



UNIVERSITY OF MALAWI
COLLEGE OF MEDICINE

GENERAL GUIDELINES ON HEALTH RESEARCH

COLLEGE OF MEDICINE RESEARCH AND ETHICS COMMITTEE (COMREC)

College of Medicine Research and Ethics Committee

Private Bag 360, Chichiri

Blantyre 3

Malawi

Telephone: +265 1 874 377

Fax: +265 1 874 740

Email: comrec@medcol.mw

29th September, 2010.

Contents

1.0 INTRODUCTION	3
2.0. Purpose of Guidelines	3
3.0 ORGANISATION, ADMINISTRATION AND FUNCTIONS OF COMREC	3
3.1 Organization and administration of COMREC.....	4
3.2 Functions of COMREC	4
3.3 Membership of COMREC	4
3.3.1 Membership Requirements	4
3.3.2 Composition of COMREC	4
3.3.3 Terms of Appointment.....	5
3.3.4 Offices	5
3.3.5 Code of Conduct	8
3.3.6 Confidentiality Agreement.....	8
3.3.7 Conflict of Interest	8
3.3.8 Attendance.....	8
3.3.9 Training of Committee Members	8
3.3.10 Finances	9
4.0 MEETINGS OF COMREC.....	9
4.1 Scheduling of Meetings.....	9
4.2 Quorum	9
4.3 Agenda	9
5.0 SUBMISSION OF APPLICATIONS FOR COMREC REVIEW	9
5.1 Review Process.....	10
5.2 Elements of the Review	10
5.3 Expedited Review.....	11
5.4 Amendments and Modifications	11
5.5 Continuing Review	11
5.6 Exemption from Review.....	12
5.7 Review of Studies of 'National Interest'	12
5.8 Decision-Making.....	12
5.9 Communicating a Decision	13
6.0 FOLLOW UP	13
6.1 Sanctions	14
7.0 SUSPENSION OR TERMINATION OF COMREC APPROVAL OF RESEARCH	14
8.0 DOCUMENTATION AND ARCHIVING.....	14
9.0 INDEMNITY FUND	15

1.0 INTRODUCTION

The three core functions of the College of Medicine (CoM) are teaching, service and research. To facilitate research function the UNIMA established College Research and Publication Committees (CRPC)¹ in all its constituent colleges. Studies conducted in the CoM include those that require participation of human subjects. All such research requires ethical review and approval. The CoM established COMREC in order to perform these function.

Guidelines for ethical and scientific standards for the conduct of research involving human subjects have been developed and established. These include the Declaration of Helsinki (WMA),² the International Ethical Guidelines for Biomedical Research Involving Human Subjects (/CIOMSWHO),³ Guidelines for Good Clinical Practice (ICH).⁴ Compliance with these guidelines helps to ensure that the dignity, rights, safety, and well-being of research participants are promoted and that the results of the investigations are credible. In addition, there are national guidelines by the National Commission for Science and Technology (NCST), formerly known as the National Research Council of Malawi (NRCM)⁵, which are based on international guidelines.

The College of Medicine (CoM) developed its first guidelines for COMREC in 1995. The CoM has undertaken a review of the original guidelines to keep them in line with both the National Commission for Science and Technology and international guidelines.

College of Medicine Requirements on Research

The CoM requires that:

1. Reviewers provide independent decision from political, institutional, professional and market influences
2. All research conducted by its faculty meet these national and international ethical and scientific guidelines
3. The reviewers should take into account the interests and needs of the researchers and having due regard of the national regulatory agencies and applicable laws
4. Approvals should be granted before commencement of the study
5. Act in full interest of research participants or concerned communities.

2.0. Purpose of Guidelines

These Guidelines are intended to facilitate and support scientific and ethical review of research involving human and animal subjects carried out in the CoM. The guidelines are not intended to supersede relevant national laws and regulations.

3.0 ORGANISATION, ADMINISTRATION AND FUNCTIONS OF COMREC

¹ University of Malawi Research Policy

² World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. 1964

³ International Ethical Guidelines for Biomedical Research Involving Human Subjects, CIOMS; 2002

⁴ ICH-Guidelines for Good Clinical Practice, 1996

⁵ Procedures and Guidelines for the conduct of research in Malawi, National Research Council of Malawi; Revised Edition October 2002

3.1 Organization and administration of COMREC

COMREC is constituted as an independent scientific and ethics committee through the National Commission for Science and Technology. Its primary responsibility is to the CoM of the University of Malawi and to the Government of Malawi through the NCST. COMREC is expected to carry out its functions of ethical and scientific review. Promotion and coordination of research and publications is the function of the Research and Publications committee. Administrative support for COMREC will come from the Research Support Centre (RSC) of the CoM.

