

# George Washington University Office of Human Research Researcher Responsibilities for Exempt Research/FAQ

## **What are the Principal Investigator (PI)'s Responsibilities for Exempt research?**

*They are the same as for any human subjects research!*

- To submit IRB application and receive registration *PRIOR* to starting research.
- PI and student oversight is required for all Exempt research and must continue through the life of the study.
- Exempt *does not* mean the research is Exempt from ethical considerations!
- Research may still subject to other applicable regulations or institutional policies (e.g., GW IRB, GWU, HIPAA, etc)

## **What is required if I want to make changes to my Exempt registered study?**

- This exempt determination only applies to the form/protocol, and as currently proposed.
- Minor changes made after the determination do not need to be reported to OHR.
- Changes that *increase* the risks to subjects require IRB/OHR review and approval PRIOR TO implementation. For example:
  - Addition of prisoners to research, research involving deception, drug/device studies (all FDA research)
  - Changes to methodology, data collection instruments, type of information being accessed or disclosed, populations, collection of some identifying information, etc.
- A change in PI requires a memo to OHR signed by the Department Chair. Changes in study personnel do not need reporting.

## **For all Exempt “Category 4” research: What if I now want to start collecting prospective data?**

- This category includes ONLY the collection of *existing data*. Changes to data collection methods require review by the OHR prior to the change, and may require submission of a Modification or upgrading to Expedited review.
- The following definitions are provided to ensure understanding of the types of data collection:

### ***Retrospective data collection:***

Information being viewed and analyzed for the study must *ALREADY EXIST* in the databases, charts, records, etc., being accessed for the research.

- No new data may be collected or added to the records for research under this category.
- Data must be recorded so that subjects cannot be identified, directly or through study codes.

### ***Prospective data collection:***

Data to be used in the research is currently, or *will* be collected on an ongoing basis.

- Implies all real time and future data collection.
- Collection of identifying information.
- Chart reviews beyond original IRB submission date.

## **What if I want to start collecting Protected Health Information (PHI; HIPAA protected) data?**

- HIPAA Research regulations may still apply if study involves review of records containing PHI.
- To maintain an Exempt determination, research must involve *only* the collection of retrospective (existing) PHI.
- Exempt research may qualify for a full HIPAA Waiver of Subject Authorization, if not practicable to conduct the research otherwise.
- Submit memo to change the Exempt determination to include a HIPAA waiver.
  - All research involving HIPAA is required to be approved by the Privacy Officer of the covered entity where the data collection will take place prior to the research taking place.

## **Is annual Review required for Exempt research?**

No. Exempt research does not require annual review, due to the low risk level. The study is “*Registered*” with this office, and *not approved*.

## **Do I need to close an Exempt study once it has been completed?**

No. Exempt research does not expire, and does not require closure with this office.