University of Venda

UNIVEN

Research Ethics Committees (RECs)

Standard Operating Procedures (SOPs)

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1. Application Procedure

The Principal Investigator/student shall submit a protocol to the relevant Research Ethics Committee at least four weeks in advance of the REC Meeting date.

Ethical approval needs to be obtained prior to the commencement of the research. The RECs will not provide retrospective approval.

All documentation for submission is available on http://www.univen.ac.za/research/research-ethics/ or can be obtained from the RECs Secretariat.

The following will need to be submitted:

1. Completed UNIVEN approved R7/R7a ensuring the following are addressed:
- Participant recruitment procedures
- Safety information
- Any payment or compensation to participants
2. Proof of Registration (Current year of application)
3. Approved Research Proposal
4. UHDC Approval letter
5. The UNIVEN Informed consent form (appendix B)
6. Conflict of interest form (appendix)
7. Other information being supplied to participants
8. Other documentation necessary for the RECs to make an informed decision regarding the research.

The RECs Secretariat will accept applications from the Schools/ Departments and principal investigators for ethical clearance on a rolling basis. The RECs Secretariat in conjunction with the Chairperson will determine whether the application requires expedited or full review. The RECs Secretariat will check the application ensuring that all relevant documentation has been submitted, should documentation be missing it will be requested.

1.1. Research for non-degree purposes

The University Research Ethics Committees considers internal applications for ethics clearance for research for non-degree purposes/ independent research.

The following will need to be submitted:

1) Completed UNIVEN approved R7/R7a ensuring the following are addressed:
2) Proof of Registration (Current year of application)
3) Approved Research Proposal
4) UHDC Approval letter
5) The UNIVEN Informed consent form (appendix B)
6) Conflict of interest form (appendix)
7) Other information being supplied to participants
8) Other documentation necessary for the UREC to make an informed decision regarding the research.

The RECs Secretariat will accept applications from the Schools/ Departments and principal investigators for ethical clearance on a rolling basis. The RECs Secretariat in conjunction with the Chairperson will determine whether the application requires expedited or full review. The RECs Secretariat will check the application ensuring that all relevant documentation has been submitted, should documentation be missing it will be requested.

2. Review process

The RECs when reviewing a proposal must protect the rights, safety and well-being of the research participants and their communities. It will do this by evaluating all factors that may influence the scientific validity and ethical acceptability of the proposal by applying the various ethical benchmarks mentioned below:

Collaborative partnership:

- Develop partnerships with researchers, makers of health policies and the community.
- Involve partners in sharing responsibilities for determining the importance of a health problem, assessing the value of research, planning, conducting and overseeing research, and integrating research into the health-care system.
- Respect the community's values, culture, traditions and social practices.
- Develop the capacity for researchers, makers of health policies and the community to become full and equal partners in the research enterprise
- Ensure the recruited participants and communities receive benefits from the conduct and results of research
- Share fairly financial and other rewards of the research

Social value:

- Specify the beneficiaries of the research, i.e., who?
- Assess the importance of the health problems being investigated and the prospective value of the research for each of the beneficiaries, i., what?
- Enhance the value of the research for each of the beneficiaries through dissemination of knowledge, product development, long- term research collaboration and/or health system improvement.
- Prevent supplanting the extant health system infrastructure and services.
- Ensure that the study is relevant to the community involved or the greater South African population

Scientific validity:

- Ensure that the scientific design of the research realizes social value for the primary beneficiaries of the research
- Ensure that the scientific design realizes the scientific objectives while guaranteeing research participants the health-care interventions to which they are entitled.
- Ensure that the research study is feasible within the social, political and cultural context or with sustainable improvements in the local health-care and physical infrastructure
- Researchers should have the appropriate qualifications and expertise to conduct the proposed research
- Researchers must be registered with their relevant statutory council g. Health Professions Council of South Africa. Where this is not available a motivation must be given from a person registered with the relevant professional body.
- In studies where there is a large clinical component and the principal investigator is not a clinician, a co-investigator who is a clinician must be appointed.
- All international collaborative research must have a local principal investigator/supervisor.

Fair selection of the study population:

- Select the study population to ensure scientific validity of the research
- Select the study population to minimize the risks of the research and enhance other principles, especially collaborative partnership and social
- Select the study population fairly and without coercion
- Identify and protect vulnerable populations.