3.2 Functions of COMREC

The main functions of COMREC are:-

1. To protect the safety of human and animal subjects participating in research by
 - Determining that the proposed research is both scientifically and ethically sound
 - Continually reviewing the safety of participants
2. Promoting research in the College and publication of results

3.3 Membership of COMREC

3.3.1 Membership Requirements

COMREC shall have multidisciplinary membership to provide adequate scientific and ethical review of research protocols submitted by college faculty. The committee shall be sufficiently qualified through the basic qualifications, experience and expertise of its members. The diversity of membership will include gender, sensitivity to community attitude, so that the committee commands respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The committee shall include external members who are not affiliated with the CoM. COMREC may from time to time consult non COMREC members with competence in special areas to assist in the review of protocols whose expertise is lacking within the committee. The committee shall include at least one lay member who is not affiliated with the college. However these individuals may not vote with the committee.

3.3.2 Composition of COMREC

COMREC shall have a maximum membership of 15 based on core competences applicable to scientific research in the CoM. The major competence categories shall be Biomedical Science, Research Methods (e.g. epidemiology and biostatistics), behavioural science and research ethics. In addition, membership of COMREC will include representatives from the following: the National Commission for Science and Technology (NCST); National Health Sciences Research Committee (NHSRC); Kamuzu College of Nursing (KCN); and the lay community. Finally, there shall be NHSRC cross-representation to facilitate the transfer of information from one committee to the other.

3.3.2.1 External Experts

COMREC shall establish a standing list of independent consultants who may provide special expertise to the committee on proposed research protocols outside the expertise scope of the committee.

3.3.2.2 Qualification Requirements and Appointment Procedures

Qualification

Appointments from the CoM must be members of staff at a minimum grade of Senior lecturer preferably have peer reviewed publications. Candidates must demonstrate experience having written a scientific research protocol or successfully conducted a COMREC approved or other relevant research.

The selection of the office bearers shall consider the following:

- Ability and experience in scientific disciplines
- Professional qualifications
- Suitability for appointment

Procedures

Members shall be appointed by the Principal of CoM, upon proposal and recommendation from faculty relevant committees and, academic departments. The appointment of a new committee shall ensure an overlap system retaining some old members of the committee to allow for continuity, the development and maintenance of expertise within COMREC, and the regular input of fresh ideas and approaches. Therefore a new committee shall be constituted 3 months before the end of the academic year to allow for training of the incoming COMREC members and to ensure a smooth and effective handover of COMREC.

3.3.3 Terms of Appointment

Appointment of COMREC members from the CoM shall be on the same terms as other CoM standing committees. There shall, therefore be no extra financial or monetary payment for membership for COM academic staff serving on COMREC. However members shall be fully reimbursed any expenses they incur on COMREC activities and will earn points for promotion. The duration of appointment for the committee shall be three (3) years. A member may be reappointed to serve another 3 year term. Normally a member can serve only two consecutive terms. A member may be allowed to resign upon giving valid reasons for resignation or may be asked to resign for incompetence, inefficiency, improper conduct, or ceasing to be a member of the College.

Vacant Position: A position that falls vacant before the end of the term of a committee shall be filled within two months following the procedures of appointment articulated above. The appointed member shall serve up to the end of the remaining term of the committee and for reappointment shall be regarded as having served a full term.

3.3.4 Offices

The leadership of COMREC shall have the following offices: the Chair, the Vice Chair, the Secretary and the Vice Secretary. Only COM academic members of staff are eligible for these positions. Members shall elect from among themselves the Chair, Vice Chair, the Secretary and Vice Secretary within a month of a new committee having being duly constituted.. The election of all the office bearers shall be ratified by the COM Principal and be under the supervision of the Principal of COM. Ex-officio members shall not hold any office.⁶

⁶ Science and Technology Act, 2003. Government of Malawi
COMREC Guidelines

Administrative support

COMREC shall have the following administrative support staff from the Research Support Centre for efficient functioning of the Committee. The support staff will include an Administrator and Compliance Officer (Inspector). The Research Support Centre (RSC) of the College shall serve as the secretariat for the committee. The centre shall be responsible for preparing materials and facilitate logistics for meetings of the committee and other follow up activities. In addition, the RSC will provide support with monitoring compliance with ethical guidelines during implementation of approved research. COMREC shall develop and establish a system of ensuring obtaining monitoring reports through the adherence office.

