LAU
الجامعة اللبنانية الأميركية
Lebanese American University
Institutional Review Board (IRB)

لجنة الأخلاقيات

TERMS OF REFERENCE

INSTITUTIONAL REVIEW BOARD

SIGNATURE SECTION AND REVISION HISTORY

RESPONSIBLE OFFICE: Office of the Dean for Graduate Studies and Research	**PREVIOUS VERSION:** V. 7, 21 JUNE 2016
PREPARED BY: Christine Chalhoub, BScH, CRA, CCRP, CIM	**CURRENT VERSION AND APPROVAL DATE:** V.8, 8 NOVEMBER 2016
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VERSION 03. MAY 2014	NAME CHANGE	LAUMC-RH
VERSION 04. SEPT. 2014	REQUIREMENTS FOR VOTING STUDENT MEMBERS (SECTION I.3)	LAUMC-RH
VERSION 05. APRIL 2015	SUBSTITUTE ROLE OF THE PROVOST BY DEAN FOR GRADUATE STUDIES AND RESEARCH	LAUMC-RH AND MOPH
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PURPOSE AND SCOPE

The Institutional Review Board (IRB) is empowered by the President's Cabinet at the Lebanese American University (LAU). It has the statutory and institutional authority to take any necessary action to protect the rights, safety and welfare of human subjects in research conducted at LAU and the University Medical Center – Rizk Hospital (LAUMC-RH) or by its Faculty and Staff at outside premises. The IRB's approval is always necessary for any research project involving human subjects. The IRB must notify the investigator in writing of its decision. The IRB also has the authority to observe or monitor any human research project to whatever extent it considers necessary to protect the research participants. (Please visit the IRB website at http://www.lau.edu.lb/IRB/)

APPLICABILITY

The IRB policies and procedures apply to all the members of the IRB and administrators of the IRB Office, under the Office of the Dean for Graduate Studies and Research.

DEFINITION

Benefit A valued or desired outcome; an advantage

Human Subjects is defined as living individuals about whom an investigator (whether professional, faculty, staff, or student) conducting research obtains (i) data through intervention or interaction with the individual, or (ii) identifiable private information."

IRB – Institutional Review Board is an independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

Minimal Risk A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests

Risk The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant.

PROCEDURES

PROCEDURE I – IRB MEMBERSHIP; ROLES AND RESPONSIBILITIES

I.1 Membership Composition

The IRB is composed of at least seven members, including both men and women, who collectively have the qualifications and experience to review and evaluate the proposed research involving human subjects. The IRB membership is in compliance with the requirements under the Lebanese Ministry of Public Health, the U.S Office of Human Research Protection and the international guidelines governing IRBs. The IRB must include the following:

- at least one (1) member whose primary concerns are in non-scientific areas
- at least one (1) member who is familiar with applicable laws, regulations, and policies and procedures of ethical and professional conduct associated with research activities
- at least one (1) member who is a resident of Lebanon but who is not otherwise affiliated with LAU and/or LAUMC-RH and who is not part of the immediate family of a person who is affiliated with LAU and/or LAUMC-RH
- at least three (3) clinical healthcare professional (and / or scientific area). *Clinical Healthcare professional primarily for Biomedical Research*
- at least one member knowledgeable in working with vulnerable population

Whenever required, the IRB will have two panels or sub-boards, one Biomedical and one Social / Behavioral, where its composition will be as stated above

I.2 Member Selection and Acceptance

The IRB members are selected by the IRB Chairman, and are subject to approval by the Dean for Graduate Studies and Research (Dean GSR). The members of the IRB are selected as per section I.1 to ensure the Board's composition requirements are met.

- *IRB Chairperson / Vice Chairperson*

The LAU Dean GSR selects the IRB Chairpersons (Chairperson and Vice Chairperson). The Dean GSR reviews the Chairpersons' performance annually and the Dean GSR, upon completion of the performance review, may reappoint the current Chairpersons.

- *IRB Administrator*

The IRB Chairperson, with the approval of the Dean GSR, shall appoint a person from the Office of the Dean for Graduate Studies and Research as a non-voting member on the IRB to serve as the Administrator. The IRB administrator will serve such term as the chairperson will determine and may be removed by the chairperson at any time.

- *IRB Non-voting member*

The IRB Administrator is a non-voting member and provides administrative support to the IRB. Other individuals such as consultants, guest speakers, visitors, Principal Investigators invited to present their research, as applicable, may attend the meeting but may not vote during the meeting decisions.

