University of La Verne Institutional Review Board Policy and Procedure on Modifications, Continuing Review, and Closure Forms
Approved March 10, 2017, Amended December 8, 2017

1. Modifications

Expedited and Standard Review Approvals

For non-exempt research, all changes to your protocol must be approved by the IRB prior to implementation. Examples of modifications include changes to inclusion criteria, procedures, methods of recruitment/advertising, informed consent, instruments, etc. An Amendment form must be filed in IRBManager.

> **Exception**: If there is a change that is, "necessary to eliminate apparent immediate hazards to the subject" (45 CFR 46.103.b.4, 21 CFR 56.108.a) prior IRB review and approval is not necessary. These types of events should be incredibly rare and require the filing of an Adverse Events form in IRBManager within 5 days of the incident. Permanent changes to protocol should be then undertaken by filing an Amendment form in IRBManager.

Types of Modifications

Modifications can be major, minor or administrative in nature. If there are more than 3 modifications filed within a calendar year, a new application must be filed. The three types of modifications get three different types of reviews by the board. The review type is dependent on whether there is increased risk and how much the risk is increased. Before selecting the type of review your amendment will receive, review the definition of minimal risk, below.

Minimal risk: "the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (45.CFR.46.102(i)).

Administrative Modifications

These are minor changes that do not affect participants. For example, this could be changing the audio transcription company from one confidential company to another, changing typographical errors in the informed consent, updating recruitment materials, updating personnel (except for PI).

Procedure

After the amendment is submitted through IRBManager, IRB Administration will review your proposed changes. The application may be sent back for revisions/clarifications. Once approved, a letter will be issued that states you may implement the new changes.

Minor Modifications

Minor modifications are changes that, 1) increase the risk and it is not more than minimal risk overall, 2) the research itself is minimal risk (even if there is no increase), and 3) changes do not significantly alter the research design (if the research design is significantly altered, the current study would have to be closed and a new Initial IRB Application be submitted in IRBManager, which will undergo IRB review as if it is a new study). For example, changing the wording in the consent form or other approved documents, and changing minor activities.

Procedure

After the amendment is submitted through IRBManager, the Area Committee and Chair will review your proposed changes. The application may be sent back for revisions/clarifications. Once approved, a letter will be issued that states you may implement the new changes.

Major Modifications:

Major modifications are changes that, 1) increase the risk and it is more than minimal risk overall, 2) the research itself is more than minimal risk (even if there is no increase), and 3) changes are those consistent with necessitating a standard (full board) review. For example, an open-ended question regarding sexual trauma is added to a confidential interview protocol, and adding a new measure that examines illicit drug use in a study deemed confidential and not anonymous.

Procedure

After the amendment is submitted through IRBManager, the Area Committee will review your proposed changes. The application may be sent back for revisions/clarifications. Then, the amendment will be reviewed by the full board, which meets monthly (see IRB Monthly Committee Meetings on our website for more information). More revisions may be required at this point in the process. If approved, a letter will be issued that states you may implement the new changes.

Informing Study Subjects of Significant New Findings

You are required to inform participants of significant new findings during the course of your research that could affect their decision to participate (45 CFR 46.116 (b) (5)). You must also file an Amendment in IRBManager that details the new findings, protocol changes, and how you will notify the participants (with the final form of these materials attached). Communication of these changes (e.g. mail, email, etc.) is based on the level of urgency associated with the new findings.

2. Exempt Research

If your study received an exempt determination, you can make minor changes to the study without notifying the IRB. The following table lists items that should be submitted as an amendment and those that do not need to be submitted.

Table 1. List of items that require or do not require an Amendment for exempt determinations.

No Amendment Required	Amendment Required
Editorial or administrative revisions to informed consents, information sheets, flyers, and other advertisements	Adding new study population
Adding new recruitment material as long as the study population doesn't change and it follows the IRB's requirements	Adding new procedures
Increases or decreases in the number of subjects as long as you are not adding a new study population	Adding a new funding source
Change in personnel (except for PI)	Change in PI or Co-Investigator
	Adding questions to a survey that increases risk (e.g., questions about illegal drug use, sexual trauma, drug use, etc.) when the study is confidential rather than anonymous
	Disclosing a conflict of interest
	Changes in inclusion/exclusion criteria
	Anything that changes the study so that it no longer qualifies for an exemption will require a new Initial IRB Application submitted through IRBManager

Procedure:

If your exempt study requires an Amendment, please complete one in IRBManager for review. While IRB Administration can alone review and approve the amendments, some amendments may change the study to no longer qualify as exempt, which would necessitate the filing of a new Initial IRB Application.

3. Continuing Review

Standard Reviews
Extensions must be filed before the expiration of a study for standard reviews unless the research is no longer in the data collection phase and/or is only accessing archival follow-up clinical data. Otherwise the study will need to be submitted as a new Initial IRB Application and re-reviewed, which may identify areas of revision that will change the protocol from the previously approved protocol. Thus, it is highly discouraged to allow a study to expire if additional data needs to be collected.

Extensions will be filed in IRBManager, and if approved, will extend the approval one year from date of extension approval. The review type is dictated by the prior review. Unless stated otherwise by the reviewers in the initial approval, extensions can be granted by IRB Administration on expedited review approvals provided an amendment is not filed that is minor or major at around the same time (which would necessitate the Area Committee reviewing the extension). For standard review approvals, IRB Administration and expedited procedures can also approve extensions unless specified otherwise by the board.

Expedited Reviews
Extensions are generally not required for expedited approved applications (there are no expirations), except in circumstances the La Verne IRB deems necessary. The La Verne IRB will document any instances of continuing review for expedited applications and the necessity of doing so in IRBManager.

Exempt Reviews
Extensions are generally not required for exempt approved applications (there are no expirations), except in circumstances the La Verne IRB deems necessary. The La Verne IRB will document any instances of continuing review for exempt applications and the necessity of doing so in IRBManager.

Limited Reviews
Extensions are generally not required for limited review approved applications (there are no expirations), except in circumstances the La Verne IRB deems necessary. The La Verne IRB will document any instances of continuing review for limited review applications and the necessity of doing so in IRBManager.

4. Closure Forms

Closure forms must be filed for every study, regardless of whether it expires or is voluntarily closed. Closure forms are filed in IRBManager and approved by IRB Administration.