WHITWORTH
UNIVERSITY

Whitworth University IRB Procedures

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Adopted November 25, 2024

Introduction

This document summarizes the procedures of the Whitworth University Institutional Review Board for the Protection of Human Subjects in Research (IRB). The goal of this document is to support consistency in the work of the IRB across changes in membership, and to provide transparency to the Whitworth community. It is not meant to be a "how to…" document or guide to the applications; for those, see the Guide to IRB Applications on OneAegis and the application templates on our Policy & Templates page.

Administrative Procedures

Appointment of Members

Procedure

- The IRB Chairperson or the IRB Chairperson's designee identifies nominees with the help of the department chairs of the departments responsible for supplying members to the IRB. This typically takes place in April, coinciding with nominations for membership in other committees, but may take place any time a position becomes vacant.
- The nominees are approved by the IRB at the last meeting of the IRB of the academic year, typically in April.
- The IRB Chairperson submits the list of approved nominees to Faculty Executive to appoint formally, in consultation with the Provost.

Notes on Membership

- Appointments are for terms of three years.
- Members may serve consecutive terms indefinitely.
- Departments responsible for supplying members to the IRB may fill a single three-year term with several members serving single years in alternation.

Publication of Current IRB Members and Calendar

Procedure

- At the first meeting of the academic year, IRB members supply the IRB Administrator with the following information, or updates to the following information for returning members:
    - Name
    - Earned degrees
    - Representative capacity
    - Indications of experience
    - Relationship to institution
- Explanation of categories of information
    - *Representative capacity* includes members' academic department, but members may also indicate capacity to represent specific vulnerable populations, or other relevant capacities.
    - *Indications of experience* includes currently valid CITI course completions, board certifications or licenses, or other professional credentials not listed as *Earned degrees*.
    - *Relationship to institution* is "full-time employee" for all members except the community member; for the community member, it is "unpaid consultant".
- The IRB Administrator compiles the member information and adds an additional category of *Role* and notes which roles each member fulfills. A member may have more than one role. Roles may be fulfilled by more than one member. The IRB Administrator is appointed by the Provost. The IRB Chairperson, Vice Chairperson, and Secretary are elected at the first meeting of the academic year. The roles to be indicated are:
    - Knowledgeable about regulations (typically attached to the Administrator)
    - Scientific areas
    - Nonscientific areas
    - Community member
    - Administrator
    - Chairperson
    - Vice chairperson
    - Secretary

  The year each member's term expires is also indicated.
- The IRB Administrator posts the list of current IRB members at https://www.whitworth.edu/cms/administration/sponsored-programs/irb-policy-and-consent-templates/ before the second meeting of the academic year.
- The IRB Administrator compiles the calendar for the academic year, indicating full board meetings and deadlines for applications to be reviewed at each meeting, and posts the calendar at https://www.whitworth.edu/cms/administration/sponsored-programs/irb-policy-and-consent-templates/ before the first meeting of the academic year.

Notification to IRB Members of Applications Approved by Expedited Review

Procedure

- When the IRB Chairperson creates the agenda for each full board meeting, any application approved by expedited review since the previous full board meeting is added to the agenda, including the following information:
    - Title of research project
    - Name of principal investigator
    - Names of reviewers
    - Link to the complete application

