Clinical Research Shared Service Standard Operating Procedure

SOP 203-RNN Chemotherapy and Investigational Drug Administration

Approval signature: [Signature]
Michael Bookman, M.D., Director of CRSS

Approval date: 23 Dec 2011

Original approval date: 1/5/04
Revision date: 1/18/05, 12/17/08, 12/22/11

Purpose: To enforce compliance with University of Arizona Cancer Center (UACC) and University of Arizona Medical Center (UMC) policies and procedures regarding administration of chemotherapy and investigational drugs.

References:
- UMC - Chemotherapy and Biotherapy Administration Protocol (1220)
- UACC - Chemotherapy/Biotherapy Administration (UACC PRO-11)
- UMC - Cytotoxic and P & U Listed PCRA Pharmaceutical Agents and Wastes Management Plan (SA 1018E)
- UMC - Investigational Studies by Non-University of Arizona Medical center Nurses (NURAD 7)
- UMC - Inpatient Pharmacy - Investigational Drugs (2.28)
- UMC - Handling of Investigational Drugs (5.03)
- UMC - Medication Administration and Potentially Harmful Drugs Protocol (1590.0)
- UACC - Use of Chemotherapy/Biotherapy Pharmacy Orders & Electronic Order Sets (UACC POL-34)
- All SOPs are applicable to this SOP.

Authors:
Revised by SOPRC.

Target Audience or Responsibilities:
All personnel who administer chemotherapy or investigational drugs at the University of Arizona Cancer Center.

Tools:
- UACC/UMC Policies and Procedures (Attachments 1-8).

Definition of Terms:
- **Chemotherapy:** Treatment with anticancer drugs.
- **Investigational Drug:** A new drug for which an IND (Investigational New Drug application) has been filed with the FDA (U.S. Food and Drug Administration) and which may be lawfully used for clinical investigations in humans. Currently marketed drugs may be considered
investigational and require that an IND be filed if the use of the product is outside the approved labeling for the drug in connection with a research study.

**Safety Issues:**
To provide quality patient care by certified staff. To enhance the safe delivery of chemotherapy and investigational drugs and ensure compliance with UACC/UMC guidelines.

**Process Steps:**
1) All new research nursing staff will be chemotherapy-certified by attending and passing the two day class titled “Administration of Chemotherapy” offered by UACC/UMC prior to administering chemotherapy or investigational drugs to patients. In addition, new research nurses who have little or no prior oncology experience will also attend the two class session titled “Basic Oncology Review”.

2) All research nursing staff will review UACC/UMC policies for the administration, handling and disposal of cytotoxic agents and wastes within the UACC/UMC facilities (Attachments 1-8).

3) All research nursing staff who are employed by any entity to conduct investigational studies within UACC/UMC must complete the annual Healthcare Affiliate packet with initial and/or annual competencies to verify continued competency to perform such tasks.

4) Review and update of UACC/UMC policies will be documented annually or as notified of policy changes.
Attachment 1

Chemotherapy and Biotherapy Administration Protocol (1220)
DEPARTMENT OF PATIENT CARE SERVICES

Chemotherapy and Biotherapy Administration Protocol (1220.0)

IMPLEMENTATION DATE: 3/8/93
REVISION DATE: 8/12/94, 2/9/98, 1/9/02, 2/19/02, 7/16/02
12/21/04, 6/16/09, 5/18/10
REVIEW DATE: NEXT REVIEW DATE: 5/2013
SIGNED BY:

Heidi Costello, RN, BSN, MBA  Jayne Matte-Wilson, RN, BSN  Lori Throne, RN, BC, MSN
Director, Adult Health Services  Director, Critical Care Services  Director, Women & Children Services

PURPOSE:
To outline the guidelines for safe administration of chemotherapeutic and biotherapy agents in accordance with the recommendations for nursing education and practice established by the Oncology Nursing Society.

SUPPORTIVE DATA:
The administration of chemotherapeutic and biotherapy agents requires specific training and knowledge.

CHEMOTHERAPY/BIOThERAPY ORDERS:
1.0 Chemotherapy/biotherapy orders must be written by an Attending Physician, Fellow or Nurse Practitioner on the Chemotherapy Order Form.

1.1 Chemotherapy/biotherapy for non-cancer diagnoses may be written using computer order entry (eg. hydroxyurea for sickle cell anemia). These orders must be verified by the attending physician before they become active. The orders will be transcribed on the Chemotherapy Medication Record and verified by two RNs. (Both RNs must have minimally completed the UMC Administration of Chemotherapy and Biotherapy Agents for Non-Oncology Nurses course or at least 1 RN has received specific training and education in the administration of chemotherapy/biotherapy.)

2.0 All information outlined by the form should be completed, including the signature of the responsible Physician, Fellow or Nurse Practitioner.
3.0 The chemotherapy/biotherapy orders are then transcribed by the Unit Assistant onto the Chemotherapy Medication Record.

3.1 For units on Electronic Medication Administration Records the Chemotherapy orders are to be transcribed by the pharmacist and be included in the eMAR sheets. The eMAR is then transcribed to the chemotherapy administration record by the Unit Clerk.

4.0 Following the transcription of the orders, two RNs (both of whom have received specific training and education in administration of chemotherapy/biotherapy) must verify the information on the chemotherapy/biotherapy orders including:

4.1 Patient Name and Medical Record Number.

4.2 Patient diagnosis.

4.3 Patient's height, weight, and calculated body surface area (BSA) * Height and Weight should be actual and current!

4.4 Appropriateness of each drug, dose, and route of administration, including verification of calculations for patient dose, length of infusion, and days of administration.

4.5 Special administration requirements, if any.

4.6 Protocol modifications, if any.

4.7 Date therapy is to begin.

4.8 Signature of Attending Physician, Fellow or Nurse Practitioner.

4.9 Premedications and/or antiemetics if appropriate.

5.0 Following verification of the orders, two RNs (both of whom have received specific training and education in administration of chemotherapy/biotherapy) must verify the transcription of the orders to the chemotherapy medication record.

5.1 Check each drug, dose, route of administration, and dates of administration.

5.2 Place " / " in the boxes for days which the drugs are not to be administered - DO NOT ENTER DATES AT THIS POINT.

5.3 Verify any additional information regarding administration of the chemotherapy/biotherapy.
5.4 Both RNs who have verified the transcription of the orders to the medication sheet must document verification in the following fashion:
   - Sign at the top middle of the chemotherapy order sheet. These signatures must be the same signatures of the two RNs who sign on the physician order sheet.
   - Initial each chemotherapeutic/biotherapy agent on the Medication Administration Record in the space provided to the left.
   - Initial and sign each eMAR in the MAR checked by area and the 2nd Check (as required) areas.

PRIOR TO ADMINISTRATION:
6.0 Obtain the Chemotherapy Documentation Form. Complete baseline information, including pertinent laboratory data, (BUN, creatinine, WBC, platelet count), baseline diagnostic testing (i.e. EKG, MUGA)

7.0 With two RNs, check the drugs sent from pharmacy against the chemotherapy/biotherapy orders or chemotherapy medication record for:
   7.1 Correct patient
   7.2 Correct drug
   7.3 Correct dose
   7.4 Correct date/time
   7.5 Correct route

8.0 Both RNs should initial the chemotherapy documentation record in the designated area. * If administering the first dose - both RNs should enter the appropriate dates for all days chemotherapy/biotherapy is to be administered starting with the block designated as Day 1.

9.0 Obtain prescribed pre-medications and antiemetics - be certain all necessary drugs are available prior to administering the chemotherapy/biotherapy. Do not administer the pre-meds until a site for the administration of the chemotherapy/biotherapy is established.

10.0 A Time Out is performed at the bedside. Both RN’s must take medication and medication record to the bedside and check 2 patient identifiers against the label on the chemotherapy and verify the correct patient, correct drug, correct dose, correct date/time and correct route. This check should include a double check of the programming of the IV pump.
ROUTE OF ADMINISTRATION:

11.0 IV route:

11.1 Avoid the dorsum of the hand, the wrist, and the antecubital fossa.

11.2 The optimal location is the distal forearm.

11.3 Avoid use of extremities with impaired venous or lymphatic return i.e.: mastectomy.

11.4 Avoid use of extremities with impaired skin integrity.

11.5 Utilize a catheter appropriate for the individual patient.

11.6 Existing peripheral IVs may be used with caution if they are less than 24 hours old, have no evidence of redness, swelling, or tenderness, have a good blood return, and are in an appropriate location for the drugs being administered.

11.7 Establish patency of the catheter using 10-15 ml Normal Saline.

11.8 Implement IV Therapy Protocol.

12.0 IM route:

12.1 It is recommended that most chemotherapeutic agents be administered in the buttocks or ventral gluteal area. The lateral thigh may be used with caution.

12.2 For drugs requiring multiple doses in sequence (i.e.: L-spar), injection sites should be rotated to avoid tissue damage and discomfort.

12.3 Please consult the Smith and Duell Clinical Procedure Manual for a review of the appropriate administration techniques of intramuscular injections.

13.0 Subcutaneous route:

13.1 Injections may be administered in the abdomen, lateral aspects of the upper arms or thighs. Refer to Smith and Duell Clinical Procedure Manual for review of techniques.

14.0 Consult Chemotherapy book and other available references for alternate forms of chemotherapy/biotherapy administration (i.e.: intra-arterial, intraperitoneal, intrapleural, intrathecal). See Table 1: Routes of Administration of Antineoplastic Agents (ONS, 1996). Routes not covered
in the UMC Chemotherapy Workshop must be administered by RNs who have been trained for that specific route.

SAFE ADMINISTRATION:
15.0 Only RNs who have obtained specific training and education should administer chemo and biotherapy. Nurses who have obtained hospital certification for the administration of chemotherapy/biotherapy may administer any chemo/biotherapy agent as ordered by the physician/LIP. Nurses who have received education and are deemed competent in the administration of particular agents (such as rituximab or oral cytoxan) specific to their area of practice may administer these agents.

15.1 RNs who have obtained outside chemotherapy certification (i.e. ONS) must obtain hospital certification before administration of chemo/biotherapy.

16.0 Administer pre-medications once site is established.

17.0 Refer to Chemotherapy book for recommendations on safe handling of chemotherapeutic/biotherapy agents. Personal protective equipment should include:
   - Chemotherapy gown (long-sleeve plastic lined, with cuffs).
   - Chemotherapy gloves. If patient or caregiver has a known or suspected latex sensitivity or allergy, gloves should be made from an alternative material.
   - Mask with clear eye shield if potential for splash.
   - Chemotherapy disposal bag.

GUIDELINES FOR IV ADMINISTRATION:
18.0 Site selection as for # 10.

19.0 Establish patency, prime IV tubing using normal saline.

20.0 The vesicant "pushes" may be administered via the side arm of a running NS IV hung specifically for the chemotherapy. Protective attire must be worn by the RN and a 2 X 2 gauze pad should be placed under the port of the sidearm to catch any accidental leakage.

21.0 Use slow even pressure on plunger of syringe - NEVER USE FORCE - if resistance is met, reassess patency using NS.

22.0 Checking for blood return:

22.1 Every 3-5 ml for one time push infusions.
22.2 At least once a shift, with chemotherapy/biotherapy bag changes, and prn for continuous peripheral infusions.

22.3 At least once every 24 hours with lab draws, with chemotherapy/biotherapy bag and tubing changes, and prn for central line continuous infusions.

23.0 All continuous infusions which contain a vesicant agent or severe irritant agent must be administered through a patent central line, right atrial catheter, or implanted infusion port. Central lines are recommended for severe irritant infusions in patients at risk for infiltration.

24.0 15-20 ml of normal saline should be administered between drugs and after the infusion of the last agent.

25.0 After completion of the infusion, if the catheter is to be removed, hold pressure to the site for 3-4 minutes and instruct the patient to avoid dangling the extremity for 15-20 minutes.

26.0 A clave should be used during the infusion. The clave must be changed after completion of the chemo/biotherapy or any time the IV tubing delivering chemotherapy/biotherapy is changed. IV tubing must be disposed of after completion of the infusion or, for continuous infusions, changed every 24 hours when hanging a new medication bag or as otherwise directed (i.e., change every 8 hr. with continuous Etoposide due to instability).

**EXTRAVASATION MANAGEMENT:**

27.0 If a chemotherapeutic/biotherapy agent extravasates:

27.1 Stop the infusion, but do not remove the catheter/needle.

27.2 Obtain extravasation kit and prepare equipment.

27.3 Contact the physician/LIP.

27.4 Blood return versus no blood return.

   27.4.1 Blood Return.
   a. Disconnect IV tubing from cannula.

   b. Attach 5 ml syringe to cannula.

   c. Aspirate 3-5 ml of blood from IV line.
d. Remove syringe containing blood and attach syringe containing antidote (refer to extravasation kit or pharmacy).

e. Apply ice or hot pack (see 25.4.2.5. below).

27.4.2 No Blood Return.
a. Remove IV and continue with antidote subcutaneous (SQ) at IV site.

b. Administer multiple SQ injections (pin-cushion style) of antidote approximately 1/2 inch apart to include entire suspected extravasation site.

c. Change needle (using 25 gauge needle) every puncture to maintain sterility.

d. Total dose of antidote will depend on the size of the extravasation.

e. Apply ice or hot pack.

f. Apply ice pack for extravasation related to all vesicants EXCEPT vincristine or vinblastine.

g. Apply topical ointments as needed, if ordered.

h. Cover lightly with an occlusive sterile dressing.

i. Keep extremity elevated for 24 hours.

j. Observe the site regularly for pain, erythema, induration, ulceration or necrosis.

k. Document occurrence to include:

l. Date and time of occurrence.

m. Site of extravasation.

n. Name and amount of drugs administered at time of extravasation.

o. Total amount of vesicant administered at the time of extravasation.

p. Treatment administered.
q. Physician/LIP notified of occurrence.

r. Patient education.

s. Follow-up instruction.

t. Notify Wound Care Nurse of patient with extravasation noting medication infiltrated, location of extravasation, date, and time of event.

**MONITORING:**

28.0 Monitor the patient throughout the administration for any reactions to the drugs.

29.0 Consult the Chemotherapy book for drug specific administration.

30.0 If the patient c/o tingling, lightheadedness, generalized pruritus, or shortness of breath - STOP THE INFUSION IMMEDIATELY, contact physician/LIP and provide safety.

**DISPOSAL OF CHEMOTHERAPY/BIOOTHERAPY:**

31.0 All supplies used in the administration of chemotherapy/biotherapy will be placed in the puncture-proof zip-lock bag and disposed of in the "yellow chemo" bin or in the "black box" for P-listed and U-listed chemicals.

32.0 For spills, wash area immediately with soap and water. Wear personal protective equipment to clean up small (<5 ml) spills using a gauze pad. For large spills call Environmental Services. Provide for safety of patient and staff. Refer to Chemotherapy Handbook for further detail.

**PATIENT/FAMILY INSTRUCTIONS:**

33.0 Implement Teaching Protocol for Patient Receiving Chemotherapy/Biotherapy. Review with patient/significant other reportable symptoms and who to contact.

**DOCUMENTATION:**

34.0 Complete all documentation, including the chemotherapy medication record and the chemotherapy documentation form.

35.0 **See Policy and Procedure 2.16 – Department of Pharmacy Services for current list of cytotoxic and biological agents.**

**ATTACHMENTS:**

Addendum A: Routes of Administration of Antineoplastic Agents

Addendum B: Rituximab Administration for Non-cancer Indications
REFERENCES:

Cancer Chemotherapy Manual (2001) Facts and Comparisons, University of Utah


Addendum A
ROUTES OF ADMINISTRATION OF ANTINEOPLASTIC AGENTS

ROUTE: Oral

ADVANTAGES: Ease of Administration.

DISADVANTAGES: Inconsistency of absorption.

POTENTIAL COMPLICATIONS: Drug-specific complications.

NURSING IMPLICATIONS: Evaluate compliance with medication schedule. Teach patient handling techniques.

ROUTE: Subcutaneous Intramuscular

ADVANTAGES: Ease of administration. Decreased side effects.

DISADVANTAGES: Adequate muscle mass and tissue required for absorption.

POTENTIAL COMPLICATIONS: Infection, bleeding.


