SP/2012-2013/027Fv

STANDARD OPERATING PROCEDURES

RESEARCH ETHICS COMMITTEE

UNIVERSITY OF PORT HARCOURT

PORT HARCOURT

December, 2012

Foreword

The main business of any university the world over is teaching, research and community service. Many of the breakthroughs in the world today, be it in science, arts, agriculture, social sciences, are results of the effort of researchers.

However, it is important to note that there are ethical standards that must be followed or adhered to in carrying out researches. These standards are established to guarantee best practices in any research endeavour.

The vision of the current leadership of the University in setting up the Research Ethics Committee is to ensure that there is a structure that would coordinate and monitor research activities in the University to ensure compliance with the ethical standards.

A competent Research Ethics Committee as set up by the management will enable the University resolve all ethical issues and give research outcomes from the University international recognition and credibility.

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1. INTRODUCTION

This Standard Operating Procedure (SOP) describes operations of the University of Port Harcourt Research Ethics Committee. Produced in accordance with the Guidelines of the National Code of Health Research 2006 and the WHO *Operational Guidelines for Ethics Committees That Review Biomedical Research,* it will guide the operations of the Committee to ensure it attains its objectives.

This SOP will be used by the Committee and researchers on human participants and animals in their activities related to the review and conduct of researches to ensure the attainment of the highest ethical standards. The SOP covers all forms of research on individual persons, whether they be volunteers or patients, and include the study of treatment which might benefit the individual patient (therapeutic research) and the acquisition of knowledge that may be of no immediate benefit to the healthy volunteer (non-therapeutic research). The SOP also applies to non-clinical research on humans and animals.

The University of Port Harcourt Research Ethics Committee shall promote the following principles of biomedical ethics in its activities:

- autonomy (respect for the person - a notion of human dignity)
- beneficence (benefit to the research participant)
- non-malfeasance (absence of harm to the research participant)
- justice (notably distributive justice - equal distribution of risks and benefits between
- communities)

The researches for review by the Committee shall come from within and outside the University Community. Research has been defined as a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalisable knowledge. These investigations could raise ethical issues because of the need to subordinate to some extent, the immediate interests of the participants to the objective of the advancement of knowledge and therefore, must be subjected to ethics review. The Ethics Committee will receive and review all forms of research related to humans, animals and biochemical products whether they are Therapeutic/Non –therapeutic research, Intervention research, Observation research clinical or non clinical research and other forms of research. A useful rule of thumb is that if an investigation will generate new knowledge which can be generalised or transferred to others, or presented at a scientific meeting, or submitted for publication or for a higher qualification,that investigation is as research. Clinical audits through examination of patient records; observation of activities of individuals; health systems research to improve efficiency, cost-effectiveness and equity in health care, all are recognised as valid research. Non clinical research includes studies of anatomy, physiology and laboratory investigations not involving patients. Quantitative and qualitative researches involving humans, animals and biochemical products also require ethics reviews because in one form or the other, ethical issues are involved.

2. RATIONALE

The purpose of the Standard Operating Procedure is:

- To facilitate the work of the Research Ethics Committee by ensuring prompt and timely review of proposals
- To ensure effective and efficient communication with researchers to minimize delays in the execution of projects

This document aims at facilitating the attainment of goals of the Research Ethics Committee which are:

i. to maintain ethical standards of practice in research;
ii. to protect research participants and investigators from harm or exploitation;
iii. to preserve the research participant's rights, which take preference over society's rights;
iv. to provide reassurance to society that this is being done.

3. FUNCTIONS AND OPERATIONS OF THE RESEARCH ETHICS COMMITTEE

3.1. Activities of the Research Ethics Committee

The activities of the Research ethics Committee shall be:

a. Regular Meetings: The Committee meets every month to appraise its activities and plan on how to attain its objectives. The meeting holds on the 3rd Thursday of the Month at 2.00pm at the Registrar's Committee Room.

b. Review of Research Proposals and Materials: This is the major function of the Committee. Decisions on the outcome of the reviews of proposals are taken during the regular meeting. Decisions on proposals given expedited review are ratified at the statutory meeting.

