

BACKGROUND

The original regulatory system applied to grants. Each investigator was required to seek approval from his or her *institutional* IRB. Thus, each IRB reviewed the protocol for one of its own investigators.

The 1981 FDA regulations required IRB review for clinical investigations. While many clinical investigations were single site, an increasing number were not. Central IRBs work with both sponsors and investigators to accomplish the same goal as internal IRBs: protection of human subjects.

Two Possible Responses:

There are two usual relationships. The fee schedule for each is very different.

a) Preferred relationship:

The sponsor may elect to work directly with IRC to conduct review of one or all of the studies from that sponsor and for one or all of the investigators on the study. The sponsor is considered to be IRC's "client." Review of the study protocol (design, etc.) is negotiated between the IRB and the sponsor's representative. When approval is granted it is with the condition that it cannot be initiated at any individual site without separate review of the principal investigator. Likewise, modifications are first presented to the IRB.

An IRB is expected to have a direct relationship with investigators. Each investigator is expected to submit to the IRB an application to participate on the study.

In this scenario, all sites may be set to expire at the time the master approval expires which may be much less than a year. Expiration of all sites is better for the sponsor and the IRB; it may be difficult for a late arriving investigator.

b) Relationship without direct sponsor involvement:

Adhering more closely to the traditional model, some sponsors continue to keep at arm's length from the IRB. These sponsors insist that each investigator submit the entire study and investigator packet individually.

The major problem with this model is that the IRB must negotiate each concern and requested change individually with each investigator who, likely, will each refer the question to the sponsor. Although this is traditionally done when there are multiple IRBs for multiple investigators, when working with a central IRB it is very redundant, time consuming and confusing in addition to being costly.

NON REVIEWABLE SITES - LOCAL IRB

IRC has a very strict policy about review of sites that have their own internal IRB. IRC will not ever knowingly approve an investigator for work at a facility where another IRB has prior jurisdiction without agreement from that IRB. Put another way, our IRB will not step knowingly into another IRB's jurisdiction without permission. Waiver and certification can be on our separate form or on the investigator application form. The form assures us, in writing, whether or not there is an IRB and, if so, whether it agrees to defer to our IRB.