ROUTE: Intravenous.

ADVANTAGES: Consistent absorption. Required for vesicants.

DISADVANTAGES: Sclerosing of veins over time.

POTENTIAL COMPLICATIONS: Infection, phlebitis.

NURSING IMPLICATIONS: Check for blood return before and after administration of drugs.

ROUTE: Intra-arterial*.

ADVANTAGES: Increased doses to tumor with decreased systemic toxic effects.

DISADVANTAGES: Requires surgical procedure or special radiography equipment placement.

POTENTIAL COMPLICATIONS: Bleeding, embolism.
NURSING IMPLICATIONS: Monitoring for signs and symptoms of bleeding. Monitor PTT, PT.

ROUTE: **External Pump.**

ADVANTAGES: With intra-arterial port patient freedom increased.

DISADVANTAGES: Patient lies flat for 3-7 days during drug infusion.

POTENTIAL COMPLICATIONS: Pump occlusion malfunction.

NURSING IMPLICATIONS: *Intense patient education needed for pump and catheter care. Specialized nursing education regarding arterial pumps and catheters.

ROUTE: **Internal (implanted) pump.**

ADVANTAGES: Greater mobility.

DISADVANTAGES: Cost: cost effective only with long term therapy; (i.e.: 3-6 months).

POTENTIAL COMPLICATIONS: Pump occlusion malfunction.

ROUTE: **Intrathecal** - **Intraventricular**

ADVANTAGES: More consistent drug levels in cerebrospinal fluid.

DISADVANTAGES: Requires lumbar puncture or surgical placement of reservoir or implanted pump for drug delivery.

POTENTIAL COMPLICATIONS: Headaches, confusion, lethargy, nausea and vomiting, seizures.

NURSING IMPLICATIONS: Observe site for signs of infection. Monitor reservoir or pump functioning. Assess patient for headache or signs of increased intracranial pressure.

ROUTE: **Intraperitoneal**

ADVANTAGES: Direct exposure of intra-abdominal metastases to drug.

DISADVANTAGES: Requires placement of Tenckhoff catheter of intraperitoneal port.
POTENTIAL COMPLICATIONS: Abdominal pain, abdominal distention, bleeding, ileus, intestinal perforation, infection.

NURSING IMPLICATIONS: Warm chemotherapy solution to body temperature. Check patency of catheter or port. Instill solution according to protocol—infuse, dwell, and drain or continuous infusion.

ROUTE: **Intrapeural.**

ADVANTAGES: Sclerosing of pleural lining to prevent recurrence of effusions.

DISADVANTAGES: Requires insertion of a thoracotomy tube.

POTENTIAL COMPLICATIONS: Pain, infection.


ROUTE: **Intravesicular.**

ADVANTAGES: Direct exposure of bladder surfaces to drug.

DISADVANTAGES: Requires insertion of Foley catheter.

POTENTIAL COMPLICATIONS: Urinary tract infections, cystitis, bladder contracture, urinary urgency, allergic drug reactions.

NURSING IMPLICATIONS: Maintain sterile technique when inserting Foley catheter. Instill solution, clamp catheter for 1 hr., and unclamp to drain.

*SPECIALIZED NURSING EDUCATION MAY BE REQUIRED FOR CERTAIN ADMINISTRATION METHODS. REFER TO: INDIVIDUAL STATE NURSE PRACTICE ACTS AND AGENCY POLICIES AND PROCEDURES.
Addendum B
RITUXIMAB ADMINISTRATION FOR NON-CANCER INDICATIONS

PURPOSE:
Development of guidelines for the safe administration of Rituximab, a biotherapeutic agent, for the treatment of prophylaxis of organ transplant rejection.

Rituximab Orders:
1.0 Rituximab may be ordered in cardiac ICU and step-down settings to prevent or treat transplant rejection.

2.0 The agent must be ordered, transcribed and verified by two RNs as outlined in sections 1.0 through 5.4. Both RNs verifying rituximab orders must have received training/education in the administration of rituximab.

Rituximab Administration:
3.0 Only RNs who have demonstrated competency may administer rituximab.

3.1 Competency is obtained by completing hospital certification through Nursing Staff Development or participating in unit-based training and education on the administration of rituximab.

4.0 RN will follow administration procedures for chemotherapy/biotherapy agents as outlined in sections 6.0-25.0.

5.0 The RN will pre-medicate as ordered by the physician/LIP. Diphenhydramine and acetaminophen are recommended to prevent infusion reactions.

6.0 During the infusion, the RN will monitor for infusion reactions, including hypotension, rigors, and fevers, as well as hypersensitivity reactions such as bronchospasm and urticaria. Incidence of infusion reactions decreases with subsequent infusions.

7.0 The RN will titrate the rituximab infusion according to the following guidelines or as ordered by physician/LIP.

7.1 The first dose will begin at the rate of 50mg/hr. The RN may titrate up by 50mg/hr increments every 30 minutes if no infusion reactions occur, for a maximum rate of infusion at 400mg/hr.

7.2 Subsequent doses will begin at 100mg/hr. and may be increased every 30 minutes by 100mg/hr increments if no infusion reactions occur for a maximum rate of infusion at 400mg/hr.
7.3 If infusion reactions occur after dose titration, RN will decrease infusion rate to initial rate of infusion (50 or 100 mg/hr) and notify physician/LIP. Infusion reactions often subside with slowing down rate of infusion.

8.0 RN will monitor vital signs with every dose increase, and with changes in patient status.

9.0 All patients receiving rituximab should be placed on cardiac telemetry monitoring during the infusion unless ordered otherwise by physician/LIP.
Attachment 2

Chemotherapy/Biotherapy Administration (UACC PRO-11)
**SUBJECT:** Chemotherapy/Biotherapy Administration  
**PROCEDURE NO:** UACC PRO-11  
**AUTHOR:** Patti Stumbo RN, MBA, OCN, Iris Delfakis BSN, OCN  
**ORIGINAL APPROVAL DATE:** September 2002  
**REVIEW/REVISION DATES:** 9/03, 9/04, 10/07, 09/08, 09/09, 01/10, 2/10, 3/10, 5/10, 9/10, 4/11, 6/2011

**PURPOSE:** To establish guidelines for safe administration of chemotherapy/biotherapy agents in the outpatient setting in accordance with the recommendations for nursing education and practice established by the Oncology Nursing Society, Cancer Chemotherapy Guidelines and Recommendations for Practice, 2nd & 3rd Edition.

**PROCEDURE:**

1.0 **Supportive Data:**

1.1 The administration of chemotherapy/biotherapy agents requires specific training and knowledge, including successful completion of the UMC Administration of Chemotherapy Course and Practicum; the Oncology Nursing Society Chemotherapy Provider course or other approved Chemotherapy administration education.

1.2 All references to chemotherapy also include all biotherapy.

1.3 Nursing working in the Pediatric BMT/Hematology-Oncology Clinic shall also complete the UMC Pediatric Focus: Oncology and Chemotherapy Course.

2.0 **Patient Scheduling:**

2.1 All patients new to Arizona Cancer Center need to have an initial oncology evaluation with an attending physician, Fellow or mid-level provider.

2.2 Scheduling for chemotherapy treatments in the Pediatric Clinic will be coordinated by the unit clerk to be included in regular clinic visits, allowing additional time as necessary for infusions.

3.0 **Chemotherapy Orders- Further reference PM 3 Medication Control and Handling**

3.1 All cytotoxic drugs, regardless of indication shall be written on order form #UMC 45-93 Pharmacy Orders. For commonly used regimens, pre-printed orders will be utilized, but will not preclude hand written orders.
3.2 Chemotherapy orders for pediatric patients are written by the attending physician, fellow, resident or nurse practitioner on the chemotherapy order form MR 1378.

3.3 An attending physician or nurse practitioner or physician assistant (in the appropriate specialty as defined by the Pharmacy and Therapeutics Committee) will write all orders for cytotoxic drugs.

3.3.1 New treatment regimens written by a nurse practitioner or physician assistant will be co-signed by an attending physician.

3.3.2 All orders for cytotoxic drugs written by a first-year clinical fellow will be co-signed by an attending physician.

3.3.3 All orders for cytotoxic drug will be signed. Verbal orders will not be accepted.

3.4 All information outlined by the form should be completed, including the date, time and signature of the responsible practitioner, and the date the therapy needs to be started.

3.5 Cytotoxic drug names must be spelled out unless the names appear on an approved abbreviation list. Initials of drugs are not acceptable.

3.6 All orders shall include the patient's current height, weight and calculated body surface areas, unless the dose ordered does not need to be calculated based on the above.

3.7 Doses that are within 10% of a patients BSA are acceptable and need not be called to the ordering practitioner's attention.

3.8 Any protocol or dose modifications need to be specified on the order sheet.

3.9 Because the timing of these regimens is vital, if an appointment to receive cytotoxic drug falls within 1 day, plus or minus, of the next dose due, no prior approval by provider is necessary to proceed.

4.0 Consent for Chemotherapy/Biotherapy
4.1 At the beginning of a new treatment regimen, a Chemotherapy/Biotherapy consent must be signed. Reference UACC Procedure 31.

5.0 Preparation of Cytotoxic Drugs
5.1 Refer to Department of Pharmacy Services Policy and Procedure #2-16 for Ordering, Preparation and Storage of Antineoplastic Drugs.

5.2 Chemotherapy orders are submitted to the Pharmacy for processing.

5.3 For Pediatric patients, orders are submitted to the 3rd Floor Satellite Pharmacy for processing.

5.3.1 Medications are not actually prepared in the pharmacy until RN staff has confirmed arrival of the patient and have verified that all infusion parameters have been met.

5.3.2 Nursing staff shall review the chemotherapy orders, administration criteria, laboratory results and verify appropriate access for administration before requesting medication from the Satellite pharmacy.
Following verification of orders, the clinical pharmacist will dispense the chemotherapy.

Pharmacy will prime the tubing for all chemotherapy drugs

Two (2) pharmacists will verify by initialing on the nursing encounter form that the BSA is correct and dispensed chemotherapy matches the written orders. (For Orange Grove only: the pharmacist and nurse will verify by signature on the nursing encounter form that the dispensed chemotherapy matches the written orders.)

Prior to administration

The charge nurse (for Orange Grove only: assigned nurse) checks the orders for completeness and accuracy and double checks the BSA calculation, initialing it if correct.

In the Pediatric Clinic the assigned RN and a second RN certified to administer chemotherapy shall separately review the orders.

The assigned RN shall also ensure that a Consent for Chemotherapy Administration (Form - MR 2367) has been completed and signed by the parent or patient representative.

The assigned RN will check all pertinent lab results and contact the ordering practitioner as needed if results fall outside of administration parameters.

Two (2) RNs (treating nurse at chair/bedside) independently (both nurses to check separately from the other) check the drugs (including growth factors) against the chemotherapy orders for:

- Correct Patient (using 2 patient identifiers)
- Correct drug
- Correct dose
- Correct date
- Correct route

Both RN's will initial, indicating their review, on the Nursing Visit Data Form (Encounter) in the designated areas

In the Pediatric clinic, both RN's will initial the medication and dosage indicating their review and sign the Pediatric Chemotherapy Administration For – MR 1264

Treating RN to transcribe ALL medications that are ordered to the Nursing Visit Data Form

Obtain prescribed premedication and antiemetics – be certain that all necessary drugs are available before administering the chemotherapy

The administering RN must ensure that the correct medication is being given to the correct patient by checking the medication and using 2 patient identifiers immediately prior to starting ALL infusions.

All chemotherapy infusions will be infused using the Alaris pumps guard rails whenever possible.

Route of administration: IV Route
5.6.1 Optimal location for placement of peripheral IV is the distal forearm.

5.6.2 Veins of choice are smooth and pliable; the large veins of the forearm are preferred.

5.6.3 Avoid extremities with impaired venous or lymphatic return, i.e. mastectomy, lymph node dissection.

5.6.4 Avoid extremities with impaired skin integrity; injured or sclerosed veins; areas of flexion.

5.6.5 Utilize a catheter size appropriate for the individual patient and medication to be delivered.

5.6.6 If venipuncture is unsuccessful, utilize the opposite arm or a site proximal to the first venipuncture.

5.6.7 Existing peripheral IV’s may be used with caution if they have no evidence of redness, swelling, or tenderness; have a good blood return and are in an appropriate location for the drugs being administered. Existing IV’s may NEVER be used for the administration of a vesicant.

5.6.8 Establish patency of the catheter using 10-15ml of NS or a compatible flush solution.

5.6.9 Implement IV (Peripheral) Therapy Management Protocol #AHP 1560

5.6.10 Port-a-Cath (PAC) and other Central Venous Catheters (CVC), Peripherally Inserted Central Catheters (PICC) may be used for chemotherapy infusions as long as a good blood return is maintained.

5.6.11 All 24 hour infusions regardless of medication type must be administered through a central line (PICC, PAC, etc)

5.7 IM Route

5.7.1 It is recommended that most chemotherapeutic agents be administered in the buttocks or ventral gluteus area. The lateral thigh may be used with caution.

5.7.2 For drugs requiring multiple doses in sequence (i.e. L-spar), injection sites should be rotated to avoid tissue damage and discomfort.

5.7.3 The preferred site for IM injections for Pediatric patients is the Lateral Thigh. Emla or Lidocaine Cream should be utilized prior to administering the injection.

5.8 Subcutaneous route

5.8.1 Injections may be administered in the abdomen, lateral aspects of the upper arms or thighs.

5.9 Intraperitoneal

5.9.1 Prior to administering Intraperitoneal chemotherapy, review the Nursing Procedure for Infusion Ports, implanted subcutaneous (venous, Intraperitoneal) Protocol Adult Health Protocol AHP #1500.
5.9.2 Intraperitoneal infusions are currently not administered in the Pediatric Clinic.

6.0 Intraventricular (Omaya reservoir) route:
   Reference the Arizona Cancer Center Protocol AZCC PRO-15

7.0 Intravesical Installation:
   Reference the Arizona Cancer Center Protocol AZCC PRO-17

8.0 Safe Administration
8.1 Only RN's who have been certified by UMC in the administration of chemotherapy may
   administer chemotherapy.
8.2 Refer to ONS Cancer Chemotherapy Guidelines and Recommendations for Practice, 3rd
   Edition, for recommendations for safe handling of chemotherapeutic agents.

8.3 Personal Protective Equipment (PPE):
8.3.1 A protective outer garment/lab coat will be worn by the RN staff when administering
   chemotherapy.
8.3.2 Chemotherapy gloves will be worn when administering chemotherapy. If a patient or
   nurse has a known or suspected latex sensitivity or allergy, gloves chosen should be
   made from an alternative material.
8.3.3 Goggles will be worn if there is potential for a splash.
8.3.4 Chemotherapy and materials contaminated with chemotherapy will be discarded in a
   chemotherapy disposal bag or designated disposal container.

8.4 Spill kits will be readily available and are currently stored in the Clean Utility Room. In the
   Pediatric clinic spill kits are located on the top shelf of the rolling storage cart located by the
   tube station.

9.0 Research Drug Administration
9.1 With non-hematology patients, the ordering physician will note on the treatment orders if any
   deviation from the standard practice of administration will be allowed and specifically, the
   ANC parameters if they differ from the standard of ANC <1500.

9.2 The research nurse, after reviewing the most recent lab results, will write on the nursing
   encounter form "ok to treat" with name, date and time, indicating patient has met parameters
   of study to continue treatment.

9.0 Definitions:
9.1 Vescicant – agent that has the potential to cause blistering and/or tissue necrosis
   (See Appendix A for a list of current medications that meet this definition)

9.2 Irritant – Chemotherapy agent that may inflame and irritate the peripheral veins and
   surrounding tissue (See Appendix A for a list of current medications that meet this definition)

9.3 IV push – Medication that is administered via a syringe, manually into a side arm of a running
   IV solution or hub to hub

9.4 IV Infusion – Medication mixed with compatible IV solution in a bag/bottle that is
   administered via gravity or through an IV pump
10.0 Guidelines for non vesicant IV administration
10.1 Determine that IV line is patent.

10.2 IV “pushes” may be administered via the side arm of running NS or compatible IV solution hung specifically for the chemotherapy. A 2 x 2 gauze should be placed under the port of the sidearm to catch any accidental leakage.

