KGH Research Institute

Standard Operating Procedure **Safe Handling of Cytotoxic Drugs and Bodily Fluids**			
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1.0 POLICY

The W.J. Henderson Centre for Patient-Oriented Research (WJHCPOR) will be responsible for protecting and providing a safe environment for users, research participants, volunteers, visitors, Kingston Health Sciences Centre (KHSC) employees, and KHSC's equipment and facilities from exposure to cytotoxic drugs. WJHCPOR recognizes that the preparation, handling, administration and disposal of certain drugs considered to be cytotoxic requires safe work practices, procedures and controls to limit and reduce occupational exposure for users and KHSC employees that work with cytotoxic drugs and/or handle bodily fluids, wastes and biospecimens from research participants undergoing cytotoxic drug treatment.

Reviewing this standard operating procedure (SOP) does not constitute training; **ALL** users and KHSC employees involved in the transport, handling, administration, and/or disposal of cytotoxic drugs, as well as users who handle, prepare and dispose bodily fluids, wastes and biospecimens from research participants undergoing cytotoxic drug treatment and/or involved in spill management, **MUST** receive initial and ongoing training on the possible risks and necessary precautions and procedures to follow when handling cytotoxic drugs and/or bodily fluids, wastes, and biospecimens from research participants undergoing cytotoxic drug treatment.

Cytotoxic drugs **MUST** only be transported, handled, administered, and disposed by research nurses who have received the appropriate education and training. Research nurses who have received the appropriate education and training **MUST** also carry out all of the handling, preparation and disposal of bodily fluids, wastes and biospecimens as well as the clean up of **ALL** spills associated with research participants undergoing cytotoxic drug treatment.

Research nurses using cytotoxic drugs do so under the auspices of their individual competence and under their "Scope of Practice" as outlined in the "Scope of Practice, Controlled Acts Model" in the Regulated Health Professions Act (RHPA) and **MUST** follow the recognized guidelines from the Oncology Nurses Society "Safe Handling of Hazardous Drugs (3rd edition; 2018)" and the Cancer Care Ontario (CCO) "Safe Handling of Cytotoxics" (see Section 5.0: References).

The use of cytotoxic drugs as part of a clinical trial is under the medical supervision/oversight of the principal investigator at **ALL** times. The principal investigator (clinician) **MUST** be accessible (located in KHSC-KGH site) and readily available at all times when a research participant is undergoing testing and/or monitoring as part of a clinical research project or clinical trial in the Clinical Investigation Unit (CIU) within the WJHCPOR. If the principal investigator is not available, arrangements must be made in advance by the principal investigator for a co-investigator (clinician only) to be made available as the delegate for oversight.

The use of cytotoxic drugs **MUST** only occur in the CIU (Connell 4, Room 2-4-021-0) located within the WJHCPOR. Follow-up visits for research participants (where cytotoxic drugs are not administered) can occur in other designated areas on Connell 4. Research participants (including children) who are not receiving cytotoxic drugs as part of a clinical trial can be in the same area as research participants receiving cytotoxic drugs. It is encouraged that research participants receiving cytotoxic drugs should be placed together in assigned infusion chairs and/or beds and not be scattered in between other research participants not undergoing cytotoxic drug treatment. Privacy screens are available for use to assist with the separation, if needed.

Preparation of all cytotoxic drugs **IS NOT ALLOWED** to be carried out within the WJHCPOR. KHSC's Pharmacy Services Department in designated locations within the hospital can only carry out this procedure. KHSC's Pharmacy Services Department **MUST** follow the National Association of Pharmacy Regulatory Authorities (NAPRA) "Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations" (see Section 5.0: References).

Please refer to KHSC's "Hazardous Drug List" (see Appendix A) for cytotoxic drugs that pertain to this SOP. The use of Category 1 hazardous drugs **MUST** not be transported, handled, administered, and disposed by users who are pregnant, breastfeeding or actively trying to conceive. In addition, users who are pregnant, breastfeeding or actively trying to conceive **MUST** not handle, prepare, and dispose of any bodily fluids, wastes, and biospecimens from research participants undergoing Category 1 hazardous drug treatment nor should they have **ANY** direct research participant care responsibilities.