c. Follow up of ongoing research works: The committee follows up research works through:

i. Review of quarterly project status report from researchers: The Researcher shall send follow-up reports quarterly to the Committee to update the Committee on the progress of the Research and at the end of the research, three copies of the final report shall be submitted to the Committee. The decision on this report may be to allow the continuation of the research, suspend or terminate the research.

ii. Activities of the Follow-up subcommittee: A subcommittee shall be appointed by the Committee to monitor the implementation of every research at the time the proposal is approved. The follow-up shall be continuous, from the commencement to the end of the project. The report of subcommittee up shall be presented during the statutory meetings of the Committee. Where the need arises, an emergency meeting may be called to take decisions on research works found to contravene ethical principles.

iii. Review of other reports and communications related to an approved proposal: The Committee will receive reports from researchers, participants, institution(s), sponsor(s) and other stakeholders on the implementation of proposals it has approved. These reports may include the following:
   a. Report of adverse events from the research
   b. Request for modification of the research in order to address some challenges
   c. Responses to communications generated by the Committee
   d. Other forms of inputs that will contribute to the attainment of the goals of the Committee.

d. Other activities: The other activities that can be carried out by the Committee include, but not limited to:

i. Creation of awareness on ethics in research works through seminars, workshops, posters, flyers and billboards, letters to Departments/faculties, etc.

ii. Development of materials on Ethics in research. These materials shall include Guidelines on ethics in different forms of research and involving different types of materials.

iii. Development of the capacity of the members and university community on research ethics through the conduct of training workshops or seminars.

iv. Submission of an annual report of its activities to the University of Port Harcourt. The report should contain the following:

- The list and dates of meetings held in the year
- The reports of the activities, including the projects reviewed and approved
- The membership

4. The Committee's meeting

4.1. Procedure for the Committee's meetings

The requirements of the meeting are as follows:

1. Quorum for a normal meeting shall be formed by the presence of at least 4 members.
2. Minutes of Meetings:
   - The Secretary of the Committee shall distribute the minutes of previous meetings with the circular for the meeting at least 3 days before the scheduled meeting.
   - Each member of the Committee is expected to read the minutes and correct as appropriate.
   - During the meeting, the members shall go through the minutes again and make corrections as appropriate after which the minutes shall be adopted
   - Corrected copies of the minutes shall be stored by the Secretary and included in the Annual Report of the Committee's activities. The Minutes of the Committee shall have sufficient details to show:

- Attendance at meetings
- Actions taken by the Committee
- The vote on these actions including the number of members voting for, against and abstaining
- The basis for requiring changes or disapproving research
- A written summary on controversial issues and their resolutions
- Records of continuing oversight activities
- Copies of all correspondences between the Committee, applicants, researchers, sponsors and any other agent consulted in the discharge of the Committee's duties
- Statement of complaints or information/data that is used to determine decision(s)

3. Reviews of research proposals:
   - The Chairman shall present all proposals for review during each meeting
   - The reports of reviewers on the proposal shall be presented to the Committee
   - Members shall make their inputs to the proposal in regards of the ethics of the research
   - The Chairman shall summarise the decision on the proposal.
   - Decision shall be arrived at by a consensus of the members present
   - When considered necessary, a representative of the research team can be invited to make presentation to the Committee
   - Committee members who have conflict of interest shall leave when decisions on the proposal shall be taken in the meeting.

4.2. Elements of the Review

The primary task of the Research Ethics Committee is the review of research proposals and their supporting documents, with special attention given to the informed consent process, documentation, and the suitability and feasibility of the protocol. The Committee will take into account prior scientific reviews, if any, and the requirements of applicable laws and regulations. The following aspects of the proposal/protocol will be considered, as applicable:

a. Scientific Design and Conduct of the Study:

i. the appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants;
ii. the justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities;
iii. the justification for the use of control arms;
iv. criteria for prematurely withdrawing research participants;
v. criteria for suspending or terminating the research as a whole;
vi. the adequacy of provisions made for monitoring and auditing the conduct of the research

vii. the adequacy of the site, including the supporting staff, available facilities, and emergency procedures;
viii. the manner in which the results of the research will be reported and published;