- *IRB Voting member*

All IRB members are voting members. The Chairperson can only vote when there is a tie.

Selected individuals have 2 weeks to reply to the invitation to serve on the IRB. Once acceptance has been received, the IRB Administrator will prepare an acceptance package that includes:

- Non - disclosure agreement
- Documents required such as training certificate (s)

An accepted appointment takes effect once the IRB Administrator receives the above agreements signed and this date constitutes the basis on which the term of appointment is recorded. The IRB Administrator tracks all the members' records.

I.3 Requirements for Voting Student members

The IRB at LAU considers it necessary to include student-voting members on its board since students are used extensively in research projects within the university. This will allow for the right to represent such a group in addition as an approach to educate future researchers. The following requirements must be followed when appointing a new student to the board:

- Graduate student (one from a scientific background and one non-scientific)
- Recommendation letter from a Faculty member, co-signed by the Chair of the Department
- Hold a GPA of 3.0 and above
- Copy of CV, highlighting some form of research background
- Provide a one page document highlighting interest in serving on the IRB
- Interview with the IRB Chair
- Membership appointment for 1 year, subject to re-appointment for another year at the discretion of the IRB Chair
- Sign confidentiality agreement
- Complete the NIH training mandating by the office
- Attend a training specific for the LAU IRB

I.4 Membership Term of Appointment and Training Requirements

- Term of Appointment - The Dean GSR shall appoint a majority to terms of two (2) years each and the remaining members to terms of three (3) years each. Subject to reappointment by the Dean GSR, each IRB member is eligible to be reappointed to the Board for 6 consecutive years.
- Training Requirements - In order to fulfill its mandate to protect the rights, safety and welfare of human subjects, all IRB administrators and members of the board are required to complete training in protecting human research participants. The IRB administrators, members and others charged with the responsibility to review, approve, oversee the human subject research should receive detailed training on the Policies and Procedures and any other guiding regulations and policies applicable to human research.

  All new Chairs and members are required to complete an Orientation Program provided by the Office of the Dean for Graduate Studies and Research as well as the training requirements listed below before beginning term on the board. Chairs and members are also required to meet the continuing education requirements by attending human research protection related conferences, workshops, online courses,

seminars, or lectures at least once every two years for continuing members. The office will maintain the training records for IRB chairs and members. Basic training requirements are:

- "Protecting Human Research Participants" offered by the National Institute of Health (NIH) http://phrp.nihtraining.com/users/login.php
- Or equivalent including CITI (Collaborative IRB Training Initiative) http://www.citiprogram.org/

I.5 Membership Evaluation and Attendance

IRB Chair, Vice Chair, members and IRB administrators are evaluated annually by the Dean for Graduate Studies and Research.

Each member is expected to attend **at least two-thirds** of the scheduled meetings. Attendance records are reviewed annually. The Dean GSR will recommend the removal of a member who has not attended one-half of the scheduled meetings over a twelve-month period. Membership roster will be reviewed and amended at least annually in order to highlight any modifications made.

I.6 Resignation and Removal from the Board

Resignation — A member of the IRB may resign from the board by signed written notice to the IRB Chairperson.

Removal from the board — The IRB Chairperson may remove a member *for just cause* by giving written notice to the member including the date on which the removal takes effect, which must not be an earlier date than the date on the notice which is received. The notice must state the reasons for removal.

Just cause includes misconduct, inability to perform the functions required of the member, neglect of duty, and breach of any of the collective duties of the IRB or the individual duties of the member.

I.7 Membership Non-Disclosure and Conflict of Interest

- Non-Disclosure - IRB Members, visitors, and guests respect the confidentiality of the IRB deliberations and findings and do not disclose these until the PIs are formally notified by the IRB of their decision. Furthermore, IRB business must remain confidential and confined to the board itself.

- Conflict of Interest - All members of the IRB are responsible for making known any potential or perceived conflict of interest with regard to membership on the board and concerning any protocols reviewed by the board. They are required to self-identify conflicts of interest and recuse themselves from participating in the discussion and abstain from the vote on research activities if they are:

  - Listed on the protocol/project, or will be included (or reasonably may be expected under academic standards to be included) as a co-author on a publication of the project's results;
  - Receiving funding from the study as listed in the study budget;
  - Family member of the PI; or
  - Having a financial interests in a business that is supporting or facilitating the protocol/project under review, or the interest is in a business that is known to a IRB member to own or have license rights to the technology

A member of the Board who makes a disclosure under this section must not

- Take part, after the disclosure in any deliberation or decision of the board relating to the transaction; or
- Be included in the quorum when a vote on the decision is to be taken; or
- Sign any document related to the research project

When members recuse themselves, they must leave the room during the discussion and vote on the research except to provide information at the IRB's request prior to the discussion and vote. Abstaining from voting must be documented in the Minutes of the meeting.

