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

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

(Identifiers/codes are retained.)

Your project is a *Prospective* review study whose subjects can be identified.
Submit:
* IRC Review of Data, Documents, Medical Charts, Records, Pathological or Diagnostic Specimens Form#2
* A data collection form
* HIPAA Authorization or waiver, as applicable.
* 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

(Identifiers/codes are not retained.)

Your project is a *Retrospective* review study whose subjects cannot be identified.
Submit:
* IRC Exemption Form
* Check off exempt category 4
* A data collection form
* A Certification of De-Identification Form.

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

Yes

(Identifiers/codes are retained.)

Start Here

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?

No

(Identifiers/codes are not retained.)

Your project is a *Retrospective* review study whose subjects cannot be identified.
Submit:
* IRC Exemption Form
* Check off exempt category 4
* A data collection form
* A Certification of De-Identification Form.

Your project is a *Prospective* review study whose subjects cannot be identified.
Submit:
* IRC Review of Data, Documents, Medical Charts, Records, Pathological or Diagnostic Specimens Form#2
* A data collection form
* A certification of de-identification form
* You may need to submit an Informed Consent when 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.
HIPAA Authorization or waiver, as applicable.

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