b. Recruitment of Research Participants

i. the characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, and ethnicity);
ii. the means by which initial contact and recruitment is to be conducted;
iii. the means by which full information is to be conveyed to potential research participants or their representatives;
iv. inclusion criteria for research participants;
v. exclusion criteria for research participants;

c. Care and Protection of Research Participants

i. the suitability of the investigator(s)'s qualifications and experience for the proposed study;
ii. any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action;
iii. the medical care to be provided to research participants during and after the course of the research;
iv. the adequacy of medical supervision and psycho-social support for the research participants;
v. steps to be taken if research participants voluntarily withdraw during the course of the research;
vi. the criteria for extended access to, the emergency use of, and/or the compassionate use of study products;
vii. the arrangements, if appropriate, for informing the research participant's general practitioner (family doctor), including procedures for seeking the participant's consent to do so;
viii. a description of any plans to make the study product available to the research participants following the research;
ix. a description of any financial costs to research participants;
x. the rewards and compensations for research participants (including money, services, and/or gifts);
xi. the provisions for compensation/treatment in the case of the injury/disability/death of a research participant attributable to participation in the research;
xii. the insurance and indemnity arrangements;

d. Protection of Research Participant Confidentiality

i. a description of the persons who will have access to personal data of the research participants, including medical records and biological samples;

ii. the measures taken to ensure the confidentiality and security of personal information concerning research participants;

e. Informed Consent Process

i. a full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent;
ii. the adequacy, completeness, and understandability of written and oral information to be given to the research participants, and, when appropriate, their legally acceptable representative(s);
iii. clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals;
iv. assurances that research participants will receive information that becomes available during the course of the research relevant to their participation (including their rights, safety, and well-being);
v. the provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project;

Guidelines on obtaining informed consent are contained in Annex 1.

f. Community Considerations

i. the impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn;
ii. the steps taken to consult with the concerned communities during the course of designing the research;
iii. the influence of the community on the consent of individuals;
iv. proposed community consultation during the course of the research;
v. the extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health needs;
vi. a description of the availability and affordability of any successful study product to the concerned communities following the research;
vii. the manner in which the results of the research will be made available to the research participants and the concerned communities.

4.3. Expedited Review

a. Protocols requiring expedited reviews: A proposal may receive expedited review in the following circumstances:

- Research is found to involve no more than minimal risk
- Minor changes in previously approved research during the period for which approval is authorized

c. Expedited review may be carried out by the Chairman of the Committee or reviewer(s) appointed from among the members of Committee. In reviewing the protocol, the reviewer(s) exercise all the powers of the Committee except that they cannot disapprove the research.
d. The decision of the reviewer(s) shall be presented by the Chairman at the regular meeting of the Committee for discussion and ratification.

4.4. Decision-Making

The following considerations shall guide the Committee's decision making process:

i. 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. Examples include research works in which the member is involved either as a researcher or supervisor.
ii. a decision may only be taken when sufficient time has been allowed for review and discussion of an application in the absence of non-members (e.g., the investigator, representatives of the sponsor, independent consultants) from the meeting, with the exception of EC staff;
iii. decisions should only be made at meetings where a quorum is present;
iv. the documents required for a full review of the application should be complete and the relevant elements should be considered before a decision is made;
v. only members who participate in the review should participate in the decision;
vi. Decisions shall be arrived at by consensus; when a consensus appears unlikely, the members shall vote and the majority opinion will be upheld.
vii. advice that is non-binding may be appended to the decision;
viii. in cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified;
ix. a negative decision on an application should be supported by clearly stated reasons.

4.5. Communicating a Decision

The decision of the Committee on the application should be communicated in writing to the applicant according to the Committee's procedures, within two weeks of the meeting at which the decision was made. The communication of the decision will include, but not limited to the following:

i. the exact title of the research proposal reviewed;
ii. the clear identification of the protocol of the proposed research or amendment, date and version number (if applicable) on which the decision is based;
iii. the names and (where possible) specific identification numbers (version numbers/dates) of the documents reviewed, including the potential research participant information sheet/material and informed consent form;

