UCI Office of Research

**Institutional Review Board**
**Human Research Protections**
**Protocol Event Table – When to Report Events to the UCI IRB**
*Version 02-04-22*

| Type of Event | Relevant Definitions | Reportable? | Timeframe for Submission | Reporting Process | IRB Review Process |
|---|---|---|---|---|---|
| Minor Deviation that occurs **at a UCI site** (UCI Main Campus, UCIMC, including UCIMC satellite clinics) **or occurs at a non-UCI site where the UCI IRB is the IRB of record**.[1] | **Deviations** that are minor and 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. | REPORTING NOT REQUIRED<br><br>A submission may be required by the Sponsor. | If required by the sponsor to report, at the time of annual renewal. | Submit a Deviation Tracking Log with the renewal. | Deviation Tracking Logs will be reviewed by HRP Staff, with the assistance of the UCI IRB, as applicable. |
| Major Deviation that occurs **at a UCI site** (UCI Main Campus, UCIMC, including UCIMC satellite clinics) **or occurs at a non-UCI site where the UCI IRB is the IRB of record**. | **Emergency deviations** involve a departure from the approved protocol to avoid an immediate hazard to the participant. | **REPORTING REQUIRED**<br><br>Emergency deviations may occur without time for prospective IRB review and approval. | Within **5 business days** of the Lead Researcher (LR) learning of the event. | If the deviation meets the definition of an Unanticipated Problem (UP - see below), submit an UP via Reportable Events in KRP.<br><br>Otherwise, submit an amendment via KRP. | UPs are received by the IRB Compliance Manager and reviewed by the UCI IRB.<br><br>Amendments are received by HRP Staff and reviewed by the UCI IRB. |
| | **Non-emergency deviations** are planned (non-emergent) and represent a major change in the approved protocol. | **REPORTING REQUIRED**<br><br>Major, non-emergency deviations should be submitted to the UCI IRB for prospective review (in advance of the event). | As soon as the anticipated deviation is known to the study team. | If the deviation will occur within 48 hours, submit a Prospective Deviation request via Reportable Events in KRP.<br><br>Otherwise, submit an amendment via KRP. | Prospective deviation requests and amendments are received by HRP Staff and reviewed by the UCI IRB. |
| Noncompliance Minor Deviation that occurs **at a UCI site** (UCI Main Campus, UCIMC, including UCIMC satellite clinics) **or occurs at a non-UCI site where the UCI IRB is the IRB of record**. | **Noncompliance** is a failure 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. | REPORTING NOT REQUIRED<br><br>Often noncompliance that is NOT serious or continuing is considered a minor deviation. | If required by the sponsor to report, at the time of annual renewal. | Submit a Deviation Tracking Log with the renewal. | Deviation Tracking Logs will be reviewed by HRP Staff, with the assistance of the UCI IRB, as applicable. |

[1] If the UCI IRB is not the reviewing IRB, the UCI IRB will work together with the reviewing IRB to investigate the matter.

| Type of Event | Relevant Definitions | When Reporting Applies | Timeframe for Submission | Reporting Process | IRB Review Process |
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| Serious Noncompliance that occurs **at a UCI site** (UCI Main Campus, UCIMC, including UCIMC satellite clinics) **or occurs at a non-UCI site where the UCI IRB is the IRB of record**. | **Serious Noncompliance** is a failure 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 that has a significant adverse impact either on the rights or welfare of participants or on the integrity of the data. | **REPORTING REQUIRED** | Within **5 business days** of the LR learning of the event. | If the deviation meets the definition of an UP, submit an UP report via Reportable Events in KRP.<br>Otherwise, complete the New Information Report via Reportable Events in KRP. | Reportable Events are received by the IRB Compliance Manager and reviewed by the UCI IRB. |
| Continuing Noncompliance that occurs **at a UCI site** (UCI Main Campus, UCIMC, including UCIMC satellite clinics) **or occurs at a non-UCI site where the UCI IRB is the IRB of record**. | **Continuing Noncompliance** is 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. | **REPORTING REQUIRED** | Within **5 business days** of the LR learning of the event. | If the deviation meets the definition of an UP, submit an UP report via Reportable Events in KRP.<br>Otherwise, complete the New Information Report via Reportable Events in KRP. | Reportable Events are received by the IRB Compliance Manager and reviewed by the UCI IRB. |
| Unanticipated Problem that occurs **at a UCI site** (UCI Main Campus, UCIMC, including UCIMC satellite clinics) **or occurs at a non-UCI site where the UCI IRB is the IRB of record**. | 1. **Unexpected** (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; **and**<br>2. **Related or possibly related to participation in the research** (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); **and**<br>3. Suggests that the research places subjects or others at a **greater risk of harm** (including physical, psychological, economic, or social harm) **than was previously known or recognized**. | **REPORTING REQUIRED** | Within **5 business days** of the LR learning of the event. | Submit an UP Report via Reportable Events in KRP. | UPs are received by the IRB Compliance Manager and reviewed by the UCI IRB. |

| Type of Event | Relevant Definitions | When Reporting Applies | Timeframe for Submission | Reporting Process | IRB Review Process |
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| Sponsor and/or DSMB Upgrades Adverse Event to an Unanticipated Problem that occurs **at a UCI site** (UCI Main Campus, UCIMC, including UCIMC satellite clinics) **or occurs at a non-UCI site where the UCI IRB is the IRB of record**. | See above definition for **Unanticipated Problem (UP)** | **REPORTING REQUIRED** | Within **5 business days** of the LR learning of the Sponsor and/or DSMB's assessment of the event. | Submit an UP Report via Reportable Events in KRP. | UPs are received by IRB Compliance Manager and reviewed by the UCI IRB. |
| Holds and/or Suspensions that occurs **at a UCI site** (UCI Main Campus, UCIMC, including UCIMC satellite clinics) **or occurs at a non-UCI site where the UCI IRB is the IRB of record**, including:<br>• FDA Clinical Hold (21 CFR 312.42)<br>• Sponsor Imposed<br>• DSMB Imposed<br>• UCI Investigator Self-Imposed Administrative Hold | See above definitions for:<br>1. **Unanticipated Problem (UP)**<br>2. **Serious Noncompliance (SNC)**<br>3. **Continuing Noncompliance (CNC)** | **REPORTING REQUIRED** | For holds and/or suspensions that meet the definitions of UP, SNC, or CNC, report within **5 business days** of the LR learning of the Hold and/or Suspension.<br>Otherwise, report with the next modification transaction. | 1. If the hold and/or suspension was imposed because of risks possibly related to research **and** the risk related issues meet the definition of an UP, submit an UP via KRP.<br>2. If the hold and/or suspension was imposed because of risks resulting from noncompliance that occurred **and** the risk related issues do NOT meet the definition of an UP, submit a new information report via Reportable Events in KRP.<br>3. If the hold and/or suspension was imposed because of issues NOT related to possible risks **and** the related issues do NOT meet the definitions of UP, SNC, or CNC, submit an amendment via KRP. | 1. UPs and NIRs are received by the IRB Compliance Manager and reviewed by the UCI IRB.<br>2. Amendments are received by the HRP staff and reviewed by the UCI IRB. |