Favourable risk-benefit ratio:

- Assess the potential risks and benefits of the research to the study population in the context of its health risks.
- Assess the risk-benefit ratio by comparing the net risks of the research project with the potential benefits derived from collaborative partnership, social value, and respect for study populations.
- Risk to participants and/or the environment must be minimised

Independent Review:

- Ensure public accountability through reviews mandated by laws and regulation
- Ensure public accountability through transparency and reviews by other international and non- governmental bodies, as appropriate
- Ensure independence and competence of the reviews.

Informed Consent:

- Involve the community in establishing recruitment procedures and incentives.
- Disclose information in culturally and linguistically appropriate formats.
- Implement supplementary community and familial consent procedures where culturally appropriate.
- Obtain consent in culturally and linguistically appropriate formats.
- Ensure the freedom to refuse or withdraw
- The method utilised must be ethically and legally acceptable.

Respect for Recruited Participants and Study Communities:

- Develop and implement procedures to protect the confidentiality of recruited and enrolled participants.
- Ensure the participants know they can withdraw without penalties
- Provide enrolled participants with information that arises in the course of the research
- Monitor and develop interventions for medical conditions, including research-related injuries, for enrolled participant's at least as good as existing local norms.
- Inform participants and the study community of the results of the research
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(Emanuel et al., 2004)

2.1. <u>Review of research proposals</u>

- Members of the RECs will be responsible for reviewing all categories research proposals submitted for that particular meeting.
- Research involving minimal risk to participants (category 2) will follow the expedited review process.

- Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine psychological examinations or tests.
- When category 3 proposals are reviewed at the meeting each member present will have an opportunity to raise any comments, he/she may have. These will be discussed, and a decision reached.
- The RECs will strive to have consensus on all decisions made; however, in instances where there is no consensus, the matter will be put to vote. A minimum of 70% of the members present will need to be in favour of the matter to result in an approval.
- Category 2 proposals will be allocated to respective members for in-depth review as delegated by the Chairperson. The decisions from the expedited review will serve at a scheduled RECs meeting for noting.
- The RECs will not review proposals for ethical approval if data collection has already begun. In such instances, this will be reported to the relevant DVC.
- On completion of the review process the researcher, the supervisor will be informed of the outcome of the review, according to the following criteria:
    - Full Approval: No changes to proposal
    - Provisional approval: This is subject to minor changes - the changes and/or clarifications are to be made by the researcher and re-submitted to the Chairperson for final approval
    - Provisional approval subject to piloting of the data collection tools
    - Re-submission: The ethical issues need to be further addressed and the revised proposal will need to be re-evaluated by a full RECs
    - Rejected: The proposal does not meet the ethical requirements, the specific reasons will be accurately recorded
    - Termination or suspension of prior approval: The specific reasons will be accurately recorded.

3.2. Communication of reviewed decisions

All decisions will be recorded in the RECs minutes with each principal investigator receiving the outcome of their application in a written communique. It is not unusual for the committee to recommend changes to the proposal. When corrections have been requested the proposal should be re-submitted to the RECs Secretariat with a RECs recommendation template clearly outlining the corrections recommended by the RECs. This should be received by the RECs Secretariat as soon as possible but no more than 6 months after initial review. **The application will be cancelled should no feedback have occurred within 6 months.**

4. Convened meeting

The RECs will undertake the following:

- Review category three research proposals and their supporting documentation (e.g. letters or information and consent, advertisements, questionnaires etc.)
- Note all category 2 proposals approved through expedited review (RECs)
- Recommend any necessary protocol amendments such as change of title, change to methodology etc.
- Assess safety monitoring
- Decide on recertification
- Note any adverse events occurring in previously approved studies

- Consider allegations of research misconduct or other complaints
- Confirm completion of studies
- Address general and policy matters

4.1. Meeting procedure

The meeting will start with the Chairperson opening the meeting and ensuring that the meeting is quorate. The Administrator will record those present as well as any apologies. Previous minutes will be corrected and accepted. Matters arising will be dealt with followed by relevant business. The Chairperson will facilitate any discussions and will summarise the various viewpoints of the committee.

5. Administration of RECs

The RECs Secretariat/Administrator will be responsible for administrating the business of the RECs. He/she will report to the Chairpersons of the RECs. All RECs documentation will be sent to him/her for collation and distribution to the RECs members.

