## University of Pittsburgh Protocol Log for Noncompliance / Deviations

**Protocol #:**
**PI:**
**Protocol Title:**

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Subject ID#** | **Date of Event**  | **Date PI was notified of event**  | **Brief Description of Event** | **Does the event represent non-compliance that must be reported to the IRB[[1]](#footnote-1) ? If yes, list date.**  | **Was the event reported to the sponsor, DSMB or an external group? If yes, list group and report date**  | **Provide a Corrective Action to Prevent Future Occurrence of the Event as applicable.**  | **PIs Initials and date** |
|       |       |       |       | Yes [ ]  No [ ] Date:       |       |       |      Date:       |
|       |       |       |       | Yes [ ]  No [ ] Date:       |       |       |      Date:       |
|       |       |       |       | Yes [ ]  No [ ] Date:       |       |       |      Date:       |
|       |       |       |       | Yes [ ]  No [ ] Date:       |       |       |      Date:       |
|       |       |       |       | Yes [ ]  No [ ] Date:       |       |       |      Date:       |

**Adverse event logs should be maintained separately.**

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|  **Noncompliance/ Deviation Logs are mandatory for**: * Greater than minimal risk studies
* Studies that meet the federal definition of a “clinical trial”
* Studies for which reporting is required by the funding agency

Noncompliance/ Deviation Logs are not required to be submitted at annual review but must be available upon request. Noncompliance/ Deviation Logs are recommended but non-mandatory for all other studies.Noncompliance/ Deviation Logs should be reviewed on an ongoing basis to determine if it is a pattern of noncompliance that requires a change in the protocol, a revised corrective action plan or continuing noncompliance reportable to the IRB.  |
| **Examples of Unanticipated Problems and Noncompliance/Deviations that must be reported to the University of Pittsburgh IRB within 10 days of the PI becoming aware of the event include but are not limited to:** * Any accidental or intentional deviation from the IRB-approved protocol that involves risks (e.g., missed safety labs, incorrect dosing or labeling);
* Any deviation from the protocol taken without prior IRB review to eliminate apparent immediate hazard to a given research subject;
* Any publication in the literature, safety monitoring report, interim result, or other finding that indicates an unexpected increase in the risk to benefit ratio of the research;
* Any complaint of a subject that indicates an unanticipated risk or which cannot be resolved by the research staff;
* Any other untoward event that affects the welfare or the privacy, confidentiality or other rights of research subjects or members of their family (e.g. lost or stolen research data);
* Performing non-exempt human subject research without obtaining prospective IRB approval;
* Initiating research activities prior to obtaining consent;
* Implementing protocol modifications without obtaining prospective IRB approval;
* Altering the informed consent process from that described in the IRB approved protocol;
* Obtaining consent using an outdated consent form, when the new consent form contained new information that may have caused the subject to change their mind about participating;
* Having research activities performed by individuals who are not sufficiently trained or credentialed to perform the task.
* Having non-licensed physician investigators or research staff obtain consent for studies that involve a drug, a device or surgical procedure:
* Conducting research during a lapse in IRB approval;
* Not adhering to inclusion/exclusion criteria;
* Enrolling more subjects than were approved in the protocol of a greater than minimal risk study;
* Performing research at an unapproved site
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| **Examples of Noncompliance/ Deviations that are not reportable but should be documented in a log include:** * Obtaining consent using an outdated consent form when there were no substantive differences between the consent form that was used and the consent form that should have been used (i.e., dates in the footer)
* Protocol deviations that do NOT adversely affect the rights and welfare of human subjects or significantly compromise the quality of the research data
* Subject noncompliance that does not involve risk or alter the data
* Performing non-safety related research procedures outside the protocol specified window, i.e., involuntarily administering a questionnaire outside of the protocol specified window.
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1. Noncompliance that is reportable to the IRB is outlined in Chapter 17. This includes:

Noncompliance that meets the definition of an unanticipated problem involving risks to human subjects or others in that it is related or possibly related to the research, is unexpected and places research subjects or others at greater risk of harm (physical, psychological, economic or social) than was previously known or recognized.

Noncompliance that may significantly adversely affects the rights or welfare of participants, or significantly compromises the research data.

In PittPRO, these submissions are titled Reportable New Information (RNI). In OSIRIS, these are titled Noncompliance or Unanticipated Problems Involving Risks to Human Subjects or Others. [↑](#footnote-ref-1)