The Chair

The chairperson shall provide the overall direction for efficient functioning of COMREC and therefore shall among other duties:

- Chair all COMREC meetings, directing discussions, leading review and voting on research proposals.
- Take an active role in establishing and reviewing COMREC guidelines and procedures.
- Chair sub-committees of COMREC, where applicable.
- Conduct expedited reviews with a subset of the full COMREC.
- Monitor and report any attempts to influence or coerce COMREC members.
- Liaise with the Dean of Postgraduate Studies and Research on research issues affecting the Committee and vice versa
- Resolve any issues arising during the work of the board or refer unresolved issues to the institution.
- Represent the COMREC in communicating with other constituencies within and without the institution, including researchers and government regulators;
- Ensure assessments and audits are conducted as required by the institution and COMREC Guidelines; and
- Ensure the membership and proceedings of COMREC fundamentally comply with government policies, directives and regulations.
- Ensure that COMREC discharges its duties in accordance with the University of Malawi Research Policy.
- Work with the COMREC Administration to ensure the above.

The Secretary

Is responsible for:

- Assist the COMREC Administrator with administration of the review process (assignment of reviewers, compiling/editing of reviewers' comments)
- Assist the COMREC Administrator with preparation of agenda and minutes of meetings of COMREC
- Assist the COMREC Administration staff with review of guidelines and SOPs as when necessary

As the administrative structure and capacity for support to COMREC improves, it is anticipated that this function will become redundant, subsumed by the COMREC Administrator.

College of Medicine Research and Ethics Committee (COMREC) Administrator

The College of Medicine Research and Ethics Committee, COMREC Administrator, provides administrative support to the College of Medicine Research and Ethics Committee (COMREC) by assisting with submission and review coordination. Provides technical assistance to investigators involved in human subjects research. Provides recommendations for improving the COMREC review process. These functions include:

- **Submission Assistance.** Assists investigators with the application submission process. Interprets and advises investigators on applicable policies, procedures, guidelines, national regulations, and other compliance related requirements. Answers various questions and may guide investigators through some processes.
- **Application Screening:** Screens research study applications to determine completeness and accuracy. Determines if studies meet review criteria for “exempt”, “expedited”, or full board by reviewing the COMREC application, protocol and consent forms, ensuring they receive appropriate review according to national regulations. Screens applications for determining national interest studies and advises applicant to submit such applications to the National Health Sciences Research Committee as per the 2005 Government Policy Measures for the improvement of Health Research Co-ordination in Malawi. Screens revised applications and resubmissions, reviews changes, and if acceptable, forwards to COMREC Chairperson for final approval.
- **Administrative Assistance.** Establishes record of incoming mail into COMREC database. Distributes exempt and expedited studies to COMREC Chairperson for review. Coordinates with principal investigators for preparation of material for board meetings. Generates correspondence on behalf of COMREC Chairperson.
- Stamps consent forms appropriately. Distributes correspondence to Investigators.
- **Review Coordination.** Act as a liaison between the COMREC, the Chairperson, Investigators, Research Support Centre, and other relevant Institutional Committees. Responsible for following up with investigators to ensure they are aware of time limits and deadlines. Coordinates and schedules monthly reviews and annual review reports with the COMREC.
- **Meeting Coordination.** Coordinates meetings for the COMREC. Creates agenda, and ensures there is an appropriate composition of members to make quorum according to national regulations. Ensures proper procedures are followed. Creates COMREC letters with instructions for corrections based on deliberations at the meeting. Takes minutes, prepares written draft, and distributes to the Chairperson as required.
- **Process Improvement.** Makes recommendations for streamlining COMREC review process such as the revision of guidelines, SOPs, applications and consent forms, investigator notification, prior categorization and assignment of application submitted for board review.

