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| --- | --- | --- | --- |
| **PI:** **IRB#**  **Study Title:**  **Funding source:** **Grant #:**  **Brief Description of Problem:** | | | |
|  | **Yes** | **No** | **NA** |
| **FUNDING SOURCE:** |  |  |  |
| Is this study federally funded? |  |  |  |
| Is this study FDA regulated? |  |  |  |
| **DETERMINATION:** | | | |
| **Represents Serious Non-Compliance**, defined as:  Noncompliance that, in the judgment of the University IRB, significantly adversely affects the rights or welfare of participants, or significantly compromises the quality of the research data.  Examples of serious non-compliance include, but are not limited to:  performing non-exempt human subject research without obtaining University IRB approval  implementing substantial modifications to a research study without obtaining formal University IRB approval  failing to systematically obtain research subjects’ informed consent as required by the IRB approved protocol  failing to comply with federal regulations governing human subject protections (this includes activities of the University IRB and/or University IRB Office staff) |  |  |  |
| **Represents Continuing Non-Compliance**, defined as:  Noncompliance that has been previously reported or a pattern of ongoing noncompliance that, in the judgment of the University IRB, significantly adversely affects the rights and welfare of participants or significantly compromises the quality of the research data. |  |  |  |
| **Represents Risk to Human Subjects or Others**, defined as: places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized |  |  |  |
| **CORRECTIVE ACTION PLAN** | | | |
| Was a Corrective Action Plan provided by the investigator? |  |  |  |
| Is Corrective Action Plan acceptable? |  |  |  |
| Are changes required to the Corrective Action Plan? |  |  |  |
| **POSSIBLE COMMITTEE ACTIONS:** |  |  |  |
| Request additional records or information about the event and its outcome |  |  |  |
| Interview the involved investigators, research staff, and/or research subjects |  |  |  |
| Interview other individuals who may have knowledge of the event |  |  |  |
| Request an independent audit of the event/protocol or of other related protocols. |  |  |  |
| **IMPLEMENT ADMINISTRATIVE ACTIONS:** |  |  |  |
| Request the IRB Chair (or Vice Chair) to meet with the involved investigator and/or research staff, and the appropriate department chair and/or dean to discuss the event/problem |  |  |  |
| Request corrective plan of action and/or written standard operating procedures from the involved investigator and/or his/her department chair or dean |  |  |  |
| Require members of the research team to participate in pertinent training and education programs |  |  |  |
| Notify other organizational entities (e.g., legal counsel, institutional risk management, the Authorized Institutional Official, the Research Integrity Officer, the UPMC Clinical Trials Office) as warranted |  |  |  |
| Suspend the PI’s privilege to serve as a PI or requiring a replacement of the PI for the protocol(s) in question |  |  |  |
| **REQUIRE MODIFICATION OF THE ASSOCIATED PROTOCOL** | | | |
| Instruct the investigator to develop an addendum consent form to provide information concerning the event to subjects currently enrolled in the study. |  |  |  |
| Require the investigator to perform additional follow-up or monitoring of the enrolled subjects |  |  |  |
| Revise the timeframe for continuing University IRB review |  |  |  |
| **TERMINATE OR SUSPEND UNIVERSITY IRB APPROVAL OF THE RESEARCH STUDY** | | | |
| Terminate or Suspend University IRB Approval of the Research Study |  |  |  |
| **CORRESPONDENCE (note if direct letter or cc)** | | | |
| Letter to PI: |  |  |  |
| Letter to OHRP |  |  |  |
| Letter to FDA |  |  |  |
| Letter to Funding Agency |  |  |  |
| Letter to IO |  |  |  |
| Other: |  |  |  |
| **INVESTIGATOR RESPONSE:** | | | |
| Is a response required from the investigator? |  |  |  |
| Was investigator’s response reviewed? Date Reviewed: \_\_\_/\_\_\_/\_\_\_ |  |  |  |
| Was investigator’s response acceptable? |  |  |  |
| **STATUS:** |  |  |  |
| Is this matter closed? Date Closed: \_\_\_/\_\_\_/\_\_\_ |  |  |  |
| **COMMENTS:** |  |  |  |
|  | | | |