

Continuing Review and Expiration of Research

OHSU Policy

- A. The IRB will conduct continuing review of research at intervals appropriate to the degree of risk, but not less often than once a year. The Board will determine the appropriate review interval.
- B. Continuing review of research will be substantive and meaningful. Each continuing review will ensure that the 45 CFR 46.111 criteria for approval of research are still satisfied in order to re-approve. The IRB will also consider, at a minimum, unexpected results of ongoing research, unanticipated problems, the effects of the research project itself, regulatory changes and new knowledge gained.
- C. Continuing review will be conducted by the convened IRB, with recorded vote on each study, unless the research is otherwise appropriate for expedited review.
- D. No human subject research may be conducted without prior approval from the IRB. A study that lapses past the review date is considered to have an expired IRB approval and therefore all such research must stop. Subjects may not be enrolled and no research information/data may be collected from currently enrolled subjects until the approval is reinstated. There is no provision for any "grace" or "extended approval" period.
- E. If a study has expired, the PI may appeal to the IRB for continued subject contact during the lapse. Research procedures may only continue if, upon appeal, the IRB finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions.
- F. All information/data collected and subjects enrolled during a lapse period and without special permission from the IRB are considered to be the result of unapproved research activities.
- G. The OHSU Research Integrity Office (ORIO) will issue continuing review reminders, however the Principal investigator is responsible for ensuring that the IRB receives the continuing review application with sufficient time for review. Late submissions cannot be guaranteed timely review.

Effective: 2/26/2008