



## Submission Information Policies

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## Introduction

Welcome to working 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. 278.4100 Or [gbowker@pearlirb.com](mailto:gbowker@pearlirb.com). Pearl IRB does business 8:00am – 5:00pm EST Monday thru Friday. However, we know this business, at times, necessitates the exchange of information at all times day and night. If you require consultation with Pearl IRB at other hours, please email or call 317.445.7790.

## Board Membership

Pearl IRB commits 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 is available and ready for review. To facilitate this process there are forms available on the Pearl IRB website. [www.pearlirb.com/resources/forms](http://www.pearlirb.com/resources/forms). If the forms don't work for you, don't worry, we at Pearl expect to work together to ensure that all the documentation is review ready.

## Process Overview

Meetings are held on a weekly basis. Materials must be submitted by end of business on Wednesday of each week. (OR, received by start of business on Thursday). If you think you may be very last minute, contact Pearl IRB to discuss options that may allow you to still meet your timeline. The board will thoroughly review your documents prior to the IRB meetings held every Thursday at 4:00pm. You or your PI may be asked to attend the meeting, so please be prepared. By Friday you will have your decision in writing via fax or email. A hard copy of the minutes will go in the mail on the following Monday.

To be clear:

Day 1 Thursday	Day 7 Wednesday	Day 8 Thursday	Day 9 Friday	Day 12 Monday
Documents at Pearl IRB	Board members complete review	Board Meeting	Response to You via email or fax	Hard copy of response in mail

## Potential Board Responses

**Approve:** 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 Date.

*Your further action: None, Congratulations, get started.*

**Approve pending modification(s):** The IRB approves research pending modifications when it determines that the regulatory and IRB SOP requirements for approval are met, but the IRB requests minor, directed modifications.

*Your further action: Submit modifications for approval by expedited review. If the required modifications are not made, you will be contacted*

**Approve with query(ies):** The IRB approves research with query 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 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 Date.

*Your further action: You don't have to reply, but if so, 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 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 notification of OHRP and FDA.*

## **Continuing Review**

The IRB will let you know how often they would like to see an update on your study. It will be required on, at least, an annual basis. Pearl IRB will send you a report template and a timeline for submission 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; we need to know. If your not sure, 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 has the potential to change the risk profile, Pearl IRB must be notified within five working days. If you are not sure, 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.