Human Research Protection Program

MEMORANDUM

DATE: December 16, 2019

TO: Researchers Utilizing UT Southwestern Institutional Review Boards

FROM: Rhonda Oilepo, MS, CIP, CHRC
Director, Human Research Protection Program
UT Southwestern Medical Center

RE: HRPP Policy on Prompt Reporting of Unanticipated Problems to the IRB

Federal regulations require institutions to establish written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and applicable regulatory agencies, of any unanticipated problems involving risk to human participants or others.

> *This letter addresses only portions of the procedure pertaining to unanticipated problems that require Prompt Reporting to the UTSW IRB. Reporting timeframes and definitions can be found in our HRPP Policy and Procedure Manual as well as on the HRPP Reportable Event Website. Reference: 45 CFR 46.108(4)(i), 21 CFR 56.108(b)(1).*

Events or problems that do not meet criteria for prompt reporting are recognized by OHRP and the FDA to not yield information useful to IRBs - often lacking context and detail - often incomplete and unanalyzed - and as such inhibit an IRB's ability to assure the protection of human subjects (e.g., Individual IND Safety Reports unanalyzed by multicenter sponsors/safety committees). The PI should analyze and track all information received from the Sponsor and/or local events to determine whether prompt reporting to the IRB is required. The OIRB, IRB Chair or designated reviewer will return a tracking log or report to the investigator without being reviewed by the IRB if that information does not meet criteria for prompt reporting.

In order to meet criteria for prompt reporting, before any other consideration, events or problems must first be analyzed by the local investigator considering the need for substantive action (implementing actions if necessary to eliminate immediate hazard). The first criteria in this analysis must be whether the event or problem is unanticipated (e.g., not in protocol documentation / not within the frequency and severity expected for population's underlying condition). See the *Reportable Events Guidance* for remaining criteria and further clarification.

If events are anticipated, reporting is still required but should be in the form of a summary as part of the next progress report sent to the IRB for continuing review.

If you have any questions, please feel free to contact our office at (214) 648-3060.

Thank you for your assistance in protecting human research participants at UT Southwestern Medical Center.