The RECs Administrator will perform the following functions prior to the RECs meeting:

General:

- Inform RECs members of meeting and closing dates for agenda items and documentation
- Collate documentation for the RECs agenda
- Obtain and verify information/documentation and ensure administrative procedures are completed prior to compilation of the agenda
- Ensure documentation submitted for the agenda is complete, with all signatures and necessary paperwork
- Finalize the agenda in consultation with the Chairpersons of RECs
- Prepare agenda and documentation including making copies of agenda/ documentation
- Prepare all documentation for distribution to the members with a signing roster allowing for RECs members to acknowledge receipt of agenda and documentation
- Dispatch agenda/ documentation to RECs members 7-10 days before the meeting
- Prepare RECs attendance register
- Keep a file with all RECs members' Curricula Vitae, contact details and confidentiality forms
- Ensure in the case of student proposals that the student is correctly registered for the year
- Arrange any special/ad hoc meetings if necessary
- Ensure that RECs review of research proposals is within 7-10 days
- Contact specialist members required to attend RECs meetings
- Keep all RECs documentation.

Expedited review:

- Inform members who are required to review proposals for expedited review
- Ensure those members receive the documentation timeously
- Follow up on allocated reviews
- Write and distribute letters to researchers informing them of the RECs decisions
- Allocate ethics clearance numbers to approved category 2 research.

The following functions are performed during the RECs meeting:

- Advise Chairperson on RECs quorum prior to commencement of meeting
- Monitor quorum during meeting to ensure it is acceptable
- Record those present and any apologies
- Record conflict of interests
- Record and correct any amendments to previous minutes submitted for approval
- Minute RECs meetings and ensure accurate recording of decisions, including any amendments requested by the committee
- Monitor those who leave the meeting and record in minutes
- Ensure attendance register is signed by all members present
- Assist with the interpretation and implementation of student research rules, policies and procedures.

5.1. **Post-meeting responsibilities:**

- Compile minutes
- Write and distribute letters to researchers informing them of the RECs decisions
- Allocate ethics clearance numbers to approved category 3 research
- Organise any additional meetings if necessary.

5.2. **Record keeping**

It is an ethical and legal requirement that all documents pertaining to research on human and animal participants and the environment be kept for future reference and audit purposes. The RECs will keep all RECs documentation for 15 years in accordance with the GCP guidelines.

6. Informed consent

All research approved by the RECs on human participants must have the UNIVEN Informed consent form (appendix B) compiled according to the guidelines in Appendix.

Each participant or, where necessary, the participant's legally authorised representative, must be given sufficient time to read the letter of information and consent and have the opportunity to ask questions. There should be no coercion or undue influence.

The letter of information and consent should be in a language understandable to the participant or representative, allowing them to make an informed decision to participate in the research. Only then may the participant or representative sign the letter of information and consent. In the case where the participant is illiterate, verbal consent may be given in the presence of a literate witness who will verify and sign the letter of information and consent on behalf of the participant, indicating that informed verbal consent was given.

The letter of information and consent must include the following:

- The qualification/s and contact details of the researcher/s
- Participants' responsibilities
- Purpose of the research
- Any risks and benefits to participants
- Outline study procedure e.g. placebo or control groups if necessary
- Duration of study
- Alternative procedures or treatments
- Confidentiality
- A statement that participation is voluntary, and that non-participation will not result in any penalty

- A statement that ethical approval for the study was obtained
- A statement that sponsors or the ethics committee may inspect research records
- Compensation for research related injury
- Contact details of the REC
- Contact details of the person to contact should there be research related injury
- The letter of information and consent must be written in simple language.

8. Record keeping

In keeping with legal and ethical requirements, all researchers/principal investigators will be required to keep all information, including data sheets and informed consent documents, for at least 5 years. This is in line with the GCP guidelines.

These records must be orderly and accessible should the need arise. In the case of student research, the respective department/ programme must house the records for at least 5 years.

9. Ethics training

All researchers should have relevant ethics training. Committee members will have on-going ethics training.

10. Appeals procedure

Researchers have the right to appeal decisions made by the committee or may have concerns regarding RECs process. The appeal must be submitted by the principal investigator to the Chairperson of the RECs through the RECs secretariat. There must be a clear motivation for the appeal which should be supported by a subject specialist/Dean of school other than the principal investigator. The RECs Chairperson or delegated member may then seek outside consultation about the research.

