research assignments are really only educational exercises and do not fulfil the definition of research. In these cases DESC/REC approval may not be required on condition that the project remains within the scope of what is classified as low-risk research. The responsibility for determining this lies with the supervisor (not the researcher), who must consult the DESC

or REC office (i.e. only the DESC/REC may provide exemption from approval).

In some instances the researcher may wish to have a formal letter from the REC office reflecting that the project is considered exempt from REC approval (for example, if requested by the funder). Such requests should be made to the central REC office, not the DESC.

Another grey area is that between research and quality assurance or programme evaluation, particularly where the evaluation involves a systematic collection of data or information. Typically, the purpose of such investigations is to provide information that could improve internal systems or programmes, and not to contribute to generalizable knowledge, and the information is not intended for the public. Thus, if an investigation is only intended for internal purposes, and the burden and risks to the participants remain low, it may be exempt from ethical approval. Again, such an exemption should be provided by the REC office.

However, in an academic environment it is quite likely that the results of such an evaluation may be suitable for publication or presentation at a conference. (For example, an evaluation of a teaching programme or new curriculum may have been done originally for internal use, but the results of such an evaluation, once completed, could be considered valuable if disseminated more widely.) In such cases the lack of ethical approval would be problematic. Hence, great care

should be taken before deciding that a programme evaluation or quality assurance exercise is NOT research.

Finally, it is important to note that the REC does not give retrospective ethical approval to any project that has already been completed. Thus, it is essential that researchers clarify whether ethical approval for a specific project is required, or not, prior to beginning the data collection.

5.2 Does the research involve humans?

Not all research projects conducted at the various faculties at Stellenbosch University will require formal ethics review and approval. Use the following four screening questions as a guide as to whether you need DESC/REC approval. If in doubt, consult your supervisor or a member of your department's DESC.

1. Does the research involve direct interaction with, or data gathering from (this includes completion of questionnaires) human participants as individuals, members of a group, organisation or institution?

2. Does the research involve information about an institution or organisation that is not in the public domain? (For example, a project that explores the link between staff turnover and post level.)

3. Does the research involve accessing information from a database that contains information linked to personal identifiers (names, ID numbers,

student numbers, etc.)? OR does the researcher have access to the codes that link the information in the database to the identity of the participants?

4. Does the research involve information that is in the public domain but that could be regarded as sensitive, or potentially sensitive? (For example, research that involves the analysis of identifiable tweets from those in public positions in order to evaluate trends in influence on freedom of speech in South Africa.)

'No' answers to all four questions indicate that your project probably does not need REC/DESC approval. A 'yes' answer to one or more questions means that the project does require approval.

5.3 The importance of risk classification

The Stellenbosch University REC/DESC system functions according to the ethical risk classification of the research project, REGARDLESS of the researcher's level of study. Hence, on occasions even undergraduate student projects that carry a relatively high ethical risk may require review and approval from the REC. Stellenbosch University policy requires that the level of ethics review (DESC or central REC) is determined by the ethical risk of the particular research and not the level of degree. The rationale behind this decision is twofold: the higher the level of risk, the more in

depth the ethical review process should be. If a less-experienced researcher (e.g. a student at undergraduate or Honours level), chooses a topic that is particularly sensitive, a higher level of scrutiny is required to ensure that the risks to participants and the institution are reduced as far as possible.

6 WRITING A RESEARCH PROPOSAL FOR REC SUBMISSION

The Humanities REC serves all faculties, and thus reviews a very wide range of research proposals. Some of the suggestions made below may therefore not be relevant to all research proposals. This section should thus be viewed as a guideline, not a prescription.

A common misperception among researchers across departments is that the research proposal submitted for REC review does not need to be complete, but can be a 'first draft' or a 'concept note'. 'Getting REC approval out the way' is mistakenly seen as the first step in the research development process. This approach should be avoided at all costs. The version submitted to the REC must be a final version of the proposal in order for the REC to conduct a proper review and risk-benefit assessment of the proposed research. Furthermore, the REC requires that the final version of the proposal is proofread by an expert in the language in which it is presented before submission.

