Institutional Review Board
Submission Requirement Presentation

Institutional Review Board Office
Dean of Graduate Studies and Research
Lebanese American University

LAU
الجامعة اللبنانية الأميركية
Lebanese American University

Overview

- What is Research?
- **Required Steps to consider before or during IRB Submission preparation**
- Institutional Review Board
- IRB Submission requirements
  - Faculty & Staff Research
  - Student Research

LAU
الجامعة اللبنانية الأميركية
Lebanese American University

Questions

- What is research?
- Are there any regulations?
- Are you aware of any oversight?

Conduct of Research involving

Human Participant

What is Research?

A systemic investigation, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**

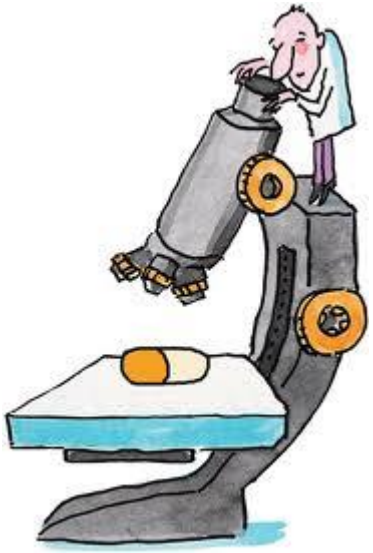
What is Human Subject?

A **living individual** about whom an investigator conducting research obtains:

- **Data through intervention or interaction with the individual**, *or*
- **Identifiable private information**

Types of Research

- Type
  - Survey / Questionnaire
  - Interviews
  - Assessment tools
  - Retrospective studies
  - Basic / Genetic
  - Intervention



- Research conducted across all disciplines

Required Steps to consider before or during IRB Submission preparation

- Is my research project funded?
- Am I taking part in a sponsored study such as a sponsored Clinical Trial?
- Does my research involve transfer of data or material to and from LAU / LAU Medical Center Rizk Hospital?

Please review the following slides to answer these questions and guide you

Is my research project funded?

- If No – then proceed to the next slide
- If Yes, please ensure the following
  - Did you notify the GSR office?
  - Did you review the study budget with the budget office
    - LAU budget office for non patient related studies
    - LAUMCRH budget office for patient related studies
  - Did you check what kind of contract is required?

Am I taking part in a sponsored study such as a sponsored Clinical Trial?

- If No – then proceed to the next slide

- If Yes – please ensure the following
  - Communicate with the LAU IRB to secure clearance on the contract and the study budget

Does my research involve transfer of data or material to and from LAU /LAU Medical Center Rizk Hospital?

- If it is part of a funded or sponsored studies, terms relating to transfer of data and / or material is already part of the agreement

- If the study is not funded or sponsored, and you are the main researcher on the study, please contact the GSR or IRB office for procedure for Data Sharing Agreement or Material Sharing Agreement

IRB Requirements

OUTLINE

- What is an IRB?
- Does my study require IRB review?
- What is the IRB Submission Process?
- Are there any IRB fees?
- What are the timelines for IRB Review?
- What happens after my application has been reviewed by the IRB?

LAU
الجامعة اللبنانية الأميركية
Lebanese American University

WHAT IS AN INSTITUTIONAL REVIEW BOARD?

The Institutional Review Board:

- Ensures that the proposed research conducted under its auspices encompasses the ethical principles of the Belmont Report and the protections provided by the regulations and guidelines governing research

- Responsible for the review and approval of research projects involving human subjects conducted at LAU and the LAU Medical Center – Rizk Hospital (LAUMC-RH) or by its faculty, physicians, staff and students at outside locations.

LAU
الجامعة اللبنانية الأميركية
Lebanese American University

Institutional Review Board *Responsibilities*

- Ensures the protection of the rights, safety and wellbeing of human subjects

- Functions as a "human subject advocate"

- Ensures that the PI
  - every effort to minimize risk
  - incorporate safeguards to protect those risks

Types of Participant Risk to Consider

Vulnerable Population Require additional Protection measures

Vulnerable population include:

- Children
- Embryos and Fetuses
- Pregnant Women
- Mentally disabled
- Elderly
- Educationally disadvantaged subjects
- Economically disadvantaged subjects
- Hierarchical social structure (e.g students, staff, prisoners)

Does my study require IRB review?

