Institutional Review Board
Deviations and Violations Policy

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Responsibility: OIRB		**Page: 1 of 4**

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Policy

1. During the conduct of a study, changes to the protocol may be proposed or unintentional changes in the conduct of the study may be discovered. Changes to the IRB-approved protocol, planned or otherwise, are governed by:
    a. Federal and State Regulations
    b. UTHSCSA IRB Policies and Procedures
    c. Institutional Policies and Procedures
2. Federal regulations specifically require the IRB of record to review proposed changes in a research activity, and to ensure that such changes in approved research are not initiated without prospective IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject [45 CFR Part 46.103(b)(4)(iii) and 21 CFR Part 56.108(a)(4)].
3. Investigators are also responsible for conducting human subject research in accordance with:
    a. UTHSCSA Institutional Review Board (IRB) reviews and determinations
    b. UTHSCSA IRB Policies and Procedures
    c. All applicable Regulatory Sponsor requirements
4. Departures during the conduct of a research study constitute a protocol deviation, violation or exception and as such must be reported to the UTHSCSA IRB.
5. Definitions and examples:
    a. Protocol deviations
    b. Protocol violations
    c. Emergency violations

Overview

1. Any permanent change to the protocol constitutes an amendment that must be submitted to the IRB for approval prior to initiation.
2. The IRB will not approve blanket requests to deviate from a protocol; an amendment must be submitted for recurring deviations and exceptions that will apply to more than one participant.
3. Deviations and violations may be identified in a number of ways including:
    a. A report by an individual can be made directly to the IRB Office.
    b. The IRB may learn of event through its continuing review of ongoing research.
    c. Compliance reviews (audits) conducted by the Office of Regulatory Affairs and Compliance or one of the HSC affiliated institutional compliance offices.
    d. A report by an individual can be made directly to the Office of Regulatory Affairs and Compliance (Hotline) or one of the HSC affiliated institutional compliance offices.
    e. A report by another committee, department, institution, or official.
    f. An audit or report from the study sponsor or sponsor's monitoring entity.
4. Individual deviations are not generally considered UPIRSOs or Noncompliance.
5. All Violations are evaluated by the IRB as possible noncompliance and/or UPIRSOs and require prompt reporting to the IRB.
6. All Emergency violations are considered UPIRSOs and require prompt reporting to the IRB
7. Collective evaluations of all departures (deviations and/or violations) could contain instances of possible noncompliance and/or UPIRSOs and require prompt reporting to the IRB.

Procedure

1. Tracking and reporting protocol deviations and violations to the IRB is the responsibility of the PI
    a. Deviations.

i. Tracking -As each deviations occurs, the PI should consider the following:
    1. Taking into account all the departures individually and collectively, have any of these occurrences had an effect on or possibly affected subject rights, safety or welfare?
        a. If yes, submit promptly to the IRB using the Prompt Report Form
    2. Taking into account all the departures individually and collectively have any of these occurrences had an effect on or possibly affected the science of the study?
        a. If yes, submit promptly to the IRB using the Prompt Report Form
    3. For any occurrences due to study personnel's failure to follow the protocol, evaluate the circumstances which lead to the events
    4. Determine if any actions need to be taken (or have been taken) to prevent reoccurrence

ii. Summarize at Continuing Review:
    1. Deviations must be summarized in the progress report form at the time of continuing review

b. Violations
    i. Prompt Reporting
        1. All violations should be reported to the IRB within 7 days using the Prompt Report Form.
    ii. Tracking: Violations should be tracked by the investigator. As each violation occurs, the PI should consider the following:
        1. Taking into account all the departures individually and collectively, have any of these occurrences had an effect on or possibly affected subject rights, safety or welfare?
            a. If yes, submit promptly to the IRB using the Prompt Report Form
        2. Taking into account all the departures individually and collectively have any of these occurrences had an effect on or possibly affected the science of the study?
            a. If yes, submit promptly to the IRB using the Prompt Report Form
        3. For any occurrences due to study personnel's failure to follow the protocol, evaluate the circumstances which lead to the events
        4. Determine if any actions need to be taken (or have been taken) to prevent reoccurrence
    iii. Summarize at Continuing Review:
        1. Violations must be summarized in the progress report form at the time of continuing review.

c. Emergency Violations
    i. Prompt Reporting

1. Emergency violations should be reported to the IRB according to the UPIRSO Policy using the Prompt Report Form.

ii. Tracking: Emergency violations should be tracked by the investigator. As each violation occurs, the PI should consider the following:
   1. Taking into account all the departures individually and collectively, have any of these occurrences had an effect on or possibly affected subject rights, safety or welfare?
      a. If yes, submit promptly to the IRB using the Prompt Report Form
   2. Taking into account all the departures individually and collectively have any of these occurrences had an effect on or possibly affected the science of the study?
      b. If yes, submit promptly to the IRB using the Prompt Report Form
   3. For any occurrences due to study personnel's failure to follow the protocol, evaluate the circumstances which lead to the events
   4. Determine if any actions need to be taken (or have been taken) to prevent reoccurrence

iii. Summarize at Continuing Review
   1. Violations must be summarized in the progress report form at the time of continuing review.

2. Review of Deviations and Violations
   a. Deviations
      i. Reports provided at the time of continuing review will be placed on a meeting agenda to be reviewed by the IRB at the next appropriate IRB meeting as part of the continuing review.
      ii. Prompt reports of cumulative deviations will be reviewed according to the noncompliance policy.
   b. Violations
      i. Prompt reports regarding violations will be reviewed by the IRB Chair, Research Regulatory Director or Associate Director according to the noncompliance policy.
   c. Emergency Violations
      i. Emergency violations will be reviewed by the IRB according to the UPIRSO policy and procedure

References

Definitions (see Glossary)

Regulatory (see Policy on Policies Policy and Procedure)