Review Procedures

Conduct of Initial Review

Procedure

- Submitter completes and submits application on the OneAegis system (https://whitworth.oneaegis.com/Login.aspx).
- If the principal investigator is a different person from the submitter, the principal investigator either approves the application or returns it to the submitter for changes.
- If an additional signator is indicated on the application, the additional signator either approves the application or returns it to the submitter for changes.
- If the principal investigator is a student, the faculty assurance either approves the application or returns it to the submitter for changes.
- The IRB Administrator may:
    - Request revisions or more information.
    - Assign the determination: *Not Human Subjects Research*:
        - The principal investigator is notified of the determination, and research may begin.
    - Assign the determination: *Exempt Research*:
        - The principal investigator is notified of the determination and the category, and research may begin.
    - Send for *Expedited Review*: Reviews are assigned to two IRB members.
    - Send for *Full Board Review*: Preliminary reviews are assigned to two IRB members.
- IRB members complete reviews within five business days and return decision and comments to IRB Administrator.
- IRB Administrator may change review level if indicated by reviewers.
- For *Expedited Review*:
    - If no changes are required, IRB Administrator records the approval of the application. The Principal Investigator is notified of approval, and research may begin.
    - If changes are required, the IRB Administrator returns the application to the submitter.
    - When the changes have been submitted, the IRB Administrator may:
        - Approve the application.
        - Forward the application to the reviewers to approve.
    - When the application has been approved, the principal investigator is notified of approval, and research may begin.
- For *Full Board Review*:
    - Preliminary reviews and application are added to the Full Board meeting agenda.
    - IRB members may make additional comments before the meeting.
    - At the meeting, the IRB members discuss the application and any required changes; they may decide to:
        - Approve the application.
        - Prospectively approve the application pending minor changes.
        - Return the application to the submitter for major changes.
        - Disapprove the application.
    - If the application is approved with no changes:
        - The principal investigator is notified of approval, and research may begin.

- If the application is prospectively approved pending minor changes:
  - The submitter submits the changes.
  - The IRB Administrator confirms changes and records approval.
  - The principal investigator is notified of approval, and research may begin.
- If the application is returned to the submitter for major changes:
  - The submitter submits the changes.
  - The application is added to the next Full Board meeting agenda for additional discussion and decision.
- If the application is disapproved:
  - The Principal Investigator is notified of the disapproval and rationale.

Documenting Reliance in Initial Review

Procedure for Applications Where Whitworth Relies on an External IRB

- Before starting the application, the submitter gathers the following documents and information (the external IRB should be able to provide all of these upon request):
    - Letter of determination by the external IRB
    - Application approved by the external IRB
    - A draft of the reliance agreement from the external IRB (does not need to be signed)
    - External IRB name
    - External IRB Federalwide Assurance Number (FWA#)
    - External IRB IRB Organization Number (IORG#)
- When completing the initial application, Section 1, the submitter answers the question "Is the primary responsibility for the study subject to the Whitworth IRB only" with "NO"; this reveals the questions to attach the letter of determination, approved application, and draft reliance agreement, and to fill in the external IRB name, FWA#, and IORG#.
- During review, the IRB may request additional protections for the Whitworth site; the principal investigator will request these from the external IRB and add updated documents to the application.
- After any requested changes have been made, the IRB Administrator will send the reliance agreement to the Provost to sign (either through the OneAegis system or on paper if requested by the external IRB).
- The IRB Administrator returns the reliance agreement signed by the Whitworth Provost to the principal investigator to request the signature of the Institutional Official of the external IRB.
- The principal investigator adds the fully signed reliance agreement to the application.
- The IRB Administrator confirms the fully signed reliance agreement and continues approval processing.

Procedure for Applications Where an External IRB Relies on Whitworth

- Before starting the application, the submitter gathers the following information (the external IRB should be able to provide all of these upon request):
    - External IRB name
    - External IRB Federalwide Assurance Number (FWA#)
    - External IRB IRB Organization Number (IORG#)
- When completing the initial application, Section 1, the submitter answers the question "Will any external IRBs rely on the Whitworth IRB for oversight?" with "YES"; this reveals the questions to fill in the external IRB name, FWA#, and IORG#.
- After the application is approved by the Whitworth IRB, the letter of determination, approved application, and draft reliance agreement will be available to the principal investigator to download from the OneAegis system and supply to the external IRB.
- The external IRB may request changes; these need to be approved by the principal investigator and the Whitworth IRB.
- After any requested changes are made, the IRB Administrator will send the reliance agreement to the Provost to sign.

- The IRB Administrator returns the reliance agreement signed by the Whitworth Provost to the principal investigator to request the signature of the Institutional Official of the external IRB.
- The principal investigator adds the fully signed reliance agreement to the application.
- The IRB Administrator confirms the fully signed reliance agreement and continues approval processing.

Determination of Continuing Review Period and Requirement of Independent Verification

Procedure

- The IRB determines at the time of initial review whether continuing review must occur more frequently than annually, and whether verification is required from sources other than the investigators that no material changes have occurred since the previous IRB review.
- Lack of an explicit determination indicates that continuing review will occur annually, and that independent verification is not required.

