Extended Approval Policy for Human Subjects Research

Background
Current federal regulations for non-exempt research involving humans require that studies undergo continuing review by the Institutional Review Board (IRB) at least annually, depending on the degree of risk to participants (per 45 CFR 46.109(e) and 21 CFR 56.109(f)). Some research, however, may be granted a longer approval period in accordance with the scope of Iowa State University’s Federalwide Assurance. This Extended Approval Policy outlines the conditions under which research involving humans at ISU may be granted a two-year approval.

Policy
Certain types of non-exempt research involving humans at ISU will be granted a two-year approval period. The longer approval period will eliminate the need for principal investigators (PIs) to submit continuing review applications on an annual basis. To be eligible for two-year approval, the research must present no more than minimal risk to human subjects (as determined by the ISU IRB via convened or expedited review), and it must not include any of the following:

- Federal funding, including federal training and program project grants and federal no-cost extensions
- FDA regulated components (i.e., food products or additives, dietary supplements, medical devices [including activity monitors], drugs, vaccines, biologics)
- Contractual obligations or restrictions that preclude eligibility for two-year approval (i.e., a non-federal sponsor or funder requires annual IRB review)
- Prisoners as subjects
- An NIH-issued Certificate of Confidentiality (or plans to seek a Certificate of Confidentiality)
- Any findings of serious or continuing noncompliance related to the study or the principal investigator within the past two years
- Any incidents that meet the definition of an unanticipated problem involving risks to subjects or others within the past two years (Definitions can be found in the IRB document entitled “Reporting Adverse Events and Unanticipated Problems” available at the IRB website.)

The IRB (including the IRB Chairs/Co-Chairs), at its discretion, reserves the right to make exceptions to this policy and require more frequent review.

Submission Requirements
Research projects eligible for extended approval will be reviewed in accordance with 45 CFR 46.110 and other regulatory or ISU policy requirements, except that approval will be valid for two (2) years. Principal investigators are responsible for submitting materials for continuing review in sufficient time to allow for IRB review to occur (generally, three to four weeks prior to expiration); courtesy reminders will be sent prior the continuing review date.

1 This policy does not apply to exempt research, which has an approval period for the life of the project.
During the two-year approval period, principal investigators are also responsible for

- reporting to the IRB any changes in funding or sponsorship that involve federal agencies; and
- obtaining approval for any change(s) to the IRB-approved protocol, *prior to implementation of the change(s)*, unless the change is necessary to eliminate apparent immediate hazards to participants.

**Monitoring**

(1) Annually, a notice will be sent to PIs asking whether any of the following have occurred:

- Changes in study procedures not previously reported to and approved by the IRB
- Serious adverse events or unanticipated problems not previously reported to the IRB
- The addition of federal funding

If none of the aforementioned changes have occurred, no response or submission to the IRB is required and the study can continue per the IRB-approved protocol. If one or more of the changes have occurred, PIs must immediately request approval of modifications or report the adverse event or unanticipated problem.

(2) A random sample of studies granted a two-year approval will be reviewed periodically via Post Approval Monitoring to confirm that the funding status has not changed, the level of risk has not increased to more than minimal, and that any changes made to the protocol have been approved by the IRB prior to implementation.