What Documents Do I need to Submit for a Review of Data/Specimens?

Question 1: are the data, records, documents, pathological specimens, or diagnostic tests, to be reviewed already available (*existing) before the research proposal is submitted to the IRB?

Will the information be recorded by the investigator in such a manner that subjects can be identified directly or through identifiers (codes) linked to the subjects?

Yes

Your project is a Retrospective review study whose subjects can be identified.

Submit:
* An IRIS application to the IRB requesting review under Expedited Category
* Check off expedited Category 5
* An application checklist
* A Chart Review Protocol
* A data collection form
* A HIPAA authorization Form
* You may need to submit an Informed Consent when a physician-investigator wishes to review the charts of his/her patients since he/she will have the chance to ask the patients for their consent during their clinic visit with him/her.

On the other hand if the researcher is not the patient’s treating physician and you can justify a waiver of consent submit a Request for waiver or alteration to requirements of consent.

No

Your project is a Prospective review study whose subjects cannot be identified.

Submit:
* An IRIS application to the IRB requesting review under Expedited Category
* Check off expedited review category 5
* An application checklist
* A Chart Review Protocol
* A data collection form
* A Certification of de-Identification Form

Yes (Identifiers/codes are retained)

Your project is a Retrospective review study whose subjects can be identified.

Submit:
* An IRIS application to the IRB requesting Exempt review
* Check off exempt category 4 in the IRIS application.
* Application checklist
* A Chart Review Protocol
* A data collection form
* A Certification of De-Identification Form.

No (Identifiers/codes are not retained)

Your project is a Prospective review study whose subjects cannot be identified.

Submit:
* An IRIS application to the IRB requesting review under Expedited Category
* Check off expedited review category 5
* An application checklist
* A Chart Review Protocol
* A data collection form
* A HIPAA authorization Form
* You may need to submit an Informed Consent when a physician-investigator wishes to review the charts of his/her patients since he/she will have the chance to ask the patients’ for their consent during their clinic visit with him/her. On the other hand if the researcher is not the patient’s treating physician and you can justify the waiver of consent submit a Request for waiver or alteration to requirements of consent.

*existing: information that is existing at the time the project is submitted to the IRB for initial review.