Purpose:
This SOP will provide standard operating procedures for the receipt, storage, accountability, preparation, dispensing, and disposition of investigational agents.

References:
- The University of Arizona Medical Center, Department of Pharmacy Services Policy and Procedure, the University of Arizona Cancer Center Pharmacy Handling of Investigational Drugs 5.03.
- The University of Arizona Medical Center, Department of Pharmacy Services Policy and Procedure, The University of Arizona Cancer Center Pharmacy Drug Storage Equipment Maintenance and Quality Control 5.05
- All SOPs are applicable to this SOP.

Authors:
Revised by SOPRC.

Target Audience or Responsibilities:
This SOP applies to those members of the clinical research team involved in the handling, dispensing, administering and destruction of investigational agents. This includes the following:

- Principal Investigator (PI) or Co-Principal Investigator (Co-PI)
- Sub-investigator
- Research Nurse Coordinator
- Cancer Center Investigational Pharmacist
- Cancer Center Pharmacy Technician

Tools:
- The University of Arizona Medical Center, Department of Pharmacy Services Policy and Procedure, The University of Arizona Cancer Center Pharmacy Handling of Investigational Drugs 5.03, dated December 6, 2003.
• The University of Arizona Medical Center, Department of Pharmacy Services Policy and Procedure, The University of Arizona Cancer Center Pharmacy Drug Storage Equipment Maintenance and Quality Control 5.05, dated April 2, 2007.
Policy: Handling of Investigational Drugs

This policy and procedure will provide standard operating procedures for the receipt, storage, accountability, preparation, dispensing, and disposition of investigational drugs.

Procedure:

1.0 The Pharmacy will handle investigational drugs under the direction of the Principle Investigator (PI) and in accordance with the Institutional Review Board approved investigational protocol, The University of Arizona Medical Center (UAMC) and The University of Arizona Cancer Center (UACC) institutional policies, Federal and State regulations, and in accordance with Federal and International Good Clinical Practice guidelines. There will be a designated investigational drug service (IDS) to oversee this policy and procedure.

2.0 Personnel who routinely work in the UACC pharmacy will be trained on this policy and procedure and the training will be documented. Training will be done upon hire and once per year. Periodic reminders, clarifications, and training updates will be done as needed.

3.0 Each study will have an associated pharmacy binder or file. The pharmacy binder or file will be study specific and will serve as the storage location for pharmacy related records. It will be maintained in the pharmacy until the study drug is removed and the study is closed after which point it will be moved to the University of Arizona’s central long term storage facility.

4.0 A signature log to document the initials and signatures of all pharmacy staff that have participated in a study will reside in the pharmacy binder or file.

5.0 In general, the pharmacy will use its own internal format for the pharmacy binder or file, the investigational agent accountability record (IAAR), temperature logs, dosing worksheets (if applicable), and any other forms required for the study. Sponsor formatted binders or forms may be used if approved by the IDS pharmacist.

6.0 Procurement and Receipt

6.1 The IDS staff will make arrangements with the PI and/or sponsor to obtain investigational agents. Whenever possible, agents will be shipped directly to the pharmacy.

6.2 An entry into the IAAR will be made for each receipt of an investigational agent. The quantity received, date received, new balance, lot number, expiration date (if known), and recorder’s initials will be documented.
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6.3 The contents of investigational drug shipments will be confirmed with the shipping records (also known as packing slips). Any discrepancy or damage to the contents will be documented on the shipping record and brought to the immediate attention of the study sponsor and shipping agent, if applicable.

6.4 Once the contents of the shipment are confirmed, the shipping records will be signed by the receiving pharmacist or pharmacy technician, dated, and stored in the pharmacy binder. If there is a drug request form associated with the order, it will be filed with the packing slip. If there is a receipt form associated with the order, it will be completed and returned in the method specified by the sponsor. If the original receipt form must be returned to the sponsor, a copy of the receipt form will be placed in the pharmacy binder.