I.8 Membership Roles and Responsibilities

- The IRB Chairpersons are responsible for:

  - Chairing at IRB initial and continuing review of all research protocols;
  - Conducting initial and continuing review of research protocols that may be approved through the expedited review procedure;
  - Reviewing (and approving) modifications required by the IRB at convened meetings to secure approval;
  - Determining whether an activity meets the definition of human subject research
  - Determining exempt status of research involving human subjects;
  - Participating in the development of human subjects research policies and procedures;
  - Attending conferences, workshops, online courses, seminars, or lectures pertaining to human subjects' research at least annually.

- The IRB Administrator (s) is responsible for preparing and maintaining adequate Documentation of Board's activities, including, but not limited to:

  - Retention of copies of all documents submitted by Investigators and reviewed by the Board, including information about any initial and continuing review;
  - Maintenance of written records of all IRB meeting and of all actions taken by it, and any decisions and any recommendations made
  - Retention of copies of all correspondence between the IRB and Investigators
  - Maintenance of records of IRB's continuing review of research activities
  - At the discretion of the chairperson, distribution of the agenda for each meeting no less than seven (5) business days prior to such meeting and distribution of the Applications and research projects to be reviewed no less than seven (7) business days prior to such meeting;
  - Assuring that the minutes of each meeting are completed and circulated to the members of the Board at least 1 week before the upcoming scheduled meeting;
  - Maintaining a list of all Board members' details and qualifications;
  - Maintain and update IRB Policies and Procedures and related documents as required and disseminate to all members
  - Any such additional duties as the Chairperson, may from time to time prescribe

- The IRB voting members are responsible for but not limited to the following:

  - Reviewing and approval, or approval with modification any research project submission
  - Review and deferral or denial of a research project submission

- Require documentation of Informed Consent from human subjects except to the extent waived in accordance with the relevant policies and procedures (IRB.4)
- Notify the Principal Investigator in writing of its decision with regards to a submitted research project or of modification required to obtain its final approval
- Ensure there is continuing review of all research activities at intervals appropriate to the risk involved, but no less than once a year, with the authority to observe or have a third party observe the informed consent process and conduct of the research activities
- Seek assurance from the Principal Investigator that there is on-going regulatory compliance and adherence to the approved protocol by the Investigator (s) associated with a research project, with the authority to conduct or have a third party conduct an audit of the research site (s) and/or research files and/or require progress reports from the Principal Investigator
- Restrict, suspend or terminate an approval of a research project that is in not in compliance or that has been associated with an unexpected serious adverse event to the subjects

- Consultants / External Reviewers

At the discretion of the IRB Chairperson, consultants may be used to supplement or provide expertise not available on the IRB. When, in the opinion of the Chairperson, the IRB membership lacks the expertise needed to review a protocol, the Chairperson, identifies potential expert consultants. In addition, the IRB may vote to defer action on a protocol and may require an expert in the scientific area or discipline to review the research and provide consultation to the IRB.

If the consultant agrees to review the research and confirms in writing that he/she has no conflict of interest, he/she will also be asked to sign the Non-Disclosure agreement; then he/she will be provided with all documents relevant to the specific protocol under review. Consultants are asked to attend the meeting to present their findings relative to the scientific merits of the study, risks and benefits to subjects, and to answer questions; however, if the consultant is unavailable to attend the meeting, he/she may provide written comments for distribution to the IRB members. Consultants are non- voting members. They may participate in the deliberations and make recommendations, but may not vote. Their attendance as a Consultant is recorded in the minutes of the meeting.

- Investigators

At the discretion of the IRB Chairperson, Principal Investigators may be asked to attend the IRB meeting at a time when their projects will be reviewed to present the research project and answer any question the members of the board might have. PIs must leave the meeting before board deliberation and may not vote on the project.

- Guest Speakers and Visitors

At the discretion of the IRB Chairperson, visitors may be permitted to attend IRB meetings. Prior approval must be secured from the IRB chair.

PROCEDURE II – TYPES OF REVIEW

The IRB follows three distinct review types while reviewing research involving human subjects – *Refer to the Appendix Section* of this document. These types are based on the regulations governing research and relate to the degree of risk to research participants. A summary of timelines for IRB review can be found on the IRB website.

