I. Purpose

To ensure study biological agents are handled and prepared appropriately to prevent occupational hazards and environmental contamination. For the purpose of this policy, biological agents include any substance that is made from a living organism or its products (i.e., recombinant or synthetic nucleic acid molecules and viruses).

II. Procedures

A. Receipt and Storage:

Receipt and storage of any investigational biological agent is similar to other hazardous pharmaceuticals.

1. If the medication packaging is damaged, gown according to procedures and open package in the biologic safety cabinet to prevent accidental exposure in the event that vials/ampules are also damaged.
2. The storage of products will be separate from other investigational pharmaceuticals and labeled as "Biohazard". Study biological agents should be stored in the Hematology/Oncology Pharmacy Satellite or the Investigational Drug Service (IDS) Pharmacy.
3. A cytotoxic spill kit and copy of the spill/exposure policies shall be available in all storage areas.

B. Preparation/protection of Personnel and Work Area:

1. Personal Protective Equipment (PPE): In addition to the required cleanroom attire (i.e. barrier gown, gloves, mask and head cover) protective barrier disposable garments must be worn for all procedures involving study biological agents. All PPE is locate outside of the cleanroom area.
   a. Disposable long sleeved, closed cuffed gown with back closure.
      (i) Gown should not be worn outside of the workstation
      (ii) Contaminated gown should be changed and disposed of in the biohazardous waste container.
   b. Gloves – nitrile or latex ASTM approved
      (i) Gloves should be changed frequently or whenever soiling occurs to reduce transfer of contaminants to final containers

(ii) Gloves should be placed in a zip-lock bag and disposed of in the biohazardous waste container.

2. Containment Equipment: Work should be done in a vertical flow class II, type A or B approved hood, vented to the outside.
3. The surface of the hood should be disinfected and cleaned prior to compounding of study biological agent. Disposable wipes should be used for cleaning. Cleaning materials shall be treated as hazardous waste. Cleaning materials will be placed in a zip-lock plastic bag in the hood and disposed of in the biohazardous waste container.
4. The work surface should be covered with a plastic backed absorbent pad to catch droplets and facilitate clean up. All items required to complete the reconstitution and preparation procedure should be placed in the hood before beginning work. The absorbent pad should be placed in a zip-lock bag and disposed of in the biohazardous waste container.
5. Hands should be washed before and after handling of any study biological agents.

C. General reminders when working with study biological agents:

1. Preventing Liquid Spills:
   a. Syringe selection: Select a syringe size for agents that will not be filled more than 80% final volume. This will prevent inadvertent spills from dislodging overextended syringe plungers.
   b. Prepare I.V. solutions containing agents in unvented (solid stopper) bottles or bags. This will prevent droplet spills when the I.V. is hung.
   c. Utilize plastic backed absorbent pads with all procedures as a base in the hood. Have zip lock bag in the hood ready for waste disposal.
   d. Open needles with sheath exposed first keeping sterile hub open for attachment to syringe.
2. Preventing Study Biological Agent Aerosolization:
   a. Prepare agents in a vertical flow class II, type A or B approved hood with a face shield, vented to the outside.
   b. Measure exact dose with needle inside ampule or vial. DO NOT EXPEL AIR in hood or atmosphere. DO NOT DRAW AIR BACK INTO SYRINGE.

c. Create negative pressure in vials to decrease aerosolization when the needle is removed from vial. This is done by removing the agent from the vial without injecting any air or by removing more volume than volume of injected air.
d. Cap doses with luerlock (red) cap to prevent aerosolization.

3. Preventing Personal Contamination:
   a. Wear appropriate protective garments and gloves in preparation of all agents. Remove and place gloves in a zip-lock bag before exiting the biological safety hood. Remove the protective gown before leaving the preparation workstation.
   b. Wash hands before and after handling agents.
   c. If skin is exposed to droplets of agents, wash immediately with soap and water and ***NOT*** antiseptic scrub.
   d. If eyes are exposed, irrigate immediately at the eye wash station located in the Inpatient or Hematology/Oncology Pharmacy Cleanroom. Go immediately to Occupational Health Service or the Emergency Department for medical attention. An incident report needs to be filled out in the Safety Event Reporting System (SERS) by the individual involved within 24 hours.

4. Preventing Environmental Contamination:
   a. Place all waste in a zip-lock bag before removing from the hood.
   b. The surface of the hood should be disinfected and cleaned of study biological agent residue and debris prior to compounding. Hospital-approved disposable wipes should be used for cleaning. Cleaning materials shall be treated as hazardous waste. Cleaning materials will be placed in a zip-lock plastic bag in the hood and disposed of in the biohazard waste container.
   c. Do not touch any object outside of the biological safety cabinet with the working gloves. Remove gloves before exiting the biological safety cabinet.
   d. Remove the disposable gown before leaving the work station. Fold the arms and cuffs inside of the gown when removing it and dispose of in biohazardous waste container.

e. After dispensation of product, the IDS Pharmacy will not accept and/or store any items used for infusion including but not limited to syringes, filters, IV bags, and tubing.

