Procedure
Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: I.F.1
Section: IRB Authority and Institutional Commitment
Review Responsibility: HRPP Policy and Procedure Committee
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Subject: Procedure for Memorandums of Understanding (MOU)

Procedure:
This procedure outlines the process for establishing and maintaining a Memorandum of Understanding for sites where the VUMC Institutional Review Board (IRB) serves as the IRB of Record for all research activity at the site or for a specific research project.

I. Investigator Responsibilities.
   A. The Investigator will complete the initial MOU Set Up Questionnaire for each site and submit to the IRB for processing.
   B. The following documentation will be submitted with the Set Up Questionnaire for each site:
      1. A certificate of insurance for general comprehensive liability and professional liability for Investigators and staff involved in the conduct of research;
      2. A list of all research staff identifying their role in the study with correct titles and degrees;
      3. Verification of the Investigator’s and/or key study personnel’s VU or VUMC faculty status;
      4. Curriculum Vitas for all Investigators and key study personnel involved in the conduct of the study;
      5. Certificates for all Investigators and key study personnel, verifying successful completion of the HRPP Human Subjects Protections Training program;
      6. Names of the local contacts, Institutional Signatory Official, and Human Protections Administrator for the site requesting the IRB to serve as the IRB of Record;
      7. Certificates verifying completion of a 3-part training module located at the OHRP Website http://ohrp.osophs.dhhs.gov/humansubjects/assurance/fwas.htm is required for the Human Protections Administrator and signatory official designated on the FWA. A certificate of completion for each of the 3 sections must be retained by the individual completing the training module and copy must be submitted to the IRB.
   C. The Investigator must provide all necessary information regarding local research context in accordance with HRPP Policy I.D. The information provided should also include the following:
      1. Local contacts for IRB questions;
      2. Local contacts for research participants;
      3. Local subject injury language; and
      4. Local HIPAA language.
   D. The Investigator or representative from the external site must provide to the IRB and keep current the names, addresses, and phone numbers of local contact persons who can make decisions regarding IRB issues.
   E. The Investigator or representative from the external site must conduct a comprehensive audit at each site at least quarterly and submit the audit results and summary to the IRB within 10 days of completion.
   F. The IRB may wish to conduct their own audit of the external site’s conduct of research depending on several factors, including but not limited to, the following:
1. The level of risk of the research study;
2. The number of reported unanticipated problems involving risk to participants or others or serious adverse events (e.g., this could be an inordinate low number of reports in a high risk study);
3. The degree of local oversight provided;
4. The involvement of a Data Safety Monitor or Board;
5. An increased number of protocol deviations;
6. Complaints from participants; or
7. Any issues of noncompliance.

G. When applicable, letters of cooperation with the terms of the MOU noted from all external research sites must be submitted to the IRB before approval of the research may be granted or may include a signature line on the MOU for each external site’s signature.

H. A copy of an approved Federalwide Assurance (FWA) must be submitted to the IRB. If a FWA has been applied for, but not yet granted approval, a copy of the FWA with OHRP approval must be submitted to the IRB within 10 days of receipt.

I. An original signature on the MOU of the Institutional Official with the authority to sign contracts is required.

J. The Investigator will provide payment of the following fees determined at the time of the MOU negotiations (additional fees will be assessed for each additional site):
   1. Administrative Set Up Fee - Due within thirty (30) days of the effective date of the MOU.
   2. Annual Renewal Fee - Due within thirty (30) days of the renewal date of the MOU.
   3. IRB Review Fee(s) - Due for each individual human subjects research project reviewed by the IRB.

K. The Investigator will agree to abide by all HRPP policies and procedures including accessing the HRPP website at http://www.mc.vanderbilt.edu/irb/ to view any revisions and/or updates.

L. The Investigator will assure adherence to the agreements outlined in the MOU.

M. The HRPP may reasonably require higher insurance limits to provide sufficient coverage commensurate to the risks involved in the research study which may be increased depending on the amendment.

N. The Investigator will fully inform the HRPP of all locations in which human subjects will be recruited into the Research Project.

O. All Investigators and key study personnel at the external site must participate in human research protections continuing education as stated in HRPP Policy VIII.A and provide documentation to the HRPP.

P. The Investigator will comply with all oversight activities deemed appropriate by the IRB Committee, federal oversight agencies and/or federal funding agencies at all sites (e.g., monitoring, auditing).

