VAPHS Human Subjects Research Guidance #013
Activities Preparatory to VA Research

Purpose: This guidance document has been created to outline the process and highlight considerations related to using data, including individually-identifiable health information, to prepare a research protocol prior to submission of the protocol for IRB approval.

Applicable to: All human subjects research studies conducted under the approval of the VAPHS Research and Development (R&D) Committee.

VAPHS Investigators must receive confirmation from the VAPHS IRB prior to beginning any preparatory to research activity.

1. The VAPHS Investigator must submit a memo to the VAPHS IRB Office to request a determination. Memos should only be submitted to the VAPHS IRB, even if the preparatory activity will be used for a protocol intended for submission to the VA Central IRB.

2. The memo should include:

    a. A brief description of the activities preparatory to research that are planned.

    b. Confirmation by the investigator that:
        (1) Access to Protected Health Information (PHI) is for the sole purpose of preparing a research protocol.
        (2) No PHI will be removed from the covered entity.
        (3) Access to PHI is necessary for the preparation of the research protocol.
        (4) VHA information (including de-identified data and individually-identifiable information) will not be disclosed to a non-VA person or entity (e.g. study sponsor) for activities preparatory to research.
        (5) Only aggregate data will be recorded. The aggregate data will only be used for background information, to justify the research, or to show that there are adequate numbers of potential subjects to meet enrollment requirements for the research study. Data and/or individually identifiable health will not be used to contact or recruit research subjects. Individually identifiable health information will not be recorded.
        (6) Data and/or individually identifiable health information accessed as part of an activity preparatory to research will not be used to contact or recruit research subjects. This is not a pilot study.

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

4. Activities preparatory to research only encompass the time to prepare the protocol and ends when the protocol is submitted to the IRB.

5. A Data Use Agreement (DUA)-Data Transfer Agreement (DTA) is required if the data are transferred from a data repository to the investigator in accordance with VHA Handbook 1200.12.

Frequently Asked Questions:

1. What does "Preparatory to Research" mean?

The term "preparatory to research" refers to a provision of the HIPAA Privacy Rule (45 CFR 164.512(i)(1)(ii)). This provision along with VHA policies allows a covered entity (i.e. VHA) to provide VA Investigators access to Protected Health Information (PHI) for the purpose of developing a research protocol.

Within VHA, "preparatory to research" refers to activities/reviews that are necessary for the development of a research protocol intended to contribute to generalizable knowledge.

Activities preparatory to research only encompass the time to prepare the protocol and ends when the protocol is submitted to the IRB.

2. Are Pilot Studies considered "preparatory to research"?

No. Pilot studies are not considered to be activities preparatory to research. Pilot studies are initial/preliminary investigations, usually on a small scale and exploratory in nature, that must be approved by the VAPHS R&D Committee and appropriate R&D subcommittees. Pilot studies are designed to refine data collection procedures and instruments, determine if a concept or theory has practical potential, or develop a better, more precise research design through validated scientific methodology.

3. What activities are permitted as preparatory to research, and what is prohibited?

VHA Directive 1200.05 and Handbook 1200.12 outline considerations and requirements that Investigators must follow when conducting activities preparatory to research. Key points are described below:

VAPHS Investigators are permitted to:

1. Review of PHI from data repositories or medical records without obtaining HIPAA authorization signed by the individual, or a waiver of HIPAA authorization by the IRB.

2. Access or be supplied with information from data repositories, including VA medical records, for activities that are preparatory to VA research.
    a. VHA Handbook 1200.12 notes that access to VA data repositories for reviews preparatory to research is granted only to VHA researchers. Non-VHA researchers may not access VHA data for reviews preparatory to research.

3. Investigator's must comply with all requirements set by the repository of interest.Review database output (computer file or printout) containing identifiable health information generated by the database owner, if the Investigator returns the database output to the database owner when aggregation of the information is finished (1200.05)

VAPHS Investigators are prohibited from:

1. Reviewing PHI based on their VHA employee/appointee access to PHI until the receiving a determination from the VAPHS IRB on the activities preparatory to research.
    a. The procedure and required information needed to request a VAPHS IRB determination are described in the above Section 1 of this guidance document.

2. Using data reviewed during preparatory to research activities to identify or recruit potential subjects, or to link to other data. Recruitment of subjects is not part of activities preparatory to research.

3. Recording any individually identifiable health information.

4. Removing PHI from the covered entity (i.e. VHA), or disclosing/sharing VHA information (including de-identified data and individually-identifiable information) to a non-VA person or entity (e.g. study sponsor) for preparatory to research activities.

If you have any questions regarding reviews preparatory to research, please contact:
VHAPTHIRB@va.gov

Document History

Number	Version	Effective Date	References	Actions/Comments
G-HSR #013	3.1	20AUG2019	VHA Directive 1200.05	VHA Handbook replaced by Directive (1200.05)
G-HSR #013	3.0	xxJAN2018	VHA Directive 1200.05 VHA Handbook 1200.12 VHA Handbook 1907.01 VHA Directive 1605.01 VAPHS RD Policy 017 VAPHS RD Policy 018 VAPHS RD Policy 020	Replaces VAPHS Guidance on Activities Preparatory to Research v2.1