10.3 Use slow, even pressure on plunger of syringe. NEVER USE FORCE – if resistance is met, reassess patency using NS flush.

10.4 Blood return should be checked every 3-5 ml for IV push chemotherapy.

10.5 During a continuous infusion, IV site should be checked every 30 minutes and after patient gets up to ambulate

10.6 If patient is restless, IV site should be checked every 15 minutes.

10.7 10-20 ml of NS should be administered between drugs and after the infusion of the last agent.

10.8 After completion of the infusion if the IV catheter is to be removed, hold pressure to the site for 3-4 minutes following removal and instruct the patient to avoid dangling the extremity for 15-20 minutes.

11.0 Guidelines for non vesicant Central line administration
11.1 Check for blood return and patency prior to administering any medication. If unable to obtain blood return, reposition the patient. Administer antithrombolytic as ordered. If still no blood return, inform provider. Blood return MUST be obtained prior to administering any medication.

11.2 IV “pushes” may be administered via the side arm of running NS or compatible IV solution hung specifically for the chemotherapy. Personal protective equipment must be worn when administering a vesicant or irritant. A 2 x 2 gauze should be placed under the port of the sidearm to catch any accidental leakage.

11.3 Check for blood return and patency after completion of each medication

11.4 10-20mls of NS should be given after completion of each medication

11.5 Monitor central line site for signs of redness swelling or pain during IV pushes, every 30 minutes during an infusion and after the patients gets up to ambulate. If the patient is restless monitor more often.

12.0 Guidelines for Vesicant administration
A central venous line (PAC, PICC, CVC, etc) is HIGHLY recommended for vesicants administered via IV push to minimize extravasation potential. All vesicant infusions MUST be administered via a central venous line. Note: Taxanes may be infused via a peripheral IV as long as the consent form lists tissue damage as a risk factor.

12.1 Peripheral Vesicant IV push
12.1.1 The vesicant/irritant “push” must be administered via the side arm of running NS or compatible IV solution hung specifically for that chemotherapy. A 2 x 2 gauze should be placed under the port of the sidearm to catch any leakage.

12.1.2 Use slow even pressure on the plunger of the syringe. NEVER use force - if resistance is met, STOP and reassess patency using NS or compatible IV solution.

12.1.3 Blood return must be verified every 2 – 5 ml.

12.1.4 Continuously assess the IV site for signs of extravasation.

12.1.5 Instruct patient to communicate immediately any burning or alteration in sensation at the site.

12.1.6 Once the IV push is completed check for vein patency and flush the line with a compatible IV solution.

12.1.7 10-20 ml of NS should be administered between drugs and after the infusion of the last agent.

12.2 Central line Vesicant administration

12.2.1 Check for blood return and patency prior to administering any medication. If unable to obtain blood return, reposition the patient. Administer antithrombolytic as ordered. If still no blood return, inform provider. Blood return MUST be obtained prior to administering any medication.

12.2.2 Check for blood return and patency after completion of each medication.

12.2.3 10-20 ml of NS should be administered between drugs and after the infusion of the last agent.

13.0 Extravasation Management

13.1 If a chemotherapeutic agent extravasates:

13.1.1 Stop the infusion

13.1.2 Leave the catheter in place

13.1.3 Withdraw as much of the drug and blood as possible.

13.1.4 Contact the provider

13.1.5 Administer the antidote as prescribed by provider (See Appendix A – Guidelines for Treatment of Extravasation)

13.1.6 Inform the pharmacist.

13.1.7 Fill out a PSN

13.2 Patient Monitoring
13.2.1 Instruct the patient to monitor the extravasation site and report fever, chills, blistering, skin sloughing, and worsening pain

13.2.2 Assess the extravasation area for skin sloughing periodically as needed per provider

13.2.3 Extravasation instruction sheet to be given to patient upon discharge

14.0 Monitoring

14.1 Monitor the patient throughout the medication administration for any reactions to the drugs.

14.2 Consult the chemotherapy drug references for drug specific administration.

14.3 If the patient complains of tingling, lightheadedness, flushing, generalized pruritus, shortness of breath, or chest pain STOP THE INFUSION IMMEDIATELY, contact the provider and provide for safety.

15.0 Disposal of Chemotherapy/Biotherapy

15.1 All supplies used in the administration of chemotherapy/biotherapy will be placed in puncture proof chemotherapy disposal containers. Refer to UMC Safety Policy SA 1018e – Cytotoxic Agents Management Plan.

16.0 Spill Procedure

16.1 If medication is splashed on the skin or eyes, flush with water for at least 15 minutes. Follow-up with Employee Health during normal weekday hours or Emergency Department at all other times. Complete an Employee Accident Report form.

16.2 For spills less than 100ml, use the chemotherapy spill kit to clean it up.

16.3 For large spills (greater than 100ml or ½ cup liquid) keep everyone out of the immediate spill area. Provide for patient safety. Use the chemotherapy spill kit to contain the spill.

16.4 Call Risk Management at 694-7475 or 694-6753 to dispose of clean-up material.

16.5 Complete accident report for all chemotherapy spills and send to Risk Management immediately.

16.6 For major spills, regardless of the location, security should be called at either 694-6533 or on the 84 phone line to report spill. The Chemical Spill Contingency Plan will be implemented.


17.0 Client/Family Instructions

17.1 Implement teaching with patient/significant other/family members.

17.2 Review reportable symptoms and who to contact.
17.3 Review after-hours procedure for emergencies.

18.0 Documentation

18.1 Complete all documentation on the Nursing Visit Data Form (Encounter)

18.3 Report any adverse reactions on the PSN online system and record the Adverse Reaction in the patient’s medical record.

References


University Medical Center’s Patient Care Protocols – Adult Health.
# APPENDIX A
List of known Vesicants

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Immediate Topical Therapy</th>
<th>Antidote/Treatment</th>
<th>Antidote/Treatment Administration, Patient Monitoring, and Follow-up</th>
</tr>
</thead>
</table>
| Cisplatin       | Apply ice for 6-12 hours following sodium thiosulfate antidote injection (Merck and Co., 2005). | **Antidote:** Sodium Thiosulfate  
**Mechanism of Action:** Inactivates Cisplatin | • If possible aspirate the chemotherapeutic agent by withdrawing 3-5 ml of blood with a clean syringe before removing IV catheter.  
• Inject 2 ml of sodium thiosulfate per 1 mg of Cisplatin suspected to have extravasated. Inject the solution subcutaneously into the extravasation site using a 25 gauge or smaller needle (change needle with each injection)  
• Assess the site for blister formation and skin sloughing periodically  
• Instruct patient to monitor the site and report fever, chills, blistering, skin sloughing, worsening pain, arm or hand swelling and/or stiffness |
| Dactinomycin    | Apply ice pack for 15-20 minutes at least four times a day for the first 24 hours | No known antidotes or treatment | • Assess the area for pain, blister formation and skin sloughing periodically.  
• Instruct patient to monitor the site and report fever, chills, blistering, skin sloughing, worsening pain, arm or hand swelling and/or stiffness |
| Daunorubicin    | Apply ice pack (but remove at least 15 minutes prior to Totect treatment) | **Antidote:** Totect  
**Mechanism of Action:** Unknown  
**Dose:** The recommended dose is based on the patients BSA  
Day 1 - 1000mg/m2  
Day 2 – 1000mg/m2  
Day 3 – 500 mg/m2 | • The first Totect infusion should be initiated as soon as possible and within 6 hours of the extravasation.  
• Totect should be infused over 1-2 hours in a large vein in an area other than the extravasation site (use other arm if possible, otherwise use vein distal to extravasation site)  
• DMSO should not be applied to the |
<table>
<thead>
<tr>
<th>Drug</th>
<th>Clinical表现为</th>
<th>Treatment</th>
<th>Side Effects</th>
</tr>
</thead>
</table>
| Docetaxel          | May cause hyper pigmentation, redness, and tenderness (Sanofi-Aventis, 2007). Extravasation reactions are self-limiting. May cause mild symptoms followed by edema, erythema, and occasional pain and blister formation—usually resolving within 3 weeks (Ascherman, Knowles, & Attkiss, 2000) | Apply ice pack for 15-20 minutes at least four times a day for the first 24 hours | No known antidote or treatment. | • Assess the area for pain, blister formation and skin sloughing periodically.  
• Instuct patient to monitor the site and report fever, chills, blistering, skin sloughing, worsening pain, arm or hand swelling and/or stiffness |
| Doxorubicin        | Apply ice pack (but remove at least 15 minutes prior to Totect treatment) | *Antidote: Totect*  
*Mechanism of Action: Unknown*  
*Dose:* The recommended dose is based on the patients BSA  
Day 1 - 1000mg/m²  
Day 2 - 1000mg/m²  
Day 3 - 500 mg/m²  
In patients with creatinine clearance values < 40 ml/min dose should be reduced 50% | | • The first Totect infusion should be initiated as soon as possible and within 6 hours of the extravasation.  
• Totect should be infused over 1-2 hours in a large vein in an area other than the extravasation site (use other arm if possible, otherwise use vein distal to extravasation site)  
• DMSO should not be applied to the extravasation area.  
• Assess the site for blister formation and skin sloughing periodically  
• Instuct patient to monitor the site and report fever, chills, blistering, skin sloughing, worsening pain, arm or hand swelling and/or stiffness |
| Epirubicin | Apply ice pack (but remove at least 15 minutes prior to Totect treatment) | Antidote: Totect  
*Mechanism of Action*: Unknown  
*Dose*: The recommended dose is based on the patients BSA  
Day 1 - 1000mg/m²  
Day 2 - 1000mg/m²  
Day 3 - 500 mg/m²  
In patients with creatinine clearance values < 40 ml/min dose should be reduced 50% | - Instuct the patient on SE of Totect:  
N/V, diarrhea, stomatitis, bone marrow suppression, elevated liver enzyme levels, infusion site burning  
- Monitor patients CBC and liver enzyme levels  
- The first Totect infusion should be initiated as soon as possible and within 6 hours of the extravasation.  
- Totect should be infused over 1-2 hours in a large vein in an area other than the extravasation site (use other arm if possible, otherwise use vein distal to extravasation site)  
- DMSO should not be applied to the extravasation area.  
- Assess the site for blister formation and skin sloughing periodically  
- Instuct patient to monitor the site and report fever, chills, blistering, skin sloughing, worsening pain, arm or hand swelling and/or stiffness  
- Instuct the patient on SE of Totect:  
N/V, diarrhea, stomatitis, bone marrow suppression, elevated liver enzyme levels, infusion site burning  
- Monitor patients CBC and liver enzyme levels |
| Idarubicin | Apply ice pack (but remove at least 15 minutes prior to Totect treatment) | Antidote: Totect  
*Mechanism of Action*: Unknown  
*Dose*: The recommended dose is based on the patients BSA  
Day 1 - 1000mg/m²  
Day 2 - 1000mg/m²  
Day 3 - 500 mg/m²  
In patients with creatinine clearance values < 40 ml/min dose should be reduced 50% | - Instuct the patient on SE of Totect:  
- The first Totect infusion should be initiated as soon as possible and within 6 hours of the extravasation.  
- Totect should be infused over 1-2 hours in a large vein in an area other than the extravasation site (use other arm if possible, otherwise use vein distal to extravasation site)  
- DMSO should not be applied to the extravasation area.  
- Assess the site for blister formation and skin sloughing periodically  
- Instuct patient to monitor the site and report fever, chills, blistering, skin sloughing, worsening pain, arm or hand swelling and/or stiffness  
- Instuct the patient on SE of Totect: |
<table>
<thead>
<tr>
<th>Drug</th>
<th>Treatment Plan</th>
<th>Antidote:</th>
<th>Precaution</th>
</tr>
</thead>
</table>
| Meclorethamine | Apply ice for 6-12 hours following sodium thiosulfate antidote injection (Merck and Co., 2005). | Sodium Thiosulfate  
Mechanism of Action: Neutralizes mecloethamine to form nontoxic thioesters that are excreted in the urine | Inject 2 m. of sodium thiosulfate per 1 mg of mecloethamine suspected to have extravasated.  
Inject the solution subcutaneously into the extravasation site using a 25 guage or smaller needle (change needle with each injection)  
Assess the site for blister formation and skin sloughing periodically  
Instuct patient to monitor the site and report fever, chills, blistering, skin sloughing, worsening pain, arm or hand swelling and/or stiffness |
| Mitomycin C   | Apply ice pack for 15-20 minutes at least four times a day for the fist 24 hours. | No known antidotes or treatment                                          | Assess the area for pain, blister formation and skin sloughing periodically. |
| Paclitaxel    | Apply ice pack for 15-20 minutes at least four times a day for the first 24 hours. | No known antitdote or treatment                                          | Assess the area for pain, blister formation and skin sloughing periodically.  
Instuct patient to monitor the site and report fever, chills, blistering, skin sloughing, worsening pain, arm or hand swelling and/or stiffness |
| Vinblastine   | Apply warm pack for 15–20 minutes at least four times per day for the first 24 hours. Elevate extremity. | Hyaluronidase  
Mechanism of Action: Degrades hyaluronic acid and promotes drug diffusion. | Admininster 1 ml of the hyaluronidase solution as five separate injections, (each containing 0.2 ml’s) subcutaneously into the extravasation site using a 25-guage or smaller needle (change needle with each injection) |
<table>
<thead>
<tr>
<th>Drug</th>
<th>Instructions</th>
<th>Antidote: Hyaluronidase</th>
<th>Additional Instructions</th>
</tr>
</thead>
</table>
| Vincristine  | Apply warm pack for 15 – 20 minutes at least four times per day for the first 24 hours. Elevate extremity (peripheral extravasations) | *Mechanism of Action:* Degrades hyaluronic acid and promotes drug diffusion.           | • Administer 1 ml of the hyaluronidase solution as five separate injections, (each containing 0.2 ml’s) subcutaneously into the extravasation site using a 25-gauge or smaller needle (change needle with each injection)  
    • Assess the area for pain, blister formation and skin sloughing periodically.  
    • Instuct patient to monitor the site and report fever, chills, blistering, skin sloughing, worsening pain, arm or hand swelling and/or stiffness |
| Vindesine    | Apply warm pack for 15 – 20 minutes at least four times per day for the first 24 hours. Elevate extremity (peripheral extravasations) | *Mechanism of Action:* Degrades hyaluronic acid and promotes drug diffusion.           | • Administer 1 ml of the hyaluronidase solution as five separate injections, (each containing 0.2 ml’s) subcutaneously into the extravasation site using a 25-gauge or smaller needle (change needle with each injection)  
    • Assess the area for pain, blister formation and skin sloughing periodically.  
    • Instuct patient to monitor the site and report fever, chills, blistering, skin sloughing, worsening pain, arm or hand swelling and/or stiffness |
| Vinorelbine  | Apply warm pack for 15 – 20 minutes at least four times per day for the first 24 hours. Elevate | *Mechanism of Action:* Degrades hyaluronic acid and promotes drug diffusion.           | • Administer 1 ml of the hyaluronidase solution as five separate injections, (each containing 0.2 ml’s) subcutaneously into the extravasation site using a 25-gauge or smaller needle (change needle with each injection)  
    • Assess the area for pain, blister formation and skin sloughing periodically.  
    • Instuct patient to monitor the site and report fever, chills, blistering, skin sloughing, worsening pain, arm or hand swelling and/or stiffness |
<table>
<thead>
<tr>
<th>extremity (peripheral extravasations)</th>
<th>with each injection)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Assess the area for pain, blister formation and skin sloughing periodically.</td>
<td></td>
</tr>
<tr>
<td>• Instruct patient to monitor the site and report fever, chills, blistering, skin sloughing, worsening pain, arm or hand swelling and/or stiffness</td>
<td></td>
</tr>
</tbody>
</table>

Irritants with vesicant properties

Oxaliplatin

Classified as a nonvesicant. There have been case reports of local pain, inflammation and tissue necrosis that suggests that this is an irritant with vesicant like properties.

In case of an extravasation, warm compresses may reduce local pain and inflammation. DO NOT use cold compresses as they may precipitate or worsen the cold neuropathy that is associated with Oxaliplatin.

