IRB SOP 602
Protocol Deviations and Non-Compliance

Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide guidance in the reporting requirements and responsibilities of the Investigator and the University of South Alabama Institutional Review Board (USA IRB) regarding protocol non-compliance and deviations.

Scope

This SOP applies to all research protocol non-compliance and deviations occurring at a USA research site, for a study in which USA IRB is the IRB of record.

USA IRB does not require reporting of deviations that occur at other research sites in multi-center trials. If the research was reviewed by an External IRB, the researcher should adhere to the policies and procedures of the External IRB.

Definitions

Continuing non-compliance: A pattern of repeated actions/omissions taken by an investigator or key research personnel that indicates a lack of ability and/or willingness to comply with federal regulations or USA IRB policies/guidelines. Repeated minor or major protocol deviations may constitute continuing non-compliance.

Non-compliance: Failure to comply with applicable Federal Regulations or USA IRB policies/guidelines

Deviations include intentional (planned) or unintentional departures from the IRB approved protocol or study plan. Deviations may be categorized as Minor Deviations, Major Deviations

is not done per protocol, and there is no increased potential for risk to the participant or damage to the integrity or completeness of the data

2.0 Major Protocol Deviations

2.1 Reporting Procedures

Major Protocol Deviations are to be reported to the USA IRB within 7 calendar days of becoming aware of the event. Major Protocol Deviations are reported through IRBNet using a Deviation Reporting Form. This form should include a corrective action plan for IRB for review and approval. This corrective action plan will outline what steps the investigator has taken or will take to resolve the event and to prevent such events from occurring in the future.

Examples of Major Protocol Deviations include, but are not limited to the following:

- Participant met withdrawal criteria during the study but was not withdrawn;
- Participant received an excluded concomitant medication;
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- Failure to perform study procedures outlined in the protocol where participant safety or data integrity may be significantly and negatively impacted;
- Inadvertent loss of samples or data;
- Any medication error made by the site involving incorrect treatment, dose, administration, and/or preparation;
- Any medication error made by the participant which, in the opinion of the investigator, placed the participant at an increased risk than was previously identified
- Failure to obtain informed consent prior to initiation of study-related procedures;
- Falsifying research or medical records;
- Working under an expired professional l3CID 20 >>BDC /TtTJ E.998 (o)-5ts
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2.2 Review by the IRB Committee

Major Protocol Deviations are administratively reviewed by the Office of Research Compliance or IRB Office staff by adding reviewer comments to the submitted package in IRBNet, selecting a recommendation and checking the box confirming the review has been completed. This manner confirms the date of review. Information including deviation description, corrective action, risk to the participant or data, and other pertinent information is listed on the agenda for Full Board review.

Major Protocol Deviations will be forwarded to the IRB Chair for review if the deviation presents significant risk to the participant(s) or if the event is medically complex. The

3.0 Protocol Exception

3.1 Reporting Procedures

The IRB only requires reporting of protocol exceptions that meet the criteria for a major deviation. Minor deviations, when known in advance, do not need to be reported to the IRB prior to implementation.

A protocol exception is a temporary, planned protocol deviation that is approved by the sponsor or fundingagency, (and, if applicable, the FDA) and the IRB, prior to its implementation. Protocol exceptions are typically granted for a single participant or a

3.2 Review by the IRB Committee

- Termination of the research
- Require a response from the investigator with a plan of corrective action
- Initiate audits of all or some part of th] v À • š] P š } Œ [• š] À ‰ Œ } š } } o •
- Modification of the research protocol
- Modification of the information disclosed during the consent process
- Additional information provided to past participants
- Modification of the annual review schedule
- Acquire additional information pending final outcome
- Requirements that current participants re-consent to participate (if applicable)
- Monitoring of the research and/or consent process

4.2 Continuity of Care of Research Participants when study is suspended

After the IRB has decided to suspend/terminate a research project, the IRB may make recommendations to investigators regarding ongoing care and treatment of the research participants. The IRB shall take into consideration the risk to the participants from withdrawal of any investigational drug, device, or social or behavioral interventions. Interventions may be permitted to continue by another qualified physician or social/behavioral scientists and need further supervision of the participant(s).

4.3 Final Outcome

If a finding of research noncompliance has been made, the IRB, IRB chair, or designee shall decide which corrective action(s) should be taken.

Corrective actions may include any of the following:

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- required training with respect to human subjects research and the regulatory requirements for the conduct of such research;
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Regulated Documents

45 CFR 46.103, 109
21 CFR 56.108, 109

University Related Documents

Protocol Deviation Reporting Form (located in IRBNet forms and templates)
Protocol Exception Request Form (located in IRBNet forms and templates)
IRB SOP 807: Research Procedures Conducted Without IRB Approval

History:

Effective Date: March 2024
Revisions:October 2018, March 2024

Responsible Office:

Office of Research Compliance and Assurance

Protocol Deviation Infographic