



# **BYLAWS OF THE INSTITUTIONAL RESEARCH BOARD (IRB)**



## **\*\* Contents \*\***

Name .....	Page 3
Mission .....	Page 3
Authority .....	Page 3
Relationship to the the faculty administration .....	Page 4
Membership .....	Page 4
The IRB review process .....	Page 6
• Types of IRB review.....	Page 6
• Review protocols .....	Page 7
• Suspension or termination of research.....	Page 10
Procedures .....	Page 12
Informed Consent .....	Page 12



## **I. NAME and LOGO**

The name of the board is the Mansoura Faculty of Medicine Institutional Research Board (hereinafter called "MFM-IRB").

## **II. MISSION**

The Mission of Mansoura Faculty of Medicine Institutional Research Board (MFM-IRB) is to:

- Ensure that the rights, safety, and welfare of human subjects and animals in research are protected and consistent with applicable legal, ethical, and institutional guidelines.
- Assess and evaluate the risks and benefits of proposed research, and ensure that risks to human subjects are kept to an absolute minimum and are justified by potential benefits of the research.
- Ensure the confidentiality of information obtained from research subjects to the extent allowed by law.
- Ensure that, where appropriate, an Informed Consent is obtained from each research subject.
- Facilitate high quality research at Mansoura Faculty of Medicine

## **III. AUTHORITY**

1. Review all funded and unfunded research by faculty, staff, or students that involves the use of human subjects, prior to the beginning of the research.
2. Review all research involving human subjects conducted by researchers not directly involved with the university yet who propose to use university faculty, students, staff and/or facilities in their research.
3. Determine the type of review (exempt, expedited, or full board) that the research requires.



4. Disapprove, modify, or approve research protocols based upon consideration of the protection of human subjects and faculty interest and benefits.
5. Suspend or terminate a research project
6. Require progress reports and perform such monitoring, as it deems necessary.
7. Educate the university community as to the responsibilities and duties of those conducting sound and ethical research



#### **IV RELATIONSHIP TO THE FACULTY ADMINISTRATION**

The MFM-IRB reports to the vice dean for postgraduate studies and scientific research.

#### **V. MEMBERSHIP**

The MFM-IRB consists of at least nine members, appointed by the faculty council

They should include:

- 1) Three professors representing the clinical medical departments.
  - 2) Three professors representing the surgical departments.
  - 3) Three professors representing the basic science departments.
  - 4) One professor for revision of statistical issues.
- All IRB members are appointed for three-year terms and may be reappointed based on their H-index and approved by faculty council.
  - Any vacancies that arise shall be filled in the same manner as initial appointments.
  - Members are removed only for stated cause. Failure to attend four (4) consecutive meetings may constitute cause for removal and replacement by another individual designated by the vice dean for postgraduate studies and scientific research. Members may be removed by a majority vote of the board.
  - Members receive NO COMPENSATION. Liability coverage will be provided by the university under its umbrella coverage
  - Chair and co-chair would be elected by the members of IRB.
  - **Conflict of Interest:** No IRB member shall participate in any initial or continuing review when he/she has any conflicting interest; except to provide information requested by the IRB.
  - **Confidentiality:** All IRB members operate under the clear expectation that all study materials provided to the IRB are confidential; as such, study materials may not be discussed or distributed outside of official IRB business and must be handled consistent with the highest regard for protection of confidentiality.



**All MFM-IRB members should:**

- Become familiar with IRB guidelines and procedures.
- Determine the appropriate level of review for the protocol, and notifying the principal investigator of determination.
- Review and evaluate all assigned protocols within stated timeframes.
- Participate in IRB deliberations and make recommendations for reduction of risk, improved informed consent process, or other aspects of protection of human subjects.
- Attend Board meetings

**The IRB scientific office includes faculty members, staff and secretaries appointed by the chair and co-chair**

**The scientific office should be in charge of:**

- 1- Check the IRB electronic mailbox and acknowledge receipt of new proposals.
- 2- Distribute proposals to IRB members on a rotating basis at the appropriate level of review;
- 3- Schedule meetings and meeting rooms, and notify members of meetings
- 4- Record and distribute meeting minutes.
- 5- Maintain other administrative tasks as deemed necessary by the IRB Chair and Co-chair.