The following are suggested proposal components:

- Introduction/background and rationale for the research.[5]
- Research question, aims and objectives.
- Literature review that provides support for the above.
- Methodology[6]: The methodology is a step-by-step **detailed** description of what is going to be done in order to obtain data that will be analysable and provide answers to the research questions or objectives. One of the most common REC-reviewer complaints is that the research methodology is not described in adequate detail. The REC is particularly concerned with the fair selection of participants, thus participant recruitment, selection and the informed consent process must be fully described.
- Data management and analysis: The REC must ensure that data is adequately protected from

[5] The rationale for the research is of central interest to the REC since it assists the REC in weighing up the sacrifice that the research project requires of the research participants [in terms of time, discomfort or even in some cases trauma and pain] and the benefit that can accrue to society [and possibly the participants]. Research in which participants are expected to make substantial sacrifices but where the benefits accruing to society are not clear should be ethically questioned.

[6] Methodology affects the validity of research results. When the methodology is not adequately explicated reviewers cannot evaluate the methodological rigor of the proposed study. Clearing a study to proceed that unduly inflates the risk of invalid conclusions should be seen as unethical. Asking research participants to make sacrifices towards a study that runs a too high risk of rendering no benefit should be considered unethical

unauthorised access and that participant privacy and confidentiality are maintained during the entire research process. This includes both paper and electronic data. It is thus important that these aspects are adequately addressed.

- Ethical considerations: Ideally all research proposals should contain a section discussing the ethical aspects of the project. It is insufficient to merely state that approval for the research will be obtained from the REC. Rather, this section should indicate that some consideration has been given to the principles of ethical research discussed above, as applied to the researcher's own project. Also the risk-benefit equation of the research (as discussed in Section 2), both to participants and others, should be evaluated. Steps taken to increase the benefits of the project and to decrease the risk of harm can also be described.
- Time plan and study logistics: While not essential, inclusion of a time plan is helpful.
- Strengths and limitations: Many research projects do have unavoidable limitations due to factors that may be, at least partly, beyond the control of the researcher (such as budgetary, logistical or time constraints) that may affect the choice of methodology or sample size. It is helpful for both the researcher and the reviewer if the limitations have been clearly outlined. Any steps that will be taken to reduce the problems identified should also be described.
- Reporting of results: It is advisable to describe how the results will be reported (e.g. published), and how they could be translated into action where

applicable. It is also important to include a description of how the results will be presented to all relevant stakeholders, including participants and the community, if applicable, appropriate or feasible. Unpublished or unreported results are considered a waste of time and effort and therefore also unethical.

7 SUBMITTING A NEW PROPOSAL FOR REC APPROVAL: A STEPWISE PROCESS

7.1 Final proposal and risk classification.

As described above, a final version of the proposal (and not a provisional proposal or proposal summary) should be submitted for DESC/REC approval. While completing the REC application form the applicant will be required to consider the ethical aspects of the proposal and to decide on the level of ethical risk of the proposal, as per the table below.

Risk categorisation

The concept of 'risk' applies primarily to potential risk to human research participants. However, certain research projects may also involve potential risk to the researcher or research team, the academic department and/or the institution. Such risks must also be taken into consideration when determining the overall level of risk.

Please note that the risk classification presented below is specific to the REC: Humanities and is for purposes of sifting reviews. It may not necessarily correspond to risk classifications used elsewhere, including those in international ethical guidelines and regulatory frameworks.

RISK CATEGORY	DEFINITION	EXPLANATION AND/OR EXAMPLES
MINIMAL AND LOW RISK **For the purpose of this classification, which is to determine whether or not a project can be approved by the DESC or needs to be referred to the central REC, the differentiation between minimal- and low-risk research is unimportant.*	The probability or magnitude of harm or discomfort anticipated in the research is negligible and not greater than that ordinarily encountered in daily life. (The concept of 'daily life' as a benchmark should be that of daily life as experienced by the average person living in a safe 'first-world' country). Research in which the only foreseeable risk is one of minimal discomfort or inconvenience.	• Market research surveys. • Research in which the investigation of largely uncontroversial topics is undertaken through interviews, surveys and participant observation. • The participants are adults and not considered to be a vulnerable research population (as discussed above). (Children are generally considered to be a vulnerable research population. However, this rule is not absolute and certain projects involving children may also be considered 'low risk'- DESC to evaluate.) • The research will collect information that would generally not be regarded as sensitive, such as opinions rather than personal information.
MEDIUM RISK	Research in which there is a potential risk of harm or discomfort, but where appropriate steps can be taken to	One or more of the following apply: • The research topic is considered 'sensitive'. • Information gathered is personal, rather than opinion or attitudes, or is a combination