Conduct of Continuing Review

Procedure

- OneAegis system notifies the principal investigator of the continuing review requirement at 60 days before expiration, 30 days before expiration, and at expiration.
- Principal investigator completes and submits continuing review form. This should be submitted at least two weeks prior to expiration so the review can be approved before expiration and there is no lapse in approval.
- IRB Administrator assigns review level (projects determined *Not Human Subjects Research* or *Exempt Research* do not require continuing review):
    - *Expedited Review*: Review is assigned to one IRB member.
    - *Full Board Review*: Preliminary review is assigned to one IRB member.
- IRB member completes reviews within five business days and returns decision and comments to IRB Administrator.
- IRB Administrator may change review level if indicated by reviewer.
- For *Expedited Review*:
    - If no changes are required, IRB Administrator records the approval of the continuing review and sets new expiration date. The principal investigator is notified of approval.
    - If changes or more information are required, the IRB Administrator returns the application to the submitter.
    - If changes to the research protocol are required, a modification request must be submitted.
    - When the changes have been submitted, the IRB Administrator may:
        - Approve the continuing review.
        - Forward the continuing review to the reviewers to approve.
    - When the continuing review has been approved, the IRB Administrator sets new expiration date, and the principal investigator is notified of the approval.
- For *Full Board Review*:
    - Preliminary review and application are added to the Full Board meeting agenda.
    - IRB members may make additional comments before the meeting.
    - At the meeting, the IRB members will discuss the continuing review and any required changes; they may decide to:
        - Approve the continuing review.
        - Prospectively approve the continuing review pending minor changes.
        - Return the continuing review to the submitter for major changes.
        - Suspend or terminate approval.
    - If the continuing review is approved with no changes:
        - The IRB Administrator sets new expiration date, and the principal investigator is notified.
    - If the continuing review is prospectively approved pending minor changes:
        - The submitter submits the changes.
        - The IRB Administrator confirms the changes and records approval.
        - The IRB Administrator sets new expiration date, and the principal investigator is notified.

    - If the continuing review is returned to the submitter for major changes:
        - The submitter submits the changes.
        - If changes to the research protocol are required, a modification request must be submitted.
        - The continuing review is added to the next Full Board meeting agenda for additional discussion and decision.
    - If the project is suspended or terminated:
        - The principal investigator is notified of determination and rationale, and research ceases.
- For any continuing review that indicates serious noncompliance with IRB determinations or results in suspension or termination of approval, see also the procedure for reporting suspension or termination of IRB approval.

Conduct of Modifications Request Review

Procedure

- Submitter completes and submits modification request form.
- If the principal investigator is a different person from the submitter, the principal investigator reviews and approves the modification request.
- For student research, the faculty assurance reviews and approves the modification request.
- The IRB Administrator assigns review level:
    - The IRB Administrator may request revisions or more information if required elements are missing or unclear.
    - The IRB Administrator may change the review level of the project to *Exempt Research* if the requested changes indicate that *Expedited Review* or *Full Board Review* are no longer required.
    - For *Expedited Review* or *Full Board Review* the IRB Administrator assigns review/preliminary review to one IRB member.
- If review level is changed to *Exempt Research*:
    - The principal investigator is notified; research may proceed with the modified protocol.
- IRB member completes review/preliminary review within 5 business days.
- For *Expedited Review*:
    - If no changes are required, the IRB Administrator records the approval, the principal investigator is notified, and research may proceed with the modified protocol.
    - If changes are required, the IRB Administrator returns the application to the submitter.
    - When the changes have been submitted, the IRB Administrator may:
        - Approve the modification request.
        - Forward the modification request to the reviewer to approve.
    - When the modification request has been approved, the IRB Administrator records the approval, the principal investigator is notified, and research may proceed with the modified protocol.
    - If the reviewer forwards the application to the Full Board, it is set on the next Full Board agenda for review.
- For *Full Board Review*:
    - Preliminary review and application are added to the Full Board meeting agenda.
    - IRB members may make additional comments before the meeting.
    - At the meeting, the IRB members discuss the modification request and any required changes. They may decide to:
        - Approve the modification request.
        - Prospectively approve the modification request pending minor changes.
        - Return the modification request to the submitter for major changes.
        - Deny the modification request.
    - If the modification request is approved with no changes:
        - The IRB Administrator records the approval, the principal investigator is notified, and research may proceed with the modified protocol.
    - If the modification request is prospectively approved pending minor changes:
        - The submitter submits the changes.

