VISION AND MISSION

The Health Policy and Management and Centre for Global Health Research Ethics Committee (HPM-CGH REC for short) seeks to promote high ethical standards to ensure that the rights, health and welfare of potential research participants are protected and that researchers are guided in conducting ethical research.

To this end the HPM-CGH REC has been established to ensure that the research conducted by members across the two academic units in the health and social care sector is independently reviewed in a fair and consistent manner. The task of the research ethics committee will be to review protocols to ensure the ethical conduct of research, develop guidelines for human research subject protection, identify ethical principles to guide the conduct of research, issue proposal forms to guide researchers in preparing their protocols, and to build capacity for researchers in research ethics and methodologies via the organisation of training workshop and seminars, etc.
WORKING DOCUMENT: STANDARD OPERATING PROCEDURE

Objective

The standard operating procedure (SOP) has been developed to provide a consistent framework for the operation of the committee. It sets out the ethical principles that should be considered when reviewing proposals and establishes administrative procedures.

Terms of Reference

This committee is mandated to function as the Research Ethics Committee (REC) of Health Policy and Management (HPM) and the Centre for Global Health (CGH).

Role of the REC

- The REC will review all protocols of research projects involving human participants proposed to be taken by students on our taught and research programmes and members of the staff who submits such protocols in order to safeguard the rights, safety and well being of the research subjects.

- The REC will determine that all the proposed research and interventions, are acceptably safe to be undertaken in humans or to verify that another competent expert body has done so.

- Determine that the proposed research is scientifically sound or to verify that another competent body has done so.

- Ensure that all other ethical concerns arising from a protocol are satisfactorily resolved both in principle and practice.

- Keep records of decisions and take measures to follow up on the conduct of ongoing research projects.

- The REC will take care that all the cardinal principles of research ethics, viz. Autonomy, Beneficence and Justice are taken care of in the planning, conducting and reporting of the proposed research. For this purpose the REC will require the submission of the following documents: research protocols, participant information leaflet and consent forms that researchers propose to use for research, procedures for recruitment, information about payments and compensations, and any other document the committee deems necessary to fulfil its responsibilities.

- The REC will look into the aspect of informed consent process, risk/benefit ratio and distribution of burden and benefits.

- The REC must be fully informed on the expected risks/discomforts for potential participants and must satisfy itself that there is an acceptable balance between the risk/discomfort and the benefit that is expected to result from research.
• All the participants will be given all the necessary information needed in making an informed decision to participate in research. The REC will satisfy itself about the process the researchers have adopted in giving out this information and the strategy they will adopt to make sure potential participants understand and give a free consent.

• The REC will ensure that, particularly in regard to research involving communities, those communities are engaged prior to research, their tradition, and norms and values respected and useful procedural ways of obtaining first person informed consent adopted.

• Researchers must ensure that absolute confidentiality regarding the identity of participants of research is maintained at all stages of the research and particularly in regard to published results of research.

• The REC will review protocols before a study commences and will do so within a reasonable timeframe. All members appointed for review of a particular protocol are expected to turn in their comments within a 2 week period. Any member who might not fulfil this obligation is asked to notify the REC Secretary within 48 hours of receipt of the protocols and return them to the Secretary.

• There are three outcomes for each review of protocols: approval, conditional approval, or rejection. Conditional approvals carry with them a list of specific recommendations or requirements for clarifications which the researcher must fulfil before full ethical approval for the proposed study could be given.

• The REC will document all its view in writing clearly identifying the protocol, documents reviewed, and dates of approval, disapproval, modifications and sanctions.

• The REC will follow up the research throughout the study until completion through appropriate well-documented procedures e.g. progress reports.

• The REC will examine compliance with all regulatory requirements and appropriate guidelines.

• The REC will perform its function according to this written SOP, will maintain written records of its activities and minutes of its meetings and will comply with best practice and the applicable regulatory requirements.

Composition of the REC

• The REC is composed of at least 5 members. There is no specific recommendation for a widely acceptable maximum number of persons.
• Membership must consist of a legal representative and a research expert external to the two academic units. It is also desirable for the REC to have among its members a professional representative and a lay representative.

• The members should have various backgrounds to promote complete and adequate review of research activities commonly conducted by the centre.

• The REC cannot consist entirely of men or entirely of women.

Membership requirements

• The heads of HPM and CGH are responsible for making the appointment of committee members.

• Members are selected in their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the REC’s work.

• Members must disclose in writing any interest or involvement – financial, professional or otherwise – in a project or proposal under consideration.

