



UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

FACT SHEET

Duration of IRB Approval

Institutional Review Boards may grant approval for each study for a definite period of time, however not in excess of one year (365 days).

Institutional Review Boards are also responsible for continuing review of ongoing research to ensure that the rights and welfare of human subjects are protected. The IRB is responsible for conducting continuing review of research at intervals appropriate to the degree of risk, but not less than once per year [(21 CFR 56.108(a)(1) and 56.109(e)].

The continuation of research after expiration of IRB approval is a violation of the regulations [21 CFR 56.103(a)]. If the IRB has not reviewed and approved a research study by the study's current expiration date, i.e., IRB approval has expired, research activities should stop. No new subjects may be enrolled in the study.

If the investigator is actively pursuing renewal with the IRB and the IRB believes that an over-riding safety concern (i.e., stopping the study drug may place the subject at risk) or ethical issue is involved, the IRB must be notified and may allow for some flexibility for currently enrolled subjects for the brief time required to complete the review process.