	mitigate or reduce overall risk.	of these. • The information needs to be collected with personal identifiers (name, student number, etc.). • The research participants may come from a vulnerable or marginalised group, such as those with disabilities, people living with HIV or other chronic disease, the economically or educationally disadvantaged, etc.
HIGH RISK	Research in which there is a real and foreseeable risk of harm and discomfort, and which may lead to serious adverse consequences if not managed in a responsible manner.	One or more of the following apply: • Research involving highly sensitive topics and/or very vulnerable and marginalised communities. • Research involving the deception of the participants. • Research investigating illegal activities: e.g. involving participants who are illegal immigrants or engaged in illegal activities. • By agreeing to participate in the research participants will be placed at real risk of harm. • The researcher may be placed at risk of breaking the law by carrying out certain activities, e.g. research investigating gang activities and possession of illegal firearms. • The research may reveal information that requires

		action on the part of the researcher that could place the participant or others at risk, e.g. research involving child victims of physical or sexual abuse, victims of domestic violence, etc.

7.2 Online ethics application process

Researchers are required to submit their ethics application and supporting documents via the Research Information Management System (RIMS): InfoEd. Researchers should first check with their supervisors or heads of department whether their department is registered with the Humanities REC in order to submit online ethics applications. Researchers from a registered department may either contact the REC Secretary for more information about the application process and access to the electronic application system OR visit http://wwwo.sun.ac.za/research/research-integrity-and-ethics/human-research-humanities-ethics-1/electronic-application-process.html for a direct link to the electronic form and application manuals.

7.3 Supervisor sign-off

A student (undergraduate or postgraduate) may not submit an ethics application to the DESC or REC without supervisor approval. The supervisor(s) must approve the research proposal and supporting documentation submitted for ethics review. On the electronic application form the supervisor's approval is saved as a digital signature, together

with the date and time the supervisor approved the application. All future versions of the research proposal and supporting documentation must be approved by the supervisor(s), e.g. if changes are requested by the DESC or REC after the project has been reviewed.

7.4 DESC process and approval

The primary purpose of the DESC checklist (now incorporated into the REC electronic application form) and process is to ensure that all researchers adequately consider the ethical implications of their own research. The checklist helps researchers to evaluate the potential ethical risks associated with their research. The emphasis should be on an honest and critical reflection and deliberation of the unjustifiable risks that the research participants and other stakeholders may be exposed to, and not on merely completing the checklist as a bureaucratic necessity.

However, as only medium- and high-risk research projects are requires to complete the full REC-approval process before the research commences, the DESC process should be sufficient for the majority of research projects to begin without undue delay. **Once the researcher has obtained DESC pre-approval for the project, data collection may commence.**

SUMMARY OF DESC PROCESS, AS APPROVED BY THE SENATE RESEARCH ETHICS COMMITTEE IN MAY 2012

1. All projects for degree purposes in which humans, institutions, organisations or communities/groups are involved, and which are assessed by the researcher as low risk, must be submitted to the DESC for review.

2. The REC will accept medium- or high-risk projects without an initial DESC review process, only if the research has been judged by the applicant and supervisor as medium- to high risk **and the applicant is following a process that has been approved by the respective department**, i.e. individual Departments may decide that all research must first be reviewed by the DESC.

3. The DESC reviews and pre-approves low-risk research. The DESC may request the applicant to make certain changes to the proposal, informed consent form, etc., and should provide an appropriate process for ensuring that these changes have been made prior to the implementation of the project.