• The REC will decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision.

• Members will be required to sign a confidentiality agreement at the start of their term.

• The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the REC in the course of its work.

• Members are appointed for a period of 3 years.

• Their appointments may be renewed by the Director of the centre for up to two consecutive terms.

• The REC will include rotation for some members after a period of three-years, but it will also strive to ensure continuity within the EC.

Resignation, Disqualification, Replacement of Members

• Members may resign their positions by submitting a letter of resignation to the Chairperson.

• Members may also be disqualified from continuance should the Chairperson provide written arguments to the (other) members and there is unanimous agreement.

• Members that have resigned or have been disqualified may be replaced by appointing authorities.
Independent Consultants

- The REC may be further supported in its reflections on specific protocols or requests for advice on specific ethical issues by Independent Consultants.
- Independent Consultants are appointed by the Chairperson of the REC.
- Their professional qualifications may be in the areas of community and/or patient representation, medicine, statistics, social science, law, ethics, religion. Independent Consultants are appointed for the duration of the period sought.

Conditions of Appointment

- Members and Independent Consultants are appointed to the REC under the following conditions:
  - Willingness to publicise his/her full name, profession, and affiliation;
  - All REC Members and Independent Consultants must sign Confidentiality / Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants, and related matters.

Officers

- The following officers through their respective responsibilities contribute to the good functioning of the REC:
  - Chairperson
    - Responsible to chair the meetings, invite independent consultants to provide special expertise to the REC on proposed research protocol.
  - Secretary
    - Responsible for the administrative aspect of the REC.

- The officers are selected by the REC members for three-year terms. They may be re-selected but not for more than two consecutive terms. Should they resign or be disqualified, the REC members select a replacement until the completion of the normal term.

Secretariat

- The Secretariat is composed of the REC secretary and the administrative supporting staff.
- The Secretariat shall have the following functions:
  - Organising an effective and efficient tracking procedure for each proposal received.
  - Preparation, maintenance and distribution of study files.
  - Organising REC meetings regularly.
  - Preparation and maintenance of meeting agenda and minutes.
  - Maintaining the REC's documentation and archive.
  - Communicating with the REC members and applicants.
  - Arrangement of training for personnel and REC members.
Organising the preparation, review, revision and distribution of SOPs and guidelines.

Providing the necessary administrative support for REC related activities to the Chairperson of the Committee (e.g. communicating a decision to the applicant).

Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant contemporary literature to the Committee members.

Quorum Requirements

- A minimum of 50% of the members must be present at a meeting in order to issue a valid advice and/or decision.
- Professional qualifications of the quorum requirements should consist of: At least one member whose primary area of expertise is in a non-scientific area, one research expert and at least one member who is independent of the two academic units.

COMPOSITION OF MEMBERS

Prof. Charles Normand (Head of Dept, HPM, Committee Chair)
Dr. David Smith (Ethics Expert, RCSI)
Dr. Ogenna Manafa (Ethics Expert, CGH)
Dr. Teresa Maguire (External Research Expert, Health Research Board)
Ms. Margaret Murphy (Lay Representative)
Mr. Paul Gallagher (Professional Representative, St. James's Hospital)
Ms. Marie O'Shea (Legal Representative)
Mr. Michael Brennan (Representative from School of Nursing and Midwifery)
Ms. Mandy Lee (Course Coordinator, HPM)
Dr. Fiona Larkan (Course Director, CGH)
Ms. Sheena Cleary (Senior Executive Officer, HPM, Committee Secretary)

APPLICATION PROCEDURES

Submitting a protocol

- All proposals involving human participants and carried out by researchers in HPM or CGH must be submitted for ethical approval by the REC in the prescribed application form, the details of which are given under documentation.
- For protocols to be considered for review it must be submitted 2 weeks before the next meeting with the required number of copies.
- The principal investigator, co-investigators/collaborators, must sign at least one copy of the proposal along with the application documents. The documents should be forwarded to the Secretary of the REC.
- An acknowledgement letter will be sent to the principal investigator.
Documentation

For thorough and complete review, all research proposals should be submitted with the following documents:

• Ethics application form.
• Questionnaire and all other relevant instruments.
• Participant information leaflet and consent forms (clearly identified and dated) in the language understood by potential participants.
• Any other information relevant to the study.

Review

• When an application is received, the form is checked for completeness of the information and signatures of the principal investigator, and co-investigators (if applicable), by the REC Chairperson and Secretariat.
• The application will be registered and given a unique project number.
• The application is sent to 3 reviewers to make comments, which the chair takes into consideration when the application is reviewed by the REC.
• The Assessment Form is used to guide the review and deliberation process.

