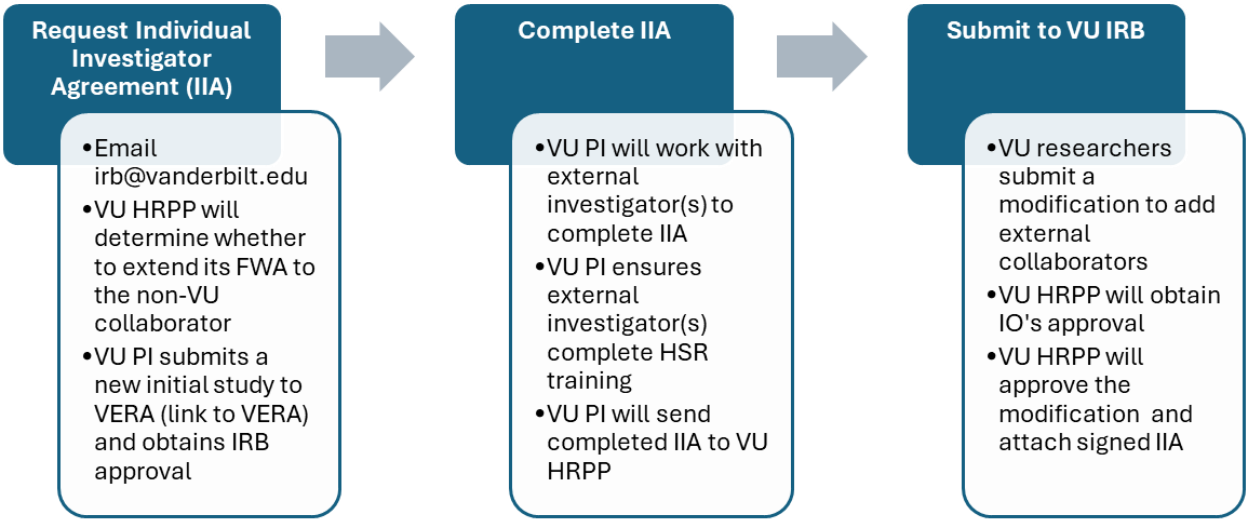
INDIVIDUAL INVESTIGATOR AGREEMENT (IIA) GUIDANCE



What is an Individual Investigator Agreement (IIA)?

An Individual Investigator Agreement or IIA is a formal contract between Vanderbilt University, a Federalwide Assured (FWA) organization, and an individual investigator who is not affiliated with an FWA organization or institutional research collaborator who is not acting as an agent of an FWA assured organization.

What does an IIA cover?

The IIA allows Vanderbilt University to extend its FWA to individual investigators by taking on responsibilities for the individual investigators to comply with the human subjects protection requirements outlined in the institutional policies and/or in the Common Rule. The IIA establishes the expectations from and obligations of the individual research collaborator related to the ethical conduct of research.

Who is covered by an IIA?

An individual investigator who is not affiliated with an FWA organization or institutional research collaborator not acting as an agent of such an organization may be covered by an IIA if they interact with

the participants and/or have access to identifiable participant research data (e.g., former students, recruiters, community partners, interviewers, etc.). Vanderbilt University may extend its FWA to cover individual investigators, if 14 conditions outlined by the HHS Office of Human Research Protection are met. The conditions are listed below.

What training is required for individual investigators?

Individual Investigators must follow the VU HRPP training requirements outlined in section "What training does my staff and I need to conduct Human Research? " of the investigator manual. VU HRPP provides access to the CITI training to the external collaborators to support ethical and smooth collaboration.

When should an IIA be requested?

VU researchers must request reliance agreement(s) prior to conducting human subject research for initial studies, and before adding new research team members to approved studies. To request a reliance agreement, VU researchers will need to email the VU HRPP at irb@vanderbilt.edu

The VU HRPP will determine whether it will extend its FWA to that individual(s) based on criteria for reviewing for unaffiliated individuals. If VU HRPP determines the criteria has been met, VU researchers will need to provide the IIA form to the external collaborator(s). The external collaborator(s) will need to complete the IIA form and return it back to VU researchers. It is the VU researcher's responsibility to provide the completed form back to the VU HRPP office.

Once received, the VU HRPP will work with the institutional official to review and sign the IIA. Once it has been signed, the HRPP office will attach it to the IRB, and complete the post review. External researchers will not be able to engaged in research procedures until all procedures have been completed and the reliance agreement has been fully executed.

What documents are required to add an individual investigator to my research study?

