

---

# Yale University Human Research Protection Program

---

## 920 PR.3 Renewal of IRB Authorization Agreements (IAAs)

---

Overview .....	1
Assessment of Performance: Background Information .....	1
Renewal Process: Documents .....	1
Approval Process .....	2
Non-renewal Due to Project Completion .....	3
Non-renewal Due to Performance .....	3
Document Retention .....	3

---

### Overview

This procedure describes the process for renewal or non-renewal of (a) an IRB Authorization Agreement (IAA) establishing one or more Yale IRBs as the IRB of record on the Federalwide Assurance (FWA) filed by a Yale research affiliate with the Office of Human Research Protections (OHRP) and (b) an IAA where Yale has established the IRB of another institution as IRB of record on Yale's FWA.

---

### Assessment of Performance: Background Information

Three months prior to (a) the expiration of the Affiliate's Federalwide Assurance (FWA), (b) the renewal date set by the IAA renewal schedule, or (c) the expiration of the current IAA, the Education and Community Outreach Manager (Manager) will review the following in preparation of a staff evaluation and recommendation to the IRB Director/Chair and Institutional Signatory Official regarding renewal or non-renewal of the IAA:

- A. Research Affiliates:
  - number of protocols conducted in the past three years; status of current projects
  - number and nature of any compliance issues, and Affiliate response to IRB actions regarding the corrective action plan
  - plans by Yale faculty for continued research with the Affiliate
  - Affiliate interest in renewing an IAA with Yale
  - Affiliate management of any change in Affiliate Signatory Official/Human Protections Administrator
  - Affiliate relationship to Yale beyond research affiliate status (e.g., IRB membership, service on Yale committees)
  
- B. IAAs Yale is IRB of Record for Another Institution
  - status of the protocol(s) covered in the IAA
  - number and nature of any compliance issues and IRB actions regarding corrective action
  - IRB interest in renewing the IAA with Yale
  - Need for any changes to the scope or nature of the IAA

---

### Renewal Process: Documents

Based on the completion of the assessment of performance, the Manager prepares a staff evaluation that includes the following elements, as applicable, using the appropriate form:

- information regarding any changes in the Signatory Official or Human Protections Administrator named on the FWA
- the number of Yale IRBs designated on the FWA
- information regarding whether or not Yale serves as the Privacy Board for research conducted under the IAA

- the scope of the IAA—whether the IAA is limited to a single project, to research with Yale faculty as principal investigators, or includes all research conducted by the Affiliate
- an overview of the organizational background
- other Yale relationships of the Affiliate
- the Affiliate research experience under the FWA
- the Affiliate’s research compliance
- the status of the Affiliate’s human research policies and procedures
- a recommendation for renewal or non-renewal of the IAA

If a renewal is recommended, the staff evaluation also includes:

- a recommendation for the term of the IAA
- a recommendation for any additions to terms of the existing IAA.
- a determination regarding the need for a meeting to review the new IAA, or if the renewal can be mailed. A meeting may be required if there has been a change in the Affiliate’s Signatory Official and/or Human Protections Administrator, or if IRB staff determines that review of the IAA commitments and responsibilities is needed.
- For research affiliates, renewal may be recommended for another three year period, or may be recommended to remain in effect as long as both parties maintain a current FWA. For IAAs with other IRBs, renewal is generally for a period of five years. In all cases, IAAs may be terminated for cause, or by the choice of either party.
- updated Affiliate human research protection policies and procedures, inclusive of all areas outlined in the Yale research affiliate template policies and specific to the needs of the Affiliate. These policies are developed by the Affiliate, with support and guidance from the Manager
- a revised IAA. If the renewal requires review by General Counsel, a draft IAA will be prepared. If no review is required, a final IAA will be prepared. When another institution is serving as IRB of record for Yale, that institution may draft the IAA for review and signature by Yale. Proposed modifications to the IAA will be negotiated with the institution, as needed.

---

## Approval Process

The staff recommendation and all supporting documents are reviewed by the IRB Director and/or Chair. If there are no outstanding issues regarding renewal, the Director/Chair approves and signs off on the evaluation/recommendation, and the evaluation/recommendation and IAA are forwarded to the Yale Institutional Signatory Official for final review, approval and execution. If staff has determined that no meeting with the research affiliate is required to execute the new IAA, the Institutional Signatory Official’s signed IAAs are sent to the Affiliate with a cover letter, instructing them to return one signed copy to the Manager. If a meeting is required, the Institutional Signatory Official’s signed copies are sent to the Manager, who arranges a meeting with the Affiliate and other staff, as deemed appropriate.

If the staff recommends renewal but there are outstanding issues requiring further assessment, the staff evaluation and supporting documentation are sent to General Counsel, with copies to the Institutional Signatory Official. Situations requiring review of the proposed IAA renewal by General Counsel may include:

- the existence of or potential for a conflict of interest with Yale University or with a Yale investigator
- concerns regarding management of adverse events, events causing risk of injury to participants or others or research compliance
- a significant change in the terms of the IAA
- other issues identified as warranting General Counsel review.

The General Counsel’s office will review the request for renewal of the IAA, and will approve, disapprove or make recommendations for modifications to the IAA. General Counsel’s recommendation will be relayed to the Institutional Signatory Official and IRB staff for follow-up. If it is decided not to renew the

IAA, a letter will be sent from the Institutional Signatory Official, notifying the Affiliate or institution of the University's decision.

---

### **Non-renewal Due to Project Completion**

IAAs generated for specific protocols or projects that have been completed at the time of FWA expiration will not be renewed unless a Yale principal investigator plans future projects with the Affiliate. If no future projects are planned, the Education and Community Outreach Manager will write to the Signatory Official of the Affiliate

- thanking them for their participation in the protocol
- notifying them that Yale shall not be named as IRB of record on an FWA renewal
- informing them that they should contact the IRB if they have plans for future research with a Yale investigator.

---

### **Non-renewal Due to Performance**

If the staff evaluation results in a staff recommendation not to renew, the staff evaluation, including the rationale for non-renewal and any supporting documents, will be sent to General Counsel and the Institutional Signatory Official for review and a final decision regarding renewal. If it is decided to renew the IAA, General Counsel will direct the terms of the renewal. If it is decided not to renew the IAA, a letter will be sent from the Institutional Signatory Official, notifying the Affiliate or institution of the University's decision.

---

### **Document Retention**

Original copies of all IAAs will remain on file with the Manager. Electronic copies will be maintained by the Institutional Signatory Official. The Manager will retain files for each research affiliate and institution with all supportive documents to the research affiliate process, and copies of all emails from OHRP regarding FWA renewals and updates. Such files may be made available to others upon request.

---

### **Reference:**

OHRP "Terms of the Federalwide Assurance", A. 10, A.13