6.5 Pumps or other similar medical devices supplied by the sponsor of a study will be sent to UAMC biomedical engineering for an initial intake check and yearly preventive maintenance. If preventive maintenance is not possible, the pump or device will be returned to the sponsor for maintenance or a replacement. If corrective maintenance or repair is required, the pump or device will be returned to the sponsor.

6.6 Temperature monitors included in shipments will be read and/or returned as instructed by the sponsor and/or shipping agent.

6.7 The internal study number reference, drug name, drug strength and expiration date will be written in or highlighted on all outer containers/cartons. Whenever possible, the same information will be written in or highlighted on all immediate vials/bottles/containers. This will be done upon receipt and before the drug is added to the storage shelf. A standardized sticker may be used for this purpose, or the information may be hand written.

7.0 Storage and Security

7.1 Investigational drugs will be stored in the pharmacy under the conditions recommended by the manufacturer or sponsor. Investigational drugs will be stored in an area of the refrigerator, freezer, or shelving area designated for investigational agents.

7.2 The pharmacy is a locked, limited access area accessible only to pharmacists on staff at this location. UACC security can over-ride access to the door in the case of an emergency, but must receive supervisory approval to do so, and must prepare a written report with the details of the event and entry and supply that report to the pharmacy supervisor.
7.3 After normal business hours, the investigational drug and record storage areas are locked within the pharmacy with access limited to pharmacists only.

7.4 Pharmacy technicians and other non-pharmacist personnel are permitted in the pharmacy only when escorted by a pharmacist and in the course of their normal business.

7.5 Expiration dates, if known, will be printed or highlighted on drug containers or cartons. Expiration dates and retest dates are monitored by the IDS staff. Expired drugs are removed from active inventory on or before their expiry date and placed in quarantine.

7.6 Also see UACC pharmacy policy 5.05 for detailed drug storage equipment information including temperature monitoring, alarms, and back up plans. Temperature logs are internally generated and are stored in a central file in the pharmacy.

8.0 Accountability

8.1 A perpetual inventory (running balance) of investigational drugs will be maintained in the IAAR. The IAAR is study specific, drug specific, and dosage strength specific. It is not necessarily lot number specific. The original IAAR is located in the pharmacy binder or file.

8.2 When a drug is received, dispensed, destroyed, or otherwise removed from inventory, an entry will be made in the IAAR. The date, quantity received, dispensed (or quantity used for preparation), destroyed or removed, lot number, and recording pharmacist or pharmacy technician initials will be recorded. If the agent is removed from inventory for a patient, the patient initials, specific dose, and patient number will be recorded. Information recorded in the IAAR will be transcribed from the pharmacy daily patient log/batch records. See section 10.11 for a description of the daily patient log/batch record.

8.3 Copies of the IAAR can be provided to a sponsor as long as such copies would not compromise a blinded study. Copies of the IAAR can be provided to the UACC Clinical Trials Office (CTO) for inclusion into regulatory binders, as long as such information would not compromise a blinded study.

8.4 Black ink should be used for all entries in the IAAR. Errors will be crossed out with a single pen stroke, then dated and initialed, and explained if necessary.
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8.5 Study monitors will be asked to make an entry on the IAAR when they audit a particular protocol and have verified the count.

8.6 In addition to the perpetual inventory, a comprehensive inventory and physical count of all investigational drugs will be done every 6 months (+/- 3 weeks). Results will be documented in the IAAR for each drug.

8.7 Examples of the IAAR for oral and IV drugs are attached to this policy and procedure. The forms can be modified to better fit the needs of individual studies and are not version controlled.

9.0 Drug Information

9.1 The IRB approved protocol and most current Investigator Brochure will be available to all pharmacy staff, either in print or in The UACC electronic database. The UACC CTO staff is responsible for notifying the IDS pharmacist of protocol updates, investigator brochure updates, and any other updates to the study in a timely fashion.