High-dose dexamethasone (8 mg BID X 14 days) have been reported to reduce Oxaliplatin extravasation inflammation.

List of Known Irritants

No known antidote or intervention is needed for irritants.

Bleomycin
Carboplatin
Carmustine
Docetaxel
Gemcitabine
Ifosfamide
Irinotecan
Liposomal Daunorubicin
Liposomal Doxorubicin
Melphalan
References


Attachment 3

Cytotoxic and P & U Listed PCRA Pharmaceutical Agents and Wastes Management Plan (SA 1018E)
University Medical Center Corporation
Tucson, Arizona

SUBJECT: Cytotoxic and P & U Listed RCRA Pharmaceutical Agents and Wastes Management Plan
POLICY: SA 1018E

Originator: Cynthia Wundrock
Responsible Person: Cynthia Wundrock
Effective Date: May 1, 1990
Revision Date: 7/9/98; 6/28/02; 6/24/05; 9/25/08, 6/18/09

PURPOSE:
To describe procedures for the identification, storage, handling and disposal of cytotoxic and P and U listed RCRA pharmaceutical agents and wastes within the confines of University Medical Center facilities and applicable off-site facilities.

1.0 To insure these agents are handled, stored and used within approved guidelines published by OSHA, NIOSH, and manufacturers' recommendations.

2.0 To insure these wastes are handled and disposed of in accordance with EPA, county and state regulations.

3.0 To insure that there is minimal risk to staff, patients, the public and the environment.

GENERAL:
1.0 Cytotoxic agents are defined as chemicals which are toxic to cells that are utilized, in particular, in cancer therapy, alone or in conjunction with other treatment modalities as well as in the treatment of other disease states.

2.0 Cytotoxic wastes are defined as those chemicals that remain in syringes, containers, tubes, vials after dispensing or if they are wastes generated by accidental spills.

3.0 Pharmaceutical P & U listed agents are defined as those pharmaceuticals and/or chemicals specifically listed by the EPA as hazardous, toxic or acutely hazardous. These items include portions remaining in containers, syringes, tubes, or vials after dispensing or that are wastes generated by accident or spillage.

4.0 The Chemical Spill Emergency Coordinator, in conjunction with the Director of Pharmacy Services or his designee, has the authority to implement the Contingency Plan in the event of a major cytotoxic or pharmaceutical incident.
5.0 All persons required to handle cytotoxic and P and U listed RCRA pharmaceutical agents or wastes will be provided with appropriate orientation, equipment and on-the-job training by their departments.

6.0 Each department that handles cytotoxic materials and P and U listed RCRA pharmaceutical wastes will have specific policies and procedures that contain information regarding, where appropriate, the safe handling, admixture, transportation, administration and disposal of these materials and wastes. These policies and procedures will be reviewed and when appropriate, revised and approved by the Safety Committee at least every three (3) years.

IDENTIFICATION:
1.0 Cytotoxic agents and P and U listed pharmaceuticals will be classified as hazardous and approved by Pharmacy Services with the assistance of the Environmental Management Officer (for the P&U listed pharmaceuticals).

2.0 Appendix 1 at the end of this policy contains the list of cytotoxic agents, their generic names, brand names and alternative names, which they are known by within UMC facilities. Appendix 2 at the end of this policy contains the list of P and U listed pharmaceutical agents.

3.0 The following is a list of the cytotoxic agents that are listed as Resource Conservation and Recovery Act (RCRA) wastes and will be disposed of as Hazardous Chemical Wastes per 40 CFR 265 if spilled or outdated before use. These wastes must be manifested to EPA approved Treatment, Storage and Disposal Facilities (TSDF) for disposal:

- Chlorambucil
- Cyclophosphamide (Cytoxin)
- Daunomycin
- 5-Fluorouracil
- Mechlorethamine (Nitrogen Mustard)
- Melphalan
- Mitomycin C
- Streptozotocin

4.0 All P and U listed pharmaceuticals will be labeled accordingly with a sticker on the outside of the individual dosage (syringe, vial, tube, etc). This will demonstrate to clinical staff that it is an item to be disposed of in a Black RCRA Pharmaceutical container that is provided for this purpose.

5.0 Black RCRA Pharmaceutical containers (2 gallon) are to be placed in each med room on each unit minimally. Additional bins for larger waste streams (14 gallon) can be placed in the dirty utility rooms. Black containers are ordered from Materials Management and there will be a checklist with each container that will
be completed and go with the container when it is full. These black containers will be considered "Satellite Accumulation areas" as per CFR 262.34 and stored for up to 180 days with a list of the contents marked, the words "HAZARDOUS WASTE" clearly labeled and a start date of accumulation labeled on the front of the container. Appendix III is a checklist that must be used whenever an item is deposited in a black RCRA container. This will help to identify, track and report on the contents in each container as required by state and federal regulatory guidelines. This checklist will stay with the container and a new checklist will be put with a new container whenever it is replaced.

6.0 When the containers are full, replacements can be obtained from Materials Management. Full containers can be picked up by contacting the Environmental Management Officer at 4-7475.

7.0 Training is on-going and available to any area that does not accurately complete the checklist or re-order a black box.

**STORAGE AND HANDLING OF CYTOTOXIC AGENTS:**

1.0 All mixing of cytotoxic agents will be performed in a Class II, Type B Biological Safety Cabinet with outside venting, if feasible.

1.1 Special aseptic techniques and precautions must be used because of the vertical (downward) airflow within the cabinet.

1.2 When feasible, no other IV admixtures will be prepared in biological safety cabinets designated for the mixing of cytotoxic agents.

1.3 The biological safety cabinet will be certified by a qualified technician at least annually or at any time the cabinet has been physically moved.

1.4 The biological safety cabinet blower will be left on continuously.

1.5 Admixtures will be performed only with the viewing window at the required opening for optimum airflow.

1.6 The number of personnel working with these agents should be minimized.

1.7 Access to the compounding area must be limited to only necessary authorized personnel.

1.8 The personnel working with these agents should be observed regularly by supervisory personnel to insure compliance with all policies and procedures.

1.9 Special procedures will be followed for major spills or acute exposures. Spill kits will be kept available within easy reach and their location known to all personnel working in the area.
1.10 Acute exposure episodes must be documented on an Employee Accident Report form (UMC 01-01). The employee must be referred to Employee Health or the Emergency Department, if appropriate, for medical follow-up.

2.0 All cytotoxic admixtures must be placed in a zip-lock bag and labeled "CAUTION-CHEMOTHERAPY DRUG". This outer bag will be delivered, along with the proper drug information, to the nurse responsible for administering the agent(s).

2.1 All cytotoxic admixture will be labeled with actual dose, diluent, date and time of preparation, recommended rate of administration, preparer, patient name and location.

2.2 Labeled IV bags must have injection port sealed before dispensed from the Pharmacy.

2.3 Before opening ampules, care should be taken to insure that no liquid remains in the tip of the ampule. A sterile, disposable alcohol gauze sponge should be wrapped around the neck of the ampule and left in place to protect the fingers when opening the ampule.

2.4 Vials should be vented with a hydrophobic filter to eliminate internal pressure, vacuum or aerosolization of the agent.

2.5 Syringes with leur-lock fittings should be used whenever possible.

2.6 Filter needles (5 micron) will be used to remove particulate matter and glass fragments from solutions provided in ampules prior to final admixture preparation.

2.7 Final agent measurement will be performed prior to removing the needle from the stopper of the vial.

2.8 Special care must be taken in priming IV sets. The distal tip cover must be removed before priming. Priming should be performed into a sterile sponge, which is then disposed of properly.

3.0 Appropriate personal protective equipment will be worn while working within the admixture area (PPE not optional in any area).

3.1 Disposable PVC or latex surgical type gloves will be worn for all procedure involving cytotoxic agents. Double gloving is recommended.

3.2 A disposable protective outer garment will be worn at all times. The garment will have a closed front and long sleeves with either elastic or knit cuffs.
3.3 All potentially contaminated garments or gloves will be removed and properly disposed of before leaving the admixture area.

4.0 Care must be taken to avoid puncturing gloves and possible self-inoculation.

5.0 Hands will be washed with a disinfecting solution before gloving and after removing the gloves.

**SPILL CLEANUP AND DISPOSAL OF P & U LISTED PHARMACEUTICAL WASTE AS RCRA HAZARDOUS WASTE:**

1.0 Find out what pharmaceutical chemical or waste has been spilled. Get the MSDS for the chemical material/waste if needed.

2.0 Determine how much of the material/waste has been spilled.

2.1 For anything other than an extremely hazardous chemical, a large spill will be considered greater than 100-ml (approximately ½-cup or more of a liquid). A large spill will require dialing 84 from a secure location to declare a **Code Orange Hazardous Materials Spill**.

2.2 Any amount of an extremely hazardous chemical will be considered a large spill (Code Orange and dialing 84 from a secure location).

3.0 If the spill involves a fire, report the fire from a secure location by dialing 84 to declare a **Code Red** involving a hazardous chemical spill – OR – dial 911 if the spill/fire is at an off-site location. Tell the Security Dispatcher (or the 911 Emergency Dispatcher if calling from off-site) the location of the fire and spill, the type of chemical, the approximate amount of the spill and whether anyone has been injured.

4.0 Small spill, less than 100-ml or ½-cup of liquid, will be cleaned up by the person that spilled or discovered the spilled chemical.

4.1 Wear the appropriate protective equipment such as gloves, goggles or splash shield, apron and/or respirator if necessary.

4.2 Usually, a small spill may be cleaned up with the materials kept in the work area. Place all clean up materials into a labeled plastic bag and then place into the black RCRA Pharmaceutical container and call the EMO at 4-7475 for pick up and disposal. Off-site locations should also call the EMO at 4-7475 to arrange for pick up and disposal.

4.3 **Do not** call for Support Services personnel to clean up any pharmaceutical chemical spill.
5.0 If the spill is determined to be a large spill or an extremely hazardous material, regardless of whether it is a liquid, gas or solid:

5.1 Immediately isolate the spill or the area. Avoid walking or moving anything through the spill. If an extremely hazardous material is spilled, evacuate the area immediately, closing the doors as you leave.

5.2 If the materials are readily at hand, use spill pillows or absorbent pads with plastic backing to dike a liquid spill.

5.3 Evacuate everyone from the area and shut doors. Wait by the spill area, well out of danger, for Security personnel, the Emergency Coordinator, and/or emergency spill response personnel to arrive. Do not allow anyone to enter the area until spill response personnel arrive.

5.4 Call Security to notify the Chemical Spill Emergency Coordinator for assistance. Off-site locations should dial 911 for immediate assistance and UMC Security to have the Emergency Coordinator paged.

6.0 Have the following information available for Security and the Emergency Coordinator:

6.1 The chemical that was spilled or released:

- Approximately how much spilled or leaked and how it occurred, example: the one-gallon bleach bottle fell onto the floor and burst open
- Where the spill is located, room number and location within the room
- If anyone was injured by the chemical when it spilled
- Your name and where you are calling from

7.0 Notify the area supervisor of the spill as soon as possible.

7.1 Security will proceed to the location of the spill and will assist with scene control and information collection until the Emergency Coordinator and/or spill clean up personnel arrive on-scene.

7.2 No one will re-enter the spill area unless they are authorized to do so by the Emergency Coordinator.

7.3 The UMCC Chemical Spill Contingency Plan will be followed for all hazardous chemical spills which constitutes a release to the environment.

8.0 An Accident Report will be filled out for every hazardous chemical or waste spill if it involved injury to anyone, potentially exposed anyone to hazardous chemicals or wastes, was a spill requiring clean up by spill response personnel, created or was caused by a fire or constituted a release to the environment.
CHEMO SPILL PROCEDURE:
1.0 If splashed on skin or eyes, rinse with lots of water for at least 15 minutes. Follow-up with Employee Health during normal weekday hours or Urgent Care at all other times and complete an Employee Accident Report form.

2.0 Keep everyone out of the immediate spill area.

3.0 Use chemo spill kit contents to clean up spill. If spill kit is not available in the immediate vicinity, obtain one from the MaCE Issue Desk at 4-6575.

4.0 Call Risk Management at 4-7475 or 4-6753 for disposal of the clean up materials.

5.0 An Accident Report should be completed for all chemotherapy spills and sent to Risk Management ASAP.

6.0 Anyone who has come into contact with the cytotoxic agent during the spill should be seen in either Employee Health or the Emergency Department nights, evenings and weekends.

7.0 The Chemical Spill Contingency Plan should be implemented in the event of a major spill of a cytotoxic agent, regardless of the location of the spill. Security should be called at either 4-6533 or on the 84 phone line to report the spill. Security will notify the Emergency Coordinator on-call, who will in turn call in additional spill clean-up personnel as needed.

8.0 All cytotoxic agents, wastes or spill clean-up materials will be divided into three (3) waste categories, biohazardous, chemotherapy and RCRA Pharmaceutical hazardous wastes.

8.1 Materials used during admixture of cytotoxics, i.e., gloves, protective garments, empty vials, IV bags and tubing, and syringes with de minimis or no visible residue on or in them, will be disposed of as biohazardous “red bag/sharps” wastes.

8.2 Any container holding more than a de minimis quantity of any cytotoxic admixture or agent that is not one of the RCRA listed agents, including syringes, IV bags, etc., materials from chemo spill kits used to clean up these agents or admixture spills and/or outdated agents in their original containers will be collected in a 5 gallon Chemotherapy Waste container and labeled as chemotherapy wastes.

8.3 The UMC Environmental Management Officer will be contacted to pick up any RCRA listed wastes of greater than de minimis quantities, used chemo spill kit materials containing these types of wastes and/or outdated listed cytotoxic
agents. These materials will be collected and packaged in appropriate DOT containers, labeled and manifested as RCRA wastes for disposal by an approved TSDF.

8.4 Biohazardous and chemical hazardous wastes containers will not be filled more than ¾’s full. Covers on all waste containers will be secured before being removed for disposal.

