1. **General Information**

**Date of Notification to IRB: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date of Occurrence: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| --- | --- | --- | --- | --- |
| **IRB #** | | **Is this a ☐Deviation ☐ Major Violation**  **☐ Minor Violation**  **(see definitions and examples in policy and on this form)** | | **Sponsor:** |
| **Protocol Title:** | | | | |
| **Protocol Version Date (or last approval of the IRB date):** | | | | |
| **Person Completing Form:** | | | **Phone Number:** | |
| **Name of Principal Investigator:** | | | **Research Site:** | |
| **Patient ID # Age:**  **Gender: ☐Male ☐Female** | | | **Did the deviation/violation occur at Jupiter Medical Center? ☐**  **If No, list facility:** | |
| **Protocol Deviation/Violation identified by:** | | | | |
| **1.** | **Describe the deviation/violation:** | | | |
| **2.** | **Explain why this occurred:** | | | |
| **3.** | **What steps were taken to resolve this particular occurrence?** | | | |
| **4.** | **What is being done to prevent similar occurrences in the future?** | | | |
| **5.** | **If a MAJOR violation has occurred, which of the following were affected? (mark all that apply)**  **☐ Subject safety and care**  **☐ Integrity of study data**  **☐ Subject’s willingness to participate in study** | | | |
| **6.** | **Will the participant continue with the research?**  **☐ Yes ☐No- List Date Stopped:** | | | |
| **7.** | **Will the research study continue?**  **☐ Yes ☐ No- List Date Stopped:** | | | |
| **8.** | **Was the subject informed of the deviation/violation? ☐ Yes ☐ No**  **Explain:** | | | |
| **9.** | **Was the study sponsor notified of the occurrence within the required time frame?**  **☐ Yes ☐ No ☐ Not a Sponsored study** | | | |
| **Name of Principal Investigator PRINT** | | |  | |
| **Principal Investigator SIGNATURE** | | | **Date** | |

**All major protocol violations** must be reported to the IRB **within (10) working days of discovery.** The principal investigator must review and sign off on the report before the submission can be routed to the IRB.

**All minor protocol violations** must be reported to the IRB, at a minimum, at continuing review, but may be reported at any time to the IRB.

**Definitions:**

**Protocol Deviation:** Any alteration/modification to the IRB-approved protocol. The protocol includes the detailed protocol, protocol summary, informed consent form, recruitment materials, questionnaires, and any other information relating to the research study.

**Protocol Violation:** Any protocol deviation that is not approved by the IRB prior to its initiation or implementation.

* **Major Violation**: a violation that may impact subject safety, affect the integrity of study data and/or affect subject’s willingness to participate in the study.
* **Minor Violation**: a violation that does not impact subject safety, compromise the integrity of study data and/or affect subject’s willingness to participate in the study.

**Major Violations**

**Examples (the list of examples is intended as a guide and is not all-inclusive)**

* Failure to obtain informed consent, i.e., there is no documentation of informed consent or the informed consent is obtained after initiation of study procedures
* Informed consent obtained by someone other than individuals authorized by IRB to obtain consent, e.g. someone other than a licensed physician investigator or designee
* Enrollment of a subject who did not meet all inclusion/exclusion criteria
* Performing study procedure not approved by the IRB
* Failure to report serious adverse event to the IRB
* Failure to perform a required lab test that, in the opinion of the PI or sponsor, may affect subject safety or data integrity
* Drug/study medication dispensing or dosing error
* Study visit conducted outside of required timeframe that, in the opinion of the PI or sponsor, may affect subject safety
* Failure to follow safety monitoring plan

**Minor Violations**

* Implementation of unapproved recruitment procedures
* Missing original signed and dated consent form (only a photocopy available)
* Missing pages of executed consent form
* Inappropriate documentation of informed consent, including
  + Missing subject signature
  + Missing investigator signature
  + Missing information (i.e. blanks not filled in, check marks not checked)
  + Copy not given to the person signing the informed consent
  + Someone other than the subject dated the consent form
* Use of invalid consent form, i.e. consent form without IRB approval stamp, or outdated/expired consent form
* Failure to follow the approved study procedures that, in the opinion of the PI, does not affect subject safety or data integrity
  + Study procedure conducted out of sequence
  + Omitting an approved portion of the protocol
  + Failure to perform a required lab test
  + Missing lab results
  + Study visit conducted outside of required timeframe
* Failure of subject to return study medication
* Over-enrollment
* Enrollment of subjects after IRB-approval of study expired
* Failure to submit continuing review to the IRB before study expiration.