9.2 A study specific “Pharmacy Fast Facts” will be generated for all clinical studies with drugs that will, or could be, dispensed from The UACC Pharmacy. The Pharmacy Fast Facts will contain a synopsis of the study and drug information as well as the drug preparation and dispensing instructions. The Pharmacy Fast Facts are located in binders in the pharmacy and in an electronic database accessible to all pharmacy staff.

9.3 Personnel that routinely work in The UACC Pharmacy will be asked to read each Pharmacy Fast Facts prior to involvement in the study. Personnel will document their training and understanding of the study by signing and dating the fast facts form. The Pharmacy Fast Facts should also be viewed prior to each dose being prepared.

9.4 Updates to the Pharmacy Fast Facts will be made based on amendments and other information that becomes available as the study is ongoing. For major changes, personnel will be asked to read and understand the updated information and document such training by signing the updated Pharmacy Fast Facts. For minor updates/changes, the information can be hand written on the fast facts (and updated in the electronic version) and a complete re-training is not necessary. The Pharmacy Fast Facts should be viewed prior to each dose being prepared. Outdated versions of fast facts will be maintained in the pharmacy binder for the study.
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9.5 Whenever possible, IDS staff will attend the Site Initiation Visits for each new study.

10.0 Dispensing

10.1 It is the responsibility of the PI, the research nurse (RN), or the clinical research coordinator (CRC) to give the IDS staff advanced notice of patients starting a study. It is the responsibility of the IDS staff to insure that an adequate stock is on hand, and to insure that pharmacy personnel have been properly trained.

10.2 Investigational drugs will be prepared and dispensed only upon a valid pharmacy order by the PI or other practitioner listed on the 1572 form. It is the responsibility of the prescriber, the research RN, and the CRC to insure that the person writing the order is on the 1572 for the study. The original order will remain part of the patient’s medical record. Copies of orders may be stored in the pharmacy in the pharmacy binder for the study, or in a central pharmacy file.

10.3 Pre-printed pharmacy order templates may be created and must be approved by the PI prior to use. Updates to the template may occur. The PI will be notified for major changes to the template.

10.4 A Pharmacy computer software system will be used such that investigational drugs are pre-built into the system along with the drug concentration or strength and the associated internal study reference number. The computer automatically calculates the dose or dose volume based on the pre-built concentration or strength and the patient’s individual parameters. These values are then printed on the drug dispensing label and are double checked by the pharmacist and either another pharmacist or a pharmacy technician prior to preparation and dispensing. If more advanced calculations are required for dosage preparation, a study specific, patient specific dosing worksheet may be utilized to document those calculations. Completed dosing worksheets will be stored in the pharmacy binder.

10.5 The physician that completes a pharmacy order performs calculations such as body surface area (BSA) and dose and enters the results on the pharmacy order. The calculations will be double checked by a pharmacist. The physician will be contacted by a pharmacist only if there is a 5% difference in the calculation. The pharmacy preferred BSA calculation is the DuBois formula. However, it is not mandated that physicians use this formula when calculating a BSA. If a specific formula is called for in a protocol, it will be noted on the pre-printed order template to prompt the prescriber to use it.
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10.6 There are no standard rounding requirements for weight, BSA or dosage calculations. The dose volume calculation for drug preparation is rounded to the nearest hundredth as a standard by the pharmacy computer software. If there are specific rounding requirements in the protocol, they will be noted on the pre-printed order and the fast facts.

10.7 When an initial order for an investigational drug is received in the pharmacy, it must be accompanied by the internal registration verification form. The registration verification form is initiated and completed by the research staff (RN and/or CRC). Any sponsor correspondence or form with registration or treatment assignment information must also be presented to the pharmacy by the research staff.

10.8 The instructions for preparing an investigational drug will be located in the Pharmacy Fast Facts. If questions arise, the study protocol, PI, and/or sponsor will be consulted.

10.9 Investigational drugs will be appropriately labeled upon dispensing as per sponsor requirements as well as applicable State and Federal regulations and guidelines.