9.0 All chemotherapy and/or biohazardous wastes containers from Pharmacy Services and patient care areas will be collected by Support Services personnel, the Environmental Management Officer or an approved contractor, and disposed of appropriately.
## APPENDIX 1

### Cytotoxic Agents

<table>
<thead>
<tr>
<th>GENERIC</th>
<th>BRAND</th>
<th>ALTERNATIVE NAMES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aidesleukin</td>
<td>Proleukin</td>
<td>IL-2, interleukin-2</td>
</tr>
<tr>
<td>Alltretinoin</td>
<td>Panretin</td>
<td>Retinoic acid</td>
</tr>
<tr>
<td>Altretamine</td>
<td>Hexalen</td>
<td>Hexamethylmelamine</td>
</tr>
<tr>
<td>Amifostine</td>
<td>Ethyl</td>
<td>Ethiofos, Gammaphos</td>
</tr>
<tr>
<td>Aminogluthimidide</td>
<td>Cytadren</td>
<td></td>
</tr>
<tr>
<td>Anagrelide</td>
<td>Agrylin</td>
<td></td>
</tr>
<tr>
<td>Anastrozole</td>
<td>Arimidex</td>
<td></td>
</tr>
<tr>
<td>Aspariginase</td>
<td>Elspar</td>
<td>L-Aspariginase</td>
</tr>
<tr>
<td>BCG LIVE</td>
<td>TheraCys</td>
<td>TICE-BCG</td>
</tr>
<tr>
<td>Bexarotene</td>
<td>Targretin</td>
<td>LGD 1069</td>
</tr>
<tr>
<td>Bicalutamide</td>
<td>Casodex</td>
<td></td>
</tr>
<tr>
<td>Bleomycin</td>
<td>Blenoxane</td>
<td>Bleo</td>
</tr>
<tr>
<td>Busulfan</td>
<td>Myleran</td>
<td>Busulfex</td>
</tr>
<tr>
<td>Capecitabine</td>
<td>Xeloda</td>
<td></td>
</tr>
<tr>
<td>Carboplatin</td>
<td>Pareplatin</td>
<td>Carboplatin</td>
</tr>
<tr>
<td>Carmustine</td>
<td>BCNU</td>
<td>BiCNU</td>
</tr>
<tr>
<td>Chlorambucil</td>
<td>Leukeran</td>
<td></td>
</tr>
<tr>
<td>Cisplatin</td>
<td>Platinol</td>
<td>Cisplatinum, CDDP</td>
</tr>
<tr>
<td>Cladribine</td>
<td>Leustatin</td>
<td>2-CdA</td>
</tr>
<tr>
<td>GENERIC</td>
<td>BRAND</td>
<td>ALTERNATIVE NAMES</td>
</tr>
<tr>
<td>Cyclophosphamide</td>
<td>Cytoxan</td>
<td></td>
</tr>
<tr>
<td>Cytarabine</td>
<td>Ara-C, Cytosar-U</td>
<td>Cytosine Arabinoside</td>
</tr>
<tr>
<td>Cytarabine Liposome</td>
<td>DepoCyt</td>
<td>Liposomal Ara-C</td>
</tr>
<tr>
<td>Dacarbazine</td>
<td>DTIC-Dome, DTIC</td>
<td>Imidazole Carboximide</td>
</tr>
<tr>
<td>Dactinomycin</td>
<td>Cosmegen</td>
<td>Actinomycin-D</td>
</tr>
<tr>
<td>Daunorubicin</td>
<td>Cerubidine</td>
<td>Daunomycin</td>
</tr>
<tr>
<td>Daunorubicin Liposome</td>
<td>DaunoXome</td>
<td></td>
</tr>
<tr>
<td>Denileukin Difftox</td>
<td>Ontak</td>
<td>DAB/IL-2 fusion protein</td>
</tr>
<tr>
<td>Dexrazoxane</td>
<td>Zinecard</td>
<td>ADR-529</td>
</tr>
<tr>
<td>Diethylstilbestrol</td>
<td>Stilphostrol</td>
<td>DES</td>
</tr>
<tr>
<td>Docetaxel</td>
<td>Taxotere</td>
<td></td>
</tr>
<tr>
<td>Doxorubicin</td>
<td>Adriamycin</td>
<td>Hydroxydaunomycin</td>
</tr>
<tr>
<td>Doxorubicin HCL Liposome</td>
<td>Doxil</td>
<td>Liposomal Doxorubicin</td>
</tr>
<tr>
<td>Epirubicin</td>
<td>Ellence</td>
<td>farmorubicin</td>
</tr>
<tr>
<td>Estramustine</td>
<td>Emcyt</td>
<td></td>
</tr>
<tr>
<td>Etoposide</td>
<td>VePesid, Toposar</td>
<td>VP-16</td>
</tr>
<tr>
<td>Etoposide Phosphate</td>
<td>Etopophos</td>
<td></td>
</tr>
<tr>
<td>Exemestane</td>
<td>Aromasin</td>
<td></td>
</tr>
<tr>
<td>Fluorouracil</td>
<td>Adrucil, Fluorouracil</td>
<td>5-FU</td>
</tr>
<tr>
<td>Flutamide</td>
<td>Euflaxin</td>
<td></td>
</tr>
<tr>
<td>Gemcitabine</td>
<td>Gemzar</td>
<td></td>
</tr>
<tr>
<td>Gemtuzumab</td>
<td>Mylotarg</td>
<td></td>
</tr>
<tr>
<td>Goserelin</td>
<td>Zoladex</td>
<td></td>
</tr>
<tr>
<td>Drug Name</td>
<td>Trade Name</td>
<td>Alternative Names</td>
</tr>
<tr>
<td>-------------------</td>
<td>------------</td>
<td>--------------------------------------------</td>
</tr>
<tr>
<td>Hydroxyurea</td>
<td>Hydrea</td>
<td>Hydroxycarbamide</td>
</tr>
<tr>
<td>Idarubicin</td>
<td>Idamycin</td>
<td></td>
</tr>
<tr>
<td>GENERIC</td>
<td>BRAND</td>
<td>ALTERNATIVE NAMES</td>
</tr>
<tr>
<td>Ifosfamide</td>
<td>Ifex</td>
<td></td>
</tr>
<tr>
<td>Interferon-Alfa-2A</td>
<td>Roferon-A</td>
<td></td>
</tr>
<tr>
<td>Interferon-Alfa-2B</td>
<td>Intron-A</td>
<td></td>
</tr>
<tr>
<td>Irinotecan</td>
<td>Camptosar</td>
<td>CPT-11, camptothecin-11</td>
</tr>
<tr>
<td>Isotretinoin</td>
<td>Accutane</td>
<td>13-cis-retinoic acid</td>
</tr>
<tr>
<td>Letrozole</td>
<td>Femara</td>
<td></td>
</tr>
<tr>
<td>Leucovorin</td>
<td>Willocovin</td>
<td>Folinic Acid</td>
</tr>
<tr>
<td>Leuprolide</td>
<td>Lupron</td>
<td></td>
</tr>
<tr>
<td>Levamisole</td>
<td>Ergamisol</td>
<td></td>
</tr>
<tr>
<td>Lomustine</td>
<td>CeeNU</td>
<td>CCNU</td>
</tr>
<tr>
<td>Mechlorethamine</td>
<td>Mustargen</td>
<td>Nitrogen Mustard, HN2</td>
</tr>
<tr>
<td>Megestrol</td>
<td>Megace</td>
<td></td>
</tr>
<tr>
<td>Melphalan</td>
<td>Alkeran</td>
<td>L-PAM</td>
</tr>
<tr>
<td>Mercaptopurine</td>
<td>Purinethol</td>
<td>6-Mercaptopurine, 6-MP</td>
</tr>
<tr>
<td>Mesna</td>
<td>Mesnex</td>
<td></td>
</tr>
<tr>
<td>Methotrexate</td>
<td>Folex, Mext</td>
<td>MTX</td>
</tr>
<tr>
<td>Mitomycin</td>
<td>Mutamycin</td>
<td>Mitomycin-C</td>
</tr>
<tr>
<td>Mitotane</td>
<td>Lysodren</td>
<td></td>
</tr>
<tr>
<td>Mitoxantrone</td>
<td>Novantrone</td>
<td>Mitox</td>
</tr>
<tr>
<td>Nilutamide</td>
<td>Nilandron</td>
<td></td>
</tr>
<tr>
<td>Octreotide</td>
<td>Sandostatin</td>
<td>Sandostatin LAR Depot</td>
</tr>
<tr>
<td>Oprelvekin</td>
<td>Neumega</td>
<td>rIL-11</td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>Taxol</td>
<td></td>
</tr>
<tr>
<td>Pamidronate</td>
<td>Aredia</td>
<td></td>
</tr>
<tr>
<td>Pegasparagase</td>
<td>Oncaspar</td>
<td>PEG-L-asparaginase</td>
</tr>
<tr>
<td>Pentostatin</td>
<td>Nipent</td>
<td>2'-deoxycoformycin</td>
</tr>
<tr>
<td>Plicamycin</td>
<td>Mithracin</td>
<td>Mithramycin</td>
</tr>
<tr>
<td>Procarbazine</td>
<td>Matulane</td>
<td>MIH</td>
</tr>
<tr>
<td>Sargramostim</td>
<td>Leukine</td>
<td>GM-CSF</td>
</tr>
<tr>
<td>Streptozocin</td>
<td>Zanosar</td>
<td>STZ</td>
</tr>
<tr>
<td>Rituximab</td>
<td>Rituxin</td>
<td></td>
</tr>
<tr>
<td>Tamoxifen</td>
<td>Novaldex</td>
<td>TAM</td>
</tr>
<tr>
<td>Temozolomide</td>
<td>Temodar</td>
<td>Methotrexolastone</td>
</tr>
<tr>
<td>Teniposide</td>
<td>Vumon</td>
<td>VM-26</td>
</tr>
<tr>
<td>ThioGUANINE</td>
<td>ThioGUANINE Tabloid</td>
<td>6-TG</td>
</tr>
<tr>
<td>Thiopeta</td>
<td>Thioplex</td>
<td>TESP A</td>
</tr>
<tr>
<td>Topotecan</td>
<td>HyCamtin</td>
<td></td>
</tr>
<tr>
<td>Toremifene</td>
<td>Fareston</td>
<td></td>
</tr>
<tr>
<td>Trastuzumab</td>
<td>Herceptin</td>
<td></td>
</tr>
<tr>
<td>Tretinoin</td>
<td>Vesanan</td>
<td>ALL-trans-retinoic acid, ATRA</td>
</tr>
<tr>
<td>Trimetrexate</td>
<td>Neutrexin</td>
<td></td>
</tr>
<tr>
<td>Valrubicin</td>
<td>Valstar</td>
<td>AD 32</td>
</tr>
<tr>
<td>Vinblastine</td>
<td>Velban</td>
<td>VLB</td>
</tr>
<tr>
<td>Vincristine</td>
<td>Oncovin, Vincasar</td>
<td>VCR</td>
</tr>
<tr>
<td>Vinorelbine</td>
<td>Navelbide</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX II

LIST OF RCRA PHARMACEUTICAL P-LISTED & U-LISTED WASTE

P-Listed (Acutely Hazardous) Waste (adapted from 40 CFR Section 261.33)

An acutely hazardous (P & U-listed) waste is defined, as follows:

(a) Any commercial chemical product or manufacturing chemical intermediate having the generic name listed in Tables 1 & 2, below.

(b) Any off-spec commercial chemical product or manufacturing chemical intermediate that, if it met specifications, would have the generic name listed in Tables 1 & 2, below.

(c) Any residue remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in Tables 1 & 2, below.

(d) Any residue or contaminated soil, water or other debris resulting from a cleanup of a spill into or on any land or water of any commercial chemical product or manufacturing chemical intermediate having the generic name listed in Tables 1 & 2, below, or any residue or contaminated soil, water, or other debris resulting from a cleanup of a spill into or on any land or water of any off-spec commercial chemical product or manufacturing chemical intermediate which, if it met specification, would have the generic name listed in Tables 1 & 2, below.

<table>
<thead>
<tr>
<th>Table 1. P-Listed Wastes</th>
</tr>
</thead>
<tbody>
<tr>
<td>P057</td>
</tr>
<tr>
<td>P058</td>
</tr>
<tr>
<td>P002</td>
</tr>
<tr>
<td>Hazardous Waste No.</td>
</tr>
<tr>
<td>--------------------</td>
</tr>
<tr>
<td>U001</td>
</tr>
<tr>
<td>U240</td>
</tr>
<tr>
<td>U002</td>
</tr>
<tr>
<td>U003</td>
</tr>
<tr>
<td>U008</td>
</tr>
<tr>
<td>U019</td>
</tr>
<tr>
<td>U070</td>
</tr>
</tbody>
</table>

**Table 2. U-Listed Wastes**
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>U021</td>
<td>Benzidine</td>
</tr>
<tr>
<td>U035</td>
<td>Chlorambucil</td>
</tr>
<tr>
<td>U044</td>
<td>Chloroform</td>
</tr>
<tr>
<td>U058</td>
<td>Cyclophosphamide</td>
</tr>
<tr>
<td>U059</td>
<td>Daunomycin</td>
</tr>
<tr>
<td>U117</td>
<td>Ethyl ether (I)</td>
</tr>
<tr>
<td>U122</td>
<td>Formaldehyde</td>
</tr>
<tr>
<td>U123</td>
<td>Formic acid (C,T)</td>
</tr>
<tr>
<td>U140</td>
<td>Isobutyl alcohol (I,T)</td>
</tr>
<tr>
<td>U154</td>
<td>Methanol (I)</td>
</tr>
<tr>
<td>U010</td>
<td>Mitomycin C</td>
</tr>
<tr>
<td>U202</td>
<td>Saccharin, &amp; salts</td>
</tr>
<tr>
<td>U220</td>
<td>Toluene</td>
</tr>
<tr>
<td>U236</td>
<td>Trypan blue</td>
</tr>
<tr>
<td>U248</td>
<td>Warfarin, &amp; salts, when present at concentrations of 0.3% or less</td>
</tr>
<tr>
<td>U239</td>
<td>Xylene (I)</td>
</tr>
</tbody>
</table>

NOTE: Some of the listed P & U pharmaceuticals or wastes can also be found in the toxicology laboratory area.

Not all pharmaceuticals are on the P&U list however; they may still exhibit one or more of the four characteristics of hazardous materials/waste (ie, flammable such as collodion or acetone). Always refer to the MSDS for the product in order to determine disposal method. When in doubt, contact the Environmental Management Officer at 4-7475. This list is subject to change.
Attachment 4

Investigational Studies by Non-University of Arizona Medical center Nurses (NURAD 7)
PATIENT CARE SERVICES ADMINISTRATIVE POLICY

SUBJECT: Investigational Studies By Non-University of Arizona Medical Center Nurses

POLICY: NURAD 7

REVIEWER: Cindy Rishel RN, PhD, OCN®
EFFECTIVE DATE: March 1986
REVISION DATE: July 2002, September 2005
REVIEW DATE: July 1999, September 2008, September 2011
NEXT REVIEW DATE: September 2014

POLICY

1.0 Personnel conducting investigational studies must comply with the nursing licensure and chart documentation requirements of The University of Arizona Medical Center – University Campus Department of Patient Care Services.

2.0 The Department of Patient Care Services must be notified in advance of non-UAMC nursing personnel being hired to conduct investigational studies at UAMC.

PROCEDURE:

1.0 All licensed nursing personnel who are employed to conduct investigational studies at UAMC must show verification that they hold a current valid license in the State of Arizona or a compact state prior to conducting/collaborating data for research.

1.1 The Principle Investigator is responsible for submitting the “Non-UAMC Nurse Researcher Tracking Form” to the UAMC Site Review Authority, as an attachment to the IRB application. (See below)

1.2 For further information, refer to Patient Care Services Administrative Policy No. Ad-16, "Documentation of Licensure," and Administrative Structure Standard Chapter 6 – “Research.”
2.0 All standard policies and procedures including charting documentation procedures must be followed in accordance with hospital and patient care services department policy. This may mean duplication of charting for the investigational study records since they are not a permanent part of the UAMC medical record.

2.1 Refer to the Department of Patient Care Services Documentation Guidelines Manual.
Non-UAMC Nurse Researcher Tracking Form

<table>
<thead>
<tr>
<th>Researcher Name</th>
<th>RN License Number</th>
<th>License Expiration Date</th>
<th>Name of Person Performing Primary Source Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

License verification includes
1) visual inspection of the original signed license
2) contacting the Arizona State Board of Nursing and following the steps below.
http://www.azbn.org/OnlineVerification.asp

- In the appropriate spaces type in first and last name
- Click on "verify" button
- Double click on the correct name displayed below
- Go to “file” and “print” to print verification
Attachment 5

Inpatient Pharmacy - Investigational Drugs (2.28)
INPATIENT PHARMACY

Investigational Drugs

Policy:

The Department of Pharmacy Services will store, label, dispense and maintain usage records of all investigational drugs in accordance with the investigator's instruction, institutional policies and the FDA's Good Clinical Practice Guidelines. The Department of Pharmacy Services will maintain a file of information on investigational drugs being used, including study protocol, drug actions, side effects, symptoms of toxicity, and any other information that may be known.

Procedure:

1.0 Procurement of Investigational Drugs

1.1 The Investigational Pharmacist will make arrangements with the Principal Investigator and the Sponsor to obtain investigational agents. These agents will be delivered to the Central Pharmacy. Drugs sent to other areas should be forwarded to the Central Pharmacy for receipt and processing by IDS (Investigational Drug Service).

1.2 The IDS will log receipt of all investigational drugs. Shipping records will be reconciled to shipping contents and any discrepancies will be reported to the study sponsor and/or principal investigator. The packing slips will then be signed, dated and filed in accordance with the study protocol in the appropriated file or binder.

2.0 Storage

2.1 All investigational agents will be stored in designated IDS areas under the conditions recommended by the manufacturer or sponsor. Agents will be stored in the investigational refrigerator, investigational freezers or on the room temperature shelving in the IDS. The temperatures of the refrigerator and freezers used to store these drugs will be monitored daily and recorded. The original copies of the temperature logs will be kept in the IDS files.

2.2 Investigational and study drugs may be stored in other areas (satellites) as long as Pharmacy policies and procedures for inventory control and dispensing are followed. The master log will be retained in IDS with drug signed out to the satellite.
INPATIENT PHARMACY

Investigational Drugs

2.3 SWOG study drugs originating from the UMC North Cancer Center may be maintained in the IDS or satellite areas while a patient is receiving treatment as an inpatient. The master log will be retained in the ACC, with drug being signed out to the inpatient Pharmacy area.