- Where a decision of the RECs is appealed by the principal investigator or by dissenting member of the Committee, the Committee shall record the reasons for the decision of the Committee under appeal and the written dissent, if any.
- Where any objection to an on-going or completed University research project is not resolved, the matter may be taken on appeal to the RECs.
- On appeal, the RECs shall invite the principal investigator to support his project, but the deliberations of the Committee will be held in camera.
- The RECs may confirm or modify the decision previously taken regarding the matter on appeal. The decision after the appeals process is final.

11. Amendments to research protocol

The RECs approve the study protocol ensuring that the research will be conducted using sound ethical principles. All amendments must be submitted to the RECs prior to being implemented. The Chairperson will decide if the amendment has minor or major implications for the study and its participants. If the change is minor it may be seen through expedited review; if the change is major it will serve at a full committee meeting.

- Minor amendment – does not change the risk-benefit profile of the study, e.g. change of title1, administrative changes, adding an investigator, changes that do not affect study design and outcomes, small changes to letter of information and consent such as editorial changes.

- Major amendment – does change the risk-benefit profile of the study, e.g. change in study aims and objectives, alterations to study procedure, changing inclusion criteria to make study more accessible, changes to letter of information and consent.

  In the case of protocol deviations, defined as a "once off" instance where the research protocol is not followed either deliberately or by mistake, the deviation will fall into one of two categories: major or minor as outlined above. If minor, the deviation must be reported to the RECs in the annual progress report. If the deviation is major, it will need to be reported to the RECs within 15 days. The Chairperson will then decide the action to be taken.

12. Adverse events reporting

All adverse events (AE), serious adverse events (SAE), adverse drug reactions (ADR), serious adverse drug reactions (serious ADR) and serious adverse experiences (SAEx) which occur during a study must be reported to the UREC.

- Adverse event (AE) is defined as 'any untoward occurrence affecting participants in a research investigation or clinical investigation participant administered a pharmaceutical product or other intervention/ investigation, which does not necessarily have a causal relationship with this treatment/Investigation.' An AE can therefore be any unintended sign (including abnormal laboratory finding), symptom, or disease temporarily associated with the use of a medicinal (investigational) product, or other intervention/ investigation, whether or not related to the medicine or investigational product or intervention.
- Adverse drug reaction (ADR) is defined as 'any noxious and unintended response associated with the use of a drug in humans or animals'.
- Serious adverse event (SAE) or serious adverse drug reaction (serious ADR) is 'any untoward medical occurrence that at any dose/ intervention: results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.'
- Serious adverse experience (SAEx) is 'any experience that suggests a significant hazard, contraindication, side effect or precaution'.

13. Continual review and recertification

All research approved by the RECs will be subject to substantive, meaningful and focused continuing review to determine that the risks and benefits of the study have not changed, that there are no unanticipated findings involving risks to participants and/or others, and that any new information regarding risks and benefits are provided to the participants. The review will occur every year, unless the level of risk requires more frequent review. The RECs may withdraw approval of a protocol previously approved.

All applications will be reviewed by the full committee. However, the final decision rests with the Chairperson or a person delegated with this responsibility. At least one member of the RECs will receive a copy of the full protocol including any modifications that have been previously approved by the RECs, with the full committee having access to the complete RECs protocol file and relevant RECs minutes/reports at the convened meeting. All studies will require continual review until the RECs receives the final study report and the completion of study form (appendix G).

All applications for continual review must be submitted by the primary investigator to the RECs on the RECs safety monitoring and annual recertification report form (appendix F) along with any other supporting documentation. This documentation will need to be sent to the RECs secretariat at least 14 days before the meeting to be added to the RECs meeting agenda and will be distributed to members for review. The RECs should receive this application at least three months before the ethics approval for the study expires; this will ensure that re-approval takes place before the studies ethical approval expires. No study may continue without valid ethical approval and re-certification.

Once the RECs have assessed the continual review application the study may:

- Continue as originally approved
- Have some modifications
- Request a site visit by the safety monitoring committee
- Be suspended
- Be terminated

The RECs secretariat will inform the principal investigator in writing of the outcome of their application and any reasons for its decision. All conditions required by the RECs must be met before continual approval will be granted. If the principal investigator appeals the decision, the RECs must ensure there is a fair hearing of the query.