### **The chairperson of the IRB should:**

- 1) Chair all regular and special sessions of the board. If the chair is unable to attend the meeting, he/she shall appoint a substitute from the Board membership
- 2) Perform all the functions of a Board member
- 3) Oversee the development and implementation of appropriate policies, procedures and guidelines directed at human subject protections and the functions and activities of the IRB
- 4) Review the IRB's policies and procedures for currency, accuracy and consistency on an ongoing basis;
- 5) Has the authority to temporarily suspend research that is not in compliance with IRB guidelines
- 6) Participates in or designates others to participate in sessions designed to inform and educate staff, and students about the responsibilities and activities of the IRB
- 7) Has the authority to authorize emergency changes to a protocol to avoid an immediate hazard to subjects
- 8) Oversee the recruitment, orientation, continuing education and retention of IRB members
- 9) Communicate sanctions relating to known or suspected problems in the conduct of human-subject research to involved investigators
- 10) Maintain a record of IRB determinations and actions
- 11) Report ethical violations by principal investigators to the appropriate University authority



## **Consultants**

If the IRB reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, the IRB must consider the inclusion of one or more individuals who are experienced in working with these subjects. In addition, when the IRB reviews proposed research that purposefully requires inclusion of handicapped children or mentally disabled persons as research subjects, the IRB shall include at least one person primarily concerned with the welfare of these subjects. This person will serve as a consultant to proceedings and may not vote. The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote.





## **VI. The Institutional Research Board Review Process**

### **1. Types of RIB Review**

#### **A. Full Review**

Full review is required for all research that has potential risk to subjects. This category includes, but is not limited to, the following:

- Research which involves the administration of drugs or other substances to subjects;
- Research involving pregnant women and/or fetuses in utero;
- Research involving subjects with life-threatening physical conditions;
- Research involving physically intrusive procedures;
- Research which previous experience (by the particular investigator or other investigators) has shown to create a potential of risk to subjects; or
- Research which potentially could put the subject at risk for legal or civil liability or invade a subject's privacy in regard to sensitive aspects of his/her behavior (e.g., illegal conduct, drug use, sexual behavior, alcohol use).

**Most research is submitted through the full review and approval process.**

#### **B. Review of Cooperative or Facilitated Research**

When the MFM is involved in multi-institutional studies it may rely on another, qualified IRB to avoid duplication of effort.

A review performed by such a Board will be referred to as a Facilitated Review.

The MFM- IRB will decide on a case-by-case basis if it may be possible to rely on an IRB at either a neighboring institution, or another local IRB. The IRB shall be determined to provide some degree of local review because of its familiarity with the MFM community.



## **2. REVIEW PROTOCOLS**

### **A. Full Review**

#### ***1) Information That the Investigator Provides to the IRB***

The investigator shall provide the following material to the MFM-IRB and any other material that the IRB may reasonably request in order to be fully informed regarding the nature of the study:

a. Study protocol which includes:

§ The title and purpose of the study, the expected risks and results of previous related research;

§ Study design and appropriateness of research methods, including a description of procedures to be performed,

§ Sponsor information including addresses and contact person;

§ Subject inclusion/exclusion criteria, justification for use of any special/vulnerable subject populations (decisionally impaired, children);

§ All compensation/reimbursement to be issued to participants, and any cost(s) incurred by participant (supplies, parking fees, etc.);

§ Provisions for managing adverse reactions;

§ An investigators brochure, for studies conducted under an investigational new drug application

§ Any compensation for injured research subjects;

§ Provisions for protection of the participants' privacy; and

b. Investigators Brochure (when one exists, one copy is sufficient);

c. The proposed Informed Consent documentation containing all the requirements set forth below or otherwise required by law;



## **2) Full Review Process**

- a) In order for the IRB to approve a study, the proposal must be determined by the IRB.
- b) A full review of proposed research shall take place at convened meetings at which a quorum of voting IRB members is present
- c) A simple majority of the members present must approve the proposal.

## **3) Full Review Determinations**

### **a) Approved:**

Protocols may be approved as submitted. Approval is made for usage of the study tools, including the Informed Consent documents, as submitted.

Once a protocol is approved, no Protocol changes, amendments, addenda, or changes in the consent form may be made without re-review and approval of the Protocol by the IRB

### **b) Conditional Approval:**

Protocols may be approved, contingent on specified changes being made and/or on confirmation of the IRB's interpretation of ambiguous information

Conditional approval may require that certain minor changes be made to the Protocol.

Changes and/or modifications must be resubmitted within 15 days of notification to the investigator or the Protocol will be closed and will require re-submission in its entirety to be reconsidered.

The IRB will determine the gravity of the corrections or omissions to be made. The IRB may elect the Chairperson to examine resubmissions for requested corrections and approve the proposal, as an expedited review. The IRB may elect to review the proposal with corrections in a future regular meeting.

