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.