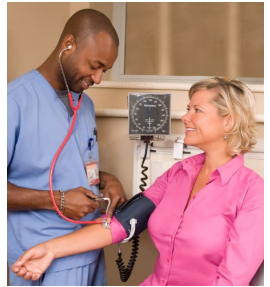


Guidance on Affiliations and Documentation for Personnel Engaged in VA Clinical Research





The person is (or will be) affiliated with a VA research study.
Will the person receive salary support from a VA award?

Yes

No

How will they be paid?

Continue to next page

Direct VA salary

If this person is a study investigator, she/he is considered a VA investigator.

•Continue to next page.

IPA to non-VA organization

- IPAs are a type of VA appointment.
- If this person is a study investigator, she/he is considered a VA investigator.
- This person cannot also hold a WOC appointment.
- This person cannot participate in a contract from the VA while serving on a VA IPA appointment. It would be a conflict of interest.

•Continue to next page.

Contract to non-VA organization

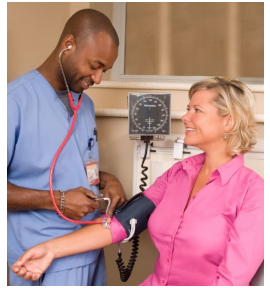
- Individuals who work under a VA contract cannot hold a VA appointment (paid, IPA, or WOC). It would be a conflict of interest.
- This person should not be included on VA study documents.*
- The person cannot be a VA Co-I, but can be a site investigator with their own non-VA organization. Follow the regulations outlined by the contract and by the non-VA organization.
- Research activity at the non-VA site may require a separate IRB submission and single-IRB exception (unless the non-VA site is UF or Brooks Rehab, which also uses UF's IRB).

•Do not continue in this document.

*Exception:

If the contract is with UF, and UF's IRB is overseeing the study, a UF employee can be listed as staff on the UF myIRB website. However, the affiliation in myIRB should be listed only as UF. Do not list a VA affiliation and do not include the contract employee in VA IRBNet.

IPAs and contracts are time-limited arrangements. They should be maintained and renewed through the full duration of the VA research. If an IPA or contract must end while the VA research is continuing, the individual should be transferred to a VA without-compensation (WOC) appointment.



Is the person the VA project Principal Investigator (funded or unfunded)?
Or is the person an eligible VA Co-Investigator who was named on or will be paid from a VA-funded award?

Yes

No

Include on:

- Study protocol document
- External IRB staff list
- IRBNet Staff List
- IRBNet Project Coversheet
- IRBNet FCOI disclosure
- Must have VA appointment (paid, IPA, or WOC)

What is their role?

Collaborator not named on or paid from a VA award
(go to page 4)

Research Coordinator, Post-doc, Student, Trainee
(go to page 4)

Non-VA Consultant named on a VA award
(go to page 5)

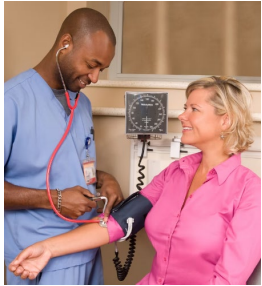
Will this person be exposed to safety hazards?

Yes

Also Include on:

- SRS

The person is a collaborating investigator on the VA study, but not named on or paid from a VA award.
Or the person is a Research Coordinator, Post-doc, Student, or Trainee.



Will this person work with human subjects or identifiable data?

Yes



- Include on:
- External IRB staff list
 - IRBNet Staff List
 - Must have VA appointment (paid, IPA, or WOC)



Will this person be exposed to safety hazards?

Yes



- Also Include on:
- SRS

No



Will this person be exposed to safety hazards?

Yes



- Include on:
- External IRB staff list
 - SRS
 - IRBNet Staff List
 - Must have VA appointment (paid, IPA, or WOC)

No



- PI decision on whether to include on IRB/IRBNet staff lists.
- Anyone who is working in VA space or accessing VA computer systems must have a VA appointment (paid, IPA, or WOC).

Although only PIs and named Co-Is are required to complete a Financial Conflict of Interest disclosure, other employees should consider submitting a disclosure (or not being involved with the study) if they know that they have a FCOI. Employees with a VA affiliation can submit through IRBNet. Employees without a VA affiliation can submit a PDF form OGE 450.

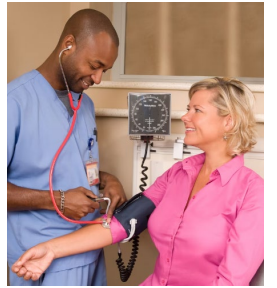
This person is a non-VA Consultant named on a VA award.

They are not permitted work with human subjects or access identifiable information as part of this study.

They are not permitted to be exposed to safety hazards as part of this study.

They are not permitted to have a financial conflict of interest pertaining to this study.

Consultants do not need to be accounted for in VA regulatory submissions.



Although only PIs and named Co-Is are required to complete a Financial Conflict of Interest disclosure, other employees should consider submitting a disclosure (or not being involved with the study) if they know that they have a FCOI. Employees with a VA affiliation can submit through IRBNet. Employees without a VA affiliation can submit a PDF form OGE 450.

