What to include with a Chart Review Proposal

Chart reviews are a common method of gathering information on a specific medical condition or set of patient characteristics. Although chart reviews do not involve direct interaction with subjects, chart reviews fall under IRB review because they involve obtaining private information about human subjects. Federal regulations define a human subject as “a living individual about whom an investigator … conducting research (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.” [45CFR46.102(e)(1)]

When submitting a chart review proposal to the IRB, a protocol narrative is needed. This narrative may be brief, but should include a defined purpose for the data collection. The narrative must also include the beginning and end dates of collection. For example, if you plan to review the medical record of every asthma patient seen in clinic in 2018, you should state exactly what information you are obtaining about the patients, explain the data you hope to find, and specify the beginning and end dates of data collection as “January 1, 2018 through December 31, 2018.”

Chart reviews may be prospective or retrospective, or a combination of the two. To qualify as retrospective, all information must be collected from a time period prior to the date the study is approved. Thus, if you expect approval on March 17, 2019, the endpoint of data collection must be on or before March 16, 2019. Investigators may submit a request for waiver of consent for the retrospective review of medical records. Note that the decision to grant a waiver of consent is the Committee’s; in certain cases, the Committee may require that an attempt be made to obtain written consent from potential subjects, even if the information was previously collected in the chart and no prospective collection is anticipated.

In general, prospective collection of information from medical records will require written consent. Ethical guidelines indicate that if it is possible to obtain consent from potential subjects, the attempt should be made to do so. The IRB Committee will usually require that a written consent form be prepared to prospectively collect data from medical records.

The Committee is also mindful of “protocol creep.” In other words, amending the protocol in the future to include information that would be retrospective then but is prospective now is not generally allowed. For example, your original protocol is approved in March 2016 to examine information from March 2015 to February 2016. Eventually, you will also want to examine the charts from March 2016 to February 2018. Rather than submit an amendment in a year, if you know now that you will want the 2016-2018 data, this request should be included in your current proposal.

Continuing reviews: Remember, since you are obtaining private information, you are considered to be studying human subjects. Consequently, when the IRB asks for the number of subjects you have enrolled in the past year, they are asking for the number of charts of individual subjects that you have studied.