



## **IRB Unanticipated Events or Adverse Event Reporting**

Examples of unanticipated events / problems or adverse events that should be reported to the IRB include:

- Publication in the literature or other finding that indicates an unexpected change to the risk/benefit ratio of the research;
- Breach in confidentiality resulting from a disclosure of confidential information or from lost or stolen confidential information, that may involve risk to that individual or others;
- Complaint of a participant or family member that indicates an unanticipated risk;
- Disqualification or suspension of investigators;
- Accidental or unintentional change to the IRB-approved protocol that involves risks or has the potential to recur;
- Deviation from the protocol taken without prior IRB review to eliminate apparent immediate hazard to a research participant
- Any deviation from the IRB-approved protocol that increases the risk or affects the participant's rights, safety, or welfare.

If you believe you have suffered harm physically or psychologically from participation in a research study, please seek appropriate medical attention immediately then report the incident/problem to the Office of Research Compliance as soon as possible at 936-261-1588 or at [researchcompliance@pvamu.edu](mailto:researchcompliance@pvamu.edu) .

If a human subject enrolled in your research study has suffered harm in any way from participation in your research study, please ask them to seek appropriate medical attention immediately then report the incident/problem to the Office of Research Compliance as soon as possible at 936-261-1588 or at [researchcompliance@pvamu.edu](mailto:researchcompliance@pvamu.edu) . Any other unanticipated problems or adverse events should be reported to the Office of Research Compliance immediately.

To report an unanticipated problem or adverse event, complete the Unanticipated Event / Adverse Events Report Form and submit it to the Office of Research Compliance at [researchcompliance@pvamu.edu](mailto:researchcompliance@pvamu.edu) .

If you have any questions, please call the Office of Research Compliance at 936.261.1553.