IRB Requirements for Studies Involving Personnel, Collaborators, or Sites Outside UW-Madison, UWHC, or Madison VA
January 2012

1. Will personnel not affiliated with the UW/UWHC/Madison VA be engaged in research for this study?
   - No
   - Yes

   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.

2. Are you asking that the HS-IRBs serve as IRB of record for the external personnel or site?
   - No
   - Yes

   TIP
   - If external personnel are engaged in research for the study, IRB oversight for their activities is required.
   - Study teams can ask the HS-IRBs to serve as IRB of record for these personnel or the personnel may obtain approval from their IRB (if they have one).
   - A request for the HS-IRBs to serve as IRB of record must be included in the initial review application.
   - NOTE: The HS-IRBs will typically NOT serve as IRB of record for exemptions.

3. Are the external personnel affiliated with an organization or entity with an IRB (e.g., university, hospital, community organization)?
   - No
   - Yes

   TIP
   - If the study is federally funded, an independent investigator agreement (IIA) will need to be completed by the external personnel and the UW. The HS-IRBs office will assist with this.
   - If the study is not federally funded, a collaborating investigator sheet will need to be provided to the external personnel. The HS-IRBs office will assist with this.
   - If the external personnel are affiliated with an organization, a letter of support also may be needed.

   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 IRB application and protocol
   A request for the HS-IRBs to serve as IRB of record must be included in the initial review application.

   An IRB authorization agreement (IAA) will be needed for studies not involving Wisconsin IRB Consortium Members or Meriter.
   The IAA is an agreement between institutions.
   The IRB office will facilitate completion of the IAA.