



Austin Peay State University Institutional Review Board (IRB)
Grants and Sponsored Programs
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Website: <https://www.apsu.edu/grants/institutional-review-board/index.php>

Protocol Deviation Report For Studies Involving Human Participants

Please submit this report if you have deviated or plan to deviate from your intended protocol during your study involving human participants. This form should be used for single-instance deviations only.

Principal Investigator (P.I.):

Faculty Advisor (if applicable):

Protocol Number and Title:

Check which statement applies to your study:

- Deviation is planned but has not yet occurred. (Please note that if you wish to change your protocol, you must submit an Amendment Request.)
- Deviation has already occurred.

1. Describe the deviation. *Please attach supporting documentation, if any.*

2. Explain the circumstances of the deviation.

3. What was the outcome of the deviation if it has already occurred?

4. Has the sponsor been notified of the deviation? YES NO N/A

5. Has the sponsor agreed to allow the participant to continue? YES NO N/A

6. In the judgment of the principal investigator, does the deviation:

- adversely affect the rights of the participant? YES NO
- adversely affect the welfare of the participant? YES NO
- decrease the potential benefit to the participant? YES NO
- increase the potential risk to the participant? YES NO

- adversely affect the scientific integrity of the study data? YES NO

7. Please briefly state the basis for your answers to the questions above in question 6.

8. Describe your plan to notify participants.

9. Describe any immediate actions taken in response to the deviation.

10. Describe your plan to prevent this deviation from occurring in the future. This management plan should be reviewed and approved by the IRB prior to implementation.

Signature:

Date:

***** APIRB use only *****

IRB Reviewer:

1. Does this report represent:

- Serious noncompliance? YES NO
- Continuing noncompliance? YES NO

2. Check which statement applies:

- No follow-up necessary.
- Further action or information is requested. Please describe it:

- Send to a convened APIRB meeting.

APIRB Chair Signature

Date