



Submission Information and Policies

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Introduction

Thank you for choosing to work with Pearl IRB!

Our goal is to provide you with the most efficient, quality review possible. One of the keys to success is clear communication and transparency. If at any time you need additional information or clarification, don't hesitate to contact us directly at 317.899.9341 or info@pearlirb.com. Regular business hours for Pearl IRB are 8:00am – 5:00pm EST Monday thru Friday (excluding holidays).

Review of this document before your submission is appreciated.

Types of Reviews Conducted

Pearl IRB conducts the following types of new submission reviews:

- Full Board Review
- Expedited Review
- Expedited Review with Waiver of Consent
- Exemption determinations
- General/Generic Recruitment (or Advertising) Material

And the following types of review associated with previously approved submissions:

- Continuing Review (for submissions previously approved by Pearl IRB)
- Amendments (to previously approved Pearl IRB submissions)
- Close-Out Reviews

Board Membership

Pearl IRB is committed to maintaining a current Board roster of qualified individuals for a quality review. To ensure that your project is not delayed, we do have adjunct members that go through the same rigorous training and meet the qualifications of a Pearl IRB core member. These adjunct members may be called upon to ensure a majority and a quorum for your review. At times, we will need additional expertise to ensure a quality review of your proposed research. Pearl maintains a cadre of consultants to advise the Board in specific areas of expertise. These advisors will not vote on the protocol, but solely provide consultation to the Board.

Preparation for IRB review Readiness

Prior to submitting documents for IRB review, it is important that all the information required for your submission is complete and ready for review. All forms must be answered completely. Should a question not apply to your submission, please use the answer "N/A". Incomplete forms or missing requested documentation (i.e, CV's and licenses) will constitute an incomplete submission and possible delay in review. Please find the submission specific requirements below.

General/Generic Recruitment (Advertisement) Material:

- Recruitment Material Submission Form

Exemption Determination:

- Exemption Determination Form

New Submissions:

- Sponsor Agreement
- Sponsor Submission Form
- Principal Investigator Agreement
- Investigator/Site Submission Form

Continuing Review:

- Continuing Review Form
- Most recent ICF and Protocol. Please supply both tracked and clean versions of each document that is being updated.
- Supply appropriate documentation if there are any additional updates (CV, license renewal, FDA inspection, etc.).
 - Changes in primary researchers may require revision of additional forms.

Close-Out:

- Close-Out Form

To facilitate this process, forms are available on the Pearl IRB website at www.pearlirb.com/resources/forms. Should you have difficulty completing these forms, we will be happy to help. Contact info@pearlirb.com.

Process Overview

Pearl IRB holds full board meetings on a weekly basis. Completed materials must be submitted by end-of-business on the Monday (5pm EST) of each week to be considered for review the following Wednesday at 5pm EST. *Incomplete documents will result in a delayed submission and, therefore, a delayed review.* If you think your submission may be delayed, contact Pearl IRB (info@pearlirb.com) to discuss options that may allow you to still meet your timeline. The Board will thoroughly review your documents prior to the scheduled weekly meeting. Please be prepared should you or your PI be asked to attend the meeting. Advance notice will be given should this be requested. By the end-of-business day of the day after the full board review (Thursday of each week), information on the determination of the submission will be sent to you via email.

IRB PROCESS OVERVIEW:

Day 1 (Monday)	Completed Documents received by Pearl IRB (by 5pm EST)
Day 7 (Tuesday)	Board members complete review
Day 8 (Wednesday)	Full Board Meeting 5pm EST
Day 9 (Thursday)	Communication of IRB determination sent to you

Potential Board Responses

Approved: The IRB approves research when it determines that the regulatory and IRB

SOP requirements are met. The IRB is approving the research to begin or continue as written per the current Protocol Version.

Your further action: None. Congratulations! Get started.

Approve pending modification(s): The IRB approves research with the designation “approved pending modifications” when it determines that the regulatory and IRB SOP requirements for approval are met, but the IRB requires minor, directed modifications.

Your further action: Submit modifications for approval (frequently these can be completed by expedited review). Please contact Pearl IRB about the required modifications if you are uncertain about how to complete.

Approve with query(ies): The IRB approves research with a “query” or “queries” when it determines that the regulatory and IRB SOP requirements for approval are met, no modifications are required, and the IRB requests information that does not impact participant safety. The regulatory and IRB criteria for approval are met without the requested information. The IRB is approving the research to begin or continue as written per the current Protocol Version.

Your further action: You don't have to reply, but if you choose to, the response will be reviewed by the expedited process.

Disapprove: The IRB disapproves research when it determines that the regulatory and IRB SOP requirements for approval are not met.

