# Individual Investigator Agreements: Guidance for Study Teams

An Individual Investigator Agreement (IIA) is a mechanism by which COMIRB assumes oversight of a single investigator who is engaged in human subjects research on a COMIRB-approved protocol. An IIA is used when that investigator's employer is not engaged in the research. If the employer is engaged in the research, an IRB Reliance (e.g., with an IRB Authorization Agreement or Smart IRB letter) should be used instead. See the Single IRB Guide web page for more information.

## Personnel who may require an IIA

- Members of the community who are not typically engaged in research as part of their professional responsibilities, but who are involved in administering the intervention, obtaining informed consent from subjects, or other activities that constitute engagement in research. However, if there is a contract with their employer allowing the investigator to participate in the research, an IAA should be used.
- Investigators whose affiliation with another academic institution is limited to an adjunct or volunteer appointment.
    - These individuals should first contact their home institution's IRB to discuss whether their site is engaged in human subjects research. If their IRB agrees that the investigator's participation does not engage their institution in research, COMIRB will execute an IIA.
    - If the investigator has a full-time or other non-adjunct faculty appointment at the external site, COMIRB will execute an IAA or Smart IRB Agreement with that site. Please see COMIRB's Single IRB Guide for more information regarding this process.

## Students from other institutions

Graduate or undergraduate students from other schools occasionally participate in our studies to gain experience conducting research. The student may use the experience to fulfill an academic requirement and/or publish a paper or poster about the results. As such, they are usually acting as sub-investigators as opposed to research staff.

If the student is using the experience for a doctoral thesis or dissertation, or any other academic requirement to conduct research, their school is also engaged in the research. They need to get approval from their own IRB or rely on COMIRB through an IRB Authorization Agreement. See the Single IRB Guide.

If the student is a medical student at another institution or any situation where the research experience is not formally part of their academic requirements, COMIRB will allow their

participation under an IIA. However, the student is required to notify their school's IRB about their involvement in the research and fulfill any of their IRB's requirements.

If the student's activities involve one of our affiliated health systems, the health system will have additional requirements for the student to fulfill.

## COMIRB Requirements for Individual Investigators

The IIA outlines the roles and responsibilities of the Individual Investigator. The IIA must be signed by the Individual Investigator and the Institutional Official, and an amendment adding the investigator must be submitted by the local study team and approved by COMIRB before the external investigator can perform any research activities.

In order for COMIRB to enter into an IIA with an external investigator, the investigator and study team must fulfill some additional requirements:

- The investigator must obtain a Person of Interest (POI) number.
- The investigator must complete University of Colorado Denver's required Human Subjects training course in CITI and the HIPAA training course if the investigator will access PHI.
- The investigator must complete the University's annual Conflict of Interest (COI) disclosure in InfoEd.
- The local study team must add the Individual Investigator to the protocol's personnel form in InfoEd, and COMIRB must approve an amendment containing the fully-executed IIA and any other relevant documents before the Individual Investigator may conduct any research activities.
- The study team must complete and submit a copy of the IIA to COMIRB. This should be signed by both the external investigator and the Institutional Official (IO). COMIRB staff will obtain the IO's signature after the partially-executed IIA has been provided. The external investigator may not conduct any research activities until this agreement has been signed by both parties and COMIRB has approved it in an amendment.