Guidelines for the Research Ethics Committee of the Faculty of Dentistry (REC-FD)

Introduction:

The Research Ethics Committee (REC-FD) was established to ensure all members of staff within the Faculty of Dentistry, and the supervised students who are registered with the university and who plan to undertake any research which involves humans, animals, biomaterials, basic sciences or any other research in dentistry should have ethical approval prior to commencing such research.

REC-FD should provide independent, competent, and timely review of the ethics of proposed studies, in their composition, procedures and decision-making. They need similarly to demonstrate competence and efficiency in their work. REC-FD members are responsible for carrying out the review of proposed research before the commencement of the research. They also need to ensure that there is a regular evaluation of the ethics of ongoing studies that received a positive decision.

Types of Review procedures:

Two review procedures will be followed according to the type of the proposed study, the degree of involvement of the human subjects, the type of materials tested and the ethical status of the project.

1- Comprehensive Review:

Comprehensive review should be done for any human study that involves trying new treatment protocols, new pharmacological agents, new devices or biomaterials, radiographs and photographs.

It should also be done for any animal experiment, where new treatment protocols, new pharmacological agents, new devices or biomaterials and if there is an expected hazard of infection.

The decision of whether the applied research requires compressive or expedited review, should be taken by either the chairman or the vice chairman of the REC-FD and another member who is relevant to the specified field of the research.

Quorum requirements: The proposal should be evaluated by the REC-FD members, in the presence of at least one member who is an expert in that specific field of the applied research. The minimum number of members that compose quorum should be at least half of the members. REC-FD has the right to seek advice from any external consultant in the field if needed.

Duration: Time period of 4-6 weeks will be required to perform a comprehensive review

2-: Expedited Review:

Expedited review should be done for any study that does not fit the criteria described in the comprehensive review section.

Quorum requirements: Two members including the vice chairmen and another member of the RRC-FD will review and take a decision in the expedited review.

Duration: Time period of maximum 2 week will be required to perform an expedited review

The application process:

The applicant, who is required to be a qualified researcher responsible for the ethical and scientific conduct of the research, should submit the application form provided by the REC-FD, including all the required documents. A signed soft copy should be submitted to the office of REC-FD. The submitted documents may include, but is not limited to:

1. A signed and dated application form.

2. The protocol of the proposed research (clearly identified and dated), together with supporting documents.

3. A summary (as far as possible in non-technical language), synopsis, or diagrammatic representation (flowchart) of the protocol with a description (usually included in the protocol) of the ethical considerations involved in the research.

4. Case report forms, diary cards, and other questionnaires intended for research participants.

5. 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).

6. Investigator(s)'s curriculum vitae (updated, signed, and dated).

7. Material to be used (including advertisements) for the recruitment of potential research participants.

8. Informed consent form (clearly identified and dated) in the language(s) understood by the potential research participants and the use of any compensation for study participation.

9. A statement of agreement to comply with ethical principles set out in relevant guidelines.

10. Any previous decision taken in relation to this specific research.

Elements of the Review:

The primary task of the REC-FD lies in the review of research proposals and their supporting documents, with special attention given to the informed consent process, documentation, the suitability and feasibility of the protocol. REC-FD needs to take into account prior scientific reviews, if any, and the requirements of applicable laws and regulations.

The following should be considered, as applicable:

- Scientific Design and Conduct of the Study.

- 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.

- The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.

- The justification for the use of control groups.

- The manner in which the results of the research will be reported and published.

- Recruitment of Research Participants and the characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, and ethnicity).

- Inclusion and exclusion criteria for research participants.

- Care and Protection of Research subjects.

- The suitability of the investigator(s)'s qualifications and experience for the proposed study.

- The dental care to be provided to research participants during and after the course of the research if needed and the adequacy of supervision and psycho-social support for the research participants.

- Steps to be taken if research participants voluntarily withdraw during the course of the research.

- A description of any financial cost to research participants and the rewards and compensations for research participants (including money, services, and/or gifts).

- The provisions for compensation/treatment in the case of the injury/disability/death of a research participant attributable to participation in the research.

- Protection of research participant confidentiality.

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

- The measures taken to ensure the confidentiality and security of personal information concerning research participants.

- Informed Consent Process with a full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent.

- 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).

- The provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.

- The impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn, the steps taken to consult with the concerned communities during the course of designing the research and the extent to which the research contributes to the enhancement of local healthcare, research and the ability to respond to public health needs.

- The manner in which the results of the research will be made available to the research participants and the concerned communities.

These guidelines will be continuously updated under the discretion by the REC-FD.