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.