Standard Operating Procedure **Infusion Pumps**			
SOP Number:	SOP-IP-02	Category:	Lab Process
Supersedes:	SOP-IP-01.1	Original Date:	December 1, 2017
		Revised:	May 1, 2019
		Pages	1 of 4
Issued by:	Director, Health Sciences Research		

1.0 POLICY

All users of the Alaris™ system infusion pump units and modules ("infusion pumps") in the W.J. Henderson Centre for Patient-Oriented Research (WJHCPOR) are required to complete the Kingston Health Sciences Centre's (KHSC) "CareFusion" online course available through the learning management system "KnowledgeNow" and have undergone hands-on training with a designated KHSC Professional Practice Leader prior to using the infusion pumps. Training familiarizes users with the function, specifications, operations, and routine operator care and maintenance of the infusion pumps to ensure research participants' safety. Infusion pumps **MUST** only be used by research nurses who have received the appropriate education and training. Research nurses using the infusion pumps 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). The use of intravenous drugs as part of a clinical trial is under the medical supervision/oversight of the principal investigator at **ALL** times.

Users should be aware that there may be clinical trials occurring within the Clinical Investigation Unit that are using cytotoxic drugs. Signs will be posted to inform users when this is occurring. For more information related to the use of cytotoxic drugs, see "Safe Handling of Cytotoxic Drugs and Bodily Fluids" SOP.

2.0 PURPOSE

To standardize the training required when intravenous infusions are administered to research participants in the Clinical Investigation Unit located within the WJHCPOR.

3.0 RESPONSIBILITY

Users are responsible for:

- Completing the CareFusion KnowledgeNow course and participating in hands-on training.

- Operating and maintaining all infusion pumps in accordance with manufacturer's instructions for safe usage and professional practice best practice procedures.

- Reporting any damage to the infusion pumps (units and/or modules) to the designated Kingston General Health Research Institute (KGHRI) staff member **immediately** so equipment repairs can be made.

- Wearing appropriate personal protective equipment when using the infusion pumps (i.e. disposable gloves).

- Disposing all regular, biohazardous, sharps and drug waste in the appropriate bins/containers. See "Disposal of Biohazardous and Sharps Waste" SOP.

KGHRI is responsible for:

- Ensuring all infusion pumps (units and modules) are in good working condition and labelled with appropriate contact information for maintenance and repair.

- Ensuring copies of infusion pump instructions (see Appendix A) are readily available to all users.

- Contacting KHSC's Clinical Engineering to arrange for routine inspections and/or repair of all infusion pump units and/or modules.

- Ensuring that all routine inspection for regular maintenance is carried out and recorded in the Maintenance Log and available for inspection.

- Ensuring all records of repair are kept and available for inspection.

- Providing appropriate personal protective equipment for users when using the infusion pumps (i.e. disposable gloves).

- Providing users with the appropriate regular, biohazardous, sharps and drug waste bins/containers in designated areas within WJHCPOR and/or KHSