

Retrospective Chart Review and Specimen Collection

Retrospective chart review or analysis of existing specimens involves the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. Existing means existing before the research is submitted to the IRB for review. The private information or specimens must be individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information) to constitute human subjects research.

Obtaining identifiable private information or identifiable specimens includes, but is not limited to:

1. Using, studying or analyzing for research purposes identifiable private information or identifiable specimens that have been provide to investigators from any source; and
2. Using, studying, or analyzing for research purposes identifiable private information or identifiable specimens that were already in the possession of another investigator

If an investigator is conducting human research activities that involves a retrospective chart review or the analysis of existing specimens, then a Use of Existing Records and/or Specimens submission must be submitted through the electronic Protocol Administration System (ePAS).

Initial Submission or Amendment Review Process

1. After the investigator gains access to the ePAS system, please select "My Home" from the upper right corner.
2. Select either "New IRB Application" or "New Amendment" from the left margin and answer the questions presented to you. For new submissions, please ensure that "Use of Existing Records and/or Specimens" on the Research Classification page (4th screen) is selected.
3. Select "Finish" at the end of the submission.
4. Select "Submit Study" from the "My Activities" list in the left margin of the screen.

You will receive an email notification from ePAS with comments/questions or your submission will be forwarded to an IRB member for review within 2 weeks of submission.

Continuing Review Process

1. After the investigator gains access to the ePAS system, please select "My Home" from the upper right corner.
2. Select "New Continuing Review" from the "My Activities" list in the left margin and answer the questions presented to you.
3. Select "Finish" at the end of the submission.
4. Select "Submit Study" from the "My Activities" list in the left margin of the screen.

You will receive an email notification from ePAS with comments/questions or your submission will be forwarded to an IRB member for review no later than one month prior to expiration.

If an investigator believes his/her activity is not human subjects research, then a "Not Human Subjects Determination" submission must be submitted through the electronic Protocol Administration System (ePAS).