

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.