**920 GD.1 Relying on non-Yale IRBs for review and approval of research**

**Overview**

It is important for Yale investigators conducting research overseen by an external IRB to recognize his/her responsibilities toward Yale and Yale Human Research Protection Program (Yale HRPP). An external IRB is responsible for reviewing the research study materials to determine whether the proposed research meets the approval criteria. Yale, which will be considered the relying institution in this case, will retain responsibility for ensuring that local requirements are met. That may include ensuring that all local ancillary reviews required to conduct the research at Yale site are completed, members of the research team meet the Yale training and conflict of interest disclosure requirements, and for communicating any local requirements pertaining to the research to the reviewing IRB. This document provides guidance to investigators who wish to utilize external IRBs for review and approval of research. It applies to investigators requesting review by external for-profit IRBs or other academic institutions’ IRBs.

**Note:** External IRB, IRB of record, and Reviewing IRB are used in this document interchangeably.

**Considerations before requesting a ceded review**

* Are there any reasons why Yale IRB should be reviewing the study instead of the external IRB? If you are not sure, contact the Yale HRPP to discuss whether ceding IRB oversight to another IRB is appropriate.
* Does the study require review by any of the Yale ancillary committees? If the study was reviewed by Yale IRB, what additional reviews would be needed? They will still apply regardless of which IRB reviews and approves the research. All ancillary reviews must be completed before the agreement is fully executed or before authorization to use an external IRB is granted.
* Has the contract with the sponsor been submitted to the Office of Sponsored Projects (OSP)? OSP will be involved in consistency review of the consent forms and the contract.
* Does Yale have an existing agreement with the IRB that will provide review? If you are not sure, contact the Yale HRPP to discuss the agreement.
* Are you familiar with the reviewing IRB’s SOPs? Have you designated a project coordinator or another member of the research staff familiar with the SOPs who will be the primary contact for the reviewing IRB?

**Requesting a ceded review**

* If there is no existing agreement with the proposed IRB of Record, obtain a contact information at that IRB and provide it to the Yale HRPP.
* Obtain a copy of the approved study protocol and template consent documents.
* Incorporate the Yale required language into the consent templates. **Note:** Do not use Yale consent templates to make the sponsor consent look like ‘Yale consent form’. Modify only the essential sections (most likely highlighted for editing) and use the **Required Consent Language** document posted on the Yale HRPP website to add the necessary sections.
* If possible, verify with OSP that the language in the consent form matches the contract. If the OSP was unable to review the consent forms prior to submission to Yale HRPP, the consistency review will be requested directly by the HRPP.
* Obtain permission from your Department Chair or Section Chief to conduct the study per your departmental procedures.
* If your Yale appointment does not meet criteria described in the Faculty Handbook, obtain permission to Serve as the PI from your Chair and the Dean of the School. The form is available in the Library section of IRES IRB.
* Obtain permission from all study team members to participate in research.
* Verify existence of any conflict of interest for any of the staff members.
* Confirm that the training requirements are met for all members of the research team: Human Subject Protection Training, Good Clinical Practice if the study is considered a clinical trial per NIH definition, and HIPAA if the research is to take place at HIPAA covered entity.
* Obtain approvals from the required ancillary committees. **Note:** if the study involves minors and requires review by the PPRC, you can submit the protocol in IRES IRB and the Yale HRPP will request the PPRC to conduct the review.
* Create and submit the study and proposed consent forms in IRES IRB. ***A Quick Guide*** on requesting a ceded review in the system is available in the Help Center section of the IRES IRB.

Yale HRPP will verify the information you submitted and may contact you with questions. You will be notified once the Authorization to Use an External IRB is granted. You will then be able to submit the study materials to the external IRB in accordance with their procedures.

**After approval by the External IRB**

Once the review is ceded to the external IRB and Yale site is approved, that IRB will become the IRB of record for the study. The investigators and research staff should work with the IRB according to their policies and procedures. All study related questions should be directed to your contact at that IRB. Some institutions may designate a single point of contact on the team at the coordinating center to facilitate communication from all the study sites. Each of the external for-profit IRBs have a single point of contact for Yale investigators. The contact information is available on the HRPP website.

The Yale HRPP and its partners will continue to have a role in the monitoring of the study even after the review is ceded. It is because as an Institution, we are responsible for conduct of the study at Yale. Remember to do the following:

* Once approved as a site by the external IRB, update the study record in IRES IRB to provide the current expiration date of research and upload the approval letter. **Note:** if Yale HRPP is notified by the external IRB when the approval is granted, you can skip this step. If you are unsure, check with the HRPP contact.
* Keep a regulatory binder and maintain an active record of all submissions to the IRB of record.
* Submit any modifications to the Yale HRPP through IRES IRB that require local review. Examples of such changes include:
* Personnel changes
* Changes of PI
* Changes in conflicts of interest
* Changes for which there is a specific institutional policy/state law requirement e.g. review by an ancillary committee
* Changes to the consent form that require amendment to the sponsor protocol e.g. Economic Considerations, In Case of Injury language sections in the consent form.
* Update the study record in IRES IRB with the new expiration date and approval of continuing review as issued by the external IRB. **Note:** if Yale HRPP is notified by the external IRB when the approval is granted, you can skip this step.
* Promptly report to the Yale HRPP any determinations of serious or continuing noncompliance or UPIRSOs that the external IRB made for the Yale site.
* Promptly report to the Yale HRPP any notifications of suspension or termination that you receive for the study from the external IRB.
* If Yale entered into a protocol specific IRB Authorization Agreement for this study, familiarize yourself with the document and the terms of the agreement in case you need to comply with additional responsibilities toward Yale HRPP.
* Update the IRES IRB when the study was completed and closed by the IRB of record.

# **Additional Information**

Quick Guide on Requesting an External IRB Review

Quick Guide on Updating the Study Under External IRB

Required Consent Language