10.10 Unless otherwise instructed by the sponsor, drugs returned by a patient will not be re-dispensed.

10.11 Dispensing of investigational agents will be integrated into the established, standard medication distribution system of the UACC pharmacy. A daily patient log/batch record is generated to record all drugs (commercial and investigational) for all patients prepared for the day. On that log, the following items, at minimum, are recorded for investigational drugs: patient name, date, medical record number, dose, dose volume, diluent, diluent volume, infusion time or rate, manufacturer name, lot number, number of vials used, time prepared, initials of pharmacy technician (preparer), initials of pharmacist (preparer and/or checker). The data from the daily patient log/batch record is used by the recorder who transcribes that information into the IAAR. The daily patient logs/batch records are maintained for at least 2 years in the pharmacy and then indefinitely in the University of Arizona long term storage central facility. The daily patient logs/batch records are available for inspection as requested.
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10.12 Investigational drugs are not prepared until the patient has arrived and a treatment chair opening is verified. In addition, the treating physician or RN will communicate to the pharmacy that the patient is "OK to treat" by verbally indicating the statement to the pharmacy, and by writing "OK to treat" or a similar phrase on the patient encounter form for the visit day before preparation can commence. The "OK to treat" implies that the treating physician or RN has verified that the patient has met all of the treatment/re-treatment criteria and procedural requirements in the protocol.

10.13 A set of labels is generated after the items on the physician order are entered into the pharmacy computer system. The set consists of 1 dispensing label that will eventually be attached to the final drug preparation, and one profile label that is a duplicate and attached to the daily patient log/batch record.

10.14 Injectable investigational drugs will be prepared in the pharmacy clean room according to the instructions provided in the investigational protocol or pharmacy manual and according to The University of Arizona Medical Center policies and procedures for the preparation of antineoplastic drugs and for gene therapy.

10.15 The pharmacist or pharmacy technician will use the internal study reference number from the computer generated label to determine which study supply to pull drug from. The physician order, the dispensing and profile labels, and the drug container must all have the same internal reference number, or the numbers must be able to be cross referenced as matches for each other.

10.16 Unless otherwise instructed by the protocol or the treating physician, actual body weight will be used for BSA calculations and for dosage calculations.

10.17 Unless otherwise instructed by the protocol, the weight recorded on the physician order will be used to calculate all doses written for on that order.

10.18 In general, physician orders are valid for a maximum of 28 days, after which date they must be re-written. Exceptions are possible only if pre-approved by the pharmacy staff.
10.19 Investigational drugs that are prepared in the IV room require and “ID check” of the vial(s) prior to drug preparation. This check must be done after the drug is pulled from the storage shelf and before the containers are taken into the IV room for preparation. The check must compare the drug name and study number on the vial to that on the drug dispensing label. The check must be documented on the profile label by circling the drug name and study number, handwriting the date, checker’s initials, and time. This check will be done by a pharmacist other than the pharmacist that will check the final preparation. In the event that a second pharmacist is not available, and RN, or a pharmacy technician not involved in the preparation of the drug can do the “ID check”.

10.20 All investigational drug preparations must have an official “Time Out” checklist completed prior to preparation (for IV drugs) or dispensing (for take home drugs). Examples of “Time Out” checklists are attached to this policy and procedure.

11.0 Disposition and immediate “on site” destruction

11.1 The term “on site” destruction is used to distinguish between drug destruction initiated by the UACC pharmacy and completed by an agent under contract versus drug returned to the sponsor (or designated agent).

11.2 Immediate “on site” destruction is required for used and partially used drug vials and for “take home” drug returned by a patient unless there is a compelling reason (as determined by the IDS staff) to retain the agent on site.

11.3 Empty and partially used vials will be placed in a chemo-safety biohazard waste container immediately after dose preparation and verification. All pharmacy personnel involved in investigational drug preparation in the clean room on a particular day will sign the daily patient log/batch record statement regarding vial destruction.