Compliance Officer

Assesses whether research approved by COMREC is being conducted in accordance with COMREC guidelines and other relevant national and international standards. This includes

assisting COMREC and investigators with good research (clinical) practice advice and conducting inspections of study sites.

Administrative Secretary

Assists in the proper functioning of the COMREC secretariat office by maintaining files, scheduling appointments, acting as a receptionist, typing, preparing reports, conducting correspondence, collecting fees, distributing information, data entry, and coordinating activities. Provides administrative support to the COMREC Administrator and Chairperson in the daily operations of COMREC.

3.3.5 Code of Conduct

All members are expected to adhere to a high degree of conduct in order to maintain the good image and reputation of the Committee and the expected respect of the Committee by the community it serves.

3.3.6 Confidentiality Agreement

Members including external experts serving on COMREC shall maintain confidentiality relating to COMREC official documents and research participants. Therefore, upon appointment all members shall sign a confidentiality statement.

3.3.7 Conflict of Interest

There is always a potential for direct or indirect conflict of interest for academic members of staff in the college who are serving on the committee. COMREC therefore has put in place mechanisms to minimise this. For example a COMREC member who is an investigator on or is linked to a research protocol under consideration by the committee, although they may participate in the discussions (open) session, shall recuse themselves from the voting(closed) session. Other examples of conflict of interest include:

- A member who holds a significant financial interest in a sponsor or product under study
- A member whose spouse or close relative has research under review by the committee
- A member who has any other special form of relationship with the investigator or sponsor of the research under consideration if such a relationship is likely to influence decision of the committee.

3.3.8 Attendance

Members are expected to attend all meetings of the Committee. Members who for valid reasons are unable to attend regular meetings of the Committee should inform the secretariat at least three days before the scheduled meeting. Absenteeism and inconsistent attendance reduces the respect of the committee. Failing to attend three consecutive meetings shall form a basis for a member being withdrawn from the committee. The Chairperson and Secretary of the Committee may not miss two consecutive regular meetings of the Committee.

3.3.9 Training of Committee Members

Members of COMREC shall have initial and continuing training regarding the ethics and science of research.

3.3.10 Finances

All resources required to run activities of COMREC shall be through the College budget. COMREC shall submit an annual budget to the Finance Officer (FO) of the College. To cover the cost of protocol review the College shall charge a processing fee of \$100 (MKW equivalent) for each new submission and resubmission for the fourth time. In keeping with the COM Research Policy of promoting research in the college, eligible investigators can apply to management for exemption from paying the processing fee.

4.0 MEETINGS OF COMREC

4.1 Scheduling of Meetings

COMREC shall meet at least once every month. The secretariat shall make available the calendar schedule of its meetings at the beginning of each year to all relevant stakeholders. The committee shall convene extraordinary meetings when necessary, provided that the stipulated quorum requirements are met. Meetings should be planned in accordance with the needs of the workload. The agenda shall generally be on a first come first served basis. COMREC may fast track the processing of protocols of 'national interest' or to meet sponsor deadlines. The secretariat shall compile all the relevant documents and materials required for review and shall be circulated to the members at least 14 days before the date of the scheduled meeting. The materials include the complete proposal package submitted for review and any other relevant documentation.

4.2 Quorum

Quorum of any meeting shall be achieved when 50% + 1 of the members attend. The quorum should preferably include the members of both genders a member whose primary area of expertise is in a non-scientific area and at least one member who is independent of the College. If the quorum cannot be achieved the meeting must be rescheduled within 2 weeks of the failed meeting. If the subsequent meeting does not achieve quorum, then the Chairperson shall make a decision based on the expertise and number of members present.

4.3 Agenda

The annual calendar of meeting shall be released in January each year and made available to all departments in the college, members and all other stakeholders. The agenda for the first meeting will include the following:

- COMREC annual report,
- The annual calendar
- Review of protocols

The last review meeting of the Committee shall take place during the last month of the academic year and will review application for the annual renewals.