iv. the name and title of the applicant;
v. the name of the site(s);
vi. the date and place of the decision;
vii. the name of the EC taking the decision;
viii. a clear statement of the decision reached;
ix. any advice by the EC;
x. in the case of a conditional decision, any requirements by the EC, including suggestions for revision and the procedure for having the application re-reviewed;
xi. in the case of a positive decision, a statement of the responsibilities of the applicant; for example:
    1. confirmation of the acceptance of any requirements imposed by the EC;
    2. submission of annual progress report(s);
    3. the need to notify the EC in cases of protocol amendments (other than amendments involving only logistical or administrative aspects of the study);
    4. the need to notify the EC in the case of amendments to the recruitment material, the potential research participant information, or the informed consent form;
    5. the need to report serious and unexpected adverse events related to the conduct of the study;
    6. the need to report unforeseen circumstances, the termination of the study, or significant decisions by other ECs;
    7. the information the EC expects to receive in order to perform ongoing review;
    8. the final summary or final report;
xii. the schedule/plan of ongoing review by the EC;
xiii. in the case of a negative decision, clearly stated reason(s) for the negative decision;
xiv. signature (dated) of the Secretary of the Committee

4.6. Follow-up

- The Ethics Committee will nominate two members of the Committee (one of whom must be specialized in the field of the research) to follow up the conduct of a research approved by the Committee. Where there are no members specialized in the field, the Committee shall nominate an external person to serve as a member of the follow-up subcommittee.
- The nomination shall be done in the same meeting as the approval of the research is done.
- The follow-up shall be from the beginning to the end of the research and research works which have not been reviewed and approved shall not be allowed in the University.
- The Heads of respective departments in which the research will be conducted will be written about the research and their support in the follow-up of the research sought.
- Ongoing communications between researchers and the Committee shall be by mails, submitted to the Secretary of the Committee.
- The follow-up procedure includes:

i. Reports on follow-up of research works shall be presented by the follow-up team at the regular meeting of the Committee expect when there is an emergency for which an emergency meeting of the Committee shall be called and the quorum shall be 1/4 (3) members comprised of the Chairman, Secretary and at least one member of the Follow-up Team. The team member will present the report on the follow-up and decisions will be taken.

ii. the follow-up reviews shall be done quarterly in the life of the project

iii. Emergency follow-up review meeting shall be called in the following instances or events requiring 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 product, and the response taken by investigators, sponsors, and regulatory agencies;
   - any event or new information that may affect the benefit/risk ratio of the study;

iv. a decision of a follow-up review should be issued and communicated to the applicant, indicating a modification, suspension, or termination of the original decision or confirmation that the decision is still valid;

v. in the case of the premature suspension/ termination of a study, the applicant should notify the Committee of the reasons for suspension/ termination; a summary of results obtained in a study prematurely suspended/terminated should be communicated to the EC;

vi. The Committee shall receive notification from the applicant at the time of the completion of a study;

vii. The Committee shall receive a copy of the final summary or final report of a study.

viii. For follow-up purposes, the REC will require an annual report or a study completion report 30 days prior to the end of the reporting year.

5. SUBMISSION OF AN APPLICATION

5.1. Application

A written application requesting a review of the ethics of proposed biomedical research shall be submitted by a qualified researcher responsible for the ethical and scientific conduct of the research. The application should be submitted to:

The Secretary;

Research Ethics Committee;
Office of the Deputy Vice Chancellor (Research and Development)
First Floor, Senate Building, Abuja Park,
University of Port Harcourt
Port Harcourt.

Additionally, electronic copies should be submitted by e-mail to otami_akubom@yahoo.com.

5.2 Application Requirements

The requirements for the submission of an application for the Ethical review of a research project include:

i. An application letter by the researcher should be sent to the Committee. Co-researchers, supervisors and heads of Department of the candidate should endorse the application

ii. All documents should be written in British English. Materials for administration in other languages shall be accompanied by the appropriate translations.

iii. Documents for submission: The documents for submission shall include the following:

