Overview

This procedure reviews the process for review and approval or denial of requests by external institutions with their own Institutional Review Board (IRB) 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 vice versa. An IAA is required for (a) an IRB outside Yale to serve as IRB of record for a study involving Yale researchers, (b) Yale to serve as IRB of record for a study involving researcher from another institution with an IRB, (c) to name Yale IRBs on its Federalwide Assurance (FWA) filed with the Office for Human Research Protections (OHRP), or (d) 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 institution with a Federalwide Assurance (FWA) under the purview of a non-Yale IRB, (b) by the IRB of an FWA 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. IAA 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 HRPP 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:

- A Request for Single IRB Review, 920 FR 7, from the Yale PI whose research generated the request, stating the reason for the request, the research activities that will take place at each institution, the risk level of the protocol, information regarding the external investigator, and contact information for the external IRB. If Yale is to be IRB of record, the request must include the plan for supervision and monitoring of the external site.
- 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
- 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 for Yale, Yale will 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 (if applicable), whether or not the external IRB is accredited, whether or not the external IRB has had experience in other IRB collaborations. 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 Institutional Official for review and signature, with a copy to the HRPP Director. 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, HRPP Director and the Manager.

**Notification to the External IRB and PI**

If the IAA is approved, a signed copy of the IAA is sent as a pdf document to the external IRB, with a cover email, requesting that a signed copy be returned to the Manager. Upon request, hard copies of the Agreement will be mailed instead of the electronic document.

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

The Manager notifies the PI of the IAA approval/disapproval and of all conditions and terms of the IAA.

**IAA Term**

The IAA term is determined on a case by case basis, depending on the scope of the agreement.

**Documentation**

The Manager maintains a file of the request, including all materials developed pursuant to the request, and the IAA