

IRB Process Research Project Submission and Timelines for Review

DOCUMENT CONTROL

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REVISION RECORD

Date	Version	Revision description
Jun. 2011	V 1&2	Initial Version – old template
Mar. 2012	V3	Old template - Contract Pre-approval clearance from legal, receipt of LAUMC-RH Signature page to initiate IRB review and IRB office then generates invoice
Aug. 2013	V4	Old template - Added fee for non-interventional studies, 20% overhead for LAUMCRH to be added to study budget and IRB approval to be sent to PI, and coping LAUMCRH administration and legal office
Apr. 2014	V5	Streamlining the process with LAUMC-RH, administrative changes
Jul. 2016	V 6	Merging processes for Submission and Sponsored/ Funded for LAU and LAUMCRH

DEPARTMENTS INVOLVED

Department / Entity	Date notified	Description of involvement
LAUMC-RH		Administration at LAUMC-RH

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Research Project Submission and Timelines for Review

1. PURPOSE

This document summarizes the steps required for submitting a research project for review:

1.1 Submission of a Research Project

1.2 Submission of a Research Project - for Funded / Sponsored Research Projects - The steps required when an investigator at LAU is planning to take part in a sponsored or funded research project.

1.3 Renewal Submission - Process for Continuing Review

1.4 Summary for Timelines of Review

2. RESPONSIBILITY

LAU Faculty
LAU Staff
LAU Student
IRB Office (Administrators)
LAU School Dean
LAU Graduate Studies and Research Office
LAU Legal Office
LAU Budget and Financial Planning Office
LAUMC-RH Staff
LAUMC-RH Administration

3. APPLICABILITY

All personnel planning to conduct a research project included all Sponsored or Funded research projects to be conducted at LAU or LAUMCRH

If the study is to be conducted at LAUMC-RH then a clearance from the hospital must be secured by filling the LAUMC–RH Signature Page

If non LAU/LAUMC-RH investigators would like to conduct their research project at LAU, they should have a facilitator, co-investigator, advisor, or mentor at LAU /LAUMCRH to be able to apply to the LAU IRB and conduct the study on premises

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4. DEFINITIONS AND ABBREVIATIONS

Initial Review means the first review by IRB of a research project

Continuing Review means a review by the IRB for the extension/continuation of a research project subsequent to the expiry date noted on the approval letter. IRB approval is normally granted for a period of 1 year at a time.

Sponsored means a clinical study or research project that is funded by a pharmaceutical / Biotechnology Company

Funded means a research project that is funded by a funding agency namely not for profit organization or could be PI initiated funded by a pharmaceutical / Biotechnology company

5. PROCESSES

5.1 Submitting a Research Project for Review

- 5.1.1** The PI must assess what type of research project he/she plans to conduct
- 5.1.2** If the research project is funded/sponsored, please refer to Section 5.2 of this document before preparing your submission.
- 5.1.3** The PI must complete the “**Research Proposal Submission Form**” and fill the applicable **IRB Application** depending on the type of research to be conducted.
 - If the study fits one of the Exempt criteria, a [Protocol Exempt Application](#) should be filled.
 - If the study does not fit one of the Exempt criteria, one of the following applications must be filled;
 - a- [Initial Protocol Application – Biomedical Research](#)
 - b- [Initial Protocol Application – Social and Behavioral Research](#)
- 5.1.4** If the research project is to be conducted at LAUMC-RH, please complete the “**LAUMC-RH Signature Page**” and secure the necessary signatures and submit along with the IRB application to the IRB Office
- 5.1.5** The PI must ensure that researchers (co-investigators, research assistants and other study personnel) involved in the research project submit a Certificate of Completion for the on-line training for the “Protecting Human Research Participants”

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<https://phrp.nihtraining.com/users/login.php>

- 5.1.6 The PI must submit all study related material such as data collection forms, informed consent, information sheet, questionnaires, surveys, interview and/or telephone scripts, referral emails/communication, advertisement, etc.
- 5.1.7 If an Initial Protocol application is filled, the PI must submit a detailed protocol or research project.
- 5.1.8 If the PI is conducting the research outside LAU, the PI must receive approval from the IRB at LAU as well as approval from the respective committee responsible for research involving human subjects or appropriate approval where the study will be conducted.
- 5.1.9 The PI then submits the completed application along with all supporting documents to the IRB office. All documents must be sent electronically, and one hard copy should be forwarded to the IRB office.
- 5.1.10 Once the IRB Administrator receives the application and checks all submitted documents, the IRB Administrator then sends an email acknowledging receipt of the Research Project to the PI. If documents are missing or incomplete – the PI is notified promptly.
- 5.1.11 When the submission is complete, the research project application and all supporting documents are forwarded for review – this step is called **Initial Review**.
- 5.1.12 Please refer to section 5.4 for a table specifying the Timelines for IRB Review
- 5.1.13 Following IRB Approval – the PI is notified and
 - If the study involves LAU students as participants, then the Dean of Student is informed, as appropriate.
 - If the study involves any other department(s), then the IRB Office will inform such departments accordingly.

