

Individual Investigator Agreement (IIA) Information & Procedures

What is an Individual Investigator Agreement?

It is a document that provides a mechanism for which an institution with a Federalwide Assurance (FWA) may extend its FWA to cover two types of collaborating individual investigators: *collaborating independent investigator* and *collaborating institutional investigator*.

A collaborating independent investigator is:

- a. not otherwise an employee or agent of the **assured** institution;
- b. conducting collaborative research activities outside the facilities of the **assured** institution; AND
- c. not acting as an employee of **any** institution with respect to his or her involvement in the research being conducted by the assured institution.

In other words, a collaborating independent investigator is not otherwise an employee/agent of UTHSC, is conducting research outside of UTHSC's facilities, and is not conducting research on behalf of any institution (i.e., will not be affiliated with any institution in publications, presentations, etc. that stem from the research being conducted).

A collaborating institutional investigator is:

- a. not otherwise an employee or agent of the **assured** institution;
- b. conducting collaborative research activities outside the facilities of the **assured** institution;
- c. acting as an employee or agent of a **non-assured** institution with respect to his or her involvement in the research being conducted by the **assured** institution; AND
- d. employed by, or acting as an agent of, a **non-assured** institution that does not routinely conduct human subjects research.

In other words, a collaborating institutional investigator is not otherwise an employee/agent of UTHSC and is conducting research outside of UTHSC's facilities under the auspices of an institution (i.e., for whom they are an employee or agent) that does not have an FWA (e.g., a private practice, a church, Walgreens, etc.).

IIAs provide an alternative to establishing additional FWAs for numerous institutions that do not hold FWAs and do not routinely conduct human subjects research.

Process for using an Individual Investigator Agreement:

1. **FIRST**, contact the IRB at 448-4824 in order to determine whether your study meets the criteria for the use of an IIA.

2. For collaborating **institutional** investigators, the appropriate authorities at the non-assured institution must state in writing that the conduct of the research is permitted at their institution. A copy of this correspondence should be included with the IRB application.
3. Download a copy of the IIA template from the UTHSC IRB [Reliance Agreements webpage](#). Complete it as follows:
 - Print the Individual Investigator's name and the title of the study (Research Covered by this Agreement) on the 1st page. Remember that this is not the Principal Investigator for the study; this is the collaborating individual investigator defined above.
 - Have the Individual Investigator complete the Investigator Signature section on the 2nd page. Remember that this is not the Principal Investigator for the study; this is the collaborating individual investigator defined above. (The IRB will complete the FWA Institutional Official section.)
4. To include the collaborating individual investigator on the UTHSC IRB application in iMedRIS (our electronic research application system), the collaborating investigator must have a UT Net ID and password. To request a UT Net ID and password for the collaborating investigator, follow the instructions outlined on the UTHSC IRB website for obtaining a UT Net ID at <http://www.uthsc.edu/research/compliance/irb/researchers/getting-started.php>.
5. Collaborating individual investigators must provide a copy of completion for the online CITI course or NIH course; this should be included with the application. The new study application (or the revision application requesting to add the collaborating investigator) cannot be approved by the IRB until all investigators have completed this human subjects protection training.
6. Collaborating individual investigators must also provide a copy of their current Curriculum Vitae (CV) or resume. This should be included with the new study application (or revision application).
7. You will attach to the new study application (or revision application) a copy of the IIA signed by the collaborating individual investigator, and the IRB will ensure that the Signatory Official or Designee for UTHSC signs the agreement.
8. The collaborating individual investigators must electronically sign off on the new study application (or revision application) verifying that they are participating in the study.
9. Upon receipt of your study application (or revision application) and attached documents, the UTHSC IRB will complete a review of the application, and an outcome letter will be issued via iMedRIS.

10. If you have already submitted the new study application (or revision application) in iMedRIS by the time that the IIA is signed by UTHSC, your IRB analyst will attach a copy of the signed IIA to your application for you.