

Required Reporting of Unanticipated Problems and Protocol Deviations

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Policy Statement

Consistent with federal regulations, UIW IRB requires prompt reporting of unanticipated problems t

7. protocol deviation in that changes were made to the protocol without prior IRB review in order to eliminate apparent immediate hazards to participants;
8. protocol deviation in that accidental or unintentional changes were made to the IRB-approved protocol that involve harm to participants or an increased risk of harm;
9. any complaint by a participant that indicates an unanticipated risk that cannot be resolved by the research team; and/or
10. enrollment of incarcerated participants or other designated vulnerable populations in a protocol that is not approved specifically for their enrollment.

The above must be reported regardless of whether they occur during the study, after study completion, or after participant withdrawal or completion.

B. Process for Reporting

1. The principle investigator is responsible for ensuring completion of the online *Unanticipated Problem/Protocol Deviation Form* and a comprehensive and accurate accounting of the event to the IRB office. Federal regulations state that all unanticipated problems are to be promptly reported to the IRB. The window for promptly reporting unanticipated problems to the UIW IRB is 5 working days (Monday-Friday).

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