5.2 Initial Submission Process for Funded / Sponsored Research Projects

- 5.2.1 For Funded / Sponsored Research Projects:
 - LAU - PI consults with the LAU Budget and Financial Planning Office and the Dean of the school regarding any new / Funded or Sponsored study –The PI submits a copy of the contract / Clinical Trial Agreement to the LAU Budget and Financial Planning Office and respective department Chair for review

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- **LAUMCRH** - PI consults with the LAUMC-RH administration regarding any new / Funded or Sponsored study –The PI submits a copy of the contract / Clinical Trial Agreement to the LAUMC-RH administration (please refer to the LAUMCRH checklist for guidance as well)
- 5.2.2 The PI / sponsor must discuss the study budget including university/hospital overhead with the Budget and Financial Planning Office (For LAU) and the Hospital Administration (For LAUMCRH), as applicable
- 5.2.3 Once PI receives clearance regarding the contract or clinical trial agreement, the PI can move forward with the IRB submission as noted in Section 5.1. The PI submits the application and all study documents to the IRB office including the Clinical Trial Agreement/ Study contract that was cleared along with the Budget for the study.
- 5.2.4 Upon receipt of the application and supporting documents, the IRB will initiate review of the study and the IRB administrator will send to the PI the “**IRB Payment Request Form**” of (a non-refundable fee of \$1500 plus VAT for interventional studies or \$200 plus VAT for non-interventional studies) to be completed, signed and returned to the IRB Office
- 5.2.5 The IRB administrator will forward the completed and signed “ **IRB Payment Request Form**” to the Budget and Financial Planning Office to generate an Invoice
- 5.2.6 The Budget and Financial Planning Office will then prepare and send the invoice to the IRB office to be delivered to the PI to process the payment.
- 5.2.7 The PI / Sponsor will then process the payment transfer
- 5.2.8 The IRB’s final decision will be given after review and payment is done.
- 5.2.9 Once Approval is granted, the Approval is sent to the PI copying the Dean of the School, Budget and Financial Planning Office and LAUMC-RH administration, as applicable. The approval email will include a statement stating that approval is granted pending contract signature - The contract or Clinical Trial Agreement must be signed along with Study Budget*
- 5.2.10 Once contract is signed, a copy of the Signed CTA and approved Budget must be forwarded to the IRB
 - **LAU** – the contract is signed along with the study budget by the (i) PI, (ii) funding agency and (iii) president or designee
 - **LAUMC-RH** – the contract is signed along with the study budget* by (i) the PI, (ii) LAUMC-RH legal representative and (iii) the sponsor / funding

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agency. The original contract will remain with the PI in the Study Specific Regulatory Binder in LAUMCRH

*Study Budget must remain unchanged from the one submitted to IRB with initial documents. Any changes related to above must be reapproved by the IRB

5.3 Renewal Submission: Continuing Review Process of previously approved studies

- 5.3.1 The IRB Office sends a notification email to the PI two months in advance prior the expiration date of the study requesting for study renewal or closure of the study
- 5.3.2 If the PI wants to renew the study, the PI must complete the IRB Continuing Review Application and submit to the IRB for review. Otherwise, the PI must complete the IRB Protocol Closure Form
- 5.3.3 For studies to be renewed and if the study is funded / Sponsored
 - 5.3.3.1 A non-refundable renewal fee (500 \$ plus VAT for interventional studies or \$50 plus VAT for non-interventional studies) is applied.
 - 5.3.3.2 The IRB administrator will complete the “**IRB Payment Request Form**” with the payment amount and send to the PI for signature
 - 5.3.3.3 Once signed form received from PI, the IRB administrator will send the completed and signed “**IRB Payment Request Form**” to the Budget and Financial Planning Office to generate an Invoice
 - 5.3.3.4 The Budget and Financial Planning Office will prepare and send the invoice to the IRB office to be delivered to the PI in order to process the payment.
 - 5.3.3.5 The PI / Sponsor will then process payment transfer
- 5.3.4 The renewal application will be reviewed, upon receipt, and the renewal approval letter will be given accordingly

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5.4 Timelines for IRB Review

Type of Review*	Timelines**	Required Application***
Full Review	Review will take at least 30-45 business 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 business 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 business days from date of submission	Protocol Exempt Application - for research projects that fit one of the exemption criteria
Classroom Project	Review will take 7 business days from the date of submission	Classroom Project Application

* Detailed explanation for the different [Types of Review](#) can be found under [Guidance Documents](#) on the IRB website

** Timelines noted are for complete submissions. If a submission is missing documents, the submission will be returned to the PI with clarifications. Timelines also vary if there are any major concerns to the project submitted.

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*** All submissions must include a completed and signed application along with all required documents as noted at the beginning of each application.

*** Whenever required, all investigators on the application must complete and sign the Investigator Financial Disclosure Form.

6. Appendices

LAUMC-RH Checklist – Research Project Submission and Initiation for funded or sponsored projects (contact the IRB office)

[Research Proposal Submission Form](#)

[LAUMC-RH Signature Page](#)

IRB Applications:

[IRB Initial Application – Biomedical Research](#)

[IRB Initial Application – Social and Behavioral Research](#)

[IRB Exempt Application](#)

[Continuing Review Application](#)

[IRB Fees](#) – Approved by the President’s Cabinet on February 24, 2012

IRB Payment Request Form – Version 6. December 2016