KHSC's hospital administration supports the longer timeframe of **seven (7) days** from the last time the cytotoxic drugs were administered for the safe handling precautions of bodily fluids, wastes, and biospecimens for all users who are working with research participants undergoing Category 1 hazardous drugs (see Appendix A). This timeframe is a reflection of a more accurate drug-specific kinetics and paediatric safe handling standards. During this time users **MUST** ensure all pre-cautions as outlined in this SOP are followed for all research participants' follow-up assessments occurring on Connell 4. During this time, user **MUST** ensure that the proper sharps containers and/or waste bins/containers are used.

2.0 PURPOSE

The purpose of this SOP is to set strict guidelines and procedures for the safe transport, handling, administration and disposal of cytotoxic drugs as well as safe handling, preparation, and disposal of all bodily fluids, wastes, and biospecimens from research participants undergoing cytotoxic drug treatment within the WJHCPOR.

3.0 DEFINITIONS

Hazardous Drug – a hazardous drug is any drug that has the capability of causing toxicity to personnel and others who come in contact with them. Hazardous drugs may include anti-neoplastics, cytotoxic, biologic, antiviral or immunosuppressive agents. NIOSH (2016) recommends that all investigational drugs be regarded as potentially hazardous until information establishes their safety. Drugs may be classified as hazardous when they possess any one of the following characteristics:

- Genotoxicity - the ability to cause a change or mutation in genetic material; a mutagen.
- Carcinogenetic - the ability to cause cancer in animal models, humans, or both; a carcinogen.
- Teratogenicity - the ability to cause birth defects in fetal development or fetal malformation.
- Fertility impairment in either men or women.
- Serious toxicity at low doses in experimental animal models or treated patients.
- Chemical structure and toxicity profile that mimic existing drugs as treated as hazardous by the five previous criteria, until properly classified.

NIOSH - the U.S. National Institute of Occupational Safety and Health. An American safety institute that publishes standards related to many topics including hazardous drugs.

4.0 PROCEDURE

Users are responsible for:

- Being properly educated and trained for the safe and proper transport, handling, administration and disposal of cytotoxic drugs as well as safe and proper handling, preparation, and disposal of all bodily fluids, wastes, and biospecimens from research participants undergoing cytotoxic drug treatment. Proof of such education and training will be required before users can access the WJHCPOR.

- Reviewing and adhering to KHSC's Administrative Policies 02-095 "Workplace Safety Management of Hazardous Drugs" (see Appendix B) and 14-222 "High Alert Medications" (see Appendix C).

- Reviewing and adhering to the KHSC's Clinical Policies and Procedures M-1710 "Administration of Chemotherapy and Biotherapy Agents for Registered Nurses (RNs) when Administered for Systemic Cancer Treatment" (see Appendix D) and M-1713 "Administration of Hazardous Drugs for Non-Cancer Indications" (see Appendix E).

- Providing and wearing appropriate personal protective equipment (PPE) for all activities associated with cytotoxic drugs and/or handling, preparation and disposal of all bodily fluids, wastes, and biospecimens from research participants undergoing cytotoxic drug treatment. PPE includes: chemotherapy gowns, chemotherapy approved gloves, safety glasses and/or face shields, and N95 respirator (if applicable). See "Personal Protective Equipment" SOP.

- Ensuring that cytotoxic drugs are double bagged in a clear seal proof bag (one time use) when transported between KHSC's Pharmacy Services Department and WJHCPOR. Compounded chemotherapy **MUST** be transported in a sealed, rigid, leak proof, semi-transparent container between the KHSC's Pharmacy Services Department and WJHCPOR. A plastic-backed absorbent pad **MUST** be placed in the bottom of the container. The container **MUST** be clearly labelled with a cytotoxic sticker.

    - Gloves **MUST** be worn during packing and unpacking containers. Users transporting containers do not need to wear any gloves during transit.

