



## NF/SGVHS Research Service Preparatory to Research

Under the "preparatory to research" provision of the HIPAA Privacy Rule, covered entities may use and disclose PHI to researchers to aid in planning for a study protocol or grant proposal. For example, to determine if the patient population of interest is available in sufficient numbers in the local community. More information is available here:

[https://privacyruleandresearch.nih.gov/clin\\_research.asp](https://privacyruleandresearch.nih.gov/clin_research.asp)

Preparatory to research activities (when conducted according to regulations) can proceed without the need for IRB approval or waiver of HIPAA authorization.

1. VA investigators must not arbitrarily review PHI based on their employee access to PHI. Rather, the Preparatory to Research activities must be documented in a designated file that is readily accessible for those required to audit such information (e.g., Compliance Officer or Privacy Officer). The activities must meet the following criteria:
  - a) Access to PHI is only to prepare a research protocol
  - b) No PHI will be removed from the covered entity (i.e., VHA)
  - c) Access to PHI is necessary for preparation of the research protocol
2. Non-VA researchers may not obtain VA information for preparatory to research activities (see VHA Directive 1605.01).
3. During the preparatory to research activities the VA investigator:
  - a) Must only record aggregate data. The aggregate data may only be used 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 requirements for the research study;
  - b) Must not record any individually identifiable health information; and
  - c) Must not use any individually identifiable information to recruit research subjects.

**NOTE:** Preparatory activities can include reviewing 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 finished aggregating the information.

4. Contacting potential research subjects and conducting pilot or feasibility studies are not considered activities preparatory to research.
5. Activities preparatory to research only encompass the time to prepare the protocol and ends when the protocol is submitted to the IRB. **(Per VHA DIRECTIVE 1200.05)**

### Other Official methods to obtain Preparatory Research Data (per VINCI Services)

- Data Access Request Tracker (DART) Preparatory to Research Request Process: [DART Preparatory to Research Request Process \(va.gov\)](#).
- Request feasibility count from VINCI. If you would like to move forward with this approach, please provide inclusion/exclusion criteria and email request to [vinci@va.gov](mailto:vinci@va.gov). For example, criteria may include ICD-9/ICD-10 codes, sex, age range, zip codes, etc.