- Any research project that involves human subjects/ participants must be reviewed by the IRB

- Human participants are defined as living individuals about whom an investigator

  (whether professional or student)

  conducting research and obtains data:

  1) through intervention or interaction with the individuals, or
  2) identifiable private information.

Does my research require IRB review? *(cont.)*

- Including any project that proposes to utilize data from personal records, medical records, observations, surveys/ questionnaires etc. must be reviewed by the IRB.

- In many of these projects, investigators remove identifiable participant information and are deemed to be "exempt" studies, but they still must be reviewed by the IRB.

What is the IRB Submission Process?

Submission Requirements* . IRB Application & Supporting documents

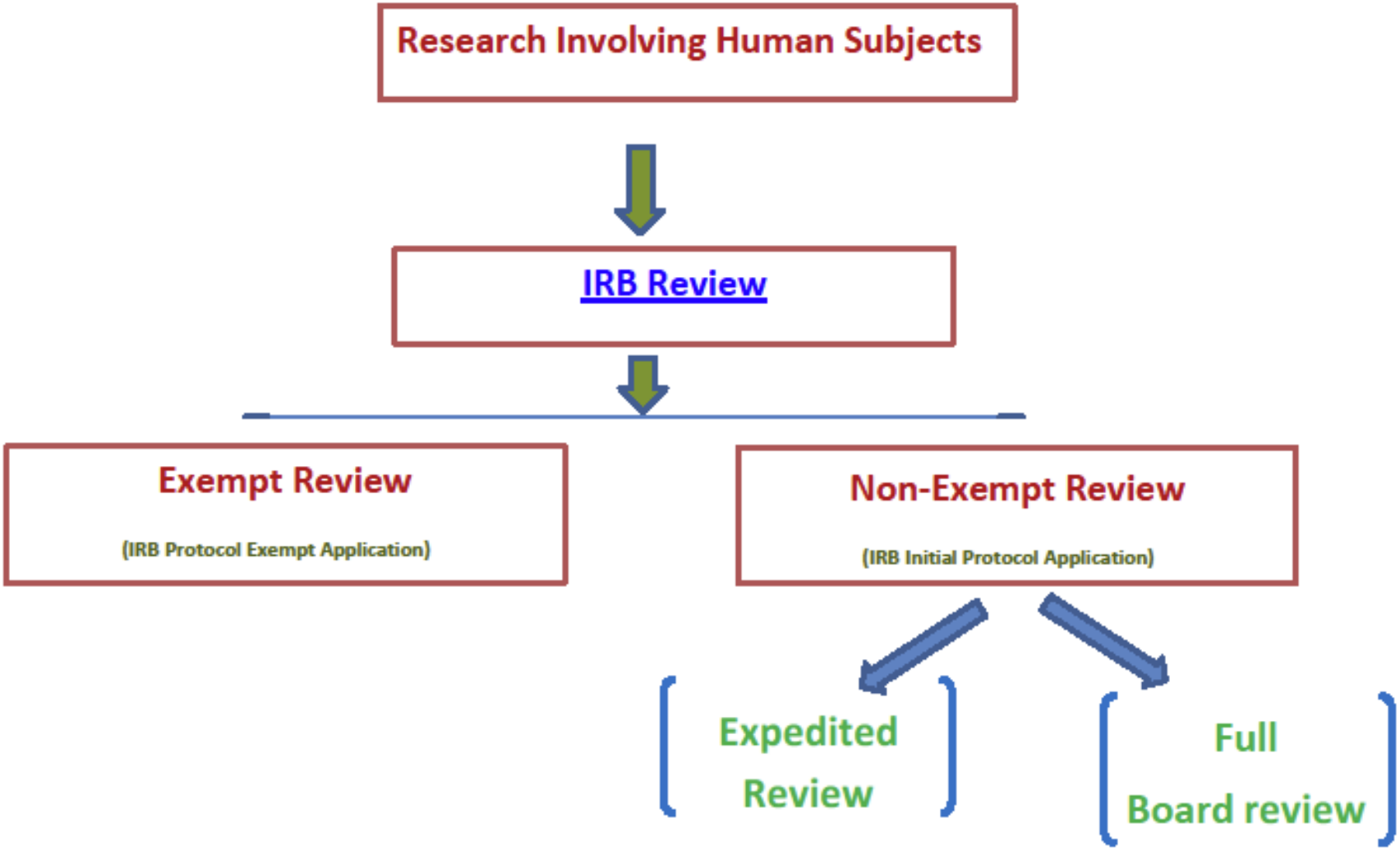
IRB#

Click above for relevant links

**ensure a complete submission in order to avoid any delays in the review process*

#Timelines for review noted below

LAU
الجامعة اللبنانية الأميركية
Lebanese American University


Research Involving Human Subjects
IRB Review
Exempt Review
(IRB Protocol Exempt Application)
Non-Exempt Review
(IRB Initial Protocol Application)
Expedited Review
Full Board review