3.0 Accountability

3.1 A perpetual inventory of all investigational agents will be maintained using either the study or drug specific accountability form provided by the sponsor or the standard IAAR form used by this institution.

3.2 Upon receipt, all agents will be logged into the study specific, agent specific accountability form.

3.3 When an agent is dispensed, destroyed, other otherwise removed from inventory and entry on the accountability form will be made. The date, the quantity dispensed, destroyed, or removed, lot number and Pharmacist or Pharmacy Technician initials will be recorded. If the agent is removed for use by a patient, the patient initials, specific dose and patient number will be recorded. Any other required information will be recorded in accordance with the study protocol.

3.4 Black ink should be used for all entries on the accountability form. Errors will be crossed out with a single pen stroke, then dated and initialed, and explained if necessary.

4.0 Drug Information

4.1 A copy of the most current protocol, along with any updates or amendments will be provided to the IDS by the Principal Investigator or the Clinical Research Center, and kept on file in the IDS office.

4.2 Whenever possible, the most current version of the Investigational Drug Brochure, MSDS, and any other data relevant to the use and dispensing of the drug will be provided to the Investigational Pharmacist and kept on file in the IDS office.
INPATIENT PHARMACY

Investigational Drugs

4.3 A study specific “Fast Facts” form will be generated for all clinical studies that will be dispensed by the Inpatient Pharmacy or Inpatient Satellites. The form will contain a synopsis of the study as well as the drug preparation, dispensing and ordering instructions. The “Fast Facts” will be located in a binder in the Unit Dose Area as well as in the study binder located in the IDS office.

4.4 A brief drug information sheet will be placed in the charts of all patients that are admitted to UMC.

5.0 Preparation and Dispensing

5.1 An investigational or study drug will be dispensed upon a pharmacist’s receipt of an order given by a physician listed on the 1572 form for the particular study, or a legally authorized representative. Documentation of patient informed consent must be available for pharmacy review.

5.2 The drug will be prepared and dispensed according to the study protocol, established Pharmacy guidelines and the Fast Facts information form.

5.3 The label for the dispensed products will be in accordance the protocol and State and Federal guidelines and regulations. It will be noted if the study is blinded and the label will reflect that blind. Each preparation will be labeled with the statement “For Investigational Use Only”.

6.0 Disposition

6.1 Study vials, bottles, or containers will be dealt with according to the protocol of the specific study. Those vials, which do not require storage after use, along with the equipment used to prepare the drug, will be disposed of in chemosafety biohazard waste containers. When containers are full, they will be sealed, transported and disposed of by incineration or current University Medical Center Institutional Policies and Procedures.
INPATIENT PHARMACY

Investigational Drugs

6.2 Any item returned from a patient, or prepared for a patient and not used will be documented on the accountability form. These items will be stored or destroyed as described in section 6.1 and documented. If the sponsor requires the return of used or unused medications, vials or containers they must provide a method of shipment.

Rafael A. Diaz, Pharmacy Director
Attachment 6

Handling of Investigational Drugs (5.03)
THE UNIVERSITY OF ARIZONA CANCER CENTER

Handling of Investigational Drugs

Policy:

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.
THE UNIVERSITY OF ARIZONA CANCER CENTER

Handling of Investigational Drugs

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.
THE UNIVERSITY OF ARIZONA CANCER CENTER

Handling of Investigational Drugs

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.
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 data
base. 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.
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.
THE UNIVERSITY OF ARIZONA CANCER CENTER

Handling of Investigational Drugs

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.
THE UNIVERSITY OF ARIZONA CANCER CENTER

Handling of Investigational Drugs

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.
THE UNIVERSITY OF ARIZONA CANCER CENTER

Handling of Investigational Drugs

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.
THE UNIVERSITY OF ARIZONA CANCER CENTER

Handling of Investigational Drugs

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.
THE UNIVERSITY OF ARIZONA CANCER CENTER

Handling of Investigational Drugs

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: ___________________________

9/20/11 Version 2.
TIME OUT Checklist for Investigational Drugs

For IV/IM/ SQ 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, 3/13/11
## Investigational Agent Accountability Record

### Investigator Name and Number (If NCI sponsor) / Name of Institution / Protocol Number / Protocol Title:
- The University of Arizona Cancer Center – North Campus

<table>
<thead>
<tr>
<th>Agent Name, Dose Form, and Strength</th>
<th>Expiration Date, If Known</th>
<th>Storage and Dispensing Area</th>
<th>Pharmacy, room 2390</th>
</tr>
</thead>
</table>

### Dispensing Record

<table>
<thead>
<tr>
<th>Line No.</th>
<th>Date (DD/MMM/YY)</th>
<th>Patient Initials (FML)</th>
<th>Patient ID Number</th>
<th>Dose</th>
<th>Quantity Dispensed or Received</th>
<th>Balance Forward</th>
<th>Balance</th>
<th>Manufacturer and Lot No.</th>
<th>Recorder Initials</th>
<th>Date Returned to Pharmacy (DD/MMM/YY)</th>
<th>Total Number of Bottles AND cap/tablets</th>
<th>Recorder Initials</th>
<th>Disposition: (D) destroyed on site (S) saved for monitor visit (R) return to sponsor Record Date and Initials (2 persons if destroyed)</th>
<th>Record Verified By</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## INVESTIGATIONAL AGENT ACCOUNTABILITY RECORD

<table>
<thead>
<tr>
<th>Investigator Name and Number (if NCI sponsored):</th>
<th>Name of Institution</th>
<th>Protocol Number</th>
<th>Protocol Title:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>The University of Arizona Cancer Center – North Campus</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Agent Name, Dose Form, and Strength

<table>
<thead>
<tr>
<th>Expiration date, if known</th>
<th>Storage and Dispensing Area</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pharmacy, room 2390</td>
</tr>
</tbody>
</table>

### Line No. | Date (DD/MM/YY) | Patient Initials (FML) | Patient's ID Number | Dose | Quantity Dispensed or Received | Balance Forward | Balance | Manufacturer and Lot No. | Recorder Initials | Time Prepared | Date (DD/MM/YY) | Number of Used/Partially Used Vials Destroyed on Site after Dose Preparation | Recorder Initials | Record Verified By | Date |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Attachment 7

Medication Administration and Potentially Harmful Drugs Protocol (1590.0)
DEPARTMENT OF PATIENT CARE SERVICES
ADULT HEALTH SERVICES

Medication Administration and Potentially Harmful Drugs Protocol (1590.0)

IMPLEMENTATION DATE: 8/12/94
REVISION DATE: 9/13/95, 7/30/98, 6/3/99, 3/15/05,
6/27/05, 8/12/05, 8/16/05, 1/17/06,
1/29/08, 4/15/08, 7/15/08, 1/20/09,
3/17/09
REVIEW DATE: 8/24/02
NEXT REVIEW DATE: 1/2012
SIGNED BY: Heidi Costello, RN, BSN, MBA
Director, Adult Health Services

PURPOSE:
To minimize medication errors by providing information for safe administration of potentially harmful drugs, as well as promotion of patient safety and maximal therapeutic effect.

SUPPORTIVE DATA:
All medication must be checked prior to administration. The inability to retrieve an incorrect drug or dosage could result in serious complications for the patient. Hemodynamically unstable patients are often supported by cardiotoxic drips which must be properly administered. Refer also to the following:

- Corporate Policy (PM 3) - Medication Control and Handling

- Corporate Policy (PM 24) - Conscious Sedation / Anesthesia Policy for Operative or Other Procedures

- Corporate Policy (PM 34) - Medication / Adverse Drug Event (ADE) Self Reporting Policy

- Corporate Policy (PM 68) – Dose Range and variable Frequency

- PCS Administrative Policy (NURPM 8) - Dopamine Infusion Outside the ICU

- PCS Administrative Policy (NURPM 9) - Narcotics Control
- Pharmacy Inpatient Policy (2.28) - Investigational Drugs

- Pharmacy Inpatient Policy (2.82) – Standardization of IV Admixtures

- UMC Drug Formulary

**General Medications.**

**SAFETY:**
1.0 All medications must be ordered by the physician or authorized licensed independent practitioner (LIP: e.g., NP, PA) prior to administration. Orders for medication will include the following:

1.1 Name of Drug

1.2 Dosage

1.3 Route

1.4 Frequency of administration
   Medications will be given within one hour of time scheduled.

1.5 When ordering IV solutions with medication admixtures, if the medical provider does not specify a concentration and base solution, pharmacy and nursing staff will utilize standard concentrations per Pharmacy Policy #2.82 “Standardization of Intravenous Admixtures”.

2.0 Orders for titratable medications should include the following information:

2.1 Name of the drug (generic preferred)

2.2 Route

2.3 Starting dosage

2.4 Maximum dosage

2.5 Goal or target for the drug

2.6 Maximum titration increment

3.0 For each shift, licensed nursing personnel will administer medications from one-half hour from their start of their shift through the end of their shift.

4.0 The patient's allergy history will be reviewed prior to administration of any drug.
5.0 The patient's identification, drug, dosage, route, and time will be checked prior to administration of any medication.

6.0 Verify expiration dates noted by pharmacy, manufacturer or authorized licensed personnel that prepared admixture on floor/unit.

7.0 All medications ordered in units (i.e., heparin, insulin, etc.) will be transcribed using the full word "units". Use only UMC-approved abbreviations.

8.0 Label all medication containers (eg. syringes, medicine cups, basins) or other solutions on and off the sterile field in perioperative and other procedural settings (including but not limited to: GI lab, Cardiac Cath lab, EP lab, Interventional Radiology, physician clinics, Cancer Center, Radiation Oncology, Dialysis and ED).

**DELIVERY:**

9.0 It is recommended that, at the beginning of each shift, the nurse check the patient's Medication Administration Record (MAR) against the medications placed in the patient's bin to see that all the medications are there. This could help prevent omitted doses and late administration of medications.

10.0 Medications are to be administered to one patient at a time.

11.0 Compare the name of the medication and dosage on the drug package with the name of the medication and dosage on the order sheet, designated medical record form and/or the MAR.

12.0 Verify the patient's identity as outlined in Corporate Policy PM 38 – Patient Identification (Use two patient identifiers). The two patient identifiers for inpatients in Adult Health Service and Women and Children Services are (1) patient name and (2) Medical Record Number (using the MAR).

12.1 Before entering the room the RN is to wash hands.

12.2 Bring the MAR into the patient's room (including isolation patients).

12.3 Place on a clean surface.

12.4 After leaving the room the RN is to wash hands.

13.0 Assure that the right medication is being given to the right patient at the right dose, the right time and the right route.

14.0 Administer the medication to the patient and record in the patient's medical record.
15.0 Omission of a medication:

15.1 If an ordered medication is not given, the time that was scheduled for administration is to be circled on the MAR.

15.2 The reason for not being given is documented in the MAR.

**DELIVERY:**

16.0 For adult administration guidelines refer to the current edition of Clinical Nursing Skills by Smith and Duell for site selection and administration technique.

17.0 For IV administration, including admixture, refer to IV (Peripheral) Therapy Management Protocol (AHP 1560.0).

17.1 For potentially harmful drugs, a pump with preprogrammed protections **MUST** be used.

18.0 **Intramuscular** injection sites for pediatric patients;

18.1 Neonates and Infants: The injection site for neonates will be in the right or left anterolateral thigh. The injection will be given with a 25 gauge 5/8 inch needle.

18.2 **Pediatrics:**
- Vastus Lateralis; 22 to 25 gauge, 5/8 to 1 inch needle.

- Ventrogluteal; 22 to 25 gauge, 1/2 to 1 inch needle.

- Dorsogluteal; 20 to 25 gauge, 1/2 to one and a half inches for the needle size. This method is contraindicated for children who have not been walking for at least one year.

- Deltoid; 22 to 25 gauge, 1/2 to 1 inch. Small muscle mass; only limited amounts of drug can be injected (0.5 to 1 ml).

19.0 **Intravenous medications:**

19.1 If more than one IV medication is to be administered, refer to pharmacy for recommended interval between doses administered.

19.2 If incompatibility information is unavailable, flush line with 0.9% NaCl between doses.

20.0 Oral medication will be given with feedings for infants and neonates unless otherwise indicated or ordered. Includes tube feedings.
20.1 Infants who are nipple feed should receive medication during the first half of the feeding.

- Medication may be mixed with a small amount (5-10 ml) of feeding in volume and given by the attached nipple.

- Medication may be mixed with small amount (5-10 ml) of feeding in syringe and slowly injected into detached nipple while infant is sucking.

20.2 Infants who are gavage fed should receive medication during the first half of the feeding. Administer medication directly to the syringe. See tube-feeding protocol.

20.3 Pediatric patients on continuous feeding will receive medication via stopcock placed between feeding tube and the pump tubing, or in second port in feeding tube when available.

- Turn stopcock "off" to feeding pump.

- Inject medication via syringe through stopcock.

- Turn stopcock "on" to feeding pump.

- For large volume of medication give in divided doses.

- If significant regurgitation occurs, notify physician/LIP, but do not repeat dose unless otherwise ordered.

21.0 Oral medications administered via a feeding tube (i.e. NG, jejunostomy, etc.) must be of consistency as to not occlude the tube.

**Medication Prescription:**

**SAFETY:**

22.0 When the following drugs require specific signatures as specified:

22.1 Cytotoxic agents: Require attending or fellow's signature in an appropriate specialty.

22.2 Loading dose of digitalis: Requires second year resident signature for pediatrics.

23.0 Heparin dosing nomogram orders for cardiac indications require patient's weight in kg., height in inches, age and gender to determine dosage calculated by pharmacy.
24.0  A written order (no verbal orders accepted) for initial doses of the following is required:

24.1  Loading doses of IV digitalis preparation for pediatric patients.

24.2  Any cytotoxic agent (applies to any dose, not just loading dose).

24.3  Any insulin for pediatric patients (applies to any dose, not just loading dose).

25.0  All IV medications drawn from a labeled vial into a syringe must be administered promptly by the individual filling the syringe or must be labeled as outlined in the pharmacy guidelines (i.e., date, time, expiration and initials of licensed individual filling the syringe).

NURSING PROCEDURE FOR SELF ADMINISTERED DRUGS
26.0  Self administration of a medication is allowed after the patient receives information about the following and is determined to be competent at medication administration.

- The nature of the medication to be administered.

- How to administer medications, including dose, frequency, route of administration, and the site of administration, if applicable.

  - Includes administration of subcutaneous injectable medications.
  - Observation by licensed personnel is required until competency is achieved.
  - Education and observations should be documented.

- The expected action and side effects.

- How to monitor the effects and report to appropriate personnel.

- Documentation of medication administration.

All doses administered by the patient will be documented and transcribed into the MAR by nurse.

POTENTIALLY HARMFUL DRUGS / DRUG INTERACTIONS:
27.0  The following medications require specific administration guidelines to prevent potentially serious side effects:

27.1  IV electrolyte infusions: Potassium - see Addendum A.

27.2  IV infusions of cardiotonic drugs - see Addendum B.
27.3 Anticoagulant therapy - see Anticoagulant Management Protocol (AHP 1040.0)

27.4 Investigational agents - see Pharmacy Inpatient Policy (2.28) Investigational Drugs, and UMC Patient Management Policy (PM 3) Medication Control and Handling.

27.5 Insulin therapy - see Insulin Therapy Protocol (AHP 1520.0)

27.6 Cytotoxic agents - see Chemotherapy Administration Protocol (AHP 1220.0)

27.7 Amphotericin B infusions - see Addendum C

27.8 Heparin Infusion Administration – see Addendum D

27.9 Thrombolytics - see Thrombolytic Treatment Protocol (AHP 2040.0)

28.0 The following medications MUST be checked by two licensed staff prior to administration:

28.1 All chemotherapeutic agents per Chemotherapy Administration Protocol (AHP 1220.0)

28.2 All narcotic infusions (including continuous, PCA and epidural infusions). See Patient Controlled Anesthesia (PCA) Management Protocol (AHP 1760.0).

