



Guidance for FAU Researchers involved in Multisite Research Studies

When an FAU investigator is the Principal Investigator responsible for the overall conduct of a multi-site, federally funded study, both the investigator and FAU are **engaged** in research according to OHRP guidance (January 26, 1999), *whether or not identifiable private information is used for research by the investigator or others within FAU*.

As part of the information submitted to the IRB, the FAU PI must include detailed information covering applicable aspects of the multi-site research that will not occur at FAU in order for the FAU IRB to evaluate the management of information that is relevant to the protection of human participants.

There are four potential administrative scenarios. FAU investigators should follow the applicable steps below to assist with their administrative obligations:

IF FAU is the coordinating center for multi-site research, where activities at FAU involve no interaction or intervention with subjects, the PI must submit coordinating center procedures as part of the IRB protocol submission (see Appendix 1e)

1. The FAU IRB will initially receive from the PI of the coordinating center /operations center an IRB protocol submission containing documentation of the center's study oversight procedures, as well as a listing of sites, contact information, and federal wide assurance numbers for each site where research participation is to occur.
2. Cooperating sites must submit separate IRB protocols to their local IRB to cover each aspect of the research involving human subjects that will occur at their respective sites.*
3. *In some cases, FAU's IRB will agree to serve as IRB of record for external personnel, particularly if the study is minimal risk and/or external personnel are not affiliated with an organization that has its own IRB. If the study team wishes to request that the FAU's IRB serve as IRB of record for external personnel, they will indicate this in the IRB application. **As part of this request, the study team must include the following details:**
 - a. Documentation of human subjects training for external personnel. (CITI training is preferred).
 - b. Request for an IRB Authorization Agreement (IAA) to be completed if the external personnel are affiliated with an organization with an IRB. The IAA will be reviewed and executed by FAU's Division of Research and the FAU Research Integrity office will facilitate this process.
 - c. Request for an individual investigator agreement (IIA) if the external personnel are NOT affiliated with an organization with an IRB AND the study is federally funded. The IIA will be reviewed and executed by FAU's Division of Research and the FAU Research Integrity office will facilitate this process.
4. At the time of initial review, the FAU IRB will review, determine and document that the operations or coordinating center has sufficient mechanisms in place to ensure that:
 - a) management, data analysis, and data safety and monitoring (DSM) systems are adequate, given the nature of the research involved;
 - b) sample protocols and informed consent documents are developed and distributed to each collaborating institution;
 - c) each collaborating institution holds an applicable OHRP-approved Assurance;

- d) each protocol is reviewed and approved by the IRB at the collaborating institution prior to the enrollment of subjects;
 - e) any substantive modification by the collaborating institution of sample consent information related to risks or alternative procedures is appropriately justified; and
 - f) informed consent is obtained from each subject in compliance with HHS regulations.
5. At the time of initial review, the IRB will assess the procedures for prompt dissemination of protocol information to all participating sites. Assessment of protocol information includes unanticipated problems involving risks to participants, protocol modifications and interim findings.
 6. At the time of initial review, if the research is federally funded, the IRB will review the grant associated with the IRB submission, either at the convened IRB meeting or using the expedited procedure, to assess for agreement and consistency.
 7. The IRB will review any updates to the coordinating center protocol at the time of each continuing review, and will follow its relevant policies for instances of unanticipated problems involving risks to participants, serious or continuing non-compliance, or suspension or termination of IRB approval.

IF FAU is the *statistical center for multi-site research*, the PI must submit statistical center procedures as part of the IRB protocol submission (see Appendix 1f for additional detail). The protocol will be handled as follows:

1. The PI of the statistical center will submit Appendix 1d (as part of an overall IRB protocol submission) along with a listing of active sites and contact information, and the federal wide assurance number for each site where research participation is to occur.
2. The FAU IRB will review Appendix 1d in cases where the FAU PI assumes the responsibilities of a statistical center for a multi-site study, where institutional activities involve no interaction or intervention with subjects, and the principal risk associated with institutional activities is limited to the potential harm resulting from breach of confidentiality.
3. At the time of initial review, the IRB will determine and document that the statistical center has sufficient mechanisms in place to ensure that: a) the privacy of subjects and the confidentiality of data are adequately maintained, given the sensitivity of the data involved; b) each collaborating institution holds an applicable OHRP-approved Assurance; c) each protocol is reviewed and approved by the IRB at the collaborating institution prior to the enrollment of subjects; and d) informed consent is obtained from each subject in compliance with DHHS regulations. The IRB will also assess the procedures for prompt dissemination of protocol information (e.g., reports of unanticipated problems involving risks to participants, protocol modifications and interim findings) to all participating sites.
4. The IRB will review the statistical center protocol at the time of each continuing review, and will follow its relevant policies for instances of unanticipated problems involving risks to participants, serious or continuing non-compliance, or suspension or termination of IRB approval.

IF FAU is the site of a *data or specimen repository for multi-site research*, the PI will submit a repository protocol (Appendix 1h)

IF the scope of the FAU study involves *multiple, separate research questions* at the differing sites **THEN** multiple separate IRB protocols will be required and the FAU PI will need to submit a blanket (administrative) protocol detailing this information.