Subject: Procedure for Addressing Compliance with the Health Insurance Portability and Accountability Act (HIPAA)

Procedure: This procedure provides guidance to assure that all studies conducted at the Vanderbilt University Medical Center (VUMC) are in compliance with the HIPAA regulations.

I. Investigator Responsibilities.
   A. Investigators wishing to create, use, or disclose PHI as part of the research activities, must include an authorization statement within the consent document.
      1. In completing the informed consent document for review and approval by the IRB, under Item #14, "Authorization to Use/Disclose Protected Health Information," the Investigator should insert the applicable template language from the optional language provided in the consent document template.
      2. The Investigator must complete all study specific information highlighted in red, to assure that all required elements of authorization are presented to the participant. When the research involves standard of care treatments that will be billed to the participant's insurance, this should be clearly stated so that the participant is informed as to the exact information to be disclosed and for what purpose.
      3. The Investigator must submit the informed consent documents with completed HIPAA authorization language to the IRB for review and approval prior to consenting participants.
   B. For studies requesting a waiver of authorization to use or disclose PHI, the Investigator must complete the additional waiver information and submit to the IRB for review and approval. When a waiver of authorization is granted by the IRB, the Investigator is required to track all disclosures of the PHI (Contact the VUMC Privacy Office for more information regarding "Tracking of Disclosures").
   C. When a study meets the criteria for exemption under 45 CFR 46.101(b)(4), Investigators may access PHI for the purpose of creating a limited data set as preparatory to research.
   D. Investigators wishing to disclose the limited data set outside of the covered entity must submit a Data Use Agreement executed between the covered entity and the recipient to the Office of Contracts Management prior to release of the limited data set. An example of a "Data Use Agreement" is available for external use.

II. IRB Privacy Board Responsibilities.
   A. The IRB will review all IRB applications and human subject research proposals for adequate privacy measures to maintain the confidentiality of the research participants and their data.
   B. For new study and continuing review applications requiring HIPAA authorization language incorporated under Item #14 in the informed consent document, the IRB is to compare the informed consent document to the IRB approved template language for congruence.
      1. The inclusion of this language will be reviewed at the level of review required by the study specific elements.
2. When the IRB finds modifications to the template language beyond that approved for study specific information, the IRB Committee will review the authorization language.

C. The IRB may review and approve requests for a waiver of authorization under standard or expedited procedures.

D. The IRB may review and approve the use and disclosure of a limited data set through expedited procedures.

III. Regulatory Compliance Analyst (RCA) Responsibilities.

A. The RCA will pre-review all new submissions for appropriate privacy template language in Section #14 of the informed consent document, as agreed upon by the IRB.

B. The RCA will contact the Investigator or study contact to request revision to informed consent document(s) that do not contain the appropriate template language.

C. The RCA will review all continuing review submissions to verify that appropriate privacy template language has been inserted in the informed consent document(s).

D. The RCA may prepare the study for IRB review and approval prior to receiving the appropriate template language. However, the reviewers must be made aware that the necessary revisions have been requested and the status of the approval must be pending receipt of these changes.