Human Research Protection Program
155, South Grant Street
Ernest C. Young Hall, Room 1032
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E-mail: irb@purdue.edu

Reports of Noncompliance

All reports of noncompliance should be made to the Human Research Protection Program (HRPP) and associated Institutional Review Board (IRB). The HRPP/IRB encourages prompt self-disclosure by Principal Investigators discovering a potential noncompliance in their research.

Noncompliance - Failure to comply with any of the federal or state regulations or institutional policies governing Human Subjects Research or the requirements or determinations of the IRB.

Initial reports can be made either orally or in writing; however, a written follow up may be requested by the HRPP. Specifically, reports should be sent to irb@purdue.edu. Do not include identifying information about a participant in this report.

Section A: Protocol Information

Principal Investigator Name (Last, First):_____

Protocol Number: _____

Protocol Title:_____

Sponsor/Funding Agency (if applicable):_____

Does the noncompliance being reported involve any other collaborating organizations outside of Purdue University? ☐ No ☐ Yes
If yes, please list all collaborating organizations: _____

Report: ☐ Initial ☐ Follow-Up

Type: ☐ IRB Requested ☐ Self-Report

Section B: Noncompliance Information Assessment

In this section, you will categorize the nature of the event that you are reporting to the IRB. When you complete the report include flyers, tests, consent forms, or any other documentation related to the noncompliance. You may attach a separate document if the description does not fit in the space provided.

Please check the box(es) that apply to the event(s). You may need to choose more than one.

☐ The researchers in this study collected data without an active HRPP/IRB protocol, and/or conducted research activities after the study expiration date (examples include advertising, recruitment, data collection or data analyses).
Please describe all activities that were conducted without an approved protocol. If data analysis occurred, indicate if the data are/were deidentified.

☐ The researchers in this study changed study procedures (e.g. recruitment methods, study population, number of participants, data collection techniques, consent form wording) without proper IRB review/approval.
Please indicate all activities that were conducted. Be specific about the reason(s) why the study was changed and why IRB review and approval was not sought in advance.

☐ The researchers in this study are reporting a noncompliance related to study documentation. (Examples, failure to obtain signatures on a consent form, loss of consent forms/study data, failure to retain study information).
Please describe what study documentation requirements were not met. If materials are lost, please indicate the last known location, format, nature of the data, and how materials were misplaced or breached.

☐ Other noncompliance (Examples: unauthorized key personnel changes, failure to disclose potential financial conflict of interest).
If the noncompliance being reported does not fit into the categories described above, please provide a detailed description of the event.

Section C: Noncompliance Correction and Certification

What remedies have you put into place for this incident(s)? (Examples, increased training, document security, additional staff, proposed changes to the consent form).

Please explain your plan to avoid a future recurrence of the noncompliance.

Principal Investigator Certification

My signature certifies that I am providing accurate information to the best of my current knowledge about the event(s). I understand and acknowledge that the Human Research Protection Program (HRPP) and associated Institutional Review Board (IRB) will review and make a determination about this event and any data collected as a result of noncompliance. I have directed any key or non-key personnel on this study to cease any activity which may lead to further noncompliance.

Principal Investigator's Signature

Date

Section D: IRB Review (For HRPP/IRB Office Use Only)

☐ Expedited review sufficient

☐ Refer to Full Board

Determinations and/or Recommended Action(s):

☐ No non-compliance was committed

☐ Investigative subcommittee for further review/fact finding

☐ Refer to Research Quality Assurance Unit for Post-Approval Monitoring

☐ Re-training or remediation

☐ Suspend the study pending further review.

☐ Report to Institutional Official.

☐ Other: _____

_____

_____

Reviewer's Comments:

_____ _____

IRB Chair's or Designee's Signature Date