*Your further action: When the IRB **disapproves** a new study it is rejecting the research as submitted. If you wish to revise the study, it must be resubmitted as a new study. When the IRB votes to disapprove a change in previously approved research, the change cannot be implemented but the research may continue as previously approved by the IRB.*

When Pearl IRB disapproves a study or study amendment, you can count on a phone call or email requesting further discussion and explanation!

Suspend Accrual: The IRB suspends accrual when it determines that continuing accrual, or enrollment of new subjects, could threaten the safety or well-being of potential study participants.

Your further action: A conference call with the client is required to obtain any additional information prior to the IRB's determination to suspend accrual. If a conference call cannot be scheduled during the IRB meeting, the IRB Co-chair may conference with you prior to the IRB meeting. Remember - The vote to suspend accrual will not be taken until you are notified. Accrual remains suspended until the IRB votes to lift suspension of accrual. The IRB informs the local IRBs, if applicable and the client of the suspension of accrual.

Suspend Study Intervention: The IRB suspends study intervention when it determines that continuing the intervention could threaten the safety or well-being of study participants.

Your further action: A conference call with the client is required to obtain any additional information prior to the IRB's determination to suspend study intervention. If a conference call cannot be scheduled during the IRB meeting, the IRB Co-chair may conference with you prior to the IRB meeting. Remember - The vote to suspend study intervention will not be taken until the conference call has occurred. The study intervention remains suspended until the IRB votes to lift suspension of study intervention. The IRB informs the local IRBs, if applicable, of the suspension of the study intervention.

Suspend Approval of Research: The IRB suspends approval of research when it determines that continuing research activities could threaten the safety or well-being of study participants.

Your further action: A conference call with the client, is required to obtain any additional information prior to the IRB's determination to suspend approval of research. If a conference call cannot be scheduled during the IRB meeting, the IRB Co-chair may conference with you prior to the IRB meeting. Remember - The vote to suspend approval of research will not be taken until the conference call has occurred. The study remains suspended until the IRB votes to lift suspension of approval of research. The IRB notifies OHRP and when applicable, FDA, of the suspension of IRB approval. The IRB informs the local IRBs, if applicable, for which they are the IRB of record of the suspension of the approval of research

Terminate Approval of Research: The IRB terminates approval of research when it determines that the research irreparably and adversely affects the safety or well-being of study participants.

Your further action: A conference call with the client is required to obtain any additional information prior to the IRB's determination to terminate approval. If a conference call cannot be scheduled during the IRB meeting, the IRB Co-chair may conference with you prior to the IRB meeting. Remember - Before the IRB terminates approval of research, the IRB considers enrolled participants. Where the termination could harm subjects further, the IRB will consider alternative actions. The vote to terminate will not be taken until the conference call has occurred. The IRB notifies OHRP and when applicable, FDA, of the termination of IRB approval. The IRB informs the local IRBs, if applicable, for which they are the IRB of record of the termination of the approval of research.

Lift Suspension: The IRB lifts any type of suspension when it determines that the safety or well-being of study participants is no longer threatened.

Your further action to obtain a lift of suspension: You may request that a suspension be lifted. The request must include a corrective action plan. The request and corrective action plan are reviewed by the convened IRB. The IRB may request modifications to the submitted corrective action plan if the IRB determines that additional modifications are necessary before the suspension may be lifted. The IRB may choose to require

documentation of implementation of the corrective action plan prior to lifting its suspension. The IRB votes whether or not to lift its suspension. Pearl IRB notifies the client, and any local IRB, if applicable when suspension has been lifted. When lifting suspension of approval, the IRB will consider notifying OHRP and FDA.

Continuing Review

The IRB will let you know how often they would like to see an update on your study. An update will be required on an annual basis (unless otherwise determined by the Pearl IRB). Pearl IRB will send you a report template and a timeline for the submission of materials back to Pearl IRB for review. It is important that you keep the IRB current on any protocol changes, deviations, or unanticipated problems. Even if you have stopped the research project; we need to know. If you have any questions, contact Pearl IRB and we will assist you in the decision making process.

Unanticipated Problems

Unfortunately during the course of research, unanticipated problems arise. When an incident occurs that potentially places subjects or others at greater risk of physical or psychological harm than was previously recognized and warrant consideration of substantive changes in the protocol or informed consent process/ document of other action in order to protect the safety, welfare or rights of the subjects, Pearl IRB must be notified within 5 (five) working days. If you are not sure that the problem you have identified meets these criteria, let us know anyway. Pearl IRB will assist you in making the determination. Please understand that serious unexpected adverse events are considered an unanticipated problem. It is imperative that the proper corrective actions take place in order to protect the safety, welfare, or rights of subjects or others connected to the study.

Closeout

Congratulations! You've reached a milestone in completing your study. Contact Pearl IRB to ensure the closure of the study is properly documented. It is important that the IRB document your study as completed.

We Are Here to Help

If you have any questions or concerns, please do not hesitate to contact us. We are looking forward to working with you, both now and in the future.