### **c) Revise and Resubmit.**

Action on protocols may be deferred because of inadequate information, or failure to meet certain conditions. A request to revise and resubmit to the IRB may be made if the protocol does not contain sufficient information to justify approval and/or substantive justification and clarification is needed. The Board will inform the investigator of the necessary follow-up and may bring the investigator to an IRB meeting to provide clarification.

### **d) Denied:**

The level of risk involved may be deemed by the IRB to be inappropriate for initiation at MFM.



#### **4) Notification**

The Board will issue written notification of the result of the review to the individual named as the submitter within 3 weeks of the determination.

Rationale for the result will be provided in the written notification. The Chief of Staff and the Medical Board will be copied on all written notifications.

Investigators are responsible for notifying the sponsor of the research of the IRB's decision.



## **B. Review of Cooperative or Facilitated Research**

### ***1) Information that the Investigator Provides to the IRB***

- All materials required for Full Review; and
- Documentation of approval (letter or stamped document) from the Cooperative IRB.

The MFM-IRB review should determine if the institution will accept the study protocols as approved by the Cooperative IRB. MFM recognizes that alterations to study protocols (i.e. to materials other than the Consent Form to be utilized at MFM) which have been approved by a larger IRB, may impose hardships to the researcher.

MFM pertains only to MFM participation.

### ***2) Cooperative or Facilitated Research Review Process***

- a) In order for the IRB to approve a study, the proposal must be determined by the IRB to demonstrate the criteria listed required in a Full Review.
- b) A Full Review of proposed research shall take place at convened meetings at which a quorum is present.
- c) A simple majority of the quorum must approve the proposal.

### ***1) Cooperative or Facilitated Research Review Determinations***

#### **a) Approved:**

Protocols may be approved for implementation at MFM. Approval is made for usage of the study tools, including the Informed Consent documents, as submitted. Once a protocol is approved, no protocol changes, amendments, addenda, or changes in the consent form may be made without re-review and approval of the protocol by the IRB. (Expedited review of changes may be available at the discretion of the Chairperson  
Time frames for continuing reviews will be described at the discretion of the IRB.

#### **b) Conditional Approval:**

Protocols may be approved, contingent upon answers to informational questions posed by IRB members. The PI or their designee may be asked to present the materials in person to answer questions without delay. If a delay of 90 days results, the protocol will be closed and will require re-submission in its entirety to be reconsidered.

#### **c) Denied:**

The study may be deemed inappropriate (any factor may be identified such as but not limited to the level of risk involved to the study subject, a lack of complete/appropriate Informed Consent, etc.) or, if requested for implementation at MFM the study may be deemed by the IRB to be inappropriate for initiation at MFM.



### **3) Notification**

The Board will issue written notification of the result of the review to the individual named as the PI or their designee within 10 business days. Rationale for the result will be provided in the written notification. The Chief of Staff and the Medical Board will be copied on all written notifications. The PI is responsible for notifying the sponsor of the research of the IRB's decision.



### **3. SUSPENSIONS OR TERMINATION OF RESEARCH**

#### **A. Grounds for Suspension or Termination**

The IRB shall have the authority to suspend or terminate research that is not being conducted in accordance with the protocol(s) approved by the IRB, other institutional, or regulatory requirements, or has been associated with any serious harm to participants. Concerns regarding the conduct of research shall be reported immediately to the Chairperson of the IRB by any individual having such knowledge.

#### **B. Notification of Suspension or Termination**

Any suspension or termination of research shall include a statement of the IRB's action and the Chairperson shall report its decision promptly to the Principal Investigator, the Compliance Department, MFM Medical Staff Office.

Notification must be given to Departments in which research activities are taking place within one business day. Notification may occur via email and/or letter. Both the investigator and the study particulars shall be stated in the notification, as well as the date of suspension of operations.

It is the responsibility of the investigator to report suspensions



## **VII. Procedures**

### **Summary of the procedures of reviewing proposals**

- 1) All proposals must be submitted prior to the initiation of research.
- 2) The Chairpersons will receive applications and determine the appropriate level of review for the protocol
- 3) If the proposal is determined to be exempt, the principal investigator will be notified of the status within 10 days of receipt; approved, approved pending minor revision, revise and resubmit, or not approved
- 4) If the proposal is determined to require full Board review, the proposal will be reviewed from the statistical, ethical, scientific point of view and for plagiarism.
- 5) The MFM-IRB reserves the right to make further inquiries, reconsider a proposal, and reverse its own determination based upon changes in legislation or noncompliance with the terms of the proposal
- 6) The MFM-IRB shall not concern itself with the quality of the protocol or its methodological approach, but rather shall assess the overall risk/benefits to the participants/society.
- 7) Proposals submitted by researchers outside of the institution must have prior approval by their institution to conduct such research.
- 8) Ethical violations will be reported to the Director of Human Resources, Vice Dean of postgraduate studies and the faculty Dean.
- 9) Final report will be delivered within two weeks of admission at a maximum.





