Terms of Reference

The Committee for the Protection of Human Subjects in Research is an independent Committee whose members are nominated by the Deans of the Health Sciences Centre (HSC), Kuwait University. The Committee shall be chaired by Prof. Michael Diejomaoh, Chairman of the Dept. of Obs. & Gyn, Faculty of Medicine and the members shall select a secretary from among themselves.

Membership

a. Prof. Michael Diejomaoh – **Chairperson**.
b. Four to six members nominated by the Faculty of Medicine to a three year renewable terms. These faculty members shall be from among the professional academic staff who are experienced with research on human subjects.
c. A member nominated from the Faculty of Dentistry.
d. A member nominated from the Faculty of Pharmacy.
e. A member nominated from the Faculty of Allied Health.
f. Any other person with special knowledge or expertise may be invited to attend meetings of the Committee as appropriate.

Functions

a. To establish mechanisms for the ethical review of all research activities involving human subjects.
b. To ensure that the study is conducted according to globally accepted standards of good clinical practice (as defined in the **ICH E6 Guideline for Good Clinical Practice, July 2002** (please see the link on left side menu)), in agreement with the latest revision of the **World Medical Association Declaration of Helsinki –**

Ethical Principles for Medical Research Involving Human Subjects, 59th WMA General Assembly, Seoul, October 2008 (please see the link on left side menu) and in keeping with local regulations and moral values.

c. To ensure the potential risks involved in procedures involving human subjects relative to the benefits to be expected.

d. To ensure that adequate safeguards for the relief of trauma or stress are included in the protocol.

e. To ensure the suitability of the investigator(s) for the proposal in relation to his/her qualifications, experience, supporting staff and available facilities.

f. To ensure that the "informed consent form (in both Arabic & English)" is in an understandable language and specifies the name and designation of the informing person.

g. To review the adequacy and completeness of the written information given to the subjects or an acceptable relative and if necessary a legal representatives.

h. To check documents of "informed consent" which include the following:

   1. A fair explanation of the procedures to be followed.
   2. A description of attendant discomfort and risks.
   3. A description of the benefits to be expected.
   4. An offer to answer any inquiries concerning the procedure.
   5. An undertaking that the subject is free to withdraw consent and to discontinue participation in the project at any time.
   6. An assurance that measures would be taken for the confidentiality of data.

The Committee shall consider any other matters referred to it by the Deans of the Health Sciences Centre (HSC), Kuwait University.

Procedures

a. Principal Investigator(PI) should submit the research proposal/protocol attached with the special the COMMITTEE Forms to the Committee secretary.
b. The PI should submit the COMMITTEE forms according to his/her research, and to fill the appropriate set of forms concerning the research, and whether the research involves adults or children or both.
c. To submit both Arabic and English forms.
d. The PI can submit only the Cover form (without the Informed Consent Forms) if the research involves only:
   - Pre-collected samples
   - Collecting data from records (patients' medical history records)
   - Collecting data through distributing a questionnaire sheet, in such case, however, PI should enclose a copy of the questionnaire in both Arabic and English languages.
e. The Committee's deliberations shall be confidential and the decisions taken shall be communicated directly to the investigator(s).

Any proposal involving change of the membership or functions of the Committee shall be referred to the Health Sciences Centre Deans Council.

The Consent Form

The subject's consent must be confirmed at the time of consent and the signature of both the subject and the person conducting the informed consent must be dated. If the subject is unable to read, oral presentation and explanation of the written informed consent form and information to be supplied to the subject must take place in the presence of an impartial witness. Consent must be confirmed at the time of the oral consent by the signature of the subject or by a locally recognized alternative (e.g. the subject's thumb

print or mark). All signatures must be dated. The witness and the person conducting the informed consent discussions must also sign and personally date the consent document.

A copy of the signed consent document must be given to the subject. The original signed consent documents will be retained by the investigator.

The investigator shall not undertake any aspect of the investigation until valid consent has been obtained.

Confidentiality

Subject names shall not be supplied to the sponsor. Only the subject number and subject initials will be recorded in the case report form. The subject will be informed that representatives of the sponsor, independent ethics committee, or regulatory authorities may inspect their medical records to verify the information collected, and that all personal information made available for inspection will be handled in the strictest of confidence and in accordance with local data protection laws.

The investigator will maintain a personal subject identification list (subject numbers with corresponding subject names) to enable records to be identified.

Protocol Amendment

The Joint Committee must be informed of all subsequent protocol amendments. These must be evaluated to determine whether formal approval need to be sought and whether the informed consent document should be revised.

Ongoing information

Unless otherwise instructed by the JOINT COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH, the investigator must submit to the committee:

- Information on serious or unexpected adverse events from the investigator's site, as soon as possible.
- Expedited safety reports from the sponsor, as soon as possible.
- Periodic reports on the progress of the study.

The committee has a mechanism in place to follow and monitor each project that was granted ethical approval to ensure that it conforms with the committee's decisions and recommendations upon which ethical approval was granted.