IRB oversight for non-NIH employees working at an NIH site

Are all AIs that are conducting human subjects research on your protocol an NIH Federal Employee?

YES → *No additional agreements needed for the NIH to provide IRB oversight*

NO

Are they an IRTA/CRTA, Visiting Fellow or Special Volunteer?

YES → *No additional agreements needed for the NIH to provide IRB oversight*

NO

Are they a contractor working at an NIH site with an NIH employee?

YES → *No additional agreements needed for the NIH to provide IRB oversight*

NO

This AI may need a written agreement with the NIH to provide IRB oversight for their activities. Contact IRBO

SEE ADDITIONAL INFORMATION ON THE FOLLOWING PAGE

1. This guideline is applicable only when all the research activities conducted by the non-NIH investigator are occurring at an NIH site. Additional considerations may apply if any of the research is taking place at a non-NIH site.
2. All individuals that are conducting human subjects research (HSR) at the NIH require IRB oversight. Some individuals are automatically covered by the NIH IRB (those in the green boxes) whereas others may need an additional agreement for the IRB to have the authority to oversee their activity. An individual is conducting HSR if they are doing ***any*** of the following:
    a. Obtaining informed consent for participation in research
    b. Intervening or interacting with human subjects
    c. Accessing identifiable private information or identifiable biospecimens
3. ***Visiting Fellows (VF)*** are only those persons working at NIH under the Visiting Fellow program for international trainees. Please refer to OIR sourcebook and Manual Chapter. This does NOT include fellows from academic or other institutions within the US.
4. ***Special Volunteers (SV)*** are only those persons with the Intramural Personnel Designation (IPD) of Special Volunteer (see manual chapter describing requirements for an SV). This does not include other onsite collaborators, although they may appear as volunteers in NED. Please see the information sheet posted here describing the different volunteer types.
5. ***Contractors:*** NIH contractors who are conducting all of their research activities at an NIH site under the supervision of an NIH federal employee are automatically provided NIH IRB oversight. If the NIH contractor is working off-site, NIH IRB oversight may be provided through a written agreement or at the discretion of the OHSRP Director. If an agreement is needed, the type of agreement will be determined by the NIH IRBO.
6. There are different mechanisms by which the NIH IRB can assume oversight for a non-NIH investigator working on site. Which agreement is needed will be determined by the NIH IRBO. General considerations are described below, but the specific circumstances will dictate which agreement is appropriate. Detailed instructions for seeking these agreements are posted on our website here.
    a. Reliance Agreement: If the non-NIH investigator is from another research institution that holds their own FWA, a reliance agreement may be used. For example, trainees or collaborators from academic medical centers.
    b. Individual Investigator Agreement (IIA): If the non-NIH investigator is not from an institution that holds an FWA, then an IIA may be executed. Individuals covered under an IIA are treated as if they are an NIH employee for human subjects protections purposes when working on a specified NIH protocol. They will be required to comply with NIH HRPP human subjects training requirements Policy 103 – Education Program
7. If the non-NIH investigator is covered under a reliance agreement and all of their activities are occurring at the NIH site, the protocol should contain a brief description of what activities the non-NIH investigator will be performing at NIH. For example, *"Dr XYZ will conduct all activities described in the protocol"* or *" Dr XYZ will be performing history and physical exams and lumbar punctures".*