II.1 Initial IRB Review at a Convened Meeting

Human subject research that does not fit any of the Expedited or Exempt review categories will require a Full IRB review at a convened meeting. The IRB Chair or delegate assigns the review to two IRB members for protocols that require review at a convened meeting. The assigned reviewers will review the IRB application using the "IRB Primary Reviewer Checklist" provided at the time of his/her assignment.

The IRB meets once a month or as requested by the IRB Chairperson. IRB applications that fall under full review are placed on the agenda and will be discussed at the upcoming scheduled meeting. When reviewing research, the convened IRB is responsible for determining the approval status and appropriate approval period (up to one year) of a study under review, and must notify the investigator and institutional officials of its decisions. *(Refer to Section IV for Meeting Proceedings)*

II.2 Research Appropriate for Expedited Review

Regulations governing research allows the IRB to review certain applications on an expedited basis if they meet specified criteria. The Expedited Review Process applies to the following and the categories for Expedited review process are found under *the Appendix Section*.

- Expedited Review – Applicability (http://www.hhs.gov/ohrp/policy/expedited98.html)

  - Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
  - The categories in this list apply regardless of the age of subjects, except as noted.
  - The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
  - The expedited review procedure may not be used for classified research involving human subjects.
  - Investigators are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

The IRB Chair reviews or delegate review to an appropriate member for protocols that are granted expedited review. In the event both the IRB Chair and Vice Chair are unavailable, the IRB Administrator shall select a reviewer from the IRB membership roster to conduct expedited review.

The assigned reviewer will review the IRB application using the "IRB Primary Reviewer Checklist" provided at the time of his/her assignment. In reviewing the research, the reviewer may exercise all of the authorities of the convened IRB except that the reviewer may not disapprove the research. Additionally, the reviewer may refer the application to the convened IRB for a standard review if deemed necessary.

Within approximately 20 calendar days following receipt of a complete submission, the IRB will notify the investigator and the relevant institutional officials of its decision; or the IRB will request additional information needed to complete the review.

II.3 Exempt Research

Some human subject research might fall under an Exempt review process, if the research project fits one of the exemption criteria, as stated in the 45CFR 46 101 (b). The Office of the IRB will make the final determination if a research project falls under an Exempt Category. Research may be exempt from review when the only involvement of human subjects in the research falls into one of the Exempt categories http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html – *Refer to the Appendix Section of this document*. However, studies exempt from full / expedited IRB review are not exempt from the ethical principles for the protection of human subjects.

The IRB Chair reviews or delegates review to an appropriate member for research projects that fall under exemption criteria. In the event both the IRB Chair and Vice Chair are unavailable, the IRB Administrator shall select a reviewer from the IRB members to conduct expedited review.

The assigned reviewer will review the IRB application using the "IRB Reviewer Checklist – Exempt" provided at the time of his/her assignment. If a study qualifies for exemption, the research project will be approved and investigators will be notified in writing. Investigators are required to submit to the IRB changes in the research project that may change the level of review.

Within approximately five calendar days following receipt of a complete submission, the IRB will notify the investigator and the relevant institutional officials of its decision; or the IRB will request additional information needed to determine the exempt status.

II.4 Continuing Review and Modifications to previously approved research

- Continuing review of a previously approved research

Submission of a protocol for continuing review is required for all non-exempt approved protocols where research activities are ongoing, including but not limited to continuing recruitment and enrollment of participants; research tests, procedures, and other interactions and interventions; review of identifiable information; data analysis; and follow-up of previously enrolled participants. The IRB Application for Continuing Review must be submitted at least 45 days prior to the expiration date for convened IRB review and no later than two weeks for expedited review. Depending on the type of research project, continuing review may be performed by expedited review or at a full convened meeting depending on the degree of risk and if the study was initially approved by expedited review.

Continuing review may stop only when:

- The research is permanently closed to the enrollment of new participants,
- All participants have completed all research-related interventions, and

- Collection and analysis of private identifiable information has completed.

The continuing review of research projects can also include proposed modifications to a previously approved project, including supporting documents (e.g. consent forms, advertisements, sponsor protocol) or the addition of new documents and must be accompanied by the new documents or the proposed revised versions of the previously approved or submitted documents.

It is important to note that no research related activities may occur after the protocol expiration date unless the PI contacts the IRB and the IRB Chair (or authorized designee) determines that it is in the best interest of subjects to continue during the lapse in IRB approval.