4. THE RESEARCHER MAY START THE DESC PRE-APPROVED MINMAL OR LOW-RISK PROJECT.

5. Medium- and high-risk research is referred to the REC either directly by the DESC (or after the applicant has made any changes the DESC may request) for a full REC review.

7.5 REC ratification process

Once the DESC has pre-approved a low-risk project, the completed and signed-off DESC form is submitted to the REC, together with a copy of the research proposal and other relevant documents. The documents are then reviewed by a rotating sub-committee of the REC, e.g. chairperson and one other REC member. Once this sub-committee is satisfied that the DESC has considered the ethical aspects of the research project and that any ethical concerns have been addressed, their pre-approval is ratified at a REC meeting (a list of projects appears in the agenda) and the REC issues a final letter of ethical clearance.

The REC reserves the right to suspend the DESC's pre-approval and request changes or clarifications. For minor issues, the reviewer may request additional information or changes without suspending the DESC pre-approval. However, for more substantial issues the DESC pre-approval will be suspended and the applicant will be notified that the project will need to serve at the next REC meeting. The REC office will request an amended application form, and any outstanding or additional documents.

7.6 Direct REC submission for medium- and high-risk research

A researcher may submit an ethics application directly to the REC without prior DESC review if the application is considered to be of medium- or high-risk (and if direct

submission is permitted by their approved departmental processes (See 7.4:2). The application will be reviewed by the REC only if all the relevant signatures are included (applicant, supervisor and Head of Department). Signatures (or the electronic declaration, if the E-form is used) are deemed very important because they represent a contract between the researchers and the REC, and indicate that the researcher has agreed to comply with REC processes and applicable norms and standards for ethical research.

8 OBTAINING INSTITUTIONAL (ORGANISATIONAL) APPROVAL

If SU students, staff or alumni will be included in the research as participants or used as a data source, the researcher must apply for institutional permission from the Senior Director: Institutional Research and Planning. This request must include the research proposal, informed consent form(s) and questionnaires/data collection tools. For more information on this application process, please contact the Senior Director: Institutional Research and Planning (http://suno25.sun.ac.za/portal/page/portal/Administrative_Divisions/INB/Home) or the REC: Secretary.

The Senior Director: Institutional Research and Planning is willing to accept applications for institutional permission once they have obtained either DESC [low-risk research], or REC [medium/high-risk research] ethical clearance. The Senior Director: Institutional Research and Planning requires proof that the DESC/REC has diligently reviewed the ethics application.

When permission is required from external institutions and organisations, it is imperative that such permission is INFORMED institutional permission. [This means that the institution understands the purpose of the study, knows how the results will be disseminated and is clear on whether its identity will be revealed or not.]

When organisations and institutions are selected using snowball sampling, it is acceptable to submit a copy of the request for institutional/organisational approval (i.e. the letter requesting organisational permission to access data or participants) to the DESC or REC for review. This is applicable to cases where a large number of organisations are going to be asked to participate in a study, but the specific organisations have not yet been approached or agreed to participation.

In cases where archival data (e.g. archives not available in the public domain), will be accessed or used as a data source, formal permission to access this data must be obtained from the curator. Special care should be taken with archival data. If there is to be a formal contract for accessing and using archival data, should be scrutinised by a legal representative of Stellenbosch University. This can be done through the Division for Research Development's Contracts Office.

9 USEFUL INFORMATION AND LINKS

Codes and Guidelines

Ethical Guidelines for Good Research Practice. Association of Social Anthropologists of the UK and the Commonwealth.

Research Ethics Framework. Economic and Social Research Council (UK) 2010. (update of 2005 published framework). Available at http://www.esrc.ac.uk/_images/framework-for-research-ethics-09-12_tcm8-4586.pdf.

Ethical Decision-Making and Internet Research Recommendations from the AoIR Ethics Working Committee (Version 2.0) 2012. Available at http://www.aoir.org/reports/ethics2.pdf.

Ethics in Health Research: Principles, Structures and Processes. Department of Health, 2015. http://www.doh.gov.za/docs/Policies/2014/EthicsinHealthResearchFinalA.pdf

The Belmont Report April 18th 1979. National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. Available at http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html

Ethical Guidelines. Social Research Association (UK), 2003.Available at http://the-sra.org.uk/wp-content/uploads/ethics03.pdf.

