DMID Guidelines for Investigational Study Product Management

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Frequently Asked Questions (FAQs)

Q1: What type of devices would be acceptable for back-up monitoring? For example, will they have to be certified by The National Institute of Standards and Technology (NIST)?

A1: The guidelines do not specify the exact type of device to be used for back-up temperature monitoring to allow as much flexibility as possible for the clinical research site to satisfy the requirement. Provided the back-up device is independent and separate from the primary, continuous monitoring and recording device and is calibrated with a Certificate of Traceability and Calibration Testing (also known as Report of Calibration) that is traceable to a NIST standard, any device will be sufficient. An example of a minimum/maximum thermometer was provided, but a sophisticated device would also be acceptable, so long as the indicated criteria are able to be fulfilled with the selected device.

Q2: When manually recording the back-up temperature monitoring device reading(s), must we also record the min/max reading?

A2: When manually recording daily temperature readings from a back-up temperature monitoring device that does not record temperatures (e.g. a basic Min/Max thermometer), document the current temperature as well as the minimum and maximum temperatures since the last reading (then reset the memory). Some sites may have a digital back-up monitoring device for which manual readings are not required if the device records readings (current temperature along with minimum and maximum temperatures) that are downloaded (or printed) and saved.

Q3: Do we need continuous temperature monitoring devices and alarm systems for monitoring room temperature?

A3: The guidelines state in section 4.3, Continuous Temperature Monitoring and Recording, that temperature logs must be maintained for areas of study product storage (e.g., chart recorders). Continuous temperature monitoring and recording devices are required and must provide real-time and min/max temperature information for the designated study product storage area in which the system is installed. In addition, all study product storage areas and equipment must have an alarm system to notify authorized personnel, 24 hours a day, 7 days a week, 365 days a year, of any temperature deviation/excursion from the acceptable temperature range, so that the Research Pharmacist may take immediate action, to prevent loss of study product. Our expectation is that all study product storage areas, including room temperature, should be temperature and alarm-system monitored based on the guidelines. If the clinical site believes that any of the DMID guidelines outlined in this document cannot be met, the protocol team must discuss with DMID PST to determine how best to proceed.

Q4: Does every study require a prescription or medication prescribing order? We need clarification since we currently aren't using prescriptions. If prescriptions are mandatory, will the randomization information (printout) suffice?

A4: A study protocol may or may not specifically require a prescription or medication prescribing order to dispense study product, but there should be some mechanism to inform the Research Pharmacist of the study treatment the participant has been assigned, authorization to dispense or prepare the study product, and a mechanism to verify that the prescriber is authorized to prescribe that treatment (e.g. randomization list, treatment assignment list, etc).

Q5: Per Section 6.2.2, where a study product requires only a single level or one step of non-compounding manipulation, an authorized health care practitioner may be called upon to prepare study product immediately prior to administration to a subject. This section also states that the Research Pharmacist must first label and dispense the study product to the authorized health care practitioner. Are there any circumstances where a nurse or certified person could dispense the medication?

A5: For the purposes and scope of the guidelines, only the Research Pharmacist should dispense study product. The term "dispense" generally means to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner and may include preparing, packaging, compounding or labeling of that controlled substance. We recognize that the described process may not reflect the procedures in place for all sites that may require the use of this scenario and certain circumstances may need to be discussed in advance with the protocol team. It is the responsibility of the PI to ensure all local jurisdiction and state rules or regulations comply with the procedures performed at the clinical site, including dispensing and labeling requirements. In addition, as per the guidelines, the Research Pharmacist must provide detailed instructions and training for study product preparation to the authorized health care practitioner and documentation of this training should be maintained in the site pharmacy.

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