- Modifications to a previously approved research

Research regulations require that modifications in approved research, during the period for which approval has already been given, may not be initiated without prior IRB review and approval except where necessary to eliminate apparent immediate hazards to human subjects. If the change represents more than minimal risk to subjects, it must be reviewed and approved by the IRB at a convened meeting. The IRB Amendment Application must be submitted for all modifications.

Modifications to an already IRB approved research can be categorized into one of three: Amendment, Deviation, or Violation

II.5 SAEs and Unanticipated Problems

All Serious Adverse Events and Unanticipated problems must be reported to the IRB and will be reviewed by a designated member. *(Please refer to IRB.6)*

II.6 Vulnerable and Special Population

When the IRB reviews research that involves categories of participants vulnerable to coercion or undue influence, the IRB Administrator shall make certain that one or more individuals who are knowledgeable about or experienced in working with such participants will be present at the meeting.

PROCEDURE III – RISK / BENEFIT ANALYSIS

Risks to research participants posed by taking part in a research should be justified by the anticipated benefits to the subjects or society. One of the major responsibilities of the IRB, therefore, is to assess the risks and benefits of the proposed research *(IRB Handbook)*.

III.1 Types of Risk

The risk to which research participants might be exposed to is classified into the following *(as detailed on the U.S. Office of Human Research Protection webpage)*:

- **Physical Harm**: Medical research often involves exposure to minor pain, discomfort, or injury from invasive medical procedures, or harm from possible side effects of drugs. All of these should be considered "risks" for purposes of IRB review. Some of the adverse effects that result from medical procedures or drugs can be permanent, but most are transient. Procedures commonly used in medical

research usually result in no more than minor discomfort (*e.g.*, temporary dizziness, the pain associated with venipuncture). Some medical research is designed only to measure more carefully the effects of therapeutic or diagnostic procedures applied in the course of caring for an illness. Such research may not entail any significant risks beyond those presented by medically indicated interventions. On the other hand, research designed to evaluate new drugs or procedures may present more than minimal risk, and, on occasion, can cause serious or disabling injuries

- **Psychological Harm**: Participation in research may result in undesired changes in thought processes and emotion (*e.g.*, episodes of depression, confusion, or hallucination resulting from drugs, feelings of stress, guilt, and loss of self-esteem). These changes may be either transitory, recurrent, or permanent. Most psychological risks are minimal or transitory, but IRBs should be aware that some research has the potential for causing serious psychological harm.

- **Social and Economical Harm**: Some invasions of privacy and breaches of confidentiality may result in embarrassment within one's business or social group, loss of employment, or criminal prosecution

III.2 IRB Considerations

Once the risks have been identified, the IRB must assess whether the research presents greater than minimal risk. The regulations allows the IRB to provide **expedited review** of proposals if certain conditions exist (the research must present no more than minimal risk, and the involvement of human subjects must fall into one or more categories as listed in the Appendix section). Alternatively, when the proposed research presents no more than minimal risk, waiver or modification of consent requirements may be available.

III.3 IRB Criteria for Review (Exempt / Expedited Research Projects)

The reviewer follows the same criteria noted in section below, IV.6 Criteria for Approval when assessing research projects that fall under Exempt or Expedited review. For Exempt review, the reviewer follows the guidance presented in the IRB Reviewer form for studies that fall under Exempt status. As for Expedited review, the reviewer uses the same IRB Reviewer form as for studies that fall under Full review – IRB Primary Reviewer Form.

PROCEDURE IV - MEETING PROCEEDINGS

IV.1 Pre-meeting proceedings

- Frequency and Schedule of Meetings

IRB meetings are to occur at least once a month or more regularly upon the call of the IRB Chairperson, at such times and places as the IRB Chairperson may designate. The IRB meeting dates and times are determined by the end of each year for the following year and posted on the IRB website. Dates/times are subject to change due to change in protocol volume, or other unforeseeable situations. IRB members will be giving advanced notice if any changes are made. Meetings are cancelled or rescheduled by the action of the IRB Chairperson if

- There are insufficient number of applications to be discussed,
- Inability to secure a quorum,
- University holiday; or
- Other reasons that may arise that makes a meeting unnecessary or inappropriate

- Distribution Prior to IRB Meetings

The IRB administrator sends out reminders of the date, time and location of each meeting by email to all members at least 5 days prior to the upcoming schedule meeting.

All members will receive the agenda and minutes a minimum of 5 days prior to the scheduled meeting.

The IRB uses **a primary reviewer system for full IRB review**. Two members are selected by the chair or delegate, one as the primary reviewer and the other as a secondary reviewer for a research project. Copies are sent to the primary and secondary reviewers assigned to each study project along with the "IRB Primary Reviewer Checklist". These materials are provided to any member upon request. The originals of the submission materials will be retained in the Office of the IRB and will be available during the IRB meeting.