D. Specific Pharmaceutical Handling:

1. Handling Agents In Vials:
   a. Liquids -
      (i) Create negative pressure in vial or vent with hydrophobic filters to avoid aerosolization of the agent.
      (ii) Accurately measure desired dose with needle in liquid.
      (iii) Select a different location on the vial stopper when preparing subsequent doses.
   b. Powders for reconstitution -
      (i) Vent vial before reconstitution to prevent pressure built-up and aerosolization.
      (ii) Reconstitute as directed.
      (iii) After study biological agent is dissolved, handle as liquid in vials.
   c. I.V. Bottle/Bag Preparation:
      (i) Prepare I.V. solution containing agents in closed system containers only (solid rubber stopper bottles or bags).
      (ii) Measure investigational agent dose and diluent accurately.

E. Dispensing of Agents:

1. Dispensing Container: Dispense final drug product in a capped (red cap) plastic syringe (without a needle) or I.V. bag.
2. Labeling: Label as per normal practices and include an auxillary label "For Investigational Use ONLY."
3. Packaging: All agents must be packaged in double, leak-proof containers labeled as Biohazard (i.e., double-bagged in Zip-lock bags).
4. Transport: Dispense drug directly to the study nurse in the CRU or other clinic area. If the agent will be administered in the operating room, the CRU nurse will transport the study drug.

F. Handling Biological Agents (i.e., viruses, viral vectors, etc.) spills:

1. Isolate area.
2. Obtain hazardous spill kit and follow Spill Kit SOP.
3. Put on protective gloves, gown and mask.
4. Absorb material using spill pillow and absorbent pads. For powder spills dampen absorbent pads and blot.
5. Dispose of all materials used in cleaning process in biohazardous waste bag.
6. Wash hands and any exposed body areas with soap and water.
7. Call Environmental Services to decontaminate area where spill has occurred.
8. Replace cytotoxic spill kit.
9. Follow additional study specific procedures, when applicable.

G. Treatment of personnel exposed to agents.

1. If skin is exposed to droplets of agents wash immediately with soap and water and ***NOT*** antiseptic scrub.
2. If eyes are exposed, irrigate immediately.
3. If needle stick occurs, wash the affected area for 5 minutes (per hospital policy).
4. Read and follow specific recommendations in the Material Safety Data Sheet (MSDS) related to the exposed study biological agent.
5. Notify Supervisor immediately.
6. Go immediately to Northwestern Memorial Physician's Group (NMG) Corporate Health or the Emergency Department with a copy of the MSDS (if available) for medical attention.
7. Complete an incident report in the Safety Event Reporting System (SERS) within 24 hours.
8. Refer to Administrative Policy and Procedure Manual Subject: Blood or Body Fluid Exposure Management: Healthcare Workers (HCWs) for complete process.

H. Waste Disposal of Agents:

1. Place all needles, syringes and glass ampules/vials containing the investigational product into sharps container. A plastic zip-lock bag is to be used inside the vertical flow hood for the collection of all materials used in preparation (i.e.,

gloves, pads, wipes, etc.). Seal this bag at the end of each operation and discard in the specially marked biohazard waste container.

2. Utilize the biohazard waste containers for the collection of all biohazardous waste and contaminated materials (gloves, gowns, alcohol swabs, paper towels and zip-lock bags). Environmental Services personnel will collect filled containers and deposit them in a separate biohazard collection bin for removal by a licensed waste disposal service for incineration at 1000 degree centigrade (2000 degree Fahrenheit) as currently recommended by the American Society of Health-system Pharmacists.
3. Do not clip or crush needles from syringes due to the aerosolization of study biological agent particles during this process. Place the entire needle-syringe system in the sharps container.
4. Do not throw any waste down the sink. All waste must be in a type of closed system - a vial, syringe, intravenous or piggyback solution bag and disposed in the biohazardous waste container.
5. Used HEPA filters will be disposed and incinerated along with the waste.

I. Special Requests from Sponsors:

1. If a sponsor requires any item to be saved and shipped back to them, the IDS Pharmacy will not be able to take back and store these items. The study team will need to coordinate pick up with a courier immediately following the infusion.

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Approvals **[as applicable]**:

Key Stakeholders (e.g., Pharmacy, etc.): 08/2017, 03/2021
Director, Research Compliance: Date
Chief Operating Officer, Manne Research Institute: Date