|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Researchers:**   * **Use this log for tracking Minor or Administrative** [**Deviations**](https://research.uci.edu/wp-content/uploads/55-Protocol-Deviation-and-Violation-Reporting.pdf)**.**   + While UCI does not require that deviations be submitted for IRB review, Lead Researchers (LRs) may choose to report these deviations at the time of renewal by submitting this log with the renewal application in [KRP](https://uci.kuali.co/protocols/portal/protocols).   + Maintain one continuous log that reflects all deviations that have occurred on study. Upload an updated log at each continuation.   + **Please do not include subject identifiable data with the log.** * **Do not use this log to report Serious and/or Continuing Noncompliance or Unanticipated Problems.** For additional information, visit the HRP webpage, [Reporting of Unanticipated Problems.](https://research.uci.edu/human-research-protections/post-review-responsibilities/)   Deviations are events that do not affect the risk/benefits of the study or do not significantly affect the subject's rights, safety or welfare; and/or on the integrity of the data. Often a research sponsor may require submission of deviations to the IRB of record.  *Examples of minor or administrative deviations include: follow up visits occurring outside the protocol required time frame because of the participant’s schedule, or blood samples being obtained at times close to but not precisely at the time points specified in the protocol. Minor deviations may occur due to an intentional change made by the LR, the subject’s lack of adherence to the protocol or other external factors outside of the Investigator’s control (e.g. weather conditions, holidays, etc.) that impact the conduct of the protocol.*  Human Research Protections (HRP) staff will review this log and will work with the IRB Chairs in assessing events. Should no further action be required (e.g., events constitute submission of an Unanticipated Problem or Serious Noncompliance), HRP Staff will include the log in the protocol file. | | | | | | | | | |
| **Protocol Information** | | | | | | | | | |
| **IRB Number:** | | |  | | | | | | |
| **Lead Researcher (LR):** | | |  | | | | | | |
| **Protocol Deviations** | | | | | | | | | |
| **Date of Event** | **Subject Reference #** | **Was the event unexpected?[[1]](#footnote-1)** | | **Was the event related or possibly related to the research?1** | **Did the event place subjects or others at a greater risk of harm than was previously known?1** | **Did the event have a significant adverse impact on the rights or welfare of subjects or on the integrity of the data?[[2]](#footnote-2)** | **Did the event involve a potential breach of Protected Health Information (**[**PHI**](http://www.research.uci.edu/compliance/human-research-protections/researchers/protected-health-information-hipaa.html#phi)**)?[[3]](#footnote-3)** | **Brief Description of Deviation** | **Provide a Corrective Action and Prevention (CAPA) plan to address the event and to ensure that noncompliance does not re-occur. Alternatively, specify why a CAPA is not necessary.** |
|  |  | Yes  No | | Yes  No | Yes  No | Yes  No | Yes  No |  |  |
|  |  | Yes  No | | Yes  No | Yes  No | Yes  No | Yes  No |  |  |
|  |  | Yes  No | | Yes  No | Yes  No | Yes  No | Yes  No |  |  |
|  |  | Yes  No | | Yes  No | Yes  No | Yes  No | Yes  No |  |  |
|  |  | Yes  No | | Yes  No | Yes  No | Yes  No | Yes  No |  |  |
|  |  | Yes  No | | Yes  No | Yes  No | Yes  No | Yes  No |  |  |
|  |  | Yes  No | | Yes  No | Yes  No | Yes  No | Yes  No |  |  |
|  |  | Yes  No | | Yes  No | Yes  No | Yes  No | Yes  No |  |  |
|  |  | Yes  No | | Yes  No | Yes  No | Yes  No | Yes  No |  |  |
|  |  | Yes  No | | Yes  No | Yes  No | Yes  No | Yes  No |  |  |
| **Continuing Noncompliance**  The UCI Human Research Protections [Policy 52](https://research.uci.edu/wp-content/uploads/52-Research-Non-compliance.pdf) defines *continuing noncompliance as a* ***pattern*** *of noncompliance that indicates an* ***inability or unwillingness*** *to comply with applicable laws, regulations, or institutional policies pertaining to the protection of human subjects and/or with the requirements or determinations of an IRB.* | | | | | | | | | |
| If multiple protocol deviations have occurred in the past year, does this reflect a pattern of noncompliance?  No  Yes (explain):  **OR**  N/A | | | | | | | | | |

1. **If the answers to these three questions are ALL YES, submit an Unanticipated Problems (UP) Report.** For additional information, visit the HRP webpage,[**Reporting of Unanticipated Problems**](https://research.uci.edu/human-research-protections/post-review-responsibilities/)**.** [↑](#footnote-ref-1)
2. **If the answer to this question is YES, submit a New Information Report (NIR).** For additional information, visit the HRP webpage,[**Reporting of Unanticipated Problems**](https://research.uci.edu/human-research-protections/post-review-responsibilities/)**.** [↑](#footnote-ref-2)
3. **If the answer to this question is YES, immediately report the potential breach of PHI to the UCI Health Privacy Compliance Officer at 714-456-3672 or** [**hacompliance@uci.edu**](mailto:hacompliance@uci.edu)**.** [↑](#footnote-ref-3)