        - The IRB Administrator confirms changes and records approval, the principal investigator is notified, and research may proceed with the modified protocol.
    - If the modification request is returned to the submitter for major changes:
        - The submitter submits the changes.
        - The modification request is added to the next Full Board meeting agenda for additional discussion and decision.
    - If the modification request is denied:
        - The principal investigator is informed of the determination and rationale, and research must continue under the previously approved protocol.

Conduct of Reportable Events Review

Procedure

- Submitter completes and submits reportable events form.
- The IRB Administrator assigns review level:
    - Request more information
    - Send for to IRB member for *Expedited Review*
    - Send for *Full Board Review*
    - Make an acknowledgement only
- If more information is requested:
    - The submitter provides additional information and the IRB Administrator re-evaluates the review level.
- If the form is sent to an IRB member for *Expedited Review*:
    - Member completes review within two days
    - The reviewer may
        - Request more information
        - Approve acknowledgement and/or plan of corrective action
        - Send to the Full Board for further discussion, including a recommendation for suspension or termination of approval
    - If more information is requested:
        - The submitter provides additional information and the reviewer re-evaluates the recommendation.
    - If acknowledgement is approved:
        - The IRB Administrator records the approval, the principal investigator is notified, and research may continue.
    - If the form is sent to the Full Board:
        - The form is placed on the next Full Board meeting agenda.
- If the form is sent for *Full Board Review*:
    - If the matter is exigent, the IRB Chairperson may call an additional meeting.
    - Preliminary review and form are added to the Full Board meeting agenda.
    - IRB members may make additional comments before the meeting.
    - At the meeting, the IRB members discuss the event and determine required actions. They may decide to:
        - Acknowledge the report
        - Acknowledge the report pending conditions; conditions may include supplying additional information or changing the plan of corrective action; conditions may be approved by:
            - Administrator review
            - IRB member/*Expedited Review*
            - *Full Board Review*
        - Table discussion (for example, if further investigation of the research or consultation is needed)
        - Suspend approval
        - Terminate approval

    - If acknowledgement only:
        - The IRB Administrator records the acknowledgement, the principal investigator is informed, and research may continue.
    - If acknowledgement pending conditions:
        - The principal investigator submits the changes. If this includes changes to the research protocol a modification request must be submitted.
        - The changes are approved at the level indicated, the principal investigator is notified, and research may continue.
    - If discussion is tabled:
        - Resumption of discussion is added to a future Full Board meeting agenda.
    - If approval is suspended:
        - The IRB Administrator records the suspension, the principal investigator is notified of the suspension and rationale, and research must be suspended.
        - The principal investigator meets with the IRB to identify steps to be taken before approval can be reinstated.
    - If approval is terminated:
        - The IRB Administrator records the termination, the principal investigator is notified of the termination and rationale, and research must be terminated.
- For any reportable event that involves risk to subjects, serious noncompliance with IRB determinations, suspension of approval, or termination of approval, see also the procedure for reporting suspension or termination of IRB approval.

Reporting Suspension or Termination of IRB Approval

Procedure

- For all reportable events that meet one of the following conditions:
    - Any unanticipated problems involving risks to subjects or others
    - Any serious or continuing noncompliance with the Revised Common Rule or determinations of the IRB
    - Any suspension or termination of IRB approval

  The following reports must be made:
- The principal investigator notifies any sponsor or funding agency of the reportable event and any suspension or termination of approval. They also provide documentation of the notification and any response to the IRB.
- The IRB Administrator notifies the Institutional Official (the Provost) of the reportable event and/or suspension or termination of approval.
- The IRB Administrator reports the event to OHRP using the OHRP form here: Reporting Incidents | HHS.gov
- All notifications are made within five working days of the IRB determination.