TERMINOLOGY

- Types of Review
  - FULL versus EXPEDITED

- Types of Research – Categories
  - Exempt (reviewed via expedited process)
  - Expedited (reviewed via expedited process)
  - Full (reviewed at a full board meeting)

(Refer to the Timetable for review timelines on the next slide)

IRB Review Fees for Sponsored or Externally Funded Research

- The IRB charges a fee for review of research studies involving human subjects for sponsored or externally funded research projects

- Fee schedule, visit the IRB website

- Payment is expected independent of the IRB decision and is due within 30 days of receipt of invoice. For any questions, please contact the IRB office by email at irb@lau.edu.lb.

What are the timelines for IRB Review?

Summary Table

Type of Review*	Timelines**	Required Application***
Full Review	Review will take at least **30-45 days** from date of submission (complete submission must be at least 2 weeks prior to the next scheduled meeting)	• Initial Protocol Application - for new research project • Protocol Amendment Application - for any changes or amendments to the protocol after approval • Continuing Review Application - for renewal of previously approved research project, at least annually
Expedited Review	Review will take **20 days** from date of submission	• Initial Protocol Application - for new research project • Protocol Amendment Application - for any changes or amendments to the protocol after approval • Continuing Review Application - for renewal of previously approved research project, at least annually • Request for Protocol Closure Form - notification of study closure, termination, or completion
Exempt Review	Review will take **5 days** from date of submission	• Protocol Exempt Application - for research projects that fit one of the exemption criteria

** Detailed explanation for the different Types of Review can be found under Guidance Documents.*

*** Timelines noted are for complete submissions. If a submission is missing documents, the submission will*

Submission Requirements

Initial Submission to the IRB should include the following.
Please make sure to secure the relevant required signatures on the forms:

- Completed "IRB Initial Application"*
  - IRB Initial Application - Biomedical Research
  - IRB Initial Application - Social Behavioral Research
  - IRB Protocol Exempt Application

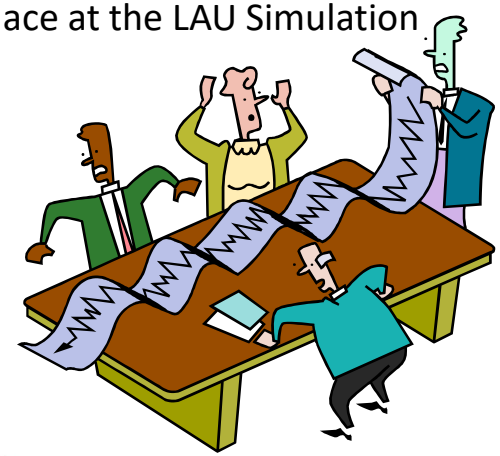
- *Letter - documented request for approval from outside centers (use the template letter provided by the LAU IRB) or*

- Completed "LAUMC-RH Signature Page" for research to be *conducted at LAU Medical Center – Rizk Hospital*

- Completed *"Simulation Center Signature Page"* for research to take place at the LAU Simulation center

- *All relevant Supporting Documents*

**Check which IRB Initial application best fits your research*



LAU
الجامعة اللبنانية الأميركية
Lebanese American University

Facutly & Staff Research

- Faculty/Staff to complete their application and submit all required documents

  (refer to checklist)

- Facutly must also complete the Research Proposal Submission Form « RPSF » after securing the signature of the respective Chair and the Dean

Student Research

There are 2 categories:

1. Category 1 - Student completing their senior studies, thesis or dissertation

2. Category 2 - Students conducting research as part of their class or Research Methodolgy Course

LAU
الجامعة اللبنانية الأميركية
Lebanese American University

Category 1.
Student Projects

Students who conduct research for their **Thesis and Dissertation Projects**

- Student must complete the IRB application

  (refer to checklist)
- Student must secure the signature of his/her advisor on the IRB application before submitting to the IRB
- Student must submit an application along with all supporting documents to the IRB for review and approval prior to commencing the project.