11.4 Leftover “take home” drugs that are returned by a patient are counted and documented by the research staff (MD, RN, or CRC) and returned in a timely manner to the pharmacy. In the pharmacy, the returns will be counted by 2 pharmacy personnel and the quantity will be documented in the IAAR. The drug(s) will then be immediately placed in the chemo-safety biohazard waste container.

11.5 The research staff (MD, RN, CRC) is responsible for compliance assessments for take home drugs. However, the pharmacy staff should contact the research staff for any discrepancies in the returned drug count, or for compliance questions.
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11.6 Chemo-safety biohazard waste containers remain in the pharmacy until they are about ¾ full. They are then sealed in the pharmacy and then transported to a secure location until they are picked up by Stericycle, Inc., a waste vendor under contract with The UACC. Waste containers are picked up 2 or 3 times a week. The waste bins are transported in 44 gallon sealed containers inside of a lined tractor trailer to Stericycle’s incineration facility at 90 N. 1100 W, Salt Lake City, Utah 85054. The ultimate method of destruction is incineration.

11.7 Sponsors are responsible for investigational drug shipments, including proper packaging and labeling.

11.8 Un-used drugs should be promptly removed from the pharmacy once all patients are off drug treatment and the accrual to the study is closed. If the sponsor does not remove the drug within a year from the last patient receiving a dose, the agent will be destroyed on site as described above in sections 11.1-11.6. The destruction will be properly documented on the IAAR.

11.9 Expired agents will be removed from active inventory and placed in quarantine on or before their use by date. Expired agents will be removed from the pharmacy by the sponsor in a timely manner. In general, if the sponsor does not remove the drug within 6 months of its expiry date, the drug will be destroyed on site as described in sections 11.1-11.6 and properly documented on the IAAR.

12.0 Sponsor or representative visits

12.1 Pharmacy visits are scheduled through the CRC. In general, unscheduled visits cannot be accommodated.

12.2 Sponsor representatives will be asked to sign in for each pharmacy visit on a pharmacy sponsor signature log located in the pharmacy binder/file.
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13.0 Protocol deviations

13.1 A deviation from the protocol with regard to drug receipt, drug storage, drug dispensing, drug accountability or any other issue that pertains to the responsibilities of the pharmacy with regard to investigational drug will be immediately reported to the sponsor. For deviations related to patient care, the PI, RN, and CRC will also be immediately notified. Deviations will be documented in a note to file. Original notes to file will remain in the pharmacy binder/folder. Copies will be distributed as indicated.

Rafael A. Diaz, Pharmacy Director

TIME OUT Checklist for Investigational Drugs

For Oral or other drugs dispensed to RN without preparation in the IV room – Complete this form after the label has been affixed to the drug container, but before it is dispensed. One checker is the pharmacist who will check the final preparation prior to dispensing. The other checker is (in order of preference) a different pharmacist, a research RN, charge RN, or pharmacy technician. NOTE: do not compromise a blinded study.

DO NOT fill in any portion of this form ahead of time. This form must be filled out in real time with the 2 checkers, the physician order, the computer generated labels, the pharmacy fast facts and sponsor dose assignment form (if applicable), the randomization form (if applicable) and the drug container present at the same time. The 2 checkers must verbally call “time out”, stop the other things they are doing and focus on this task alone. Drug should be prepared/dispensed immediately after this checklist is completed.

Patient Name: __________________________ Protocol Number:________________________
Today’s Date(month/day/year): ________ Time: ________ Study Drug Name: __________________
Print name of Checker 1: ____________________ Print name of Checker 2: ____________________

1) Verify REGISTRATION:
   * If the patient is beginning the protocol today, check that the registration is current and complete: ___ (X when done)

2) Verify CALCULATIONS:
   * If BSA is used to calculate dose, check BSA calculation – must be within 5% of dose on physician order ___ (X when done)
   * Use parameters on physician order, check dose calculation – must be within 5% of dose on physician order ___ (X when done)

