Procedure

Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: X.B.1
Section: Conduct of Research
Review Responsibility: HRPP Policy and Procedure Committee
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Subject: Procedure for Requested Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Authorization Language for Vanderbilt University Medical Center (VUMC) Research Participants

Procedure:
This procedure provides guidance on requested modifications to the HIPAA Authorization template language for research participants under the jurisdiction of the Human Research Protections Program (HRPP).

I. Investigator Responsibilities.
   A. The Investigator will update the wording in the enclosed brackets of the privacy and confidentially template language in Item #14 of the informed consent document to provide study-specific information. The Investigator will modify the template language as necessary in order to properly inform research participants of the possible study related use and disclosure of their protected health information (PHI). This modification will be submitted with new study submissions, or as an amendment to the IRB for review and approval.
   B. When the sponsor or funding agency requests inclusion of pertinent information regarding the use and disclosure of individually identifiable health information, it must be incorporated into the informed consent document in section #15 of the informed consent document; however, the information must not conflict with information in Item #14 of the informed consent document.

II. IRB Committee Responsibilities.
   A. Requests for modifications to the HIPAA template language by an Investigator will be reviewed as a part of the overall IRB review and approval process in which the study qualifies.
   B. Request for modifications to the HIPPA template language for a current study will be reviewed following the IRB amendment policies and procedures.
   C. Sponsor requested modifications to the HIPAA template language must be in accordance with current HRPP policies and procedures.

III. Regulatory Compliance Analyst (RCA) Responsibilities.
   A. The RCA will review all submissions to verify that the appropriate privacy template language has been inserted into the informed consent documents and request any necessary revisions.
   B. The RCA will verify any standardized sponsor modifications to the HIPAA template.