Category 2.
Classroom Projects

Research projects for which the primary purpose is a learning experience in the methods and procedures of research do not meet the U.S. federal definition of research and are therefore subject to consolidated review by the LAU IRB.

The following is required:

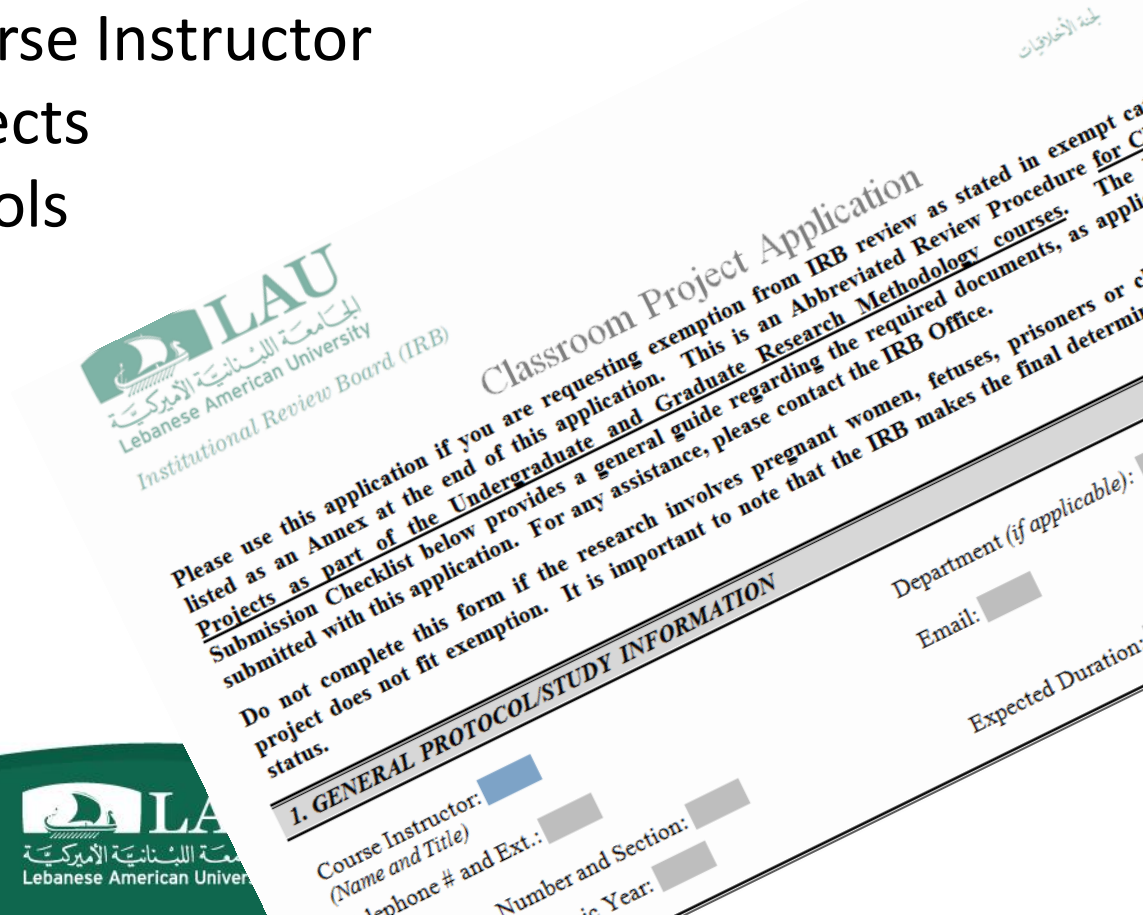
- Instructor to complete the Classroom Project Application
- Syllabus should include that the faculty /instructor has provided the students with relevant information on the protection of human participants in research
- Recommend that students take the NIH training

LAU
الجامعة اللبنانية الأميركية
Lebanese American University

Special Application

Only for Classroom Projects - RM

- Classroom Project Application
- Research Methodology Courses
  - Submitted by Course Instructor
  - Lists student projects
  - Data collection tools
  - Course syllabus