3) Verify that you have the right PATIENT:
   * Read out loud the patient name on physician order and on computer label, verify match ___ (X when done)
   * Read out loud the date of birth on physician order and on computer label, verify match ___ (X when done)

4) Verify that you have the right STUDY:
   * Read out loud the study number on physician order, the computer label and on the drug vial/container, verify match ___ (X when done)

5) Verify that you have the right DRUG:
   * Read out loud the drug name on physician order, computer label, and on the drug vial/container, verify match ___ (X when done)
   * If drug is blinded with an IVRS assignment, verify IVRS assignment to drug container(s) for match ___ (X when done)

6) Verify that you have the right DOSE:
   * Read out loud the patient dose from physician order and the computer label, verify match ___ (X when done)
   * Read out loud the dosage strength from drug container and verify to computer label ___ (X when done)
   * Compare dose to parameters in fast facts, and on sponsor provided form/communication (if one exists), verify match ___ (X when done)

Verification signatures: Checker 1: __________________________ Checker 2: __________________________

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Version 2.
TIME OUT Checklist for Investigational Drugs

For IV/IM/IO drugs prepared in the IV room – Complete this form after the drug is pulled and after the ID check is done, but before it enters the hood for preparation. One of the checkers must be the pharmacy technician or pharmacist who will prepare the drug and the second checker is the pharmacist who will check the final preparation before it is dispensed. If the same pharmacist is preparing the drug and checking it, then a second person must perform this checklist with them. The second checker can be (in order of preference) a different pharmacist, a research RN, charge RN, staff RN or pharmacy technician. NOTE: do not compromise a blinded study.

DO NOT fill in any portion of this form ahead of time. This form must be filled out in real time with the 2 checkers, the physician order, the computer generated label(s), the pharmacy fast facts and sponsor dose assignment form (if applicable), the randomization form (if applicable) and the drug container present at the same time. The 2 checkers must verbally call "time out", stop the other things they are doing and focus on this task alone. Drug should be prepared/dispensed immediately after this checklist is completed.

Patient Name: ___________________________ Protocol Number: ___________________________
Today’s Date (month/day/year): _________ Time: _________ Study Drug Name: _______________________
Print name of Checker 1: ___________________________ Print name of Checker 2: _______________________

1) Verify REGISTRATION:
* If the patient is beginning the protocol today, the registration is current and complete: ___(X when done)

2) Verify CALCULATIONS:
* If BSA is used to calculate dose, check BSA calculation – must be within 5% of dose on physician order ___(X when done)
* Use parameters on physician order, check dose calculation – must be within 5% of dose on physician order ___(X when done)

3) Verify that you have the right PATIENT:
READ OUT LOUD:
*Patient name on physician order and on computer label, verify match ___(X when done)
*Date of birth on physician order and on computer label, verify match ___(X when done)

4) Verify that you have the right STUDY:
READ OUT LOUD:
*Study number on physician order, the computer label and on the drug vial/container, verify match ___(X when done)

5) Verify that you have the right DRUG and DILUENT and TUBING:
READ OUT LOUD:
*Drug name on physician order, computer label, and on the drug vial/container, verify match ___(X when done)
*Diluent name on physician order and computer label, verify match ___(X when done)
*Tubing verified and compared to administration instructions ___(X when done)
*If drug is blinded with an IVRS assignment, verify IVRS assignment to drug container(s) for match ___(X when done)
*Verify that drug ID check was completed on profile label ___(X when done)

6) Verify that you have the right DOSE:
READ OUT LOUD:
* Patient dose from physician order and the computer label, verify match ___(X when done)
* Read out loud concentration from vial label and verify dose calculation by writing it here:

* Compare dose calculation above to computer label, verify match ___(X when done)
* Compare dose to fast facts, and on sponsor provided form/communication(if one exists), verify match ___(X when done)

Verification signatures: Checker 1: ___________________________ Checker 2: ___________________________

Version 2, 3/15/11
A. **PRINCIPLE**

Regularly scheduled maintenance and well-developed quality control procedures are essential to ensure the optimal and consistent performance of equipment and areas used for drug storage.