Typically the primary reviewer is has the experience and expertise in the type of research under consideration, though this is not an absolute requirement, depending upon the type of study. The primary reviewer is required to read the entire submission, be familiar with it, and be prepared to conduct an in depth review of all materials. The primary reviewer is expected to contact the IRB Chair or IRB administrator in advance of the convened meeting for clarifications of any unresolved issues related to the submission.

The secondary reviewer is typically an individual who can provide another perspective, for example, a lay person, local community representative, or a pharmacist. The secondary reviewer, therefore, complements the scientific or other expertise of the primary reviewer.

In the event that a special meeting is required, the IRB Administrator will notify the members at such time and in a manner to allow enough time to ensure members' availability.

IV.2 Meeting Proceedings – Order of Business

The meetings are held via videoconference between LAU Beirut and Byblos campuses, and LAUMC-RH. The following order of business is followed, but can be altered at the discretion of the IRB Chairperson if the need arises:

- Reading and acceptance of the minutes of the previous meeting
- Approval of meeting agenda
- Updates or notices, if any
- Presentation of new research projects, continuing research project applications, any other projects that require IRB members' decisions
- Final decisions taken
- Summary of decisions taken by the IRB Chairperson/Vice Chairperson in regards to exempt and expedited submissions
- Miscellaneous items of concern to the IRB
- Meeting adjourned

IV.3 Meeting Proceedings – Quorum

At the start of a meeting, the IRB Chairperson will determine that a quorum is present before calling the meeting to order. All meetings must occur with the physical presence of all participating members; provided however, that meetings may take place via videoconference, teleconference or such other means as determined by the board that allows all of the members to participate in the meeting at the same time.

A meeting quorum is a majority of the voting members (fifty percent plus one), including at least one non-scientific member. The IRB Chairperson counts towards the quorum and does not vote, except to break a tie. Administrators or non-voting members do not count towards the quorum.

A meeting cannot commence if a quorum has not been met. The Chairperson will ensure that a quorum is maintained during the course of the meeting. When the quorum fails because attendance falls below a majority due to recusal of members with conflicting interests or early departures, or absence of a nonscientist member, no further actions or votes may be taken.

If a member discloses a conflict of interest with the research under discussion, that person can be counted as a member but cannot be counted to constitute a quorum. Therefore, any member with a conflict of interest must disclose that conflict of interest before the project is discussed.

IV.4 Meeting Proceedings – Presentations, Decisions notifications

- *Presentations and discussions/decisions for full review*

  - The primary reviewer leads the discussion of the research project at the full IRB convened meeting. The Primary reviewer presents a brief synopsis of the research protocol, with the expectation that the other members have reviewed the protocol materials. The primary reviewer is expected to cover study design, background data, how the research differs from and compares to standard care or normal practices, the rationale for subject selection, the appropriateness of the inclusion/exclusion criteria, risks, benefits and alternatives, and other points relevant to implementation of the study. The primary reviewer also provides an assessment of the regulatory criteria, any conflict of interest of the study personnel and recommends specific actions to the board.

  - The secondary reviewer presents additional clarifications or commentary on the study plan, and any questions or concerns, or modifications required for approval

  - After the primary and secondary reviewers have presented the study and review comments, the protocol is opened for discussion by the IRB members. The Chairperson leads the discussion, and may direct specific questions to the assigned reviewers or other members of the IRB with specific expertise or viewpoints (e.g., a layperson, an attorney, nurse or other member who may bring a different perspective to the discussion).

  - At the end of the discussion, by a majority of those present at the meeting, each project is either: (1) approved as submitted; (2) approved pending receipt of required minor revisions to study procedures, Informed Consent Document(s), or other written materials; (3) tabled pending review at a subsequent full board meeting after receipt of significant additional information or revisions, or (4) disapproved. A vote on the motion is taken (for, against, abstain) and recorded in the Minutes. All motions are subject to majority vote of the members present at the meeting.

- The frequency of continuing review will be determined by the IRB members following review of each protocol. The frequency of continuing review is at least annual unless otherwise agreed upon and depends on the degree of risk, involvement of special population, if previous studies indicted high incidence of adverse events or if the IRB believes that close monitoring is required.

A member who is unable to be present at the convened meeting may participate by videoconference or telephone conference call, when the member has received a copy of the documents that are to be reviewed at the meeting. Such members may vote and be counted as part of the quorum.

