INSTITUTIONAL REVIEW BOARD
HUMAN SUBJECTS PROTECTION OFFICE

PENN STATE COLLEGE OF MEDICINE
PENN STATE MILTON S. HERSHEY MEDICAL CENTER

Guidance for Modifying Exempt Research

Once human participant research is determined to be exempt*, the exempt determination is valid for the life of the research unless a change is made that requires an additional review. There are only a few types of changes that require additional review.

What changes need to be submitted for review?

1. Changes that affect the determination of exemption may require a new eSubmission application to be submitted so that an IRB review can occur. When these types of changes are made to research that was previously determined to be exempt, researchers must consult with an IRB Coordinator in the Human Subjects Protection Office to determine if a new eSubmission is needed and how it should be submitted.

   Changes that ***affect the determination of exemption*** include **but are not limited to:**
   a. Addition of vulnerable populations, such as prisoners, children, adults with decisional impairment, etc.;
   b. New knowledge that increases the risk level;
   c. Survey or interview procedures that involve children that do not fall under educational research and evaluation (exempt category 1);
   d. Observational research of children that involves participation by the researcher in the activity being observed;
   e. Addition of an element that is subject to FDA regulations;
   f. Change in the way identifiers are recorded (directly or indirectly) so that subjects can be identified; or
   g. Changes to research activities that may pose more than minimal risk* to the participant.

2. In addition, the following changes that ***do not affect the determination of exemption*** should be reported to the Human Subjects Protection Office through a modification to the exempt application. (For eSubmission studies use the IRB eSubmission tool to submit the modification. For paper-based studies, submit the Modification Request Form available on the IRB website, www.pennstatehershey.org/irb.)
   a. Changes to the funding source;
   b. Changes to conflict of interest;
   c. Changes in the principal investigator or project coordinator; or
   d. Addition of medical students, residents, graduate students or fellows who will be involved in the project as part of their education. **Please note:** Other changes in research personnel do not need to be submitted to the Human Subjects Protection Office.

* Federal regulations state that if research activities meet specific criteria, the activities may be determined to be exempt from initial and continuing review by the Institutional Review Board (IRB). The exemption determinations are made by designated IRB members within the Human Subjects Protection Office.