

VAPHS Guidance on Use Preparatory to Research Issue Date 9/27/2011

In accordance with VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research, and VHA Handbook 1200.12, Use of Data and Data Repositories in VHA Research, data repositories (including VA medical records) may be used (i.e., accessed by VA investigators for activities that are preparatory to VA research without the requirement to obtain either a HIPAA authorization from the subject or a waiver of HIPAA authorization from the IRB. This includes use of Protected Health Information (PHI) for the preparation of a research protocol prior to submission to the IRB. At VAPHS, the following procedures must be followed in order to use data preparatory to research:

1. Memo to the IRB: A memo, addressed to the VAPHS IRB, should be submitted to the IRB Office. The memo should include:
 - a. A brief description of the activities preparatory to research that are planned and should also include the following representations as required by the HIPAA Privacy Rule:
 - (1) The access to PHI is only to prepare a protocol;
 - (2) No PHI will be removed from the covered entity; and
 - (3) The PHI accessed is necessary for preparation of the research protocol.
 - b. Confirmation by the investigator that he/she understands that:
 - (1) Only aggregate data may be recorded in the researcher's files, and these aggregate data may be used only for background information, to justify the research, or to show that there are adequate numbers of potential subjects to allow the investigator to meet enrollment targets or sample size requirements.
 - (2) Individually identifiable health information may not be recorded
 - (3) Data or information reviewed may not be used for contacting or recruiting subjects.
 - (4) Investigators must comply with all other access requirements set by the repository of interest.
 - (5) A Data Use Agreement (DUA)-Data Transfer Agreement (DTA) is required if the data are transferred from a data repository to the investigator. The data transferred from the data repository must be destroyed or returned to the data owner or administrator after the data are aggregated. *NOTE: If the investigator or the investigator's research staff directly accesses a data repository, the investigator must submit the HIPAA representation, described 1.a to the data repository owner or administrator with the additional statement that only aggregate data will be recorded for the preparatory to research activity and no individually identifiable information will be recorded.*

NOTE: Pilot studies are not considered to be "activities preparatory to research" and must be approved by the IRB when human subjects are involved.

2. Memos and any supporting documentation submitted to the IRB will be reviewed by the IRB Chair, Vice Chair, or designated member reviewer to determine if indeed the activity is preparatory to research.
3. A determination will be made in writing and documented on the checklist signed by the IRB Chair, Vice Chair or designee.

If you have any questions regarding reviews preparatory to research, please contact the Research Education and Policy Office at 412-360-2384.