5.0 SUBMISSION OF APPLICATIONS FOR COMREC REVIEW

Eligible applicants

All applicants must fulfil the following requirements:

- Full time member of staff of COM
- Honorary members of staff of the COM

- Full time member of staff of KCN and their Collaborators
- Students of COM/KCN submitting a proposal through their local supervisor

A complete submission of a new study must include the following:

- A covering letter from the Principal investigator
- Signed and dated COMREC application form
- The protocol of the proposed research
- Data collection tools e.g. case report forms, questionnaires etc intended for research participants;
- Investigator(s) curriculum vitae (updated, signed, and dated);
- Material to be used (including advertisements) for the recruitment of potential research participants (posters, flyers, appointment cards, etc ;)
- Informed consent form including both English and the local language(s)
- Itemized Budget
- Investigator's brochure or Product Insert
- Letter of support from head of department

All protocols submitted to COMREC will be assigned a reference number for identification. This number should be quoted in all correspondence relating to that particular protocol.

5.1 Review Process

The committee shall ensure complete proposals submitted are timely reviewed i.e. within the month of submission.

5.2 Elements of the Review

The primary focus of the review and approval process shall be on the science and ethics of the proposed research. Therefore the following elements shall be considered:

- Project title
- Names of investigators and qualifications (CVs should be appended)
- Institution of affiliation (local or international)
- Proposed sector
- Summary
- Introduction/literature review
- Justification/problem statement
- General and specific objectives
- Methodology/Materials and methods
- Ethical considerations
- Work plan (roles and responsibilities, monitoring and evaluation tools)
- Expected outcomes
- Strategies of dissemination of results
- References
- Budget
- Source of funding (proposed)

5.3 Expedited Review

Expedited Review refers to a review process that does not require the full seating of the committee. In this instance, the committee, upon deciding on an expedited review for a re-submission, shall appoint at least 3 members who will review the response and corrections made by the applicant. The review period shall not exceed 14 days from day of re-submission. In the event that this deadline cannot be met, the secretariat shall communicate the decision to the applicant by the fastest possible means and follow up with a written communication. The decision of the expedited review shall be endorsed and reflected in the minutes of the next full committee meeting.

Expedited review may apply to the following:

- Proposals/protocols that have previously been reviewed by a fully convened committee and require the PI to address minor issues
- Undergraduate students' proposal for dissertation
- Continuing review of research previously approved by committee where the research has completed enrolment of subjects and all subjects have completed all research related interventions

5.4 Amendments and Modifications

Amendments and modifications are changes to the originally approved protocol. Any proposed changes to a previously approved protocol must be submitted for review and approval by COMREC irrespective of the magnitude of perceived risks that may come with the changes. COMREC shall set out the procedures to determine whether such submission require expedited review or full committee meeting.

5.5 Continuing Review

All COMREC approvals of new applications are valid for one year. Therefore all approved studies running for more than one year are subject to continuing review annually. The application for continuing review shall be made at one three months before expiry of the previous approval. The application should be made on a COMREC continuing review form and should include a progress report detailing progress with enrolment and problems encountered. The review shall consider the following:

- Progress with enrolment
- Safety of participants
- New knowledge
- Changes in procedures

COMREC shall send reminders to investigators at least three months before expiry of approval. Studies shall be considered lapsed and inactive if continuing review application is not received one month after the expiry of the previous approval. In such instances, COMREC shall send an order to immediately cease all study related operations except those that are necessary for the welfare of subjects.

Review by external experts

The committee shall provide the terms of reference for the external experts. COMREC shall establish appropriate procedures of how comments or recommendations from external experts are incorporated into the review process

5.6 Exemption from Review

COMREC will decide whether a proposal can be exempted from review by the full committee.

Exemption from review may be considered under the following conditions:

- Research involving collection of existing data, documents, records, programme evaluation, pathological specimens, or diagnostic specimens, only if the sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to subjects.

The Chairperson shall review the application for exemption and determine whether to grant the exemption or defer to a full committee seating. Where the Chairperson has granted an exemption at his/her discretion, a full report shall be made at the next full committee meeting.

5.7 Review of Studies of ‘National Interest’⁷

Most health research being done in Malawi is generally of national interest. However, there are some studies that deserve particular attention because of their sensitive, political, and safety implications. Studies covering the following areas are to be regarded as examples of “National Interest Studies”:

- All vaccine trials
- All drug and medical device trials where patent issues are involved and where safety issues remain fully unknown
- All stem cell research
- All cloning research
- All genetic studies
- All national health surveys

All studies of “national interest” regardless of the origin of the protocol should be referred to the NHSRC who may form a standing committee for that specific project composed of members to be drawn on the basis of their expertise rather than which committee they come from. This ad hoc committee will monitor the project through to its conclusion. The project may be carried out in any geographical location as the committee sees fit. This ad hoc committee shall include a representative each from MOH, NCST and COMREC.