B. **GENERAL QUALITY CONTROL**

1. All pieces of equipment used for continuous drug storage will have emergency back up power and will have internal temperatures monitored.
2. Completed temperature charts and logs will be saved in pharmacy for a period of at least 2 years. After that, they will be maintained indefinitely at the University of Arizona’s long term storage facility.

C. **TEMPERATURE RANGES AND THERMOMETERS/TEMPERATURE PROBES**

1. Temperature ranges are pre-determined and programmed for each piece of equipment. Out of range temperatures will trigger audible alarms, and, if the equipment is used for continuous drug storage, a wired signal to UMC security.
   a. Refrigerators have an acceptable temperature range of 2°C to 8°C.
   b. The freezer has an acceptable temperature range of below -20°C.
   c. The deep freezer has an acceptable temperature range of below -70°C.
   d. The room temperature range is 20°C to 25°C.

2. Thermometers
   a. The refrigerators, freezers and room temperature storage areas will have a thermometer calibrated to NIST traceable standards. The calibration is considered valid for the time listed on the certificate of calibration.
   b. If a re-calibration is performed, the procedure used for calibration will be maintained in the equipment binder for the piece of equipment/storage area.
   c. The thermometer/temperature probe will have an appropriate range for the temperatures being measured.
D. **TEMPERATURE RECORDING**

1. Routine temperature monitoring will be done by Pharmacy personnel.

2. Refrigerators used for continuous drug storage, and the freezer will have continuous temperature monitoring via chart recorders. In addition, on all days that the Pharmacy is open for business, a manual check of the chart recorder, a manual check of the digital read out, and a manual check of any other temperature probes/thermometers present will be done and the data recorded. The manual check will be done at approximately the same time each day.

3. The deep freezer has a digital temperature read out that is manually read once per day, on days that the pharmacy is open for business. The manual check will be done at approximately the same time each day, and results will be recorded on a temperature log. A manual check of any other temperature probes/thermometers present will also be done and recorded at the same time.

4. The room temperature has a digital temperature read out that is manually read once per day, on days that the Pharmacy is open for business. The manual check will be done at approximately the same time each day, and results will be recorded on a temperature log. A manual check of any other temperature probes/thermometers present will also be done and recorded at the same time.

5. Refrigerators used for short term drug storage (staging refrigerator) will house drugs only during business hours. Temperature monitoring will consist of daily manual checks and recording.
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Drug Storage Equipment Maintenance and Quality Control

6. CHART RECORDERS

a. Charts will be changed weekly by a Pharmacist or Pharmacy technician on the same day and at approximately the same time each week.

b. Before a new chart is placed in the recorder, the date, equipment number, and initials of the Pharmacist or technician will be written near the center, innermost section of the chart.

c. A small mark and the word “start” will be placed on the vertical line of the chart that represents the day and time the chart is being started.

d. Care will be taken to ensure any written marks on the chart will not obscure any recordings.

e. When the chart is changed, a small mark and the word “end” will be placed on the vertical line of the chart that represents the day and time the chart is being removed.

f. The date of removal will be written at the center of the completed chart.

g. The completed charts will be reviewed by a Pharmacist for any gaps, spikes, trends, or any other unusual recordings. The reviewer will initial and date on the back of the chart as proof of their review. Any unusual findings will be investigated. UMC Facilities Management will be notified if necessary. An explanation should be written on the back of the chart for any investigation.

h. If the chart recorder malfunctions, UMC Facilities Management will be notified.
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Drug Storage Equipment Maintenance and Quality Control