  Note: The completed Assessment Form is the official record of the decision reached by the REC for the specific protocol.

In order to approve a research project the REC must assure itself that:

➢ The proposed research design of the study is sound and appropriate to the stated study objectives.
➢ The target study population is appropriate in terms of characteristics and number.
➢ The procedure for selection and recruitment of participants in methodology including inclusion and exclusion criteria and other issues such as advertisement detail is appropriate.
➢ The recruitment of participants is free from coercion.
➢ Any risk associated with the research is minimised to the greatest extent possible.
➢ The benefits associated with the study are maximised to the greatest extent possible.
➢ The risks to the participants are outweighed or balanced by the potential benefits.
➢ Procedures are put in place for proper management of research related injuries.
➢ The level of participants’ compensations (if any) is fair and non-coercive.
➢ The privacy of participants is protected and the degree to which confidentiality is maintained is acceptable.
➢ The method used to obtain informed consent is ethically and legally acceptable.
➢ The plans for data analysis and reporting are acceptable.
➢ The investigators have the appropriate qualifications, experience and facilities to conduct the research.
REC meeting

- The Chairperson or his/her designee chairs discussion on each application under consideration (e.g., protocol, informed consent, investigators and site qualifications, advertisements).
- The primary reviewers present a brief oral or written summary of the study design and his/her comments.
- All the various issues raised by appointed reviewers and members will be discussed before arriving at a consensus decision.
- To avoid any conflict of interest, any member with a special or particular, direct or indirect, interest in a proposal will not take part in its assessment. The members can be permitted to offer comments on the protocol or to respond to questions of other members before withdrawing.
- Only members can make decisions, expert consultants will offer their opinions and decisions can only be made in meeting where quorum is complete.
- Recommendations for modifications to the protocol, consent form, and/or advertisements as requested by the Committee are noted in the meeting minutes as ‘with modifications made by REC’ and will be communicated to the investigator.
- The Chairperson or his/her designee calls for a consensus on each element in review.

Outcomes of the Review

The REC accepts to either:

- Approve the study to start as presented with no modifications: i.e. Full Approval
- Require modifications to items noted at the convened meeting and follow-up by the Chairperson, after receipt of the requested modifications, i.e. Conditional Approval
- Disapprove the commencement of the study, stating the reason for disapproval, i.e. Rejection

شرك If the study is approved, the REC determines the frequency of Continuing Review from each investigator.

- The Secretariat sends an action letter to the investigator.
- The letter may contain a listing of each document approved, the date set by the REC for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.

شرك If the REC votes not to approve the study, the Secretariat immediately notifies the investigator in writing about the decision and the reason for not approving the study.
If the REC requires modifications to any of the documents, the Secretariat either generates the revisions to the documents, or sends a written request of the specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to the REC.

**Review of Amended Protocols**

Revised proposals, unless specifically required to go to the main committee, will be examined by the chairperson or a committee member appointed by the chairperson to expedite decision-making.

**Communicating a decision**

After the meeting the decision of the REC will be issued within 5 working days. The decision will be communicated by the Secretary through formal letter as well as e-mail. The REC will consider an application withdrawn if an applicant fails to respond to issues raised by the REC after being reminded 3 times over a period of 3 months, after which the applicant will need to submit full protocols again for review at a new Committee meeting.

**Follow up procedures**

All researchers are required to submit reports at prescribed intervals for review and a final report submitted at the end of the study. Any changes to the protocol of study should be resubmitted, quoting the project reference of the study for further approval.

- Protocol deviation, if any, should be informed with adequate justification.
- Any new information related to the study should be communicated by researchers.
- Premature termination of study should be notified with reasons along with a summary of data obtained so far.
- Any change of investigators/sites should be informed. In all the cases above the project reference of the study should be quoted.

**Record keeping and archiving**

The following records/documents will be kept and archived by the REC:

- Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments either on paper or electronically.
- Final report of the approved projects.
- Copy of all study protocols with enclosed documents, progress reports.
- Minutes of all meetings chaired by the chairperson.
- Copy of all correspondence with members, researchers and other regulatory bodies.
- Most of these will be archived for a prescribed period in accordance with College’s Good Research Practice.
Updating REC members

All relevant new guidelines will be brought to the attention of the members. Members will be provided with any training deemed necessary in order to help them carry out their duties appropriately.