1. Signed and dated application form. To facilitate communication, the application letter should contain the detailed addresses of the researchers including their telephone numbers and e-mail address.
2. The protocol of the proposed research (clearly identified and dated), together with supporting documents and annexes;
3. A summary (as far as possible in non-technical language), synopsis, or diagrammatic representation ('flowchart') of the protocol;
4. a description (usually included in the protocol) of the ethical considerations involved in the research;
5. case report forms, diary cards, and other questionnaires intended for research participants;
6. when the research involves a study product (such as a pharmaceutical or device under investigation), an adequate summary of all safety, pharmacological, pharmaceutical, and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g., recent investigator's brochure, published data, a summary of the product's characteristics);
7. investigator(s)'s curriculum vitae (updated, signed, and dated);
8. material to be used (including advertisements) for the recruitment of potential research participants;
9. a description of the process used to obtain and document consent;
10. 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 required, in other languages;

11. informed consent form (clearly identified and dated) in the language(s) understood by the potential research participants and, when required, in other languages;
12. a statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants;
13. a description of the arrangements for indemnity, if applicable;
14. a description of the arrangements for insurance coverage for research participants, if applicable;
15. a statement of agreement to comply with ethical principles set out in relevant guidelines;
16. all significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on that account. The reasons for previous negative decisions should be provided.
17. Copy of the letter(s) of support from co-investigator(s)
18. Where applicable, letter of sponsorship
19. Copies of Material Transfer Agreement where indicated
20. Evidence of informed consent training by applicant and co-investigators

iv. Number of copies to be submitted: All applicants shall submit fifteen copies of their applications and relevant documents for assessment.

v. Deadlines for submission: All applications for ethical approval should be received by the Secretary not later than the last Thursday of the month preceding the expected month of review.

vi. The Secretary of the Committee shall give an acknowledgement slip for each research proposal submitted to for review and where the submissions are not complete, the researcher shall be contacted by e- mail or telephone message to submit the additional materials.

vii. The outcome of the application shall be received in writing within 4 weeks of submission except where incomplete submissions were received

viii. All supplementary information required by the Committee should be submitted within one week of the request- not later than the second Thursday of the month for the review so that the application can be discussed in the month in question.

ix**. Fees:**

- Members of the Research Ethics Committee do not receive payment for their services.
- The Committee does not charge for the review of proposals. However, reimbursement of expenditures for the review process may be paid to the Committee. These include the cost of mailing documents, communications, etc

- Proposals submitted directly by external bodies for review will be paid for by persons who have no financial interest in the outcome of the application. A sum to be decided by the Committee from time to time shall be paid to the Secretary to cover the cost of processing the application. This sum shall cover the honorarium for not more than three reviewers who may be selected to review a proposal if required; cost of handling the materials and communications. All fees shall be receipted and carefully documented and accounted for.

6. HANDLING OF THE PROPOSAL AFTER SUBMISSION

a. **The Secretary**:

On receipt of the application, the Secretary shall:

i. Register and acknowledge all submissions
ii. Submit the documents to the Chairman within 2 days of the receipt
iii. And, as directed by the Chairman, send copies of the application to all members of the Committee and selected technical reviewers when required
iv. Receive and process all communications related to the project
v. Communicate with researchers and others as may become necessary on issues related to the application and project
vi. Where fees are to be paid, receive and handle the funds as determined by the Committee

b. The Chairman:

The Chairman shall:

i. review the submission and decide on the appropriate Review Process within two days of the receipt of the proposal
ii. Review the submission and ensure all required documents have been submitted. Where additional materials are required, the researcher shall be promptly informed.
iii. Direct the Secretary to distribute the submission to all Committee members
iv. Select additional technical reviewers for the proposal based on the areas of the study if the skills are not available among the Committee members. Copies of the proposal shall be sent to such reviewers within one week of the submission of the proposal
v. Present the reports from reviewers and follow up team members at scheduled meetings

c. Reviewers:

i. All Committee members shall be trained on the skills to review proposals and shall actively participate in the review of applications

ii. Reviewers who have conflict of interest should inform the Chairman and not participate in the review process.
iii. External reviewers who may be from within or outside the University shall review technical aspects of the proposal when the relevant skills are not found among the Committee members
iv. External reviewers shall be paid honorarium as may be decided by the Committee based on prevalent conditions and access to funds for the Committee's works.
v. A maximum of three technical reviewers shall be used for each proposal
vi. All reviewers shall use form in Annex 1 to submit their report within two weeks of receipt of the documents. All documents shall be returned along with the report.
vii. Reviewers who are members of the Committee shall present their reports during the review meeting

