I. Purpose

To promote adequate safety practices and containment procedures for clinical research involving recombinant or synthetic nucleic acid molecules. To ensure study biological agents used in research (i.e., gene therapy and/or live vaccine trials) are handled and administered appropriately to prevent occupational hazards and environmental contamination.

II. Definitions

Biological agents: For the purposes of this policy, biological agents refer to molecules used in research that contain recombinant or synthetic nucleic acids.

Gene: A sequence of nucleotides in deoxyribonucleic acid (DNA) or ribonucleic acid (RNA). Some genes act as instructions to make molecules call proteins.

Gene therapy/Gene transfer: An experimental technique that inserts a gene into a person's cells to 1) replace a mutated gene that causes disease with a healthy copy of the gene, 2) inactivate or knock out a mutated gene that is not functioning properly, or 3) introduce a new gene into the body to help fight a disease.

Viral vectors: Tools used to deliver genes (or genetic material) into cells. Commonly used vectors include adeno-associated virus (AAV) and lentivirus.

III. Policy Statement

This policy outlines the general safety procedures that must be followed when conducting a clinical trial involving the use and administration of biological agents at the Manne Research Institute and/or Ann & Robert H. Lurie Children's Hospital of Chicago. Study personnel must also be trained on the research protocol and any additional study-specific safety measures as dictated by the sponsor, Infection Prevention & Control, and/or the Institutional Biosafety Committee. Personnel should be vigilant in their compliance with both this policy and study specific safety measures (i.e., process for . returning syringe/tubing to the study group, specific isolation precautions, specific administration methods, etc.).

IV. Procedures

A. <u>Observe Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard Precautions:</u>

Follow OSHA Bloodborne Pathogens Standard Precautions for preventing transmission of

infectious agents in healthcare settings as applicable to protect patients, visitors and healthcare workers.

B. Isolation:

Participants should be placed in isolation both during and after administration based on any risk of viral shedding as indictated by the Infection Prevention and Control Letter of Support. Viral shedding could pose risks to others particularly immunocompromised, elderly, or pregnant individuals. Minimize visitors and enforce all persons entering the room to maintain isolation precautions, including parents/caregivers and staff.

C. Personal Protective Equipment:

Appropriate personal protective equipment (PPE) may include: gown, gloves, face shield or mask with protective eyewear to prevent skin and mucous membrane exposure when contact with biologics, blood or other body fluids is possible. Follow the procedures for donning and doffing PPE as outlined in the Isolation: Transmission Based Precautions Policy.

1. Wear barrier gowns (with long sleeves) during administration of the biologic agent and/or during the collection of blood, body fluids, secretions or excretions.

2. Wear facial mucous membrane protection (i.e., a mask with face shield or a mask with the addition of protective eyewear) during procedures that may generate aerosols of the biologic agent, blood, body fluids, secretions or excretions.

3. Wear clean gloves and change gloves between tasks and procedures on the same patient, after contact with the biologic, blood, body fluids, secretions or excretions or materials contaminated with these.

4. Remove all PPE immediately following contact with the biologic, the patient's blood, body fluids, secretion or excretions in a way that prevents contamination of clothing, hair, etc. Gloves are to be removed first, taking care not to contaminate the ungloved hand. Perform hand hygiene. Goggles or face shield, if used are removed next. Next remove the gown, folding the exterior inward and placing in the waste disposal hamper. Perform hand hygiene. Last, remove the face mask or respirator, if used, and perform hand hygiene. Discard of PPE in appropriately designated biohazardous waste containers.

5. Perform hand hygiene before donning and after removing gloves.

D. Delivery/Receipt:

Biological agents dispensed by the Investigational Drug Services (IDS) Pharmacy will be packaged in double, leak-proof containers (e.g., capped plastic syringe or IV bag inside a plastic bag labeled as Biohazard). The IDS Pharmacy staff will transport the agent directly to the clinical staff and location where it will be administered to the participant (i.e., Clinical Research Unit (CRU), clinic, hospital room, or operating room). The room should be posted with a Biohazard sign.

E. Waste Disposal of Agents:

1. Do not recap needles. Place all needles, syringes and glass ampules/vials are into a sharps container, unless the study protocol requests particular equipment (syringe/tubing) to be returned to IDS Pharmacy. Place items in a bag with a biohazard label, double bag with a second biohazard bag and transport to a secure location as directed by IDS Pharmacy.

2. Utilize the biohazard waste containers for the collection of all biohazardous waste and contaminated materials (including diapers, skin wipes, gloves, gowns, alcohol swabs, paper towels and zip- lock bags). Some studies may suggest medical waste to be "double bagged" prior to disposal (see study specific protocol regarding biohazard waste).

F. Administration:

1. Only authorized personnel, participant and immediate family members should be in the room during the administration of the biological agent to minimize transmission. All persons present must adhere to the study's safety protocol for PPE to be utilized during administration and for the duration of their stay inpatient/clinic visit. Note: Negative pressure rooms are not required unless dictated by the study protocol.

2. Ensure all departments/personnel involved are aware of the isolation procedures, policies and study safety measures prior to administration of the biological agent. This includes but is not limited to procedure areas (OR, IR, Procedure Suites), CRU, inpatient areas and clinics.

3. If the biological agent is administered peripheral intravenously refer to the Peripheral Intravenous Administrative Policy, Medication Administration IV Protocol in conjunction with the specific protocol procedures for administration.

4. If the biological agent is to be administered via any other route – enteral, eyes, ears, nose,

intradermal, subcutaneous, intramuscular, oral, sublingual, rectal, topical, transdermal, vaginal – please see the appropriate protocol regarding administration in conjunction with the specific protocol procedures for administration. For intrathecal administration, refer to the study specific protocol procedures.