## **VIII. INFORMED CONSENT**

### **A. General Requirements for Informed Consent**

The process of obtaining Informed Consent shall contain the following elements

- It should be obtained from the subject or the subject's legally authorized representative;
- It should be in language understandable to the subject or his or her legal representative; and
- It should be obtained under circumstances that provide the subject with the opportunity to consider whether or not to participate, and that minimizes the possibility of coercion or undue influence.

### **B. Discretionary Elements**

When required by the IRB, one or more of the following elements shall be provided to each subject:

- Statement that a/the procedure may involve unforeseeable risks to the subject;
- Description of circumstances under which the subject's participation may be terminated by the investigator without the subject's consent;
- Additional costs to the subject resulting from participation in the research (clearly stating what is reimbursable, how to obtain reimbursement, and what cost the participant shall bear);
- Consequences of the subject's decision to withdraw from the research and procedures for termination of participation by the subject;
- Statement that significant new findings developed during research which may relate to subject's willingness to continue will be provided to the subject; and/or
- Approximate number of subjects involved in the study.

### **C. Required Format**

1. The top of page one must state, "MFM" or, "Mansoura Faculty of Medicine)
2. The IRB may require the Informed Consent form to have an approval and an expiration date. The expiration date may be used to signify the required Continuing Review date and an Informed Consent form may not be used beyond the date of expiration.

### **D. Exceptions from Requirements for Informed Consent**

The IRB may approve a consent procedure which does not include, or which alters, some or all or the elements of Informed Consent.

The IRB may vote to waive the requirement to obtain Informed Consent provided the IRB finds and documents:

- The research involves no risks to participants (i.e. in the case of exempt studies);
- The rights and welfare of subjects will not be adversely affected;
- The research could not practicably be carried out without the waiver or alteration;



- Whenever appropriate, the subjects will be provided with additional pertinent information after participation; and
- The research is to be conducted for the purpose of demonstrating or evaluating local service programs that are not research programs, etc.

Obtaining Informed Consent may be waived if both the investigator and a physician who is not otherwise participating in the clinical investigation, certify in writing all of the following:

- Subject is in a life-threatening situation necessitating use of test article;
- Consent cannot be obtained because of an inability to communicate with or obtain consent from the subject;
- Time is not sufficient to obtain consent from subject's legal representative; and
- No alternative, generally approved method is available.

If immediate use of the test article is required to save the life of the subject and time is not sufficient to obtain independent determination by another physician, a determination by the IRB Chairperson shall be made, through the Emergency Use Review process. This determination applies to a single use of the investigational procedure/test only.

### **C. Documentation**

1. Informed Consent shall be documented by using a written consent form approved by the IRB. The form shall be signed by the subject or the subject's authorized representative. A copy shall be given to the person signing the form.
2. The consent form is valid for no more than one year. It shall carry an expiration date and be reevaluated with a new expiration date applied, upon request, at continuing review(s).
3. Consent forms which are permissible include all of the following basic elements:
  - a. A statement that the study involves research;
  - b. An explanation of the purpose of the research and the expected duration of the subject's participation;
  - c. A description of the procedures to be followed and the identification of any procedures which are experimental;
  - d. A designation of where the research will take place;
  - e. The disclosure of alternative procedures;
  - f. A description of risks and possible discomforts to the subject;
  - g. A description of foreseeable benefits to the subject and others;
  - h. A description of the extent to which confidentiality will be maintained;
  - j. An explanation of whom to contact if questions arise, or adverse event occurs;
  - k. A statement that participation is voluntary, that refusal to participate involves no penalty, and that the subject may discontinue participation and have any data already collected destroyed at any time; and
  - l. No language through which the subject is made to waive any of his/her legal rights or which releases the investigator, the sponsor, or the institution from liability for negligence.



4. Accompanying the Informed Consent form review should be a written summary describing the process of obtaining consent. The following elements must be present:

- a. A guide to the oral Informed Consent presentation;
- b. Witness must be present at the oral presentation;
- c. The witness signs the form; and
- d. A copy of the written summary is given to the person signing the form.