7. DOCUMENTATION AND ARCHIVING OF PROPOSAL MATERIALS

- All documentation and communication of the Committee shall be dated, filed, and archived according to written procedures.
- All archived documents can only be accessed by the written approval of the Committee after the request has been made.
- All proposals and related materials shall be stored for a minimum of five years after the completion of the study
- Documents that should be filed and archived include, but are not limited to;

1. This standard operating procedures and regular (annual) reports;
2. the curriculum vitae of all members;
3. a record of all income and expenses of the Committee, including allowances and reimbursements made to the secretariat;
4. the published guidelines for submission established by the Committee;
5. the agenda of the meetings;
6. the minutes of the meetings;
7. one copy of all materials submitted by an applicant;
8. the correspondence by members with applicants or concerned parties regarding application, decision, and follow-up;
9. a copy of the decision and any advice or requirements sent to an applicant;
10. all written documentation received during the follow-up;
11. the notification of the completion, premature suspension, or premature termination of a study;
12. the final summary or final report of the study.

Other Documents to be Stored for Retrieval include:

- Approved sample documents, including adverts, etc
- All progress reports submitted by researcher(s), institution(s) and sponsor(s)
- All reports of injuries and adverse events
- Attendance at meetings
- Date a proposal was submitted and date the approval was given

8. OTHER ISSUES RELATED TO THE REVIEW OF PROPOSALS

8.1. Process for Amendment of Research

a. A researcher may be required to amend a research in any of the following circumstances:

- Where there are changes in any part of the research protocol
- Where there are changes in the named members of the team conducting the research
- Where there are changes in research sites
- Where there are changes in the sponsorship, institutional guidelines, institutional structure, the Committees requirements, national laws or exigencies that impact on the ethical conduct of the research

b. The researcher shall submit an application for the original research approval if the proposed changes shall not involve a change in the inclusion or exclusion criteria, randomization, interventions and outcome measures.

c. The researcher shall not deviate from the approved protocol except if the deviation is necessary to eliminate immediate hazard to research participants. In all such circumstances, the researcher shall notify the Chairman of the Committee within 24 hours of such changes

8.2. Process for the suspension of research

a. A research approved by the Committee can be suspended if it is not being conducted in:

- In accordance with the requirements of the Committee
- In accordance with existing legislation
- In accordance with existing institutional guidelines, or
- Where the research is associated with unexpected serious harm to participants

b. The Secretary shall send a mail to the researcher communicating the decision of the Committee to suspend the research within 14 days of the decision. The mail shall include

the reason(s) for the decision to suspend it and shall be reported to the researchers, institution(s), sponsor(s)and the registering body

c. The researchers, institution(s) and sponsor(s) are entitled to ask for a reconsideration of the research within 14 days of the receipt of the notification the suspension

8.3. Revision of the Suspension of Research

a. A researcher whose research has been suspended can write within 6 weeks of the receipt of the mail for a review of the suspension order.
b. The Committee may review the decision to suspend the research if the reasons that led to the suspensions have been sufficiently and satisfactorily addressed
c. The case is presented at the next regular meeting of the Committee and the researcher will sign an agreement with the Committee on the findings and the agreed remedial measures
d. If the Committee allows the resumption of the research, an oversight review of the research will be carried out within six weeks

8.4. Process for the Termination of Research

- If the researcher(s), institution(s) or sponsors are unable to address the precipitants that led to the suspension of the research within 14 days, the Committee will terminate the research
- The Committee shall notify the researcher, institutions or sponsors of this decision within 14 days
- Researchers may appeal the decision of the committee within 14 days of the receipt of this notification to the national research ethics Committee

10. REFERENCES

1. Federal Ministry of Health (Department of Health Research and Planning): National Code of Health Research Ethics 2006. National Health Research Ethics Committee

2. World Health Organisation: Operational Guidelines for Ethics Committees That Review Biomedical Research TDR/PRD/ETHICS/2000.1. World Health Organisation, Geneva 2000.
3. Medical Research Council of South Africa: Guidelines on Ethics for Medical Research: General principles including research on children, vulnerable groups, international collaboration and epidemiology