28.3 Initial digitalizing dose of digoxin.

28.4 See PICU Unit Specific Care Protocol (WCP 5018.7) for additional medication.

28.5 All Heparin infusions.

28.6 All thrombolytic infusions per Thrombolytic Treatment Protocol (AHP 2040.0)

28.7 Double check all insulin doses and initiation of IV infusion.

29.0 Investigational agents may only be administered by RNs who have received specific education or training in the administration of that agent. All investigational agents must adhere to the hospital policy for investigational therapy and human subjects approval (Medication Control and Handling - PM 3).
30.0 Patients receiving certain medications may experience drug-food interactions. Specific educational content should be provided to patients receiving these drugs. Refer to Food / Drug / Herbal Interaction Teaching (NURPM 11) for specific information.

DOCUMENTATION:
31.0 All medication administration, including patient's own medications, must be documented in the appropriate area of the medical record at the time of medication administration.

32.0 Medications administered by physician/LIP should be recorded in the appropriate medication record when given. If not documented by the physician, it should be recorded by the RN who observed the medication administration. Record date, time, medication, dose, route and physician/LIP name, followed by RN signature.

33.0 When a variable dose of a medication is ordered, the exact dose administered is to be recorded.

34.0 When a variable route is ordered for administration of a medication, the exact route and site is to be charted.

35.0 If a buretrol container is used to administer intermittent IV medications, it is to be labeled with date, time started, name and dose of medication.

REFERENCES:


UMC Hospital Formulary
ADDENDUM A
Guidelines for Potassium Administration

ASSESSMENT:
1.0 All related lab results and EKG changes should be reported to the physician promptly. Depending upon the patient’s condition, KCL replacement may be stopped when K+ is 4.3-5.0. Discuss with the physician. (Refer to Potassium replacement scale per physician/LIP. (Refer to Potassium replacement scale per physician/LIP orders).

DOSAGE:
2.0 **K+ Concentration Adult:**

**Adult Peripheral Line:**
- Maintenance concentration: 40 mEq/Liter
- Replacement concentration: 10 mEq/50 ml
- Rate: 10mEq/hour: cardiac monitoring required for all infusions exceeding 10mEq/hr

**Adult Central Line:**
- Maintenance concentration: 100 mEq/Liter
- Replacement concentration: > 10 mEq/50ml or 20mEq/50ml (critical care units)
- Rate: 10mEq/hour (Maximum 40mEq/hour): cardiac monitoring required for all infusions exceeding 10mEq/hr

3.0 **Pediatric K+ Concentration:**

**Pediatric Peripheral Line:** 1 mEq/12.5 ml solution, not to exceed 1 mEq/5ml.

**Pediatric Central Line:** Recommended concentration: 1 mEq/5ml solution.

3.1 **Pediatric K+ Administration Rate:**
Recommended rate: 0.3 – 0.5 mEq/kg/hr

Maximum rate: 1 mEq/kg/hr or 10 mEq/hr, whichever is less. If > 0.5 mEq/kg/hr: Patient must be in PICU for cardiac monitoring.

5.0 Potassium infusions must be given via infusion pump - NEVER GIVE IV PUSH POTASSIUM.
Oral Replacement:
6.0 Tablets (Oral): Take potassium supplements immediately after meals or with food; never crush potassium tablets. Dilute liquid and effervescent supplements (usually in 4-8 oz. Water or juice); administer slow-release tablets with a full glass of water (8 oz). K-Dur tablets may be placed in a glass of water to form an aqueous suspension.

MONITORING / PRECAUTIONS:
7.0 Potassium should be given with caution to patients with renal failure, cardiac disease, and those receiving potassium-sparing diuretics. Oral potassium supplement should be approached with caution in patients with a history of GI bleeding or ulceration.

8.0 Potassium Replacement Monitoring Guidelines. (Note: routine maintenance IV fluid that contains potassium is not considered replacement).

8.1 Adults: Serum K+ levels are recommended after 60 mEq K+ has been administered as replacement before administering additional potassium. For continuous replacement, potassium levels should be checked every 6 hours.

8.2 Pediatrics: Potassium levels should be checked after every 1 mEq/kg has been given.

9.0 If signs of hyperkalemia appear, stop the infusion, notify the physician/LIP for further orders. S/S of hyperkalemia: Muscle weakness, twitching, hyporeflexia, bradycardia, ventricular fibrillation, oliguria, apnea.

10.0 Phlebitis: Monitor peripheral IV site for phlebitis. A physician/LIP order is required for Lidocaine to be administered IV to decrease the pain associated with potassium infusions through a peripheral line.

Adult dose guidelines: For every 10 mEq KCl/50 ml add 1ml (10mg) of 1% lidocaine.

Pediatric dose guidelines: 5 mg (1% Lidocaine) / 1 hourly dose KCl (refer to above guidelines) 50 ml solution, to be administered over 1 hour.

11.0 Calculate total hourly dose of potassium being delivered including maintenance IV, TPN, etc.

Potassium Phosphate:
DOSAGE/ADMINISTRATION:
1.0 With orders for IV phosphate, there is considerable confusion associated with the use of millimoles (mmol) versus millequivalents (mEq) to express phosphate requirements. The most reliable method of ordering IV
phosphate is by millimoles. Check the medication label to verify how much potassium is being given along with the phosphate.

2.0 Dosage Forms:

2.1 Powder Packets: contents to be mixed with about 75 ml of water.

Tablets: Dissolve in 180 to 240 ml of water.

2.2 Injection: Phosphate 3 mmol, Potassium 4.4 mEq per ml.

2.3 Rate of IV infusion: Give over 4 to 6 hours.

3.0 Usual Dosage:

Adult IV phosphate repletion:
Initial dose: 0.08 mmol/kg if recent uncomplicated hypophosphatemia

Initial dose: 0.16 mmol/kg if prolonged hypophosphatemia
Do not exceed 0.24 mmol/kg/day; administer over 6 hours by IV infusion.

3.2 Neonates: 0.5 mmol/kg/dose up to 1-2 mmol/kg/day.

3.3 Children: 0.25-0.5 mmol/kg administer over 4-6 hours and repeat if symptomatic hypophosphatemia persists.

PRECAUTIONS:

4.0 Drug Interactions:

4.1 Do not give at the same time as aluminum and magnesium containing antacids or sucralfate which can act as phosphate binders; use of K phosphate with potassium sparing diuretics or ACE inhibitors may result in hyperkalemia.

5.0 Caution:

5.1 Use with caution in patients with renal insufficiency:

5.2 Admixture of phosphate and calcium in intravenous fluids can result in calcium phosphate and calcium in intravenous fluids can result in calcium phosphate precipitation. Up to 10-15 mEq of calcium may be added per liter before precipitate may occur.

REFERENCES:


ADDENDUM B
Cardiotonic Drug Delivery

Intravenous cardiotonic drugs/drips may only be administered in the following units: Intensive Care units, Intermediate Care units, PACU or Emergency Department. Exception: It is recognized that high acuity patients outside these areas may receive selected medications per unit specific protocols. If cardiotonic medications are prescribed for pediatric patients outside the PICU, prior to the administration of the drug, the pediatric RN will check with the ordering physician/LIP, the pharmacist, and the unit nursing leadership as to the appropriateness of the order / administration of the drug on a general pediatric unit.

Safety
1.0 The RN will review the physician/LIP order, the medication bag, infusion rate, and dose calculations.

To calculate cardiotonic drip, the following formula may be used: 

\[
\text{([concentration in bag (mg/ml) \times 1000]/60 / patient's weight (kg)] \times drip rate (ml/hr)}
\]

1.2 All calculations will be rechecked by two RNs at the change of shift and whenever a new bag is hung. Two RNs to check concentration of IV drip and initial on bag label. RN signature required on ICU flowsheet.

Delivery
2.0 All cardiotonic drips are delivered via infusion pump or syringe infusion pump.

3.0 Administration of cardiotonic drugs by IV push or continuous infusion for the treatment of acute arrhythmias or hemodynamic support may only be done in the Intensive Care units, Intermediate Care units, PACU or in the Emergency Department. Single maintenance doses of medication may be given IV push in general caring areas (i.e., daily dose of dioxin given IV push to the patient who is NPO).

Assessment/Administration
4.0 Lidocaine:

4.1 Assess patient for reduction of ventricular arrhythmias.
4.2 Obtain drug level of Lidocaine - minimum of q 3 days as per physician/LIP order.

4.3 Assess for Lidocaine toxicity: drowsy, disoriented, slurred speech, paraesthesia, muscle twitching, focal/grand mal seizures.

4.4 Assess for hypersensitivity: decreased BP, decreased HR.

5.0 Beta Blocker:

5.1 Monitor patient for reduction of resting HR, exacerbation of heart failure.

5.2 Monitor PR interval closely (Adults): notify physician/LIP if > 0.20.

5.3 Monitor peripheral pulses, tissue perfusion, capillary refill, I & O, daily weights.

5.4 Hold beta blocker per physician/LIP written parameter.

5.5 Nurse to schedule medication times.

5.6 Do not give beta blockers, calcium channel blockers, ACE inhibitors and diuretics all at the same time unless ordered by physician/LIP or patient has been taking them all at home with no complications.

6.0 Digoxin:

6.1 IV administration of digoxin should be given slowly, over 2-5 minutes.

6.2 IV digitalizing doses of digoxin may only be given to adult patients in ICU and IMC areas. IV digitalizing doses of digoxin may be given to pediatric patients in general pediatric units.

6.3 Prior to administration of a digitalizing dose ordered by the physician/LIP, the nurse will obtain a rhythm strip for evaluation.

6.4 The digitalizing doses should be double checked by the RN or physician/LIP.

6.5 Once oral digoxin therapy has been instituted, an apical pulse will be obtained and charted on the medication sheet and encircled prior to the administration of the drug.

6.6 Hold the digoxin and notify the physician/LIP if the apical pulse:
  - is less than 60 bpm for adults.
  - is less than 80 bpm for pediatrics.
  - is less than 100 bpm for neonates.
• There are significant changes in baseline pulse, rhythms, physiological findings.

7.0 **Calcium Channel Blocker:**

7.1 Monitor patient for bradydysrhythmias, orthostatic changes, and dizziness. Nurse to schedule medication times.

7.2 Do not give beta blockers, calcium channel blockers, ACE inhibitors and diuretics all at the same time unless ordered by physician/LIP or patient has been taking them all at home with no complications.

8.0 **Vasoactive drips:**

8.1 Monitor patient for response to pressor agents: hemodynamic parameters, pulmonary status, peripheral perfusion, fluid status.

8.2 Monitor site for infiltration.

8.3 Notify physician/LIP for insufficient urine output.
   • Adults: < 30 ml/hr for more than 2 hours or if capillary refill is > 2 seconds
   • Pediatrics: < 1 ml/kg/hr

9.0 **Vasodilator drips:**

9.1 Monitor hemodynamic parameters and patient response to medication.

9.2 Notify physician/LIP for adverse reactions: headache, dizziness, hypotension, failure to achieve desired parameters, no resolution of chest pain.

9.3 When able, run IV nitroprusside (nipride) separate from other IV drips.

**Maintenance**

10.0 Monitor EKG as ordered and telemetry at all times. Obtain rhythm strip as defined by unit protocols.

11.0 Refer to IV (Peripheral) Therapy Management Protocol (AHP 1560.0) or the appropriate central line protocol.

**Reportable Conditions**

12.0 When using cardiotonic drips, notify physician/LIP when changes occur in parameters set by physician/LIP, acute changes in BP, significant changes in cardiac rhythm or patient mentation.
Documentation
13.0 Flowsheet documentation to include: VS, rhythms, use of infusion pump, IV site condition.

REFERENCE:

UMC Hospital Formulary

ADDENDUM C
Amphotericin B Infusion

Safety
AMPHOTERICIN B is available in different formulations including conventional amphotericin B, amphotericin B lipid complex (Abelcet), and amphotericin B liposome (Ambisome). These formulations are NOT interchangeable. Be aware that the dose and rate of administration for the lipid base products is different than conventional amphotericin B:

- Amphotericin B is dosed 0.5-1.5mg/kg/day and infused over 4 hours.
- Abelcet is dosed 5mg/kg/day and infused @2.5mg/kg/hour.
- Ambisome is dosed 3-5 mg/kg/day and infused over 2 hours.

Refer to the physician/LIP or pharmacist to determine infusion rate.

Unless specifically stated, Amphotericin B refers to any of the products listed above.

Assessment:
1.0 A physician/LIP prescription is required for the administration of IV Amphotericin B. The order is to clearly state: dosage, route, frequency, and length of infusion.

2.0 Most patients who receive IV Amphotericin B experience several of the following reactions: headache, fever, chills, muscle and joint pain, nausea and vomiting, cramping, epigastric pain and cardiac arrhythmias.

2.1 Most of these reactions are considered dose related. Acute reactions are more severe with the first few doses and usually diminish with subsequent doses.
2.2 The febrile reaction, which is accompanied by shaking and chills, usually appears one to two hours after the start of infusion and subsides within four hours after the administration is discontinued. A physician/LIP order is required for the administration of IV meperidine which may be given to stop the chills.

2.3 For severe reactions the drug may have to be stopped.

Delivery

3.0 Administer any premedications (usually one-half hour before) as ordered.

3.1 Antipyretics, antihistamines, antiemetics and corticosteroids may provide some symptomatic relief from many of the adverse reactions of Amphotericin B.

4.0 Advise patients that there may be discomfort at the infusion site.

4.1 A physician/LIP order is required for heparin to be added to the infusion to decrease the risk of phlebitis or thrombophlebitis.

5.0 The diluted drug is an emulsion and the "solution" should not be used if it contains a precipitate or foreign matter. If the Ablecet infusion exceeds 2 hours, mix the contents by shaking the infusion bag every 2 hours.

5.1 It CAN NOT be filtered with 0.22 micron filter.

5.2 All infusions should be regulated on an infusion pump.

5.3 Antibiotics should be given separately; DO NOT mix or piggyback with Amphotericin B.

5.4 Compatibility - D$_5$W only. Flush before and after with D$_5$W.

5.6 A physician/LIP order is required for the administration of 250 ml of 0.9 % NaCl before amphotericin B which may reduce the risk of nephrotoxicity as well as hydrate the patient.

6.0 Infuse Amphotericin at prescribed rate.

7.0 Monitor vital signs as ordered by physician/LIP. Notify physician/LIP of any adverse reactions.

8.0 Platelet or granulocyte infusions should be scheduled six hours apart from amphotericin infusions.
Reportable Conditions

9.0 Monitor electrolytes, BUN, creatinine, CBC and liver function tests regularly. Also note any EKG changes.

10.0 Keep an accurate intake and output. Report changes in urine appearance and volume. Renal damage is usually reversible if the drug is stopped with first sign of dysfunction.

Documentation

11.0 Record patient tolerance, any adverse reactions, dosage given and length of infusion. Record all premeds and dosage on MAR.

12.0 Record patient/family teaching and understanding.

REFERENCES:
UMC Hospital Formulary


ADDENDUM D
Heparin Infusion Administration

Safety

1.0 RN will review physician/LIP order for both intravenous (IV) bolus and continuous infusion.

1.1 When Heparin Nomogram is used two nurses will verify dosage in syringe with nomogram prior to administration of IV bolus.

2.0 Prior to initiation of continuous IV drip two nurses will verify concentration of IV infusion in bag and drip rate on pump with physician/LIP order or physician/LIP ordered nomogram and initial on medication record.

2.1 Two RNs will verify drip rate and/or pump settings following receipt of PTT results, at change of shift, or whenever a rate change is requested by the physician/LIP.

Delivery

3.0 Heparin must be delivered via infusion pump with guardrails utilized.

4.0 Once continuous infusion is started IV line should not be used to deliver any bolus medications.
Assessment
5.0 Obtain PTT every 6 hours as per nomogram or physician/LIP order until therapeutic level is achieved.

6.0 Monitor patient for excessive bruising, bleeding from IV site or gums, hypersensitivity reactions, thrombocytopenia, or tissue necrosis.

Reportable Conditions
7.0 Physician/LIP should be notified if patient exhibits signs of hypercoagulation.