Q. The Signatory Official and the Human Protections Administrator must notify the IRB immediately if a local Investigator or key study personnel receives a suspension or restriction of any duties, clinical or research related. In addition, they must notify the IRB if any Investigator or key study personnel have received a determination of serious or continuing non-compliance. Failure to do so may result in cancellation of the MOU.

R. All IRB-related communication and documents will be submitted by the Investigator to the IRB, including any electronic submissions.

II. HRPP Administration Responsibilities.

A. The Administrative Team will draft the MOU.

B. The HRPP Director will make all final determinations regarding the HRPP’s willingness to serve as the IRB of Record for a performance site “engaged” in research.

C. With the approved MOU, the IRB agrees to:
   1. Maintain and provide a copy of an approved Federalwide Assurance (FWA);
   2. Inform the HRPP Staff of the conditions of the MOU; and
3. Keep the MOU on file in the HRPP.

D. The HRPP will report promptly to the appropriate institutional officials of the external site all actions taken by the IRB regarding (a) any serious or continuing noncompliance by Investigators and (b) any suspension for cause or termination for cause of IRB approval in accordance with the HRPP policies and procedures.

E. The HRPP will verify insurance limits meet minimum requirements and will especially verify any exclusions or endorsements. If necessary, the HRPP may contact Legal Counsel and/or Risk Management for advice on indemnification language and insurance limits.

F. If the external sites require inclusion of local context such as local contact names/numbers, subject injury language, HIPAA language, conflict of interest, etc., the IRB suggests the use of one informed consent with each site’s utilizing a rider at the end to include the local information that varies from site to site.

III. IRB Committee Responsibilities.

A. The IRB Committee is responsible for determining if the Investigator and key study personnel are qualified to conduct the research in relationship to their specific roles.

B. They must verify the external site has:
   1. An OHRP approved FWA; and
   2. The Investigator and key study personnel have completed requirements for human research protections training.

C. The IRB Committee must assess if the external site has the appropriate resources to safely and ethically conduct the study. Items to be considered include, but are not limited to, the following:
   1. The number and composition of staff;
   2. The facilities, e.g. resources available to handle emergency situations, etc.;
   3. The mechanism of recruitment utilized;
   4. The process of informed consent; and
   5. Past historical experiences.

D. The IRB Committee must review the following for adherence to state law including, but not limited to:
   1. Age of consent;
   2. Capacity to consent;
   3. HIV status reporting;
   4. Screening consent;
   5. Child Assent;
   6. Confidentiality of patient records;
   7. HIPAA;
   8. Mentally and physically handicapped; and

E. Each ICD will be compared for consistency. In addition, the Committee Members must verify the appropriateness of each site’s contact names/numbers, subject injury language, HIPAA language, conflict of interest, etc.

F. If there are questions that the PI cannot answer, the IRB Committee Member will contact the IRB contact at the local site for additional information.

IV. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.

A. The RCA will verify that a MOU is in effect when an external site is identified in the IRB application as “engaged” in research and the appropriate IRB is indicated as the IRB of Record. In addition, the RCA will verify at the time of each review that the MOU is current.

B. The RCA will verify that the Investigator and key study personnel have completed the initial and, if applicable, continuing education requirements in human research protections.

C. The RCA will assure that the appropriate documentation of local research context
has been submitted for review and consideration.

D. The RCA will verify the institution’s OHRP Assurance number from the OHRP website and assure that the approval is current. Appropriate documentation of this verification will be entered into the database.

E. At the time of pre-review, the RCA will review the research for adherence to State Law including, but not limited to:

1. Age of consent;
2. Capacity to consent;
3. HIV status reporting;
4. Screening consent;
5. Child Assent;
6. Confidentiality of patient records;
7. HIPAA;
8. Mentally and physically handicapped; and

F. At the time of pre-review, the RCA will review each informed consent document and other study-related documents to assure consistency and addition of site specific information. In addition, the RCA will assure that the Committee Members discussion regarding the appropriateness of each site’s contact names/numbers, subject injury language, HIPAA language, conflict of interest, etc. is reflected in the IRB Committee Minutes.

G. If there are questions that the PI cannot answer, the RCA will contact the IRB contact at the local site for additional information.

H. At the time of pre-review the RCA will reference the MOU for the external site to verify if any additional requirements need to be met. If clarification is required, the RCA will consult with HRPP Administration and will convey additional requirements to the IRB Committee at the time of its review.