- Ensuring that the correct sharps and waste bins/containers are used when handling cytotoxic drugs and/or bodily fluids, wastes and/or biospecicmens from research participants undergoing cytotoxic drug treatment. See "Disposal of Biohazardous and Sharps Waste" SOP:

    - All bodily fluids, wastes and biospecimens from research participants undergoing cytotoxic drug treatment **MUST** be placed in the red coloured biohazardous waste bins/containers with red coloured waste bags.

    - All sharps waste (i.e. needles, blades, razors, sutures, vials, glass) exposed to cytotoxic drugs and/or bodily fluids, wastes and biospecimens from research participants undergoing cytotoxic drug treatment **MUST** be placed in the red coloured sharps bins/containers.

    - All unused or expired cytotoxic medication **MUST** be placed in the red coloured sharps bins/containers. **DO NOT** transport back to KHSC's Pharmacy Department.

    - All soft waste (i.e. tubing, gloves, masks, face shields, gauze, blue pads, IV bags, disposable gowns) exposed to cytotoxic drugs and/or bodily fluids, wastes and biospecimens from research participants undergoing cytotoxic drug treatment **MUST** be disposed in the red coloured biohazardous waste bins/containers with red coloured waste bags.

- Soiled materials that are not completely saturated can be placed in the red coloured biohazardous waste bins/containers with red coloured waste bags.

- Soiled materials that are completely saturated **MUST** be placed in the red coloured sharps bins/containers.

- Regular waste (i.e. packaging, non-soiled materials, research participant food/drink wastes, Kleenex, and paper towels) can be placed in regular garbage waste containers, unless the items are saturated with blood/tissue/bodily fluid or used during spill cleanup. These items need to go into the red coloured biohazardous waste bins/containers or red coloured sharps bins/containers.

➢ Ensuring the use of yellow cytotoxic linen bags for disposal of used linen from research participants receiving Category 1 Medications (see Appendix A). Linens that are heavily soiled or very wet, should be double bagged to prevent accidental leaks or spills. Used linens from research participants receiving Category 2 Medications or Reproductive Risk Medications (see Appendix A) can be placed in the regular blue linen bags for cleaning. All linen bags can be placed in the Dirty Linen Room on the designated cart.

➢ Ensuring the use of the Cytotoxic (Chemotherapy) Spill Kits and deactivation agent (Surface Safe) for spills involving cytotoxic drugs and/or bodily fluids, wastes, and biospecimens from research participants undergoing cytotoxic drug treatment. Cytotoxic (Chemotherapy) Spill Kits and deactivation agent (Surface Safe) are located in the large storage cabinet in the Clinical Investigation Unit (Connell 4, Room 2-4-021-0) located within the WJHCPOR and within the cupboard under the dirty sink beside the lab fridge in the Research Centrifuge Room (Connell 4, Room 2-4-041).

  o Users are responsible for primary cleaning of **ALL** cytotoxic spills using Cytotoxic (Chemotherapy) Spill Kits and deactivation agent (Surface Safe). KHSC's Environmental Services staff are responsible for the secondary cleaning of any residues left from the Surface Safe. KHSC's Environmental Services needs to be notified immediately by users to complete this task.

➢ Ensuring spills and accidental exposures are reported immediately. See "Accidental Occupational Exposure and Reporting Workplace Incidents" SOP and "Spill Control Procedures" SOP.

➢ Ensuring they familiarize themselves with the location and use of emergency eyewash station. See "Emergency Eyewash Safety" SOP.

  o When users are exposed to cytotoxic drugs in their eyes, they **MUST** flush their eyes out with tepid water using the emergency eye wash station for a **minimum of 15 minutes**. Ensure contact lenses are removed before flushing.

- When users are exposed to cytotoxic drugs on their skin, body and/or mouth, users **MUST** remove any contaminated clothing and wash the affected area(s) with soap and running water for a **minimum of 15 minutes** to flush the affected area(s). Users can use the shower in the washroom in the Clinical Investigation Unit (Connell 4, Room 2-4-021-2), if needed to wash off.

- When users are exposed to cytotoxic drugs via a needle stick injury wash the puncture site with soap and running water for 15 minutes and squeeze the puncture site to bleed freely.

