**NIMH Investigational Product Storage Temperature Log Template**

***Tool Summary*** *(Remove Tool Summary before finalizing and distributing the document)*

***Purpose:*** *This template may be used to record and document the temperature management of investigational product.*

***Audience/User:*** *Principal Investigator and study team members who are delegated to manage investigational products*

***How to Use This Template***

*This template contains two types of text: instruction/explanatory and example text.* ***Instruction/ explanatory text*** *are indicated by italics and should be deleted. Footnotes to instructional text should also be deleted. This text provides information on the content that should be included.* ***Example text*** *is included to further aid in document development and should either be modified or deleted. Example text is indicated in [brackets in regular font]. Within example text, a need for insertion of specific information is notated by <angle brackets>. Example text can be incorporated as written or tailored to a particular document. If it is not appropriate to the document, however, it too should be deleted.*

***Version control*** *is important to track document development, revisions, and amendments. It is also necessary to ensure that the correct version of this document is used by all staff conducting the study. With each revision, the version number and date located in the header of each page should be updated.*

**Investigational Product Storage Temperature Log Template**

**Protocol Title:**

**Protocol No.:**

**Principal Investigator Name:**

**Site Name:**

**Investigational Product (IP):**

**Serial Number of Temperature Monitoring Device:**

**Re-calibration Date:**

**Location of IP:**

**Recommended storage temperature:**

**Instructions:**

1. Frequency of IP storage temperature monitoring: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

2. Please notify the Sponsor immediately if there any temperature excursions are noted.

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| --- | --- | --- | --- | --- | --- | --- |
| Date(MM/DD/YYY) | Time of reading(24 hr clock) | Current Temperature(oC) | MinimumTemperature(oC) | MaximumTemperature(oC) | Staff initials | Comments |
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