Institutional Review Board
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RETROSPECTIVE AND PROSPECTIVE CHART REVIEW GUIDANCE

I. Definitions

Retrospective Chart Review- evaluates patient data that is existing at the time the protocol is submitted to the IRB for initial approval. This type of chart review uses information that has usually been collected for reasons other than research.

Prospective Chart Review- evaluates patient data that DOES NOT YET EXIST at the time the protocol is submitted to the IRB for initial review.

Combination- Some studies may involve a combination of both retrospective and prospective chart reviews. You should work closely with the IRB to determine the requirements for both portions of the study and develop a plan to stay in compliance if requirements are different for each portion.

II. Waiver of Consent for Retrospective and Prospective Data Collection/Chart Review

Most retrospective and prospective chart reviews quality for expedited review according to 45 CFR 46.110 category 5 if:

a. the research involves no more than minimal risk AND
b. the research involves materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes.

The expedited review procedure may NOT be used for studies in which identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal risk.

III. Consent and Data Collection

A Waiver of Informed Consent is frequently requested for both retrospective and prospective data collection. In order for the IRB to approve a Waiver of Consent, the following criteria must be met:

a. research is no more than minimal risk;

b. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
c. the research could not PRACTICABLY be carried out without a waiver; AND
d. when appropriate, the subjects will be provided with additional information after participation.

Studies that meet the Criteria for Waiver of Consent, also meet the Waiver of HIPAA Authorization.

IV: Study Design Elements to Consider

For Prospective studies to meet criteria for a Waiver of Consent, "not practicable" doesn't mean "inconvenient". If a study is planning on collecting data or specimens that are already being collected during clinical care for an ongoing prospective period, consider the following 2 scenarios-

A- Study involves a large number of patients, seen at multiple locations, with multiple diagnoses.....consent is likely not practicable.

B- Study involves a single specialty clinic on a smaller set of patients who are regularly seen on a routine basis.....consent could be seen as practicable. This scenario, however, would likely meet criteria for a Waiver of Documentation of Consent, but it *is* feasible that the patients and families could be consented.

Tips for Writing a Protocol for Retrospective and/or Prospective Data Collection

- Be sure to explain the study population. Is the diagnosis rare? Seen by one or many providers? Is there a place/time where patients could be identified and consented?
- Explain the number of participants. If the number is small, could you conceivably contact and consent those patients?
- What data/documents/specimens are you collecting? Are they already existing at time of IRB submission (thus completely retrospective)? Or are they (Retro) or WILL they (Prospective) be collected as part of routine clinical care?
- For Prospective data collection- Will the data not be available or the inclusion criteria assessed until after patients have already been seen/gone home? If yes, then the "not practicable" criteria is typically met, unless the number of participants is very low.
- Is your study designed to assess morbidity/outcomes and not having access to ALL the data would affect statistical outcomes? This could also support the request for a Waiver of Consent.
- Use specific dates, especially end dates with retrospective reviews.
- If able, use end dates even in prospective data collection studies (Jan. 2001- Jan. 2018), if known.
- Estimate the number of subjects you anticipate to enroll. If you need to include more charts, you will have to submit a Modification to the Protocol PRIOR to reviewing the charts, so aim high.