14. Suspension and discontinuation of research proposal

14.1. Suspension or termination by RECs:

Where the RECs are satisfied that such circumstances have arisen that a research project is not being conducted in accordance with the approved protocol and that, as a result, the welfare and rights of participants are not or will not be protected, the RECs may withdraw approval. The RECs shall also inform the researcher and the institution or organisation of its action and shall recommend that the research project be discontinued or suspended, or that other appropriate steps be taken.
Where ethical approval has been withdrawn, a researcher must discontinue the research and comply with any special conditions required by the UREC. A report to this effect must be submitted to the RECs within 2 weeks of suspension/ discontinuation of the project.
When the safety of participants is at risk, the Chairperson of the RECs in consultation with the RECs subcommittee and/or other co-opted parties will call a meeting as soon as possible but not more than seven days after receipt of such information. The outcome of such a meeting will be reported to RECs at the next quorate meeting. RECs will give a detailed written reason for suspending or terminating the study to the relevant parties e.g. the principal investigator, the relevant DVC, the study sponsor or agency, the investigator's departmental head, the South African National Health Research Ethics Council and the South African Medicines Control Council (if applicable).

14.2. Suspension or termination by researcher:

In the case where a research project is prematurely suspended/ terminated the principal investigator/researcher must notify the RECs in writing of the reasons for suspension/termination and give a summary of the results obtained in a study thus far.

15. Completion of Study

A study is considered active or on-going until all data is collected, follow up at all research sites is complete and participant participation is no longer needed. The principal investigator/researcher must submit a letter to the RECs informing them that the study is completed along with the final study report or a copy of the study abstract (in the case of student research). This should be done after the comments from the examiner's report have been addressed successfully. If a study is not closed but is allowed to expire (a lapse in approval) an administrative suspension letter may be sent to the principal investigator.

16. Research requiring additional attention

The RECs will pay special attention to research involving certain participants and certain types of research. It may be necessary in these instances for the RECs to impose additional measures to protect the well-being of the research participants. Conducting post-research investigations may also be necessary to ensure that the additional measures were implemented. Where compliance is defective, ethical approval may be withdrawn. The RECs will follow the National Health Act section 71(3)(a), where research on children for non- therapeutic interventions must fulfil the following criteria: permission from the Minister, permission from the minors' parent/s or guardian and, where the minor is capable of understanding and consenting, from the minor.

Classes of participants that require special attention include:

- Minors – those under 18 years of age
- Pregnant women
- Prisoners
- People with intellectual or mental impairment
- People for whom English is not a first language
- People from vulnerable communities
- Or any other group deemed to be applicable

Types of research requiring special attention:

- Indigenous medical systems
- Emergency medical care
- Innovative therapy/interventions
- Research requiring ambiguity of information for participants

The UREC will follow the guidelines from the Department of Health, Ethics in Health Research: Principles, structures and processes, available at http://www.nhrec.org.za/?page_id=14

17. Research for non-degree purposes (Independent Research)

All documentation for submission is available on http://www.univen.ac.za/research/research-ethics/ or can be obtained from the UREC Secretariat.

The University Research Ethics Committee considers internal and external applications for ethics clearance for research for non-degree purposes/ independent research.

The following will need to be submitted:
1) Completed UNIVEN approved format for proposal submission ensuring the following are addressed:
   - Participant recruitment procedures
   - Safety information
   - Any payment or compensation to participants
2) The UNIVEN Informed consent form (appendix B)
3) Conflict of interest form (appendix C)
4) Other information being supplied to participants
5) Other documentation necessary for the RECs to make an informed decision regarding the research.

The RECs Secretariat will accept applications from the Schools/ Departments and principal investigators for ethical clearance on a rolling basis. The RECs Secretariat in conjunction with the Chairperson will determine whether the application requires expedited or full review. The RECs Secretariat will check the application ensuring that all relevant documentation has been submitted, should documentation be missing it will be requested.

18. Handling of complaints

The RECs may receive complaints about researchers, the conduct of research, or about the conduct of the RECs. Complaints may be made by participants, researchers, staff of the institution, or others. All complaints should be handled promptly and sensitively.