Please contact the IRB for more information or Review the CP Process

Supporting Documents

Mandatory:

- ✓ Research Proposal
- ✓ Training – Human Subject Protection

As Applicable to the research:

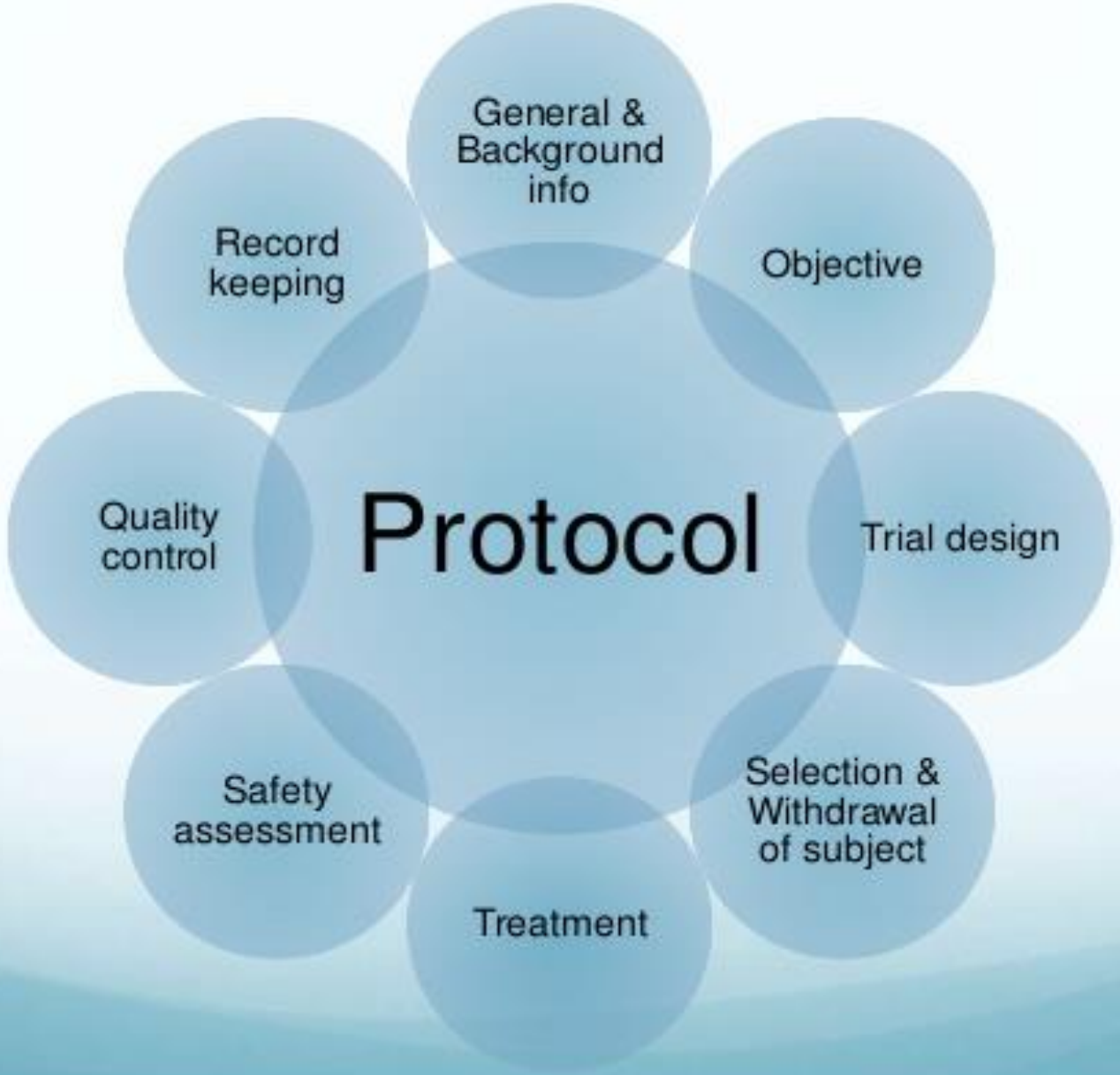
- ✓ Consent/assent form(s) Any participant information
- ✓ Surveys, questionnaires, interview script
- ✓ Advertisements, if any
- ✓ Payments or inducements to participants
- ✓ Data collection tools
- ✓ Conflicts of interest
- ✓ Letter to participating center (s)
- ✓ Investigator brochures or product monograph (drug /device trials)

