CLINICAL POLICY

Temperature Storage of Investigational Drugs

A. EFFECTIVE DATE :
March 16, 2021

B. PURPOSE :
To assure that investigational and study drugs are stored and distributed in accordance with institutional policies and procedures, storage conditions of the manufacturer, storage conditions listed in the Investigator's Brochure, and as well as any applicable state and federal laws.

C. POLICY :

1. All investigational drugs must be stored in accordance with the instructions listed in the study's IRB-approved protocol.

D. SCOPE :
This policy applies to all areas in which investigational drugs are used.

E. DEFINITIONS :

1. **Investigational Drug** – any drug, chemical, or biologic product as an active ingredient or placebo that is being used in the context of a clinical investigation. It has been granted Investigational New Drug (IND) status by the Food and Drug Administration
2. **Investigational Drug Service (IDS)** – a division of the UConn John Dempsey Hospital Department of Pharmacy that provides support for clinical drug studies including IRB consultation and dispensing services
3. **Institutional Review Board (IRB)** – the committee that conducts oversight for all research involving human subjects at UConn Health
4. **Protocol** – a document that describes the objectives, design, methods, statistical considerations, and organization of a trial
5. **Room Temperature** – 2 0 °C (68 °F) to 25 °C (77 °F)
6. **Refrigerator Temperature Range** – 2 °C (36 °F) to 8 °C (46 °F)
7. **Freezer Temperature Range** – 0 °C (32 °F) to -30 °C (-22 °F)

F. MATERIAL(S) NEEDED :
None

G. PROCEDURE :

1. A log of temperatures for IDS refrigerators, freezers, and room temperatures must be maintained by staff on a daily basis. A log for the IDS refrigerators, freezers and room temperatures must indicate the date, time, temperature, and minimum temperature for the last 24 hours, maximum temperature for the last 24 hours, and the initials of the person recording the temperature. See appendix 1A-1C for applicable temperature reading forms.
2. IDS refrigerators and freezers are on a monitoring system that is in effect 24 hours a day 7 days a week. After a recognition time of 15 minutes that the temperature is below the minimum or above the maximum,

the Environmental Control Center (ECC), pharmacy IT, and pharmacy management will get notification of an alert. ECC will contact the main pharmacy department and/or the on call pharmacy IT resource in case of actual unit failure. ECC will contact facilities management to alert them to unit malfunction and request immediate service. Investigational medication can be moved to another pharmacy refrigerator and/or freezer to be kept under quarantine.

3. Temperature monitoring devices including wireless devices for remote monitoring should have a certificate of calibration and calibrated as appropriate. The certificate of calibration will be stored in the Investigational Temperature Record Binder.
4. Any deviation from the temperature definitions described in this policy must be immediately reported to the investigational pharmacist or pharmacist in charge.
5. In the event that any stored drugs are subjected to temperatures outside of the temperature ranges described in this policy, all such drugs must be immediately quarantined. Any such event must be documented and notices must be sent to sponsors and authorized physicians. All such drugs shall remain quarantined until other instructions are received by the sponsors in writing.
6. It is the responsibility of the investigational pharmacist to keep temperature logs readily available for study site monitors and auditors to review.
7. IDS pharmacy staff will segregate investigational drugs by study protocol.
8. Under certain cases, when investigational drugs will be stored outside of the IDS pharmacy it is the responsibility of the principal investigator to ensure that storage areas and temperature ranges follow the same standards as IDS Pharmacy.

H. ATTACHMENTS :

Appendix 1A: Temperature Monitoring: Room Temperature
Appendix 1B: Temperature Monitoring: Refrigerator
Appendix 1C: Temperature Monitoring: Freezer

I. REFERENCES :

ASHP Guidelines on the Use of Investigational Drug in Organized Health-Care Settings
Code of Federal Regulations, Good Clinical Practice, CFR 21:312.62c
Connecticut Pharmacy Law
TJC Standard, MM.7.40, Investigational medications are safely controlled and administered

J. SEARCH WORDS :

None

K. ENFORCEMENT:

Violations of this policy or associated procedures may result in appropriate disciplinary measures in accordance with University By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, the University of Connecticut Student Code, other applicable University Policies, or as outlined in any procedures document related to this policy.

L. STAKEHOLDER APPROVALS :

On File

M. COMMITTEE APPROVALS :

None

N. FINAL APPROVAL :

1. Andrew Agwunobi, MD (Signed) 3/31/2021
Andrew Agwunobi, MD, MBA Date
UConn Health Chief Executive Officer

2. Anne Horbatuck (Signed) 3/31/2021
Anne D. Horbatuck, RN, BSN, MBA Date
Clinical Policy Committee Co-Chair

3. Scott Allen. MD (Signed) 3/26/2021
Scott Allen, MD Date
Clinical Policy Committee Co-Chair

4. Caryl Ryan (Signed) 3/24/2021
Caryl Ryan, MS, BSN, RN Date
VP Quality and Patient Services & Chief Nursing Officer

O. REVISION HISTORY :
Date Issued: 12/28/2012
Date Reviewed:
Date Revised: 10/26/2015, 9/1/2017, 9/1/2020, 1/20/2021, 3/16/2021