Retrospective vs. Prospective

**Retrospective**
- Retrospective research may be reviewed as exempt or expedited.
- Generally does not obtain consent (waiver).
- May request a full or partial HIPAA waiver.
- Information is already collected ("on the shelf") prior to study submission.

**Prospective**
- Prospective research may only be reviewed as expedited.
- May request consent or waiver of consent.
- May request full HIPAA authorization or waiver of HIPAA (full or partial).
- Information has not yet been documented or collected at time of study submission.
When can a Retrospective Study be Exempt?

**Exempt**

- Information recorded by the researcher must not identify the subject. Individually identifiable data elements may not be recorded.
- Retrospective projects will not qualify for exempt status if partial identifiers are needed or if a linking list is desired.
- This must be stated in the protocol, synopsis application, and HIPAA waiver, if applicable.
- If a project does not qualify for exempt status, then all federal research regulations will apply to the project. In that case, informed consent of the participant is the default requirement.

**Expedited**

Chart reviews may be reviewed under the expedited procedures if:

- Researcher will be maintaining identifiable information
- A code link is created
- Both prospective and retrospective data are accessed
When is Retrospective Research No Longer Retrospective?

- The PI wishes to include data that did not exist at the time of the initial IRB submission.
  - If the study was initially determined to be Exempt, you must submit a modification and it will be upgraded to Expedited;
  - If the study is already considered Expedited, you must submit a modification indicating you are now collecting prospective data.
Example of When Research is No Longer Retrospective

You submit an IRB application on 3/18/15 proposing to conduct a retrospective chart review. That means all data you will be accessing was collected prior to 3/18/15. At the next continuing review on 3/17/16, you decide you want to look at records that have been collected over the last year from 3/18/15 to 3/17/16. This is no longer a retrospective chart review since all the data was not in existence at the time of INITIAL IRB submission on 3/18/15. You will need to submit a modification stating you are conducting a retrospective and prospective chart review and if the study was initially reviewed as exempt, it will now need to be reviewed as expedited.