HRP-832 | 3/29/2024

**WORKSHEET: Individual Investigator Authorization Agreements (IIA)**

The purpose of this worksheet is to provide support for IRB staff evaluating requests for individual investigator authorization agreements (IIAs). If an IIA is appropriate, this worksheet provides support on executing the IIA.

1. **Requirements for IIAs (Check if “Yes”. All must be checked.**

The study falls under the definition of human research.

The individual does not have any UMN affiliation (or affiliates: Gillette, MHealth Fairview).

The individual is not affiliated with an institution that has an IRB.[[1]](#endnote-1)

The individual does not have a conflict of interest related to the study.

The individual will engage in one or more of the following study activities:[[2]](#endnote-2)

Administer study intervention(s) or activities

Obtain consent of research participants

Have access to identifiable data (collection, reporting, and analyzing)

The UMN PI has attested that they will provide oversight of the individual’s engagement for this study.

The UMN PI has provided a completed HRP-216 – FORM - External Study Personnel.[[3]](#endnote-3)

The individual has completed IRB training requirements per HRP-066 - SOP - Education and Training.

1. **Executing the IIA or External Collaborator Agreement[[4]](#endnote-4)**

For federally funded research:

Execute HRP-855 – TEMPLATE – IIA for Federally Funded Research[[5]](#endnote-5)

For non-federally funded research:

Execute HRP-856 – TEMPLATE – External Collaborator Agreement for Non-Federally Funded Research[[6]](#endnote-6)

1. Individuals affiliated with institutions that have an IRB are responsible for ensuring that they are meeting their own institution’s requirements, including IRB review to determine whether their own institution is engaged. In this case, an IIA is not warranted. [↑](#endnote-ref-1)
2. If the individual is not engaged in human research activities listed above, they do not need to be added as personnel in ETHOS and an IIA is not warranted. [↑](#endnote-ref-2)
3. HRP-216 must be uploaded into the study record prior to full IRB approval of the initial study or as part of a Modification submission. [↑](#endnote-ref-3)
4. The fully executed agreement must be uploaded into the study record prior to full IRB approval of the initial study or as part of a Modification submission. [↑](#endnote-ref-4)
5. Must be signed by the PI, external study personnel, and the institutional official or designee. [↑](#endnote-ref-5)
6. Must be signed by the PI, external study personnel, and the Senior IRB Analyst or designee. [↑](#endnote-ref-6)