Books and Journal Articles

Responsible Research: A Systems Approach to Protecting Research Participants. Federman, DD, Hanna KE, & Rodriguez, L (Eds.) 2003.

Research Ethics in Africa: A resource for Research Ethics Committees. Kruger M, Ndebele P, Horn L (Eds.) 2014.Sun Media. Available as a free download onto a tablet at https://africansunmedia.snapplify.com/product/9781920689315. (Specifically Chapters 9-Informed consent in an African context; 12-Research Vulnerability; 13-Children as research participants; 16-Ethics review of social and behavioural research in an African context; 19- Community Engagement.)

Ethics in Economics and Management Sciences: A researcher's resource. Pienaar, J. *SAJEMS* 2010.13(3):316-328.

Ethical issues and ethics review in social science research. Wassenaar D, Mamotte N 2013. In Ferrero A, Korkut Y, Lesch M, Lindsay G, Stevens M (Eds.) *The Oxford Handbook of International Psychological Ethics*. Oxford University Press.

APPENDIX

GUIDELINE FOR VISITING STUDENTS[7] WISHING TO CONDUCT RESEARCH WHILE AT STELLENBOSCH UNIVERSITY

ABBREVIATIONS

HSRC South Africa Human Sciences Research Council

PGIO Postgraduate and International Office (Stellenbosch University)

IRB Institutional Review Board (same as Research Ethics Committee)

NGO Non-government organization

IR&P Division for Institutional Research and Planning (Stellenbosch University)

REC Research Ethics Committee

SU Stellenbosch University

[7] These guidelines are generally applicable to visiting research fellows and academics as well. Points of clarification can be obtained from the host department if needed.

1. INTRODUCTION

Stellenbosch University hosts many visiting students during the course of an academic year. These students are registered for a degree at another institution but arrange, as part of an exchange or other collaborative process, to visit SU for a short period of time, usually between three to six months. Often they plan to conduct some form of research activity during this period. Occasionally students visit SU specifically for the purpose of studying this institution, its policies and practices.

Certain visiting students (and other researchers) may not want to have any formal affiliation with SU but wish to conduct research (as outsiders) that investigates SU policies and practices or they wish to gain access to a particular group of SU staff or students. Often such research projects are multi-institutional and involve other South African academic institutions as well. These requests will be handled by the Division for Institutional Research and Planning (IR&P) at SU. This office will determine the terms and conditions under which the research may proceed. The IR&P retains the right to refuse such requests.

This type of project almost always needs ethical approval from both the home institution and a local (i.e. South African) REC. The South Africa Human Sciences research

Council (HSRC), is generally prepared to review and approve such projects. The Stellenbosch University IR&P usually also requires that the researcher identify a SU academic who will act as a local contact person and facilitator, in such cases.

2. IMPLEMENTATION

These guidelines will be implemented jointly by the Postgraduate and International Office, the Division for Research Development and where applicable the Office for Institutional Research and Planning.

3. DEFINITIONS

'Human participant' is a living person about whom a researcher obtains data through intervention or interaction with that person or his or her identifiable information. However, where applicable this definition may be extended, for the purposes of this policy, to include deceased persons or foetuses.

'Animal' refers to all non-human living beings having the power of sense perception or sensation.

'Research' is any systematic enquiry aimed at producing new and generalisable knowledge, new meaning or a deeper understanding of meaning.

'Research ethics Committee' or REC, is a formally constituted committee that is mandated to review (primarily from an ethics perspective), and provide approval for research.

'Institutional Review Board' or IRB, is the equivalent of an REC. This term is used widely particularly in the USA instead of REC.

4. PURPOSE

The purpose of this document is to provide stepwise guidelines to visiting students as to the processes that need to be completed in order to obtain the necessary approvals and/or permissions needed to proceed with their envisaged research. This guideline does not apply to foreign students registered for a degree at SU. They are considered 'SU students', and therefore, are required to comply with the usual academic requirements and processes that apply to all SU students.

