Subject: Requested Modification to the Health Insurance Portability and Accountability Act (HIPAA) Authorization Language for Vanderbilt University Medical Center (VUMC) Research Participants

Definitions:
Protected Health Information (PHI): Individually identifiable health information that is or has been collected or maintained by VUMC, including information that is collected for research purposes only, and can be linked back to the individual participant.

Policy:
It is the policy of the Human Research Protections Program (HRPP) to review requested modifications to the HIPAA authorization language for use and disclosure of PHI.

I. Investigator Initiated Modifications to the HIPAA Template Language.
A. The Investigator must update the wording within the enclosed brackets to provide study-specific information. The Investigator is instructed to modify the template language as necessary in order to properly inform research participants of the possible study related use and disclosure of their PHI.
B. The Investigator may not modify the Vanderbilt template language for use and disclosure of PHI without IRB review and approval. Limited changes may be considered by the IRB if they are for participant clarification or protection.

II. Sponsor or Funding Agency Initiated Modifications to the HIPAA Template Language.
A. The IRB will not accept sponsor or funding agency initiated modifications to the VUMC specific authorization language. A sponsor or funding agency may include pertinent information regarding their use and disclosure of individually identifiable health information in section #15 of the informed consent document. Requested modifications to the informed consent document will be reviewed in the same manner as an amendment and may be reviewed by the IRB Committee, if needed.
B. The IRB, in its capacity as the Privacy Board for research at VUMC, will not accept sponsor or funding agency-initiated modifications to the VUMC specific authorization language. Limited changes may be considered by the IRB if they are for participant clarification or protection.
C. IRB disapproval of sponsor or funding agency-initiated modifications to the HIPAA authorization template language does not affect the status of the currently approved research study.