GUI 327: Organizational Statement on Calculation of Approval Periods, With Examples

Revision Dates: 3/17/07

STATEMENT

"Approval period" refers to the span of time during which the IRB approval of a protocol reviewed through Expedited or Convened procedures is valid. All approvals take effect on the "approval date" and are no longer effective on the "expiration date."

Most, but not all, IRB approvals are effective "for one year." For example, if the IRB Approval Form indicates an approval date of 12-12-06 and an annual approval period, the protocol is approved on 12-12-06 and is no longer approved on 12-12-07.

The approval date is always the date on which the IRB determined the protocol to be approved, with or without requiring modifications. For example, the convened IRB reviews a protocol on 03-03-03, determines it to be Approved With Limited Modifications, and assigns a requirement for annual continuing review. Within 2-3 days, the investigator receives the determination letter, which lists the minor modifications required for approval. One week later, the investigator has satisfactorily completed the modifications and received the IRB Approval Form. The approval of this protocol is valid as of 03-03-03 and is no longer valid on 03-03-04.

When the approval period is less than one year (e.g., quarterly, bi-annually), the approval date and expiration date follow this same method of calculation. For example, if the IRB Approval Form indicates an approval date of 02-02-02 and a quarterly approval period, the protocol is approved on 02-02-02 and is no longer approved on 05-02-02.