DETERMINING FREQUENCY OF CONTINUING REVIEW

4/3/2021

When a protocol is approved during initial or continuing review, either with no modifications or with minor modifications to secure approval, the decision includes the period for which IRB approval is to be granted. This approval period must be for one year or less, if the study is subject to FDA regulation, or if the study involves more than minimal risk; and the approval period must be appropriate to the degree of risk (45 CFR 46.109, 21 CFR 56.108 and 21 CFR 56.109).

The duration for which IRB approval is granted is based on the level of risk to subjects and, if applicable, the analysis of this risk compared to the risk of alternative care, or standard care if such a standard exists. The IRB performs this risk assessment as part of the review of each protocol, either by the reviewer using the expedited procedure for protocols qualifying for such a review, or at a convened meeting.

When the risk is great, particularly in relation to the risk associated with receiving standard care, the IRB will consider requiring that continuing review be conducted in less than one year, either determined by the time interval from approval or the number of subjects entered on the study. Some examples of protocols that may be considered for review more frequently than annually include:

- studies involving planned emergency research (21 CFR 50.24);
- phase I studies of a new drug or biologic;
- studies involving a Category A significant risk device;
- studies in which a healthy volunteer may undergo anesthesia or a medical procedure involving sedation, but with no direct health benefits;
- studies in which individuals with impaired decision making capacity will be enrolled;
- studies for which there is little external oversight or data safety monitoring; or
- studies involving gene transfer or xeno-transplantation.

The period of IRB approval, whether annually or more frequently than annually, will be documented in the written minutes of the convened meeting. The approval notification sent to the investigator will also specify the time/date determined by the IRB for when the protocol's IRB approval will expire.

Previous Version Dates: 3/13/2007, 3/2/2016