
Yale University Human Research Protection Program

920 PR.2 Authorization Agreements with Other IRBs

Overview

This procedure reviews the process for review and approval or denial of requests by non-Yale IRBs to enter into an IRB Authorization Agreement (IAA) with Yale University for Yale IRB review and oversight of research involving agents of both institutions, and for requests by Yale IRBs to enter into an IAA with another institution for that institution's review and oversight of research involving agents of both institutions. An IAA is required for an IRB outside Yale to name Yale IRBs on its Federalwide Assurance (FWA) filed with the Office for Human Research Protections (OHRP), or for Yale to name another IRB on its FWA..

Initiation of Requests

Requests to enter into an IAA with another IRB may be initiated (a) by a Principal Investigator whose research includes the engagement of staff, resources or personnel of an assured institution under the purview of a non-Yale IRB, (b) by the IRB of an assured institution whose staff, resources or personnel will be engaged in Yale research or (c) by the Yale IRB when Yale staff, resources or personnel will be engaged in research of or at another institution. Requests may be limited to a single protocol, may include all protocols engaging specific investigators, or may be broadly based to include all researchers of an external institution engaged in Yale research on Yale research sites or all Yale researchers engaged in research of another institution on another institution's sites. IAAs with other IRBs generally begin with a limited scope, e.g., specific protocols, and may be expanded as research collaboration expands, and the institutions have a history of collaboration.

Requests are made to Yale IRB Education and Community Outreach Manager (Manager).

Request Documentation

The following documents are required for development of an IAA where Yale IRBs serve as IRB of record:

- Copies of curriculum vitae of all personnel to be included in the IAA
- Verification of human research protections training
- Verification of HIPAA training, where appropriate
- Information from the Yale PI whose research generated the request, stating the role of the non-Yale investigator in the study and the plan for oversight of their work. This information may be gathered by letter, email correspondence or telephone conversation.
- Correspondence from the IRB with whom the IAA will be effected, verifying willingness to enter into an IAA. This information may be gathered by letter, email correspondence or telephone conversation.

For IAAs where another institution will serve as IRB of record, Yale will also provide documentation as required by the institution. The Manager is responsible for preparing materials in support of the request.

Staff Evaluation and Recommendation

The Manager prepares an evaluation of the request, reviewing the documents provided. The evaluation describes the scope of the request, the status of the research protocol that is tied to the request, the curriculum vitae of the researchers to be covered in the IAA, verification of the researchers' training, verification of the external IRB's registration with OHRP, whether or not the external IRB is accredited, whether or not the external IRB has had experience in other IRB collaborations, as indicated by external

IRBs designated on their FWA. The evaluation is completed for requests where Yale will serve as IRB of record as well as for requests by Yale for another institution's IRB to serve as IRB of record.

Based on the information above, the Manager makes a recommendation for approval/denial of the IAA. If the recommendation is to approve, the Manager generates a draft IAA, in concert with the other IRB, where appropriate, designating which IRBs are to be included in the agreement.

Review of Staff Recommendation

The staff evaluation, with recommendation, draft IAA and any other documents deemed necessary to support the IAA are forwarded to the IRB Director for review. Revisions to documents may be made as part of this review.

All recommendations by the IRB staff (those recommending approval of the requested IAA and those recommending to deny the requested IAA) are submitted to the Yale University Institutional Signatory Official for review, with a copy to the Institutional Signatory Official's senior administrative assistant. If the recommendation is to approve the IAA, a draft IAA and cover letter are included. If deemed necessary by the IRB, the Office of the General Counsel also reviews the materials. As part of the review, counsel may request added information, request modifications to the IAA, approve the IAA as proposed, or not approve the request. When the Office of the General Counsel has made a final determination regarding approval, counsel notifies the Institutional Signatory Official, IRB Director and the Manager.

Notification to the External IRB

If the IAA is approved, two copies, signed by the Yale Institutional Signatory Official, are sent to the external IRB, with a cover letter, requesting that one signed copy be returned to the Manager.

If the affiliation is denied, the Manager notifies both the IRB and the researcher who initiated the request of the reason for denial.

IAA Term

The initial IAA is for a term of three to five years, depending on the expected duration of the research study. Renewal terms may be longer, as deemed appropriate by the Institutional Signatory Official, upon recommendation of IRB staff.

Documentation

The Manager maintains a hard copy file of the request, including all materials developed pursuant to the request, and the IAA. An electronic file is also maintained for each external IRB, containing all materials developed pursuant to the request.