Possible complaints cover a broad spectrum from 'inadvertent technical deviations' from established protocols to allegations of scientific misconduct or fraud. The primary concern in response to any complaint is the extent to which research participants are endangered. There may also be concerns about the degree to which researchers are fulfilling their responsibilities, questions around culpability for misconduct and misleading reports being published by a researcher accused of misconduct or fraud. Often the RECs will be the most appropriate body to consider complaints in the first instance, although ultimately, the responsibility lies with UNIVEN.

The Chairpersons of the RECs will receive the complaints; he/she may delegate this responsibility to a member of the RECs. All complaints will be dealt with and may require the assistance of other persons (not necessarily members of the RECs). The UNIVEN Informed consent form (appendix B) provided to study participants will provide the contact details of RECs secretariat should participants wish to lodge a complaint. The RECs Secretariat will forward the complaint on to the Chairperson/complaints officer.

Complaints can be reported to the University Research Ethics Committee Secretariat on 015 962 9058 / Vanecia.Khoza@univen.ac.za or Whistle blowing Ethics Hotline Tollfree Telephone number: 080 021 2755 Email.univenhotline@tipoffs.com

Procedure for complaint:
- complaint referred to the Chairperson of the RECs through the secretariat
- the Chairperson would consider the complaint – including, where necessary, reference to original protocol, contact with researchers, contact with complainant
- action would be taken including, if warranted, implementing an investigation with the complainant being advised accordingly
- A report will appear at the next RECs meeting.

Where the complainant is not satisfied with the actions taken, the complaint would be referred to the relevant DVC Research and Postgraduate studies.

19. Conflict of interests by researchers

- Conflict of interest arises when the individual's private or personal interests and professional obligations are divergent to such an extent that an independent observer may have doubt as to whether or not the individual's professional actions are influenced by personal considerations, financial or otherwise. Any conflict of interests should be avoided, and all researchers must make known any potential conflict of interests. Interference by clients or funders that could compromise the integrity of the research is unacceptable.

Possible conflict of interests:

- Financial relationships of any kind by the researcher e.g. equity, stock
- Proprietary interests e.g. patents, intellectual property
- Sponsorship/donations e.g. conferences, equipment
- Funding e.g. for additional staff or facilities, payments to departments
- Co-authorship of articles
- Positions on various boards e.g. Pharmaceutical Advisory board
- Grants and retainers.

Conflict of interests that are not disclosed may have a negative impact on the well-being of the research participants; therefore, the RECs must be duly informed in order to protect the participants. All principal investigators are required to sign a conflict of interest form.

Links

National Research Ethics Guidance

- *Ethics in Health Research: Principles, Structures and Processes – SA DoH, 2004*
- *http://www.nhrec.org.za/index.php/guidelines?download=3:2015-ethics-in-health-reseach*
- *http://www.nhrec.org.za/index.php/grids-preview?download=10:doh-2015-ethics*
- *Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa – Second Edition, 2006. Department of Health, Pretoria, South Africa*
- *Ethics Guidelines – Medical Research Council*
- *South African National Environmental Management Act*

International Research Ethics Guidance

- *Belmont Report – created by the National Commission for the Protection of Human subjects of research, published in 1979.*
- *Declaration of Helsinki 2008 – developed by The World Medical Association (WMA) as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.*
- *International Ethical Guidelines for Biomedical Research Involving Human Subjects – Council for International Organizations of Medical Sciences (CIOMS)*
- *ICC/ESOMAR International Code on Market & Social Research*
- *ESOMAR Word Research Codes & Guidelines for Customer Satisfaction Studies*

- *ESOMAR Word Research Codes & Guidelines for Interviewing Children & Young People*
- *ESOMAR Word Research Codes & Guidelines for Conducting Survey Research Via Mobile Phone*
- *ESOMAR Word Research Codes & Guidelines on Social Media Research*

Registration of Clinical Trials Undertaken in South Africa

- How to register
- Further information about the South African National Clinical Trial Register

Participants' Rights in Human Research

- 'What you should know when deciding to take part in a clinical trial as a research participant' – a booklet for researchers to give to potential participants in clinical trials, South African Department of Health.
- *Participant's Bill of Rights – produced by the South African AIDS Initiative (SAAVI) for preventive HIV Vaccine Trials*

Ethics Training

- NIH Office of Extramural Research. Protecting Human Research Participants (Charges applicable)
- Training and Resources in Research Ethics Evaluation - https://elearning.trree.org