Please refer to the first page of the application for a complete list

The Research Protocol / Proposal

- *A well-written and complete protocol is essential for achieving a high quality research study.*
- *Must include the following:*
  - ***Why** the study is being done*
  - ***What** will be done in the study*
  - ***Where** the study will be done*
  - ***Who** is involved in the research study*
  - ***When** study interventions will take place*
- *Time spent on writing a detailed protocol will avoid delays during the review process and also avoid any problems while the study <u>is being conducted</u> hence will make publishing the results easier.*
- *A complete protocol is also essential for the study to be approved by the ethics committee.*

Clinical trial Protocol



IRB Review

Minimum Criteria the IRB looks at are:

- Purpose and Rational of the study
- Targeted participant population and justification
- Sample size justification
- Method of recruitment and approaching participants
- Informed consent procedure and process
- Study procedures
- Anticipated risks and potential benefits to participants
- Steps taken to protect participants including management of adverse events.

Student Advisors

- Play an important role in the students' design and development of human participant research projects.
- Ultimately responsible for the protection of the participants, even if the student is the primary investigator (PI) and actually directs the project.
- Ensure students are engaged in independent research, and instructors are responsible for research that is conducted as part of their course.
- Faculty advisors and course instructors are required to review codes of ethics relevant to the discipline of study.

Training – Human Subject Protection

All investigators and study personnel involved in the study must be listed on the IRB application and must complete the training for Human Subject Protection.

The LAU IRB requires the training through the **Collaborative Institutional Training Initiative (CITI)**

Other Relevant IRB Applications

- Continuing Review Application
  - Must be used when requesting a renewal to continue with an already IRB approved study. Please check the expiry date on the approval letter
  - Any amendments can also be submitted on this application at the time of renewal
- Protocol Amendment Application
  - Must be used want to do any modifications or changes to the protocol, or any related study documents during the IRB Approval timeframe
- Request for Protocol Closure Form
  - Must be used for notifying the IRB office that your research project is completed or terminated.

What happens after my application has been reviewed by the IRB?

- The IRB Approval Letter will
  - *Specify type of review*
  - *Reference the documents submitted and approved*
  - *Specify stamped documents that **must** be used such as consent forms, data collection tools, advertisements, etc.*
  - *Specify IRB approval expiry date (for all non-exempt research projects)*
  - *Highlight "Approval Conditions" specific for the type of review.*

- It is the responsibility of the investigator to submit a Continuing Review application to an IRB approved project prior to its expiry. The IRB office will send a reminder 2 months prior to the IRB Approval expiry date.

Overview

Graduate Studies

Research

IRB

- Main Page
- IRB Meeting Dates & Deadlines
- IRB Membership Roster
- Policies and Procedures
- Submission Requirements
- Applications, Forms & Supporting Documents
- IRB Types of Review
- Informed Consent Requirements
- Education & Training
- Student Research Projects and Classroom Projects
- IRB Registration
- References

Institutional Review Board

The Lebanese American University (LAU) Institutional Review Board (IRB) is responsible for the review and approval of research projects involving human subjects conducted at LAU and the LAU Medical Center–Rizk Hospital (LAUMC–RH) or by its faculty, students and staff at outside locations. The primary objective of the IRB is to ensure that the proposed research conducted under its auspices encompasses the ethical principles of the Belmont Report and the protections provided by the regulations and guidelines governing research.

News and Announcements

IRB submissions for Full Board Review must be submitted one month prior to the upcoming IRB meeting date.

IRB approval must be secured prior to any data collection or use for a research project involving human participants including but

Contact Us

Christine Chalhoub, BScH, CRA, CCRP, CIM
Email: christine.chalhoub@lau.edu.lb

Karmen Baroudy, M.Sc.
Email: karmen.baroudy@lau.edu.lb

LAU IRB Website

- Link http://gsr.lau.edu.lb/irb/

- Accessible
  - LAUMC-RH Homepage – Quick Links
  - Faculty Portal Homepage
  - Student Portal Homepage

IRB Office, 2nd floor Dorms A, Room 704,

Byblos Campus

Website: http://gsr.lau.edu.lb/irb/

Email: irb@lau.edu.lb

Ext. 2546

LAU

الجامعة اللبنانية الأميركية

Lebanese American University