Investigators are responsible for conducting their research in accordance with the Institutional Review Board (IRB) approved research study, university policies and procedures, and applicable federal and state regulations. Changes to the IRB approved research study (e.g., protocol, surveys, case report form(s), informed consent form(s), recruitment materials, questionnaires), whether planned or unplanned, are governed by federal regulations and IRB requirements. IRB requirements, consistent with federal regulations 45 CFR 46.104 (b)(4)(iii) and 21 CFR 56.108 (a)(4), requires that all changes to previously approved non-exempt research, no matter how minor, must be reviewed and approved by the IRB before being implemented. See the Human Research Protection Program (HRPP) Manual 8-1 “Exemptions” for policies and procedures regarding changes to exempt research.

When an immediate change in either a therapeutic or non-therapeutic research study is necessary to eliminate a hazard to subjects, the proposed change does not need to be reviewed by the Institutional Review Board (IRB) prior to its implementation. In such situations, however, investigators must report the change in protocol to the IRB immediately thereafter. Within the report, the investigator should document why the change was necessary to ensure the subject’s welfare. The IRB chair, in consultation with others as appropriate (e.g., IRB, HRPP director), will review the investigator’s response to determine if the change was consistent with ensuring the subject’s continued welfare.