FWA Coverage and Training Requirements for Volunteers Serving as AIs on NIH protocols

1. Types of Volunteers

There are several categories for types of volunteers within the NIH Enterprise Directory (NED) who may serve as AIs on NIH protocols such as the following:

- Volunteer Clinical Collaborator
- Volunteer Clinical Rotator
- Volunteer Non-Clinical Collaborator
- Volunteer Other
- Volunteer Special Volunteer

These designations will all be listed as Volunteer in the classification line in NED. However, the listing of "Volunteer" in NED (per this screenshot) does **not** automatically mean the person is a Special Volunteer, which is only one of the possible Volunteer categories as noted above.

Classification:	Volunteer
IPD:	Other
Organizational Title:	

2. Why Type of Volunteer is Relevant Regarding Serving as an AI on an NIH Protocol

The type of volunteer determines whether the volunteer is covered under the NIH Federalwide Assurance (FWA) for their human subjects research (HSR) activities on an NIH protocol. An FWA [1] is a written document submitted by an institution (not an Institutional Review Board) that is engaged in non-exempt HSR conducted or supported by U.S. Department of Health and Human Services (HHS) by which the institution commits to HHS that it will comply with requirements set forth in the federal regulations for the protection of human subjects.[2] Since all NIH research is conducted or supported by HHS, all of this research is subject to these HSR regulations, and all investigators on protocols reviewed by the NIH IRB need to be covered by an FWA.

NIH Policy 100, *NIH Intramural Research Program's Human Research Protection* describes which volunteer investigators are covered under the NIH FWA.[3]

This policy indicates that the **only type of volunteer** conducting HSR on an NIH research protocol who is automatically covered by the NIH FWA is the **Special Volunteer (SV).** These individuals will likely have a designation noted in the IPD section of the NIH Enterprise (NED) Directory that looks like this:

Classification:	Volunteer
IPD:	Special Volunteer

[1] See OHRP Assurance Process Frequently Asked Questions for additional information about FWAs.
[2] These regulations are found in the federal regulations at 45 CFR 46.
[3] See Policy 100, Section E.2.c for specific information regarding which investigators are covered by the NIH FWA

Policy 100 also explains that volunteers who are not SVs (e.g. a volunteer who is a classified as a clinical collaborator), are generally **not** covered by the NIH FWA and will need some sort of collaborative research agreement such as a reliance agreement or an Individual Investigator Agreement. [4] For example, an investigator from an academic medical center who has been classified as a Volunteer Clinical Collaborator and not an SV will likely need a reliance agreement between the two FWA holding sites (their home institution and the NIH) before that individual can be named as an AI on the NIH protocol.

3. HSR Training Requirements are Determined by Classification of Type of Volunteer

Since **SV'**s are covered by the NIH FWA for research conducted on NIH protocols, they are expected to comply with the same training requirements as those for NIH FTEs as per Policy 103, *Education Program*. This training should be documented in the NIH CITI database that is accessed via the NIH CITI Portal on the OHSRP website, because training records in this database are downloaded into iRIS automatically. The IRB analysts use the training documentation in IRIS to confirm that all protocol investigators covered by the NIH FWA are in compliance with the current NIH training requirements. SVs may need to establish a CITI account via the NIH CITI portal. (Former employees who are now SVs may already have this account established.) Additionally, SVs who have completed CITI training elsewhere and that remains in compliance with the NIH training requirements in Policy 103, can have their non-NIH CITI records added to the NIH CITI site that is accessed via the NIH CITI Portal. If an SV does not have an existing account via the NIH CITI Portal, instructions explaining how they can set up such an account as well as how to transfer CITI records from other sites can be found in these FAQs that also provide screenshots with the instructions.

Policy 103 (Section E.9) also describes training required for volunteers serving as AIs on NIH protocols who are **not SVs** and who are not covered by the NIH FWA. These investigators must comply with training as required by their home institution. If the non-NIH Investigator is not affiliated with an institution that requires or provides access to human subjects protections training (e.g., such as a physician in private practice), the investigator must take and provide evidence of human subjects protections training to the NIH.

4. Contact information for additional questions

Questions regarding training requirements for volunteers who are AIs on NIH protocols can be directed to Peg Sanders at margaret.sanders@nih.gov

[4] See Policy 105, *IRB Reliance and Collaborative Research* and Policy 109, *Coverage Under the NIH Federalwide Assurance* for additional information.