

Requesting External IRB Review

IRES IRB keeps records of studies reviewed by Yale IRBs as well as the ones reviewed by external IRBs on behalf of Yale. With the exception of studies reviewed by NCI CIRB, in order to submit a research protocol to an external IRB for review, you must first obtain authorization from the Yale HRPP office. This guide explains how to request an external IRB review for an initial study in IRES IRB.

Note: The HRPP office may independently determine that a study submitted to the Yale IRB will be reviewed by an external IRB. If that occurs, the PI will be notified and the HRPP will work with the PI and the research team on the submission to the proposed IRB of record.

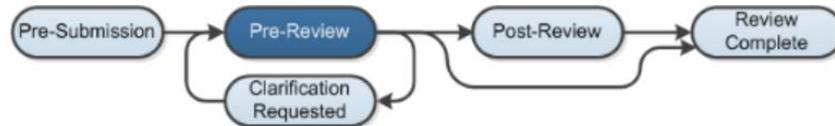
Creating an Initial Study

- Create a new study using **Create New Study** under **My Current Action**. It can only be accessed from your Inbox.
- Answer all questions on **Basic Information Screen** and upload the study protocol. Be sure to answer **YES** to question 6 indicating that you are requesting authorization to use an external IRB.

- Continue to **External IRB** page. Select the name of the external IRB in Question 1. If you cannot locate it on the list, contact external.reviews@yale.edu to discuss adding it to the selection.
- You do not need to answer questions 2 through 5. The Yale HRPP will update these fields after the external IRB issues approval of the Yale site.
- Describe the rationale for your request in question #6.

- Click **Continue** and proceed to fill out questions on the remaining screens and upload the documents as prompted. That includes templates of the proposed consent forms. Be sure to submit your request by clicking **Submit** under **My Current Actions**.

Note: External IRB requests follow a simplified submission process as shown below. Before closing your browser, make sure that the submission moved to **Pre-Review** state. If it shows as **Pre-Submission**, it has not been submitted. It will be visible in your Inbox until you submit it.



What to expect after submission

The HRPP office will review your submission for completeness. Your rationale for use of an external IRB will be considered. Based on the category of research (see 920 HRPP Procedure 4), appropriate internal permissions to use external IRBs will be sought.

In addition, the following questions will be considered by the HRPP:

- Does the Yale PI meet the Yale Faculty Handbook requirements to serve as the PI?
- Are investigators/research staff compliant with Yale training requirements?
- Are investigators compliant with COI disclosure requirements?
- Is there a potential for conflict of interests?
- Are approvals from any of the ancillary committees required? If so, have they been obtained?
- Will grant congruency be required (for federally funded studies)?
- Do the terms of the coverage for research injuries in the consent form match the contract with the sponsor?
- Does the Economic Considerations language in the consent form match the contract with the sponsor?
- Will a Genomic Data Sharing Plan certification be needed?
- Will the OHRP certification request be required?

The PI and the PI Proxies will be notified via email if any questions arise. The submission will move to the **Clarification Requested State**.

Note: For help with responding to the IRB/HRPP requests, follow the quick guide on **Responding to Clarification and Modification Requests** available in the IRES IRB Help Center.

Should the submission be authorized for use of an external IRB, the PI and the PI Proxy will receive an email with a link to the authorization letter. The letter and any other forms required by the external IRB will be available in the top area of the study workspace. The study will move to **Review Complete** state.

External IRB

2000020154: Testing with External IRB study

Entered local IRB: 3/15/2017 10:02 AM Locally confirmed: 3/15/2017 Initial approval: Approval end: Last updated: 3/15/2017 10:18 AM	Principal investigator: James Peters Submission type: Initial Study Primary contact: James Peters IRB coordinator:	IRB Office: Yale IRB Local IRB Acknowledgement Letter: Correspondence_for_2000020154.docx(0.01) External IRB: WIRB External IRB Approval Letter:
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    A([Pre-Submission]) --> B([Pre-Review])
    B --> C([Post-Review])
    C --> D([Review Complete])
    B --> E([Clarification Requested])
    E --> B
            
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You can now proceed to the External IRB to submit your protocol for review. The External IRB will notify Yale HRPP when the study is approved. The approval and expiration dates will be then updated in the system on your behalf.

Note: Denials of the request will be communicated to the PI and PI Proxy via email. The study will move to Clarifications Requested state from where it will need to be revised to indicate submission to Yale IRB.