



# OFFICE *of* RESEARCH & GRADUATE STUDIES

## IRB Guidance for Requesting Individual Investigator Agreements (IIA)

### Individual Investigator Agreements (IIA)

Documentation of an individual investigator's reliance on UIW HRPP/IRB review, when the investigator is engaged in human subject research in collaboration with a UIW (co-)Principal Investigator (PI)/Key Investigator. This individual investigator agreement is signed by:

1. The Institutional Official of UIW, or his/her designee; and
2. The collaborating individual investigator.

Please see [UIW Individual Investigator Agreements Policy](#) for more information regarding the definitions, criteria, eligibility, and responsibilities of research personnel engaged in an IIA.

### Procedure

#### 1. *Submitting a Request*

The steps below outline the process used by the UIW PI/Key Investigator, UIW HRPP/IRB, HRPP Staff, and Non-affiliated PI for the execution of UIW IIA(s). For additional information regarding the policy of this process, please see the [Requesting and Executing](#) section above.

- a. The UIW PI/Key Investigator will submit an application requesting the HRPP/IRB review of the protocol using the [UIW IRB management system](#). In the application, the UIW PI/Key Investigator must identify engaged, non-affiliated key personnel.
- b. During the administrative review of a submission, the HRPP/IRB reviewer may determine that the study proposes to use non-affiliated research staff (i.e., Non-affiliated PI) and meets the criteria of eligibility outlined in this policy.

#### 2. *Execution of IIA*

If the application needs no further information, correction, or clarification and meets the [eligibility criteria](#) outlined in this policy, the HRPP staff reviewer will initiate the execution of the IIA.

- a. HRPP Staff will send the Non-affiliated PI an IIA form for review and signature. The Signed IIA form should be returned to HRPP Staff by a Non-affiliated PI.
- b. After a signed IIA is returned to the HRPP Staff, the application and signed IIA form will be submitted to the Institutional Official for review and signature.
- c. A review of the protocol should proceed pending a decision to approve or disapprove reliance on the UIW IRB for non-affiliates. Approval of the protocol, however, should not be issued until the reliance decision is made, unless the Institutional Official advises that an approval may be issued, but non-affiliate involvement may not begin until the IIA is fully executed.



## OFFICE *of* RESEARCH & GRADUATE STUDIES

- . As stated in this policy, IIA(s) are subject to the approval of the Institutional Official and may be declined for any reason.
- d. Once fully executed, the IIA(s) will be uploaded as an attachment to the protocol(s) using the [UIW IRB management system](#).
  - . An IIA may apply to more than one protocol provided each meets the requirements stated above.
  - . If the procedures in the protocol have changed or if more non-affiliates than were originally approved become involved, the protocol will be re-evaluated to determine if the IIA will remain in effect.

Revision History  
5/20/2022