- *Notification and Documentation of Expedited Review / Exempt*

- Inform all IRB members of research projects that have been approved under the expedited/exempt review procedures, a list of such research projects will be distributed to all IRB members attending each convened meeting.

- Documentation for initial and continuing reviews conducted under an expedited review procedure include:
  - The specific permissible categories justifying the expedited/exempt review; and
  - Documentation of the review and action taken by the IRB Chairperson / Co-Chairperson or designated reviewer; and
  - A written description of types of minor changes in previously approved research which can be approved under an expedited review procedure.

- *Notifying Investigators of IRB Decisions*

The Office of the IRB will notify the Principal Investigator(s) in writing of its decisions within 5 working days. The notification letters are prepared by the IRB Administrator and reviewed and signed by the IRB Chairperson. IRB decisions include approval, approval with modifications, deferral or denial. Reasons for IRB decisions will be included in the notification letter. Letters will also include Board requested changes to the research protocol and /or informed consent forms.

IV.5 Meeting Proceedings – Voting Requirements

The following voting requirements must be met:

- Each member can have one vote unless a member has a real or perceived conflict of interest, then that member may not vote on IRB action.
- Only board members who participate in the review and discussion of a research project shall be entitled to vote. After discussing each research project during the meeting, the IRB members vote on the recommendations made by the primary reviewers.
- Members attending by telephone or videoconference count towards the quorum and may vote providing they have received all pertinent material prior to the meeting and they can participate actively and equally in the discussion of the research projects. The IRB minutes document that these two conditions are met. Follow up email vote might take place if discussion occurred during the meeting and motion to approve pending final changes.
- The IRB Chairperson does not vote except to break a tie.
- Ad hoc advisors, investigators, administrators and consultants do not vote.

According to the criteria of approval, the vote may be for approval, approval with modification, deferral or denial. Research project approval requires the approval of the majority of the IRB's quorum. Votes (for, against, abstain), those excused from voting and the attendance are recorded in the minutes.

In the event that IRB disapproves a certain application/project, overriding of IRB disapproval is prohibited.

IV.6 Meeting Proceedings – Criteria for Approval

All proposed research must meet ethical standards governing the conduct of research. The IRB confirms that the proposed IRB Protocol Application, informed consent documents and recruitment documents are accurate and complete. The IRB shall determine that all of the following requirements are satisfied in order to approve a study:

- Risks to the Subjects must be minimized
  - by using procedures that are consistent with sound research design and that do not unnecessarily expose Human Subjects to Risk; and
  - whenever appropriate, by using procedures already being performed on the Human Subjects for diagnostic or treatment purposes.
- Risks to a Human Subject must be reasonable in relation to the anticipated benefits, if any, to the Subject and the importance of the knowledge that may reasonably be expected to result;
- The selection of Subjects must be equitable;
- Informed Consent must be obtained from each prospective Human Subject or the Subject's Representative, as applicable, before any research related procedure;
- Informed Consent must be appropriately documented, in accordance with IRB.4;
- The Research Project includes adequate provision for monitoring the data collected to ensure the safety of Human Subjects;
- There are adequate provisions to protect the subject's privacy and maintain confidentiality of research data;
- There are appropriate provisions for compensation for participants as deemed appropriate, in addition to ensuring appropriate insurance or indemnity due to adverse events or unanticipated problems as a result of participating in the research project;
- When some or all of the Human Subjects are likely to be susceptible to coercion or undue influence, there shall be additional safeguards to ensure protection of the rights and welfare of these Subjects
- Disclosure of any form of conflict of interest, being financial or non-financial and appropriate ways for managing such conflict

IV.7 Meeting Proceedings – Decisions

- Decision taken at meetings by a motion announced by the IRB Chairperson / Vice Chairperson

Decisions taken during full board review meetings occur by voting and in most cases comprise one of the following:

- Approval
- Approval with Modification
- Denial
- Deferral
- Termination or Suspension of an already approved research study

- Decisions taken by the IRB Chairperson / Vice Chairperson

Decisions taken by the IRB Chairperson / Vice Chairperson are communicated to the IRB members during the next scheduled meeting. Such decisions include exempt/expedited decisions taken as per the criteria set out in Procedure II.

IV.8 Meeting Proceedings – Minutes

The minutes of each meeting are prepared and finalized by the IRB Administrator. The minutes must be reviewed and approved by the Chairperson of the IRB before circulation to the members. The Administrator then forwards the approved minutes to the members at least 1 week before the next scheduling meeting and along with the meeting reminder notification.