COMREC shall define, based on national guidelines, criteria to be used by COMREC secretariat to assess and refer such protocols to the NHSRC.

5.8 Decision-Making

In making decisions on the applications for ethical review, the committee shall take the following into consideration:

- A member shall 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;
- A decision shall 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 COMREC staff;

⁷ National Research Council, 2005
COMREC Guidelines

- Decisions shall only be made at meetings where a quorum (as stipulated in the appropriate SOPs) is present;
- The documents required for a full review of the application should be complete and the relevant elements mentioned above should be considered before a decision is made;
- Only members who participate in the review shall participate in the decision;
- Final decision will be arrived at through a consensus. If this cannot be achieved a decision will be taken through a majority vote.
- Advice that is non-binding may be appended to the decision;
- In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed shall be specified;
- A negative decision on an application should be supported by clearly stated reasons.
- Non scientific and non-ethical issues (e.g politics) shall not be used to deny a protocol approval provided approval decision is made within the confines of applicable national guidelines, laws and regulations.

5.9 Communicating a Decision

A decision shall be communicated in writing to the applicant according to COMREC procedures, within two weeks' time of the meeting at which the decision was made. The communication of the decision should include, but is not limited to, the following:

- The exact title of the research proposal reviewed;
- Clear identification of the protocol of the proposed research or amendment, date and version number (if applicable) on which the decision is based;
- 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;
- Name and title of the applicant;
- Name of the study site(s);
- Date and place of the decision;
- A clear statement of the decision reached;
- Any advice by the committee;
- In the case of a conditional decision, any requirements by the committee, including suggestions for revision and the procedure for having the application re-reviewed;
- In the case of a positive decision, a statement of the responsibilities of the applicant; e.g. the need to notify COMREC in the case of amendments to the recruitment material, or the informed consent form; the need to report serious and unexpected adverse events related to the conduct of the study etc;
- In the case of a negative decision, clearly stated reason(s) for the negative decision;
- Signature (dated) of the chairperson (or other authorized person) of COMREC.

6.0 FOLLOW UP

To promote compliance with good ethical practice, COMREC shall follow the progress of studies for which a positive decision has been reached, from the time the decision was taken until termination of the research. The committee shall establish a monitoring sub-committee that will be responsible for monitoring ongoing studies. The follow-up review intervals shall be determined by the nature and the events of research projects. However each protocol should undergo a follow-up review at least once a year. The follow-up procedure should take the following into consideration:

- The follow-up review intervals should be determined by the nature and the events of research projects,

- The following instances or events require the extra-ordinary follow-up of a study:
 - o Any protocol amendment likely to affect the rights, safety, and/or well-being of the research participants or the conduct of the study;
 - o 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;
 - o Any event or new information that may affect the benefit/ risk ratio of the study;
- In the case of the premature suspension/termination of a study, the applicant should notify COMREC of the reasons for suspension/termination; a summary of results obtained in a study prematurely suspended/terminated should be communicated to the committee;
- COMREC should receive notification from the applicant at the time of the completion of a study;
- COMREC should receive a copy of the final summary or final report of a study.

The monitoring process will take the following forms:-

- Submission of annual reports by every approved study by 30th November regardless of the date of its approval
- Submission of adverse and serious adverse events reports to COMREC
- A monitoring questionnaire that will be sent to investigators to complete and be returned to the secretariat within 30 days.
- Conducting inspections of institutions and study sites where indicated

6.1 Sanctions

COMREC generally has no authority to impose sanctions on researchers who violate ethical standards in the conduct of research involving humans.⁸ COMREC may, however, withdraw ethical approval of a research project if judged necessary. COMREC should be required to monitor the implementation of an approved protocol and its progression, and to report to institutional or regulatory authorities any serious or continuing non-compliance with ethical standards as they are reflected in protocols that COMREC approved or in the conduct of the studies.