8.0 Physician/LIP should be notified if PTT continues to increase despite reduction or discontinuance of infusion.

9.0 Physician/LIP should be notified if patient exhibits signs or symptoms of a hypersensitivity reaction.

REFERENCES:

ADDENDUM E
(IV Therapy Management)
DEPARTMENT OF PHARMACY
NURSING IV PREPARATION GUIDELINES

GENERAL INFORMATION:
It is important that strict aseptic techniques be employed whenever an IV admixture is prepared, whether in the pharmacy or out at the nursing station. Aseptic technique refers to carrying out a procedure under controlled conditions in a manner that will minimize the chance of contamination.

All objects that come in contact with the drug additive or IV solution must be sterile or contamination will result. Touch contamination by the person performing a procedure probably is the most frequent cause of contamination. This contamination occurs when proper control over manipulations is not maintained. Poor technique in the preparation of IV admixtures cannot be tolerated. Proper attitude of the person preparing an admixture is a vital element in minimizing contamination.

The danger in breaking aseptic technique is readily apparent. Not only are patients receiving IV admixtures the most critical patients in the hospital, but the IV route is the most dangerous route of administration. All natural barriers are bypassed when a drug is given directly into the vein, so the administration of a contaminated solution can have a very serious consequence. Therefore, every precaution must be taken to exercise good aseptic technique in order to avoid contaminating the admixture.
1.0 Before beginning to prepare an IV admixture it is important to:

1.1 Select a work area that is relatively free from traffic flow.

1.2 Assemble all supplies needed for the preparation.

1.3 Wash hands thoroughly.

If you have any questions, please contact your pharmacist prior to making or hanging the IV.

**MEASURE DRUGS WITH A SYRINGE:**

A needle and syringe can be used to add most drugs to an IV solution. This method of adding drug additives can be used for powdered as well as liquid drugs. Disposable needles and syringes are used for this transfer, and both are supplied sterile in individual packages.

2.0 The needle is attached to the syringe by the following procedure:

2.1 Remove the protective cover over the syringe tip by twisting.

2.2 Insert the tip of the syringe into the hub of the needle. The needle may be held on by friction or by a locking (luer-lock) mechanism. The fingers should be held well back from the point of attachment of the needle to the syringe.

2.3 Leave the needle guard in place until just before use. To remove the guard, pull it straight off or twist very gently.

2.4 Needles and syringes should be disposed of in sharps containers without recapping.

When pulling back the plunger of the syringe, the fingers should not come in contact with any part of the plunger except the flat knob at the end. The barrel of the syringe should be held in the other hand. Contamination of the medication can occur in some procedure if the plunger is touched with the fingers. This problem is more common in working with vials than with ampules because fluid is drawn into the syringe at least twice—one for the diluent and once for the reconstituted drug. It is a good practice to develop a technique that can be used safely in all situations.

A common problem in withdrawing medication is that air may also be drawn into the syringe. The presence of air bubbles in a syringe prevents accurate measurement of the solution.

3.0 To remove air bubbles from a syringe:
3.1 Hold the syringe in a vertical position so that the needle is pointing upward.

3.2 Pull the plunger back a short distance so that some air enters the syringe and solution is drawn in from the needle.

3.3 Firmly tap the barrel of the syringe with the fingers or knuckles so that air bubbles clinging to the side are freed and float to the top of the syringe.

3.4 Expel the air in the syringe by slowly pushing in the plunger until the solution is at the tip of the syringe.

3.5 Read the volume of solution by aligning the rubber end of the plunger with the graduation marks on the barrel of the syringe.

TRANSFERRING DRUGS FROM AMPULES USING A NEEDLE AND SYRINGE:

An ampule is a small glass container sealed to preserve the sterility of an injectable solution. A colored stripe around the neck of an ampule or more toward the top indicates that the neck has been weakened to facilitate opening. Regardless of its location, the stripe indicates that the neck of the ampule has been weakened. The ampule should always be broken open at the neck.

4.0 To open an ampule:

4.1 Hold the ampule upright and tap the top to remove the solution there.

4.2 Swab the neck of the ampule with an alcohol swab. This procedure does not make the outside of the ampule sterile, but it does act as a disinfectant to reduce contamination.

4.3 Grasp the ampule on each side of the neck with the thumb and index finger of each hand.

4.4 Quickly snap the neck of the ampule. If the ampule does not snap easily, rotate it slightly so that pressure is exerted at a weaker point.

4.5 Inspect the opened ampule for any particles of glass that might have fallen inside.

5.0 To transfer the drug solution from an ampule:

5.1 Tilt the ampule to approximately a 20 degree angle.
5.2 Insert a filtered needle into the ampule at about a 45 degree angle to the
ampule. Take care not to touch the ampule with the needle point around
the neck where it was broken.

5.3 Position the needle in the shoulder area of the ampule.

5.4 Pull the plunger back with the thumb and index finger or push it up with
thump of the same hand in which the syringe is held. Another method is
to hold the ampule and barrel of the syringe in the same hand and pull the
plunger back with the thumb and index finger of the other hand.

TRANSFERRING DRUGS FROM VIALS USING A NEEDLE AND SYRINGE:
Vials are glass containers sealed by a rubber closure covered with protective
aluminum band. An aluminum tab or plastic flip-off tab must be removed to insert
the needle through the rubber closure. Some rubber closures are thin, soft and
pliable, whereas others are thick, hard and brittle. “Coring”, or breaking off small
pieces of the rubber closure when it is punctured by a needle, is much more
prevalent with the latter.

The drug inside the vial may be in powder or liquid form. If the drug is in liquid
form, an extra step-reconstitution must be performed before it can be added to
the IV solution. Diluents such as sterile water for injection, bacteriostatic water
for injection, and bacteriostatic 0.9% sodium chloride injection are usually used to
reconstitute powdered drugs. The volume of a suitable diluent is specified in the
package insert and frequently on the vial itself.

6.0 To transfer a drug from a vial:

6.1 Remove the protective tab and swab the top surface of the rubber closure
with a disinfecting agent such as 70% alcohol.

6.2 Determine the correct volume of a suitable diluent to reconstitute the
powdered drug.

6.3 Using a needle and syringe, inject a volume of air equal to the volume of
solution to be removed from the diluent vial, then remove the diluent from
the vial. Whenever a liquid is withdrawn from a vial, an equal volume of air
should be first injected. For example, if 2ml of solution are to be withdrawn
from a vial, 2ml of air should be injected first. This prevents a vacuum from
being created in the vial. Alternatively, vented needles may be used so
that the dynamics of air pressure can be disregarded. Hold the diluent vial
in an inverted position in one hand so that the other hand is free to pull
back the plunger. The needle should just penetrate the rubber closure to
allow all medication to be withdrawn.

6.4 Inject the diluent into the medication vial.
6.5 Remove the needle and shake the vial until the drug is dissolved unless the vial is labeled DO NOT SHAKE.

6.6 Reinsert the needle and remove the proper volume of drug solution. Do not inject air before withdrawing the drug solution at this point unless air was withdrawn before the needle was removed (step 6.5).

6.7 Remove all air bubbles from the syringe so that volume can be read accurately. (Note: if the drug is already in liquid form, the drug vial is substituted for the diluent vial in step 3 and steps 6.4, 6.5 and 6.6 are unnecessary).

7.0 To insert a needle through the rubber closure:

7.1 Lay the needle on the surface of the rubber closure so that the opening of the needle point is facing upward (bevel up).

7.2 Exert downward pressure on the needle while tilting the syringe more vertically. This action forces the rubber closure away from the bevel of the needle to minimize the chances of coring. The needle will penetrate the rubber at an angle.

**DRUG TRANSFER TO PLASTIC CONTAINER:**
A syringe and needle are generally used to transfer a drug additive from a vial or ampule to a plastic container. It is recommended that the needle gauge be not less than 19 to ensure resealing of the protective rubber cover. The needles must be at least ½ inch long to penetrate the inner polyvinyl diaphragm.

8.0 To transfer a drug additive to a plastic container with a needle and syringe:

8.1 Remove the plastic container from its outer wrap.

8.2 Assemble the needle and syringe.

8.3 Swab the medication vial or ampule and withdraw the necessary amount of drug solution. If the drug is in powder form, reconstitute it with recommended diluents.

8.4 Swab the medication port of the plastic container.

8.5 Insert the needle into the medication port and through the polyvinyl diaphragm. The medication port should be fully extended to minimize the chances of puncturing the IV bag or side of the port (depending on where the port is located).

8.6 Inject the drug into the plastic IV bag.
8.7 Remove the needle and discard the needle and syringe into the sharps container without recapping the needle.

8.8 Shake and then visually inspect admixture.

8.9 Label admixture with patient name, room number, drug added (with amount), base solution, and rate of administration.

If you have any questions regarding preparation of IV admixtures or compatibility information, please contact your pharmacist.

Abstracted from Cedars-Sinai Medical Center's Department of Pharmacy Nursing IV Preparation Guidelines.

**ADDENDUM F**
**Dysrhythmia monitoring for patients receiving Intravenous Haloperidol (Haldol®)**

**Purpose:** To outline the monitoring requirements for patients receiving IV haloperidol.

**Supportive Data:**
Higher doses of haloperidol via intravenous administration of haloperidol appear to be associated with the development of QT prolongation. This delayed ventricular repolarization places the patient at increased risk for Torsades de Pointes, an arrhythmia which can be life threatening.

The QT interval is the measure from the start of the Q wave to the end of the T wave. This interval is dependent upon the heart rate (the faster the heart rate, the shorter the QT interval). For this reason, assessment of the QT interval is corrected for heart rate, known as the Qt(c).

**Protocol Exemptions:**
It is not necessary to implement ECG monitoring in patients who receive IV haloperidol with cumulative dosages of 4 mg or less per 24 hour period.

**Safety:**
1.0 Haloperidol is available for administration intramuscularly, orally, and intravenously.

2.0 The RN will review the physician/LIP order, the medication vial, and infusion rate, and dose calculations prior to administration of haloperidol.

**Delivery:**
3.0 Administration of haloperidol intravenously will occur only in units where continuous ECG monitoring is available.
Assessment:

4.0 Continuous ECG monitoring (telemetry) will be initiated prior to administration of IV haloperidol.

5.0 Prior to administration of IV haloperidol, the RN will assess the Qt(c) on the ECG.

5.1 If the drug is needed during emergent conditions IV haloperidol may be administered and ECG monitoring initiated as soon as possible. An example of an emergent condition is the patient who is extremely physically combative.

5.1.1 If continuous ECG monitoring (telemetry) is unavailable, the physician/LIP must be notified and a 12-Lead ECG ordered to be completed as soon as feasible (eg., patient more calm) and again 4 hours after the last dosage of IV haloperidol.

6.0 The QT(c) is first determined by assessing the QT interval and R to R interval.

7.0 The QT(c) is calculated using the function on the bedside or telemetry monitors or by using the following manual procedure:

7.1 Assess the QT interval and the R to R interval.

7.2 Calculate the QT(c) using the formula:
   • QT interval divided by the square root of the R-R interval
   \[
   \frac{QT}{\sqrt{RR}}
   \]

8.0 A normal QT(c) is < 0.45 seconds for men and < 0.46 seconds for women.

9.0 The QT(c) will be assessed every 4 hours
9.1 While the patient is on IV haloperidol therapy

9.2 For 4 hours following the discontinuation of haloperidol

10.0 The QT interval should be assessed in the same leads over time to assure accuracy.

**Reportable Conditions:**
11.0 The RN will hold the haloperidol and notify the physician/LIP if the Qt(c) is > 0.5 seconds.

12.0 The RN will notify the physician/LIP of a new onset of arrhythmia following initial or escalating dosages of haloperidol.

**REFERENCES:**


Haloperidol. Arizona Health Information Network.
Attachment 8

Use of Chemotherapy/Biotherapy Pharmacy Orders & Electronic Order Sets
PURPOSE:
This policy will serve to document the processes associated with the Use of the Chemotherapy/Biotherapy Pharmacy Orders and Order Sets.

POLICY:
Pharmacy Orders for Chemotherapy and Biotherapy will be written and processed according to safe practice standards. (See also PM 3 Medication Management)
The electronic Chemotherapy and Biotherapy Pharmacy Order Sets were created to serve as a bridge to an electronic order entry system. These electronic order sets reflect current regimens that are most often prescribed by the medical oncologists and midlevel practitioners at the University of Arizona Cancer Center. The following processes shall be followed to ensure quality and safety in initiation of all order sets.

1.0 Personnel who can initiate a hand-written or electronic pharmacy order for cancer chemotherapy are defined as follows in UMC Policy PM-3 Medication Control and Handling

1.1 Cytotoxic drugs for cancer chemotherapy shall be initiated by an attending physician, or midlevel practitioner (NP or PA) credentialed in oncology or by an oncology fellow. Dermatology attending physicians and residents may prescribe for topical chemotherapy for the treatment of skin cancer as defined by their credentialing.

1.2 Initiation of cytotoxic drugs for non-cancer chemotherapy indications (e.g. oral methotrexate for rheumatoid arthritis) shall be initiated by an attending physician, fellow, physician assistant or nurse practitioner in an appropriate specialty (including, but not limited to transplant surgery, nephrology, obstetrics, rheumatology). Credentialing in oncology is not required for non-cancer indications.

1.2.1 Patients on these medications prior to hospital admission may continue with approval (signed order) from the attending of the admitting service or appropriate subspecialty.

2.0 Electronic Pharmacy Order Sets shall be utilized whenever possible by the provider to ensure the most up-to-date regimens are available. Electronic Pharmacy Order Sets are available on the
2.1 The oncology clinical pharmacy team is responsible to ensure the most up-to-date order sets are available.

3.0 Hand Written Pharmacy Orders (not electronic order sets) - All hand written Pharmacy Orders for chemotherapy and biotherapy, whether for cancer or non-cancer indications will be written on form # MR-1378, outpatient Pharmacy Orders for Oncology Services.

3.1 Using this form will ensure necessary considerations in determining the diagnosis, dose, and other pertinent information is clearly identified for all members of the team.

3.1.1 All orders written by Non-UA Healthcare practitioners whose patients will receive infusions in one of the Oncology Services clinics will be cosigned by a UAHC physician who is properly credentialed for the infusion.

3.2 ALL components of the order form shall be completed or indicated as not applicable with description of why not applicable.

3.3 Hand written pharmacy order forms will be CLEARLY written to minimize error.

4.0 For all Electronic AND Hand Written Pharmacy Orders - To ensure safe and clearly written orders, Pharmacy Orders shall NEVER be altered or revised after the initial dose. Subsequent changes to an order will require the provider to write a NEW order for continuing the course of treatment.

4.1 Altered or revised orders following the first dose, using cross-outs for deletions or additions will NOT be accepted by the pharmacy staff and the provider will be requested to complete a new order.

4.2 ANY changes to the original order, whether for Pre-medications, Chemotherapy/Biotherapy drugs, dates or frequency will require a NEW order.

4.3 Modification to ordered dose for rounding purposes may be made ONLY by pharmacist who, at the direction of the ordering provider, may adjust the dose, as appropriate, by no more than 5% for Chemotherapy or 10% for Biotherapy.

4.3.1 The provider signature will be obtained for the verbal order within 48 hours per Policy UACC POL-6.

4.4 Photocopies of current orders produced for the purpose of adding, deleting or modifying items will not be accepted. A new order should be generated in this scenario.

5.0 Current Cycles of Pharmacy Orders

5.1 Electronically generated or hand written and signed orders for current cycles of cancer chemotherapy will be printed and stored in a Pharmacy Orders Folder. Folders will be stored in the medical records area, under usual safeguards.

5.1.1 The provider may choose to save electronically-generated orders as a .pdf file in a safe location for future use to prepare a next cycle of orders for their patient.
5.2 When a patient presents for a provider visit and is currently undergoing a cycle of chemotherapy, the Pharmacy Orders Folder will be made available to the provider.

5.3 When a patient presents for an infusion visit (no visit scheduled with the provider that day), the Pharmacy Orders Folder will be made available to the pharmacy staff.

5.4 When the course of treatment is completed, the pharmacy order will be returned to Medical Records for safe storage up to 3 months after scanning.

6.0 Scanning Current or Revised Cycles of Pharmacy Orders

6.1 Pharmacy Orders will be scanned within one working day following the first dose of therapy and filed in the electronic health record as a Treatment Order.