



MEMORANDUM

TO: UT HSC Academic Departments
University of Texas Health Sciences Center at San Antonio
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FROM: Joseph O. Schmelz, Ph.D., CIP
Director, Institutional Review Board
University of Texas Health Science Center at San Antonio

SUBJECT: IRB Policy on Prompt Reporting of Unanticipated Problems to the IRB

Federal regulations require IRBs 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.

UTHSCSA IRB Policy can be accessed at: <http://research.uthscsa.edu/irb/policy/UPIRSO Policy and Procedure.doc> Reference: 45 CFR 46.103(b)(5), 21 CFR 56.108(b)(1). (Sponsor / other institution's additional policies may apply)

This letter addresses only portions of the policy pertaining to unanticipated problems and unanticipated adverse device effects that require **Prompt Reporting** to the UT HSC IRB. [Reporting timeframes](#) are delineated in our [policy](#). Definitions of each individual [criterion](#) for prompt reporting are defined in our [Glossary](#).

Events or problems that do not meet criteria 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 IRB Chair or designated reviewer will return a report to the investigator without being reviewed by the IRB if that report does not meet criteria.

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., protocol documentation / not within the frequency and severity expected for population's underlying condition (only protocol documentation for UADE's)). See the [policy](#) for remaining criteria and further clarification.

If anticipated, reporting is still required but may 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 (210) 567-2357. Thank you for your assistance in protecting human research participants at UTHSCSA.