UCI Office of Research

Changes Ahead in 2018:

Eliminate Continuing Review for Minimal Risk Research

The federal regulations for the ethical conduct of human-subjects research have been updated. Most of the new requirements, many of which increase flexibility and reduce investigator burden, are anticipated to take effect on January 19, 2018. Changes to the Continuing Review Process are described below.

What is the change to the Continuing Review Process?

- Under the current regulations, continuing review of ongoing research is required at least annually for non-exempt research. Under the revised regulations, continuing review will no longer be required for minimal risk research (i.e., research approved via an expedited review).

When does this change take effect?

- January 19, 2018

What types of research does this regulatory change effect?

- Continuing review is eliminated for studies that undergo an expedited review (minimal risk research), *unless* the IRB reviewer explicitly justifies why continuing review would enhance protection of research participants.

- For studies initially reviewed by a convened IRB, once interventional procedures are completed and only specific procedures remain, continuing review is not required (*unless* mandated by the IRB).

  These specific procedures include:

  - Research that has progressed to the point that it involves only one or both of the following as described in the IRB-approved study:

    - Data analysis, including analysis of identifiable private information or identifiable biospecimen

    - Accessing follow-up clinical data from procedures that participants would undergo as part of clinical care

- Continuing review is not required for Exempt research reviewed under a Limited IRB review.

- NOTE: Investigators are still required to secure IRB approval for modifications, and to report unanticipated problems and noncompliance.

Three-year Abbreviated Continuing Review:

- Exempt and Expedited protocols registered/approved after January 19th will require an abbreviated Continuing Review application every three years. This brief check-in will assure that the Office of Research is following the federal records retention policy of maintaining protocol files for at least 3 years after completion of the research. UC policy for records retention is 10 years after completion.

- Exempt and Expedited protocols registered/approved before January 19, 2018 will be grandfathered into the revised regulations at the next continuing review that takes place after January 19th.

- Investigators will continue to receive email reminders to complete the abbreviated Continuing Application.