

Protocol Exceptions

Version: 1.0
Date: 10/15/2008
Approved by: Interim Vice Chancellor for Research
AAHRPP REF#: 182
AAHRPP Elements: 1.3.I

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POLICY:

- I. A protocol exception is type of planned change to the research. Unlike an amendment, a protocol exception involves a single subject or, less commonly, a small group of subjects and is not a permanent revision to the research protocol. Similar to an amendment, IRB approval of a protocol exception must occur prior to its implementation. If the research involves an investigational agent (drug, device, or biologic), prior approval by the sponsor is also required. Additionally, when the research involves an investigational device and the changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of the subjects, FDA pre-approval is required [21 CFR 812.150 (4)].
- II. The PI is responsible for submitting any protocol exceptions prior to initiation of the change to the IRB. Failure to submit all protocol exceptions represents non-compliance with the federal regulations, UIC policies and determinations of the UIC IRB. (Refer to UIC HSPP policies, *Unanticipated Problems and Other Events Requiring Prompt Reporting, Handling Complaints and Allegations of Potential Non-Compliance with Human Subject Protection Regulations, and Reporting of Unanticipated Problems, Suspensions, Terminations, and Non-Compliance.*)
- III. When a study is deemed lapsed in IRB approval, the investigator must submit a request to the IRB to continue research interventions or interactions for some or all subjects when it is in the best interest of the subjects to continue. The investigator requests a protocol exception for the continuation of certain aspects of the research on the UIC OPRS *Protocol Exception* Form. An investigator must clearly distinguish and explain what research activities from which he or she will refrain as part of the lapse and what research activities require continuation. The investigator must also explain the underlying reasons for which the protocol exception is requested for each activity and each subject where an over-riding safety concern or ethical issue indicates that it is in the best interests of the individual to continue participating.

PROCEDURE:

- I. Investigator requests for a protocol exception are submitted to the OPRS/IRB via the UIC OPRS *Protocol Exception* Form. If applicable, documentation of sponsor and FDA approval of the protocol exception is submitted to the UIC IRB along with the exception request. Additional documents may include subject information sheet or script of information to be conveyed to subject.

- II. The Assistant Director for the relevant IRB reviews the form for completeness, contacts the investigator if necessary for additional information and, in consult with the IRB Chair, assesses whether the request for exception requires review by the convened IRB (more than minor change, risk level of change greater than minimal) or may be reviewed by the IRB chair or designee (minor change, risk level of change no greater than minimal).

- III. Review of exceptions that represent minor changes and risks levels of no greater than minimal.
 - A. The chair (or IRB member designated by the chair) is provided with the protocol exception form, any supporting documentation and the protocol file, including the currently approved protocol, currently approved consent form, investigator brochure and previous reports of unanticipated problems/ events, protocol deviations and exceptions.
 - B. The chair (or IRB member designated by the chair) evaluates the impact of the protocol exception on the scientific soundness of the research, potential benefits, and the rights, safety, or welfare of the subjects.
 - C. The pre-review by the AD and review by the Chair or designee are documented using the *Protocol Exception to Previously Approved Research OPRS/IRB Review Guide*.
 - D. Protocol exceptions are handled in accordance to the following UIC HSPP policies: *Unanticipated Problems and Other Events Requiring Prompt Reporting, Handling Complaints and Allegations of Potential Non-Compliance with Human Subject Protection Regulations, and Reporting of Unanticipated Problems, Suspensions, Terminations, and Non-Compliance*.

- IV. Review of exceptions that represent more than minor changes or risks levels of greater than minimal.
 - A. The request is reviewed at a convened IRB meeting, with two primary reviewers assigned to conduct a thorough review and present the problem to the full board.
 - B. The first and second reviewers and board members are provided with the protocol exception form, any supporting documentation and the protocol file, including the currently approved protocol, currently approved consent form, investigator brochure and previous reports of unanticipated problems, protocol deviations and exceptions.
 - C. The primary reviewers document their evaluation using the *Protocol Exception to Previously Approved Research OPRS/IRB Review Guide*.
 - D. The determination is added to the protocol file and communicated to the investigator. Copies of the communication are provided to academic Department Head, JBVAMC R&D Committee (if JBVAMC is a performance site), and NU OPRS (if NU is a performance site).
 - E. Protocol exceptions are handled in accordance to the following UIC HSPP policies: *Unanticipated Problems and Other Events Requiring Prompt Reporting, Handling Complaints and Allegations of Potential Non-Compliance*

with Human Subject Protection Regulations, and Reporting of Unanticipated Problems, Suspensions, Terminations, and Non-Compliance.

REFERENCES:

[21 CFR 812.150 \(4\)](#)