7.0 SUSPENSION OR TERMINATION OF COMREC APPROVAL OF RESEARCH⁹

COMREC may recommend to CoM management suspension or termination of approval of research that is not being conducted in accordance with the guidelines or that has been associated with unexpected serious harm to subjects. Any suspension or termination or approval shall include a statement of the reasons for the committee's action and shall be reported promptly to the investigator, appropriate institutional officials, Dean Postgraduate Studies and Research and the Principal of CoM. The Principal of CoM shall then send a report of suspended or terminated studies with the reasons contained therein to the NCST and the PMBP (for clinical trials) or any other government agency responsible for research policy matters.

8.0 DOCUMENTATION AND ARCHIVING

⁸World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. 1964

⁹World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. 1964

All documentation and communication of COMREC shall be dated, filed, and archived according to written procedures. COMREC shall define the access and retrieval procedure (including authorized persons) for the various documents, files, and archives. Documents shall be archived for a minimum period of 3 years following the completion of a study. Documents that should be filed and archived include, but are not limited to,

- the terms of reference, written SOPs, and reports;
- the curriculum vitae of all committee members;
- a record of all income and expenses of the committee, including allowances and reimbursements made to the secretariat and committee members;
- the published guidelines for submission established by the committee
- the agenda of the committee meetings;
- the minutes of the committee meetings;
- one copy of all materials submitted by an applicant;
- the correspondence by committee members with applicants or concerned parties regarding application, decision, and follow-up;
- a copy of the decision and any advice or requirements sent to an applicant;
- all written documentation received during the follow-up;
- the notification of the completion, premature suspension, or premature termination of a study;
- the final summary or final report of the study and publications.

9.0 INDEMNITY FUND

Research involving human subjects carries a risk of injury. The College shall establish a fund to ensure researchers and participants are protected. Each COM funded protocol will contribute to the fund at a rate to be determined by the CoM Management.¹⁰ In the event that a participant is injured or an investigator faces liability claims, the College will use the fund to compensate.

The Fund will apply to COM sponsored research studies only. For all other studies which are NOT sponsored by COM but COM is a host site or a member of COM or an individual of COM's affiliate institution is a site investigator for such studies, the provision for insurance and indemnity cover for participants and researchers in such studies remain the responsibility of the Sponsor of such studies, if so requested by any of the ethics committee and any applicable regulatory authority. Specific legal representation and arrangements shall be sought by COM for research participants to enter into any arrangements aimed at benefiting from such a Fund when requested by either of the ethics committee prior to implementation of studies that have attracted an insurance cover for participants. COM shall ensure that any legal representation and arrangements for participants to benefit from this Fund or sponsor insurance cover are verified by the requesting ethics committee and endorsed by the National Commission for Science and Technology.

NOTE:

- According to international law and ethical guidance as stipulated in the ICH-GCP and the Geneva Convention echoed in the CIOMS, it is the responsibility of the Sponsor of a study/clinical trial to

¹⁰ College of Medicine Research Policy, 2009
COMREC Guidelines

provide compensation/insurance or indemnity for participants and researchers respectively. This must remain a standard of care.

- If National Health Sciences Research Committee (NHSRC) or COMREC asks for insurance and indemnity cover for such internationally sponsored studies, a site investigator, through COM as a site/host institution, must be obliged to inform the Sponsor of the study to provide for such a cover.
- Please NOTE the **definition**¹¹ of a Sponsor as provided for in the ICH-GCP to avoid confusing it with a study Funder. A clinical trial Sponsor is not necessarily a funder. Take note of the ethical distinction in the definition.

¹¹Sponsor of a multicentre clinical trial is not necessarily a funder but refers to an individual, company, institution or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial (ICH-GCP, 1.53);

- An Investigator is a person responsible for the conduct of the clinical trial at a trial site (ICH-GCP, 1.34)
- If required by the applicable regulatory requirement(s), the Sponsor should provide insurance or should indemnify (legal and financial coverage) the investigator/the institution against claims arising from the trial, except for claims that arise from malpractice and/or negligence (ICH-GCP, 5.8.1)
- The Sponsor's policies and procedures should address the costs of treatment for trial subjects in the event of trial-related injuries in accordance with applicable regulatory requirements (ICH-GCP, 5.8.2)
- When trial subjects receive compensation, the method and manner of compensation should comply with applicable regulatory requirements (ICH-GCP, 5.8.3)
- The financial aspects of the trial should be documented in an agreement between the Sponsor and the investigator/institution (ICH-GCP, 5.9)