The University of Texas Rio Grande Valley

IRB Protocol Deviation / Possible Noncompliance Report Form

SECTION 1: INVESTIGATOR INFOMATION

Principal Investigator:

IRB Number:

Campus:

Building/Room Number:

College/Department:

Phone:

Email Address:

Project Title:

Sponsor/Funding Agency:

SECTION 2: POSSIBLE NONCOMPLIANCE INFORMATION

1. Provide an explanation of the facts surrounding the noncompliance, including a timeline of occurrence of noncompliance and discovery.

2. Provide an assessment of the increased risk (if any) to subjects resulting from the noncompliance.

3. Explain the corrective measures taken in response to the noncompliance and explain any preventive measures that will be taken to prevent the noncompliance from occurring in the future (if possible).

4. Has this event been reported to the study sponsor / grant body?

☐ Not Applicable, there is no study sponsor or grant body

☐ Yes. Please describe response if any.

☐ No. Please provide rationale for not reporting.

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Guidance for IRB Protocol Deviation / Noncompliance

The report form should be completed by the Investigator once they are aware of the protocol deviation / noncompliance but no more than 1 business days after discovering the protocol deviation/non-compliance. All sections must be completed.

Definitions

Protocol Deviation: is an unplanned excursion from the protocol that is not implemented or intended as a systematic change.

- A protocol deviation could be a limited prospective exception to the protocol (e.g. agreement between sponsor and investigator to enroll a single subject who does not meet all inclusion/exclusion criteria). Like protocol amendments, deviation initiated by the investigator must be reviewed and approved by the IRB and the sponsor prior to implementation, unless the change is necessary to eliminate an immediate hazard to the human subjects.
- Protocol deviation is also used to refer to any other, unplanned, instance(s) of protocol noncompliance. For example, situations in which the investigator failed to perform tests required by the protocol or failures on the part of the subjects to complete scheduled visits as required by the protocol.

Noncompliance: is a failure by an investigator or any study team member to abide by the policies and procedures of the IRB or applicable regulations governing the protection of human subject research. Some examples of noncompliance include but are not limited to:

- Failure to obtain prior approval for research
- Failure to obtain renewal of approval for research
- Failure to obtain informed consent when required
- Failure to use the last IRB approved version of the protocol or consent form
- Failure to report an adverse event report according to the IRB timeline and procedure
- Performance of research at an unapproved study site
- Performance of a drug trial without a valid HSA Clinical Trial Certificate (CTC)
- Any other failure to adhere to regulations, policies and procedures related to research

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FOR OFFICE OF RESEARCH COMPLIANCE USE ONLY

Please indicate any actions that will be taken as a result of this report:

1. ☐ The informed consent form process/documents will be revised. Instructed investigator to submit an amendment requesting the revisions. If the amendment cannot be submitted at this time (e.g. requires sponsor approval first), request explanation from investigator.
2. ☐ The protocol will be revised. Instructed investigator to submit an amendment requesting the revisions. If the amendment cannot be submitted at this time (e.g. requires sponsor approval first, or system process), request explanation from investigator.
3. ☐ Currently enrolled subjects will be notified. Request a copy of the notification.
4. ☐ Other corrective and/or preventive action will be taken. Please explain:
5. ☐ The event compromised the validity of the data. Please explain:

Comments:

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FOR IRB USE ONLY

Level of Review: ☐ Full Board Review ☐ Expedited ☐ Exempt

Review Outcome:

_____	_____	_____
IRB Chair Name	Signature	Date
_____	_____	_____
IRB Vice Chair Name	Signature	Date