- Following any flushing of the eyes, skin, body and/or mouth, users **MUST** immediately go to KHSC's Emergency Department for further assessment and medical attention. Users will need to refer to the material safety & data sheets (MSDS) for more information and to confirm if the drug is a vesicant as this can cause tissue necrosis and an antidote will need to be administered to the area.

➢ Ensuring that the Pneumatic Tube System is **NEVER** used to transport cytotoxic drugs and/or bodily fluids, wastes and biospecimens from research participants undergoing cytotoxic drug treatment. Refer to "Pneumatic Tube System" SOP for allowable biospecimens or drugs to be transported in a carrier.

➢ Ensuring that the proper signs are posted:

- When users are using cytotoxic drugs, they **MUST** post a "Caution-Use of Cytotoxic Drugs" sign on the IV poles of the infusion pumps to notify the other users (see Appendix F). A similar sign should be posted and be visible for KHSC's Environmental Services to see in order to be aware when carrying out special cleaning procedures during normal cleans of the WJHCPOR.

- When users are cleaning up cytotoxic spills, they **MUST** post the "Caution-Cytotoxic Drug Spill" sign (see Appendix G). The sign can be removed after required special clean-up has been completed by the user(s) and KHSC's Environmental Services.

User's Supervisors are responsible for:

➢ Ensuring that users who have been designated to handle cytotoxic drugs and/or bodily fluids, wastes, and biospecimens from research participants undergoing cytotoxic drug treatment have reviewed all of KHSC's policies and procedures as outlined in this document.

➢ Ensuring that all users have received the appropriate education and training and continue to renew their education and training on an annual basis.

- Providing all users with appropriate PPE for all activities associated with cytotoxic drugs and/or handling, preparation and disposal of all bodily fluids, wastes, and biospecimens from research participants undergoing cytotoxic drug treatment.

- Ensuring that all users wear appropriate PPE for all activities associated with cytotoxic drugs and/or handling, preparation and disposal of all bodily fluids, wastes, and biospecimens from research participants undergoing cytotoxic drug treatment.

Kingston General Health Research Institute (KGHRI) is responsible for:

- Ensuring that users are wearing appropriate PPE when handling cytotoxic drugs and/or bodily fluids, wastes and biospecimens from research participants undergoing cytotoxic drug treatment.

- Providing red coloured sharps bins/containers and red coloured biohazardous waste bins/containers with red coloured waste bags for disposal of cytotoxic drugs and/or bodily fluids, wastes and biospecimens from research participants undergoing cytotoxic drug treatment.

- Providing yellow cytotoxic linen bags for disposal of used linen from research participants receiving Category 1 hazardous drugs.

- Providing Cytotoxic (Chemotherapy) Spill Kits and deactivation agent (Surface Safe) for spills involving cytotoxic drugs and/or bodily fluids, wastes and biospecimens from research participants undergoing cytotoxic drug treatment. Ensuring that the Cytotoxic (Chemotherapy) Spill Kits and deactivation agent (Surface Safe) are stocked within the large storage cabinet in the Clinical Investigation Unit (Connell 4, Room 2-4-021-0) located within the WJHCPOR.

- Providing cytotoxic signs for users to post in the Clinical Investigation Unit within the WJHCPOR (Connell 4, Room 2-4-021-0) (see Appendix F and Appendix G).

5.0 REFERENCES

- Legislation and Regulation RHPA: Scope of Practice, Controlled Acts Model (https://www.cno.org/globalassets/docs/policy/41052_rhpascope.pdf)

- Oncology Nurses Society: Safe Handling of Hazardous Drugs (3rd edition; 2018) (https://www.ons.org/books/safe-handling-hazardous-drugs-third-edition)

- Cancer Care Ontario (CCO): Safe Handling of Cytotoxics (https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/2161)

- National Association of Pharmacy Regulatory Authorities (NAPRA): Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations (https://napra.ca/general-practice-resources/model-standards-pharmacy-compounding-hazardous-sterile-preparations)

6.0 SOP HISTORY

SOP Number	Date Issued	Summary of Revisions
SOP-SHCDBF-01	01-MAY-2019	Original version.