IRB Requirements for Studies Involving Personnel, Collaborators, or Sites Outside UW-Madison, UWHC, or Madison VA

November 2014

TIP
Personnel may be engaged in research if they will:
- Obtain informed consent
- Administer study interventions
- Work with identifiable data/specimens
If you are unsure whether someone is engaged in research, please contact the HS IRBs office for assistance.

Will personnel not affiliated with the UW/UWHC/Madison VA be engaged in research for this study?

Yes
- External personnel MUST be listed on the study team in the IRB application
- External personnel MUST complete human subjects training
- Activities of the external personnel must be described in the Study Location section of the IRB application and in the protocol
- For external personnel affiliated with an organization with an IRB, an IRB authorization agreement (IAA) will be needed
- For external personnel not affiliated with an organization with an IRB and the study is NOT federally funded, external personnel will need to be provided with a collaborating investigator summary
- For external personnel not affiliated with an organization with an IRB and the study IS federally funded, external personnel will need to complete Individual Investigator Agreements (IIA)
- After the IRB application is received, the HS IRBs office will assist study teams in securing IAAs and IIAs. The HS IRBs office also will assist in providing collaborating investigator summaries, when applicable

No
- External personnel should not be listed on the Study Team page(s) in the IRB application
- Activities of the external personnel must be described in the Study Location section of the IRB application and in the protocol
- A letter of support from an external site not engaged in research may be required (e.g., if the site will be used to recruit subjects)

Are you asking that the HS-IRBs serve as IRB of record for the external personnel or site?

No
- External personnel should not be listed on the Study Team page(s) in the IRB application
- Activities of the external personnel must be described in the Study Location section of the IRB application and in the protocol
- If the external personnel are affiliated with an organization, a letter of support also may be needed
- External personnel will need to obtain IRB approval before they can begin study activities

Yes
- External personnel affiliated with an organization or entity with an IRB (e.g., university, hospital, community organization)

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