- VU researchers are responsible for ensuring that external collaborators have complete the required human subject training and any other applicable training (e.g., HIPAA training). If applicable, the external collaborator must complete the university's annual Conflict of Interest (COI) disclosure.
- The VU researchers must complete and submit a copy of the IIA to VU IRB. This should be signed by both the external investigator and the VU Institutional Official (IO). VU HRPP staff will obtain the IO's signature after the partially-executed IIA has been provided.
- The external collaborator must be added to VU protocol's personnel form in VERA, and VU IRB must approve an amendment containing the fully-executed IIA and any other relevant documents before the external collaborator may conduct any research activities.

- The external collaborator may not conduct any research activities until this agreement has been signed by both parties and VU IRB/HRPP has approved it in an amendment.

Where can I find the IIA template?

The IIA form template can be located on the VU HRPP Website. For more questions, please reach out to the VU HRPP Staff at irb@vanderbilt.edu

Conditions For Extending An FWA To Cover Collaborating Individual Investigators*

OHRP will permit an assured institution to extend its FWA to cover a collaborating **independent** or **institutional** investigator provided all of the following conditions are satisfied:

1. The principal investigator at the assured institution directs and appropriately supervises all of the collaborative research activities to be performed by the collaborating individual investigator outside the assured institution.
2. The extension of the coverage of the FWA is put in place by use of an appropriate written agreement, such as the sample Individual Investigator Agreement, for each collaborating individual investigator who will be engaged in the research being conducted by the assured institution. **The assured institution must maintain the Individual Investigator Agreement,** or other written agreement used by the assured institution, **on file and provide copies to OHRP upon request.**
3. For collaborating **institutional** investigators, the appropriate authorities at the non-assured institution state in writing that the conduct of the research is permitted at their institution.
4. The assured institution and the responsible IRB designated under the FWA approve the extension of the assurance through either the Individual Investigator Agreement or other written agreement used by the assured institution.
5. The following documents are made available to the collaborating individual investigator: (a) *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (see http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html) or other internationally recognized equivalent (see section B.1. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions on the OHRP website at http://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html); (b) the HHS regulations for the protection of human subjects at 45 CFR part 46 (see http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html) or other procedural standards designated by a non-U.S. institution under its FWA (see section B.3. of the Terms of the Federalwide Assurance (FWA) for International (Non-U.S.) Institutions on the OHRP website at http://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwas/fwa-protection-of-human-subjecct/index.html); (c) the FWA and applicable Terms of the FWA for the assured institution; and (d) the relevant institutional policies and procedures for the protection of human subjects of the assured institution.

6. The collaborating individual investigator understands and accepts the responsibility to comply with the standards and requirements stipulated in the documents referenced in the preceding paragraph and to protect the rights and welfare of human subjects involved in research conducted under the Individual Investigator Agreement or other written agreement used by the assured institution.
7. The collaborating individual investigator agrees to comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protections for human subjects participating in research conducted under the Individual Investigator Agreement or other written agreement used by the assured institution.
8. The collaborating individual investigator agrees to abide by all determinations of the Institutional Review Board (IRB)/Independent Ethics Committee (IEC) designated under the FWA of the assured institution and agrees to accept the final authority and decisions of the IRB/IEC, including but not limited to directives to terminate participation in designated research activities conducted under the Individual Investigator Agreement or other written agreement used by the assured institution.
9. The collaborating individual investigator agrees to complete any educational training required by the assured institution and/or the IRB/IEC prior to initiating research covered under the Individual Investigator Agreement or other written agreement used by the assured institution.
10. The collaborating individual investigator agrees not to enroll subjects in research under the Individual Investigator Agreement or other agreement used by the assured institution, prior to the research being reviewed and approved by the IRB/IEC.
11. The collaborating individual investigator agrees to report promptly to the IRB/IEC any proposed changes in the research conducted under the Individual Investigator Agreement or other agreement used by the assured institution. The collaborating institutional investigator agrees not to initiate changes in the research without prior IRB/IEC review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
12. The collaborating individual investigator agrees to report immediately to the IRB/IEC any unanticipated problems involving risks to subjects or others in research covered under the Individual Investigator Agreement or other agreement used by the assured institution.
13. The collaborating individual investigator, when responsible for enrolling subjects, agrees to obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 (or any other international or national procedural standards selected in the FWA for the institution referenced above) and stipulated by the IRB/IEC.
14. The collaborating individual investigator acknowledges and agrees to cooperate with the IRB/IEC's in its initial and continuing review, record keeping, reporting, and certification for the research covered by the Individual Investigator Agreement, or other agreement used by the assured institution. The collaborating institutional investigator agrees to provide all information requested by the IRB/IEC in a timely fashion.

*https://www.hhs.gov/ohrp/regulations-and-policy/guidance/extension-of-institutional-fwa-via-individual-investigator-agreement/index.html#:~:text=The%20extension%20of%20the%20coverage,conducted%20by%20the%20assured%20institution.