5. Monitoring of the participant is the standard practice of the area in which in the biological agent is delivered in conjunction with specific study protocol schedule of events/procedures.

6. Once administration is complete, follow all isolation procedures.

G. Accidental Exposure:

1. If skin is exposed to droplets of biologics, 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 five (5) minutes and follow the Blood or Body Fluid Exposure Management: Healthcare Workers (HCW) policy. Follow any other study specific guidance provided by the principal investigator/sponsor.

4. Read and follow specific recommendations in the Material Safety Data Sheets (MSDS) and/or investigational brochure related to the study biological agent.

5. Notify Supervisor immediately.

6. Follow the Blood or Body Fluid Exposure Management: HCWs policy for reporting to Northwestern Memorial Physician's Group (NMG) Corporate Health 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) and Bloodborne Pathogen Exposure for complete process.

9. The PI must be notified immediately, who will in turn notify the Institutional Biosafety Committee (IBC) and National Institutes of Health Office of Science Policy (NIH OSP)

for any "overt exposures" including needle sticks, skin, eye and mucous membrane exposures.

H. Spill Handling for Biological Study Agents:

1. Alert personnel within the immediate area that a spill has occurred. Close doors if the area can be isolated and post signage on door noting that a spill has occurred and do not enter. Leave the area for a minimum of 30 minutes to allow any aerosols to settle.

2. A trained study staff member will don PPE, enter the spill zone and decontaminate the spill by covering it with absorbent material, saturating the material with 10% freshly prepared bleach solution or tuberculocidal decontaminating agent (cytotoxic spill kit), wait for at least 15 minutes, and then pick-up the material for biohazardous waste disposal. If sharps are present, they must be removed hands-free with tongs or a broom and dustpan.

3. Anyone exposed to the spill without the appropriate PPE should report to Northwestern Memorial Physician's Group (NMG) Corporate Health.

4. Call Environmental Services to decontaminate area where spill has occurred.

5. Replace cytotoxic spill kit.

6. Follow additional study specific procedures, when applicable.

7. After clean-up, inform the PI who in turn will notify the IBC and NIH OSP if required.

   a. Handling of Lab Specimens Post Administration of Biological Agent:

      1) When obtaining specimens from the participant post administration of a biological agent, standard precautions should apply.

      2) All specimens (any bodily fluids) should be collected in the appropriate testing container and sent in a bag with a biohazard sign. Refer to policies relating to Standard Precautions and appropriate Specimen Collection Procedures.

   b. Equipment:

      1) Use single use items when available, when using reusable patient care items please refer to: Cleaning Disinfection and Sterilization of Reusable Patient Care

Items and Medical Equipment.

2) Specific study equipment should be maintained and returned if applicable per study protocol. If items are to be returned, they should be cleaned per the study specific protocol, and bagged/packaged to minimize potential transmission and sent to the study sponsor/study team.

3) Should biologic equipment/supplies such as syringes/tubing be shipped back to the sponsor post administration, items should be bagged appropriately (i.e., in a puncture/spill proof bag, multiple bags if necessary). The study team should arrange for these items to be picked up by a courier service. A member of the study team will take the biologic supplies and transport them to a pre designated area for the courier to receive (i.e. lab). At no time should items be taken back to IDS or to personal work spaces post administration.

c. Outpatient Visits Post Administration of Biological Agent:

1. To reduce any risk of exposure and transmission of potential viruses from a biological agent, participants should wear appropriate PPE (i.e., mask) if indicated when in common areas.

2. Participants and their families should be instructed on hand hygiene (and respiratory etiquette if applicable) for themselves and the participant. Refer to Exposure Management: Communicable Diseases policy and Hand Hygeine policy.

3. Clean equipment in-between participants refer to: Cleaning Disinfection and Sterilization of Reusable Patient Care Items and Medical Equipment.

4. Refer to specific protocol and ensure the recommended guidelines are followed for care of participant post-administration of a biological agent.

d. Other Considerations:

1. Provide patient/family with wallet card outlining any precautions to be taken once discharged from clinic. For example, considerations for family/friends who may be pregnant, immune suppressed, etc. Provide notification to other health care providers (primary physician, ancillary services, etc.)

2. It is the responsibility of all personnel involved in the handling, administration or

disposal of a biological agent to follow all applicable Institutional Policies including, but not limited to the following: Blood or Body Fluid Exposure Management: HCWs, Bloodborne Pathogen Exposure Plan, Cleaning Disinfection and Sterilization of Reusable Patient Care Items and Medical Equipment, Exposure Management: Communicable Diseases, Hand Hygeine, Healthcare Worker Responsibility in Surveillance, Prevention and Control of Infections, Investigational Products Handling and Preparation of Study Biological Agents, Isolation – Transmission Based Precautions, Protective Environmental Practices, Standard Precautions, Medical Waste Management, Specimen Collection Procedures.

V. Cross References/Related Policies

OSHA Bloodborne Pathogens Standard Precautions
Isolation- Transmission Based Precautions
Peripheral Intravenous Administrative Policy, Medication Administration IV Protocol
Blood or Body Fluid Exposure Management: HCWs
Bloodborne Pathogen Exposure Plan
Cleaning Disinfection and Sterilization of Reusable Patient Care Items and Medical Equipment
Exposure Management: Communicable Diseases
Hand Hygeine
Healthcare Worker Responsibility in Surveillance, Prevention and Control of Infections
Investigational Products Handling and Preparation of Study Biological Agents
Protective Environmental Practices
Standard Precautions
Medical Waste Management Policy
Specimen Collection Procedures
NIH Guidelines for Research Involving Recombinant or Synthetic Acid Molecules

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