When is Unaffiliated Investigator Agreement Needed?

Unaffiliated Investigator Agreements are a way for Yale University to extend the terms of its Federalwide Assurance (FWA) to external individuals from unassured institutions engaged in non-exempt human subjects research conducted by Yale investigators, regardless of which IRB serves as the IRB of Record. Any external individual affiliated with an assured institution and working on a Yale research protocol is required to have approval from his/her own Institutional Review Board (IRB). Alternatively, the institutions can enter into a reliance agreement allowing Yale IRB to serve as the IRB of record.

Answer the following questions to determine whether Unaffiliated Investigator Agreement is appropriate:

1) **Is the individual engaged in nonexempt human subjects research?** To determine whether the individual is engaged, use the Worksheet 311 (Engagement Determination), available in IRES IRB Library.
   a. If NO, the individual is not engaged, or the research is exempt, Unaffiliated Investigator Agreement is not necessary.
   b. If YES, proceed to question #2.

2) **Is the individual affiliated with an unassured institution or not affiliated with any institution?** To determine whether the institution has its own FWA, search for the name of the institution in the OHRP database.
   a. If NO, the institution has its own active FWA, Unaffiliated Investigator Agreement is not appropriate. An approval from the external investigator’s IRB or a reliance agreement will be required.
   b. If YES, either because the external investigator’s institution does not have its own FWA or the investigator does not have affiliation with any institution, Unaffiliated Investigator Agreement is appropriate.

How to Submit a Request to Add an Unaffiliated Investigator to a Protocol?

Two levels of approvals are required to add an Unaffiliated Investigator to a study:

1) Approval of the Unaffiliated Investigator Agreement by the Institutional Official or the designee, and

2) Approval to add the individual to a study.

Both approvals are processed by HRPP via IRES IRB at the same time.

The following materials are required to be submitted in IRES IRB with a personnel modification to add an unaffiliated investigator to each study:

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1 Unassured Institution is an institution that does not have its own FWA. If an institution routinely engages in federally funded research, the institution should file an FWA.
1) A completed and signed Request to Serve as a Yale University Unaffiliated Investigator uploaded in the Supporting Documents page. The request is available in the IRES IRB Library. The Unaffiliated Investigator should indicate on the request whether he or she is seeking approval as an Individual or an Institutional Investigator. Proposed investigators who are not affiliated with any institution must complete the materials for Unaffiliated Individual Investigator. Proposed investigators who are affiliated with an institution, agency or practice that is not routinely engaged in research must complete the materials for Unaffiliated Institutional Investigator.

2) Copy of the Unaffiliated Investigator CV;

3) Copy of verification of Human Subjects Protection training completed within the last 3 years (unless Yale netID was obtained, in which case the HRPP will verify the training status through Training Management System);

4) Copy of Good Clinical Practice training completed within the last 3 years if research meets the criteria for a clinical trial (unless Yale netID was obtained, in which case the HRPP will verify the training status through Training Management System);

5) Copy of verification of HIPAA training, if applicable. Note: if the unaffiliated investigator must access Yale systems, a Sponsored Identity must be requested by the Yale PI’s Business Office. HIPAA training must be completed online. Individuals who will not access Yale PHI and do not require access to Yale systems do not need a sponsored identity. Non-Yale HIPAA training certificate will be accepted.


Note – individuals without Yale netID must be listed on External Team members log uploaded in the Study Team Members along with all the necessary documentation. Acceptable training certificates are described on the HRPP website.

What does the Unaffiliated Investigator need to know before engaging in human subjects research?

Unaffiliated Investigators are required to be familiar with the following documents. These documents can be accessed by clicking on the links listed below.


D. The specific terms of the Yale University FWA http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html

E. Relevant Yale University institutional and IRB policies and procedures for the protection of human subjects https://your.yale.edu/research-support/human-research/policies-procedures-guidance-and-checklists

F. HIPAA at Yale, Researchers Guide to HIPAA https://hipaa.yale.edu/training

What does a sample letter of support for Unaffiliated Institutional Investigator look like?

Date

To Whom It May Concern:
This is to certify that ________________________________ has reviewed the protocol:

(name of Institution/agency/practice)

__________________________________________________________

(title of protocol and name of PI)

and grants permission for ________________________________ to participate in the

(name of unaffiliated institutional investigator)

activities related to this research [and, if applicable: and to use the facilities and resources of this institution in the conduct of the research.].

Please do not hesitate to contact us if you have any questions or comments.

Sincerely,

(Signature of CEO, Executive Director, Managing Partner, Owner)

Signature Name
Title

What other requirements may apply?
Additional agreements are necessary for Unaffiliated Investigators to be paid for their time. The PI should work with his/her Business Office and Office of Sponsored Projects on the appropriate agreement, e.g., Professional Service Agreement or Subaward. More information is available here: https://your.yale.edu/policies-procedures/policies/3210-professional-services-and-consulting

Revision History

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<tr>
<td>11/25/2013</td>
<td>Initial effective date.</td>
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<tr>
<td>03/01/2021</td>
<td>Providing clearer guidance on when the Unaffiliated Investigator Agreement is necessary.</td>
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