5. OBJECTIVES

5.1 To describe the pre-conditions required before a student can apply to conduct research at SU.

5.2 To explain the purpose and role of the Postgraduate and **International Office (PGIO).**

5.3 To describe ethics approval processes and structures at SU.

5.4 To describe and explain the process for obtaining institutional permission from the **Office of Institutional Research and Planning (OIR&P),** when applicable.

5.5 To describe other permissions that may be required for research involving external organisation or institution such as schools, health care facilities or business entities.

6. STEPWISE APPROACH

Visiting students are requested to read through all the following steps carefully and ensure that they have completed all the applicable processes before starting their research. These processes may take time (up to 3 months), and therefore, students are advised to start applying for approvals well in advance of their visit. It is ill-advised to arrive and only start these processes once already at Stellenbosch.

Step 1: Fulfilling pre-conditions.

Visiting students planning to conduct research, especially if it involves human participants or animals, must take note of the following requirements:

1. A written research proposal that has been reviewed and validated by their home institution as

scientifically sound (confirmed by a signed letter or similar from the department or faculty).
2. Ethics approval for the research (if humans participants are involved - see above definition), from their home institution.
3. A supervisor from their home institution.

OR

1. If the student is fully 'embedded' within a SU academic department, he or she may choose to develop a research proposal in collaboration with a SU researcher who agrees to supervise the student. In such cases the SU supervisor would most likely qualify as a co-author if the research was published or presented. This arrangement should be clarified up front to avoid misunderstandings or disputes at a later point.

Step 2: Making contact with the Postgraduate and International Office

The Postgraduate and International Office play an essential role in coordinating and facilitating a visit by a foreign student. The student needs to register with this office in order to gain access to SU facilities.

Please visit http://wwwo.sun.ac.za/international/ for further information and contact details.

The Postgraduate and International Office will put the student in contact with a suitable academic department by providing the contact details of an academic who will be willing to act as a facilitator.

Step 3: Obtaining ethics approval for the project

Many research projects done at SU require ethics approval before they may proceed. This applies to all projects involving human participants, animals or that have environmental or biosafety concerns. Students are advised to familiarise themselves with the **Policy for Responsible Research Conduct At Stellenbosch University** available at http://wwwo.sun.ac.za/research/assets/files/Policy_Documents/POLICY%20FOR%20RESPONSIBLE%20RESEARCH%20CONDUCT%20AT%20STELLENBOSCH%20UNIVERSITY.pdf

Affiliated students, once registered with the International Office, should contact the appropriate research ethics office and apply for ethical clearance for their research. Generally, a full application will be required and the project will serve at a REC meeting (held once per month). After the meeting the student will receive written feedback from the REC. He/she should respond as quickly as possible and address whatever changes or clarifications have been requested. Rarely, if the

REC has major concerns with the project, it may need to serve at a second REC meeting.

Students that are fully 'embedded' within an academic Department can and should submit their projects for approval to the Department Ethics screening committee (DESC), as per normal SU procedures. Your department contact person can assist with this process.

Please visit http://wwwo.sun.ac.za/research/research-integrity-and-ethics.html for information regarding research ethics committees and their application processes.

Step 4: Obtaining institutional approval from the Division for Institutional Research and Planning (IR&P) for all research involving SU staff or students.

All research that potentially involves SU staff or students in any capacity requires permission from the IR&P at SU. This includes recruiting students on campus. Permission is required to distribute information via mailing lists or other forms of media including social media, place adverts and conduct interviews or surveys.

Please email amlitwa@sun.ac.za for further information regarding application procedures and requirements.

Step 5: Obtaining additional permissions

Students who plan to do research at external institutions such as local schools, clinics, hospitals; NGOs (Non-government organisations), will require written permission from these organisations. Assistance and information regarding these processes is best obtained from the hosting academic department.

Step 6: Initiating the research project.

Only once all the necessary approvals are in place, the academic facilitator or department hosting the student will provide advice or assistance in the initiation of the research project. It is thus imperative that students attempt to complete these processes PRIOR to their visit. Failure to do this could mean that it becomes impractical to complete, or even start the research project during the time-period of the visit.