UNIVERSITY OF TENNESSEE GRADUATE SCHOOL OF MEDICINE
INSTITUTIONAL REVIEW BOARD
REPORTING PROTOCOL WAIVERS AND DEVIATIONS

I. PURPOSE

To provide a procedure for the accurate and timely reporting of protocol waivers and deviations from the clinical site to University of Tennessee Graduate School of Medicine Institutional Review Board (UTGSM IRB).

II. SCOPE

Applies to all personnel involved in the review of studies by UTGSM IRB.

Personnel responsible: IRB administrative staff and IRB members.

III. BACKGROUND

DHHS and other Federal regulations require that institutions develop written policies and procedures for prompt reporting of changes in research activities to the IRB. UTGSM IRB requires sites to report protocol waivers and deviations as a part of its continuing review of research.

In Accordance With:
45 CFR 46.103(4)(iii); 21 CFR 56.108(a)(4).

Definitions:

Protocol Waiver means prospective approval by the research sponsor for the local investigator to accrue a subject who does not satisfy the approved inclusion/exclusion criteria for enrollment.

Protocol Deviation means failure to follow procedures specified in the approved research protocol, in the absence of a protocol waiver, with respect to inclusion/exclusion criteria, administration of the test article, timely performance of monitoring procedures, etc.

IV. PROCEDURE

A. Protocol Waivers

1. When the local investigative site receives a protocol waiver from a sponsor, all supporting documentation should be submitted to UTGSM IRB within 10 working days. The IRB will acknowledge receipt of such waivers without comment unless the IRB determines that there are relevant safety concerns or that the waiver is repetitive for the same exclusion criteria.

2. Waivers which present subject safety concerns or which could reasonably be considered as reaching the threshold of "changes in research activity" (because repetitive for the same exclusion criteria) must not be implemented without prior IRB review and approval as specified in 45 CFR 46.103(4)(iii).
3. If the IRB requires additional information, a letter will be sent to the investigator requesting the necessary information.
4. All protocol waivers that may affect the safety of the subject or that might reasonably be considered to represent changes in the research activity will be reported to the full board by the Chairperson. A copy of the full report will be available to all board members at the next convened meeting for review and action by the board.
5. If protocol waivers might reasonably be considered to represent changes in the research activity, the IRB may require that the change be submitted as a request to revise the protocol.

B. Protocol Deviations

1. The principal investigator is responsible for reporting all protocol deviations related to a clinical study to the IRB through iMedRIS, the electronic system. All deviations should be reported as soon as possible but no later than five working days from the day the sponsor or investigator becomes aware of the event (whichever occurs first).
2. The investigator will use the Deviation Report Form to report deviations to the UTGSM IRB. Information should include the facts of the case, including subject identifier (such as subject number or initials), the date of deviation, impact on the subject's safety, and plan for preventing the deviation in the future (if applicable).
3. Upon receipt of a protocol deviation report, the IRB Assistant Director/designee will review the report for the study and will send the report to the Chairperson.
4. Should the IRB require additional information, a correspondence will be sent to the investigator requesting additional information.
5. All protocol deviations will be reported to the full board by the Chairperson. The report will be available to all board members prior to the convened meeting.
6. The IRB will determine if additional actions or follow-up are required. Further actions might include:
    a) Seeking additional information from the sponsor.
    b) Discussion of protocol compliance with the principal Investigator.
    c) Audit of investigator's site by the IRB.
    d) Increasing the frequency of continuing review period for the study.
    e) Suspension or termination of the study (SOP IRB # 029 - Noncompliance / Complaints).
7. A copy of all correspondence / reports will be kept in iMedRIS.