The IRB minutes should include, at a minimum, the following information:

- Date, time and location of meeting
- Members present: Highlight student members and not affiliated members
- Specify if any consultants/guests/others attend the meeting.
- Summary of discussion pertaining to protocol reviews, particularly debated/controversial issues
- Record of IRB decisions
- Timelines and reasons for continuing review particularly if more than once a year
- Record of voting – showing votes for, against and abstentions.
- The minutes should also provide information about members entering and leaving the meeting to allow reconstruction of who was present for each vote or any loss of quorum
- Any additional highlights, updates, etc
- Educational material presented to the members
- Adjournment time

PROCEDURE V - RECORD KEEPING AND RECORD RETENTION

V.1 Membership

The Office of the IRB maintains records for each member and uses the "IRB New member checklist" for documentation *(Refer to the Appendix Section)*. The Office of the IRB retains the IRB member roster. The information in the IRB member roster should be used to provide effective review of research and management of the IRB. The roster includes following information:

- Names of IRB members.
- Earned degrees of IRB members e.g. curricular vitae
- The representative capacity of IRB members
  - Scientist or non-scientist
  - Affiliated or non-affiliated
  - Representative of a special population
- Indications of experience of IRB members sufficient to describe each member's primary anticipated contributions to the IRB deliberations. (e.g. board certifications, licenses, etc.)

- Employment or other relationship between each member and the organization. (e.g full-time employee, part-time employee, member of governing panel or board, stockholder, paid, or unpaid consultant.)

V.2 Meeting Agenda and Minutes

Written minutes of each full IRB meeting include: (1) attendance, (2) the number of votes to approve, table, disapprove, or abstain (without individual identification), (3) the basis for requiring changes in or disapproving the research, (4) the length of time until the next review, and (5) a summary of the discussion of controverted issues and their resolution.

V.3 Research Projects and Documentation

The Office of the IRB retains files for every research project reviewed by the IRB. The IRB records for each reviewed protocol must be organized to allow a reconstruction of a complete history of all IRB actions related to the review and approval of the protocol. The IRB records should include, but are not limited to, copies of the following:

- All of the documents submitted with the research project for review initially and subsequently including, but not limited to, the application form, protocol summary, detailed protocol, recruitment materials, consent form(s), drug/device brochures, grant application, sponsor protocol, scientific evaluations, if any.
- Checklists and review documentation, including review forms signed by IRB Chairpersons or designated alternate(s);
- Ancillary board/department review and approval documentation
- IRB - approved recruitment materials;
- IRB - approved consent form;
- Progress reports, interim analyses, safety reports, DSMB report;
- Reports of injuries to subjects;
- Reports of unanticipated problems involving risk to subjects or others;
- Reports of protocol violations;
- Proposed changes to the protocol and revised documents (amendments);
- All correspondence between the IRB and investigator;
- Statements of significant new findings provided to subjects

All IRB records must be maintained for a minimum of 5 years after completion of the study and after the study is considered closed by the IRB unless otherwise requested by the Chairperson. Distributed and excess copies of all submissions will be collected at the end of each IRB meeting and destroyed by a method deemed appropriate by the IRB Chairperson.

PROCEDURE VI – ANNUAL REPORT

The IRB shall submit an annual report to the Office of the Dean GSR. The report shall include but not limited to the following:

- Summary of IRB meeting conducted
- Membership roster – updates
- Training conducted – including lectures, grand rounds, information sessions etc.
- Quality improvement activities
- Summary of departmental meetings
- Quantitative summary of types of research submitted
- Summary of funded research
- Development or modification of policies, procedures, applications and guidance documents, etc.
- Any other relevant information of importance to be noted

REFERENCES

- AAHRPP STANDARDS – DOMAIN II INSTITUTIONAL REVIEW BOARD OR ETHICS BOARD
- CODE OF FEDERAL REGULATION – 21 CFR 56
- OFFICE OF HUMAN RESEARCH PROTECTION – 45 CFR 46
- ICH GOOD CLINICAL PRACTICE – E6 (SECTION 3)
- LEBANESE MINISTRY OF PUBLIC HEALTH – IRB LAW

APPENDICES AND SUPPORTING DOCUMENTS

- NON-DISCLOSURE AGREEMENT FOR IRB MEMBERS
- IRB NEW MEMBER CHECKLIST
- IRB PRIMARY REVIEWER FORM
- IRB REVIEWER FORM - EXEMPT
- LAU IRB REVIEW PROCESS
- EXEMPT CATEGORIES
- EXPEDITED CATEGORIES