7. MANUAL RECORDING
   a. A manual temperature check and associated record keeping will be done for all drug storage equipment and areas on all days the Pharmacy is open for business. The manual check will be done at approximately the same time each day.
   b. If there is a chart recorder for the equipment, the temperature will be recorded. A visual check of the recorder and chart will also be done to ensure the pen is on the correct day and time, and that the chart recorder is functioning properly. The Pharmacist in charge will be notified for any gaps or other irregularities, and findings and action taken will be recorded on the temperature log. UMC Facilities Management will be notified.
   c. If there is a digital read out for the equipment, the temperature will be recorded.
   d. If there is a separate NIST thermometer, the temperature will be recorded.
   e. If there are any other temperature probes/thermometers present, the temperature(s) will be recorded.
   f. All temperature readings for a piece of equipment will be compared. If the temperatures do not fall within +/- 2°C of one another, the Pharmacist in charge will be notified.
   g. If any temperature recording is outside of the pre-determined acceptable range, the Pharmacist in charge and UMC Facilities Management will be notified.

E. ALARMS
   1. The refrigerators, freezers, and room temperature storage areas have audible alarms should the temperature go out of the acceptable range. In addition, any equipment used for continuous drug storage has an alarm that is wired to UMC security.
   2. Alarms (both audible and calls from UMC security) will be noted on the maintenance log for the piece of equipment or storage area. UMC Facilities will be notified and a timely assessment of the problem will be made. If the temperature cannot be consistently maintained in the acceptable range, the contingency plan will be put into place. The results of the investigation and action taken must be noted on the either the temperature log, and/or the equipment maintenance log, as appropriate for the situation.
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Drug Storage Equipment Maintenance and Quality Control

3. After hours alarms will go to UMC security first. UMC security will have a pharmacist contact list and will notify a pharmacist immediately upon receipt of an alarm.

F. MAINTENANCE
1. UMC Facilities Management will be responsible for monthly alarm checks and quarterly preventive maintenance of refrigerators, freezers and the room storage area.
2. Upon performing service, UMC Facilities Management personnel will record their actions, results, date and their name on the maintenance log for the piece of equipment/storage area.
3. Pharmacy personnel will review the entries from Facilities personnel in the binder and sign that they have done the review.

G. CONTINGENCY PLAN
1. In the event the temperature cannot be maintained, the contents of the equipment or room temperature area will be moved as described below.
2. For a refrigerator failure, the contents of the refrigerator will be moved into the second Pharmacy refrigerator. Temperatures will be monitored and saved as previously described in this procedure.
3. For a freezer failure, the contents of the freezer will be packed into a cooler box with dry ice and moved to the UMC inpatient pharmacy freezer. The UMC inpatient pharmacy freezer has continuous temperature monitoring via a chart recorder, and has an audible alarm. The pharmacy is continually staffed, and only Pharmacy staff has access to the Pharmacy. If needed, a NIST calibrated thermometer will also be placed in the inpatient pharmacy freezer. Copies of the temperature wheels and any logs will be maintained indefinitely.
4. For a deep freezer failure, the contents of the deep freezer will be moved to the PK sample/lab freezer. This freezer is located in a locked room accessible to clinical research staff only. The temperature of this freezer is continuously monitored via a chart recorder. A NIST traceable calibrated thermometer will also be placed in the freezer, if needed. The freezer is not alarmed to security. Pharmacy personnel will check the temperature daily on all days the Pharmacy is open for business, and will record findings on a temperature log. Pharmacy personnel will inspect the chart and recorder daily and note any abnormalities. Copies of the temperature wheels and any logs will be maintained indefinitely.
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5. For a room temperature failure, the contents of the storage area will be moved to the secure Pharmacy storage area. This area is accessible to Pharmacy staff only. The area does not have an alarm to security for out of range temperatures. The maximum and minimum temperatures will be monitored daily on all days the Pharmacy is open for business, and findings will be recorded on a temperature log and maintained as described in this procedure.

Written by: ___________________________ Date: __________

Approved by: ___________________________ Date: __________
Title: ___________________________ Department: ___________________________

Approved by: ___________________________ Date: __________
Title: ___________________________ Department: ___________________________

Approved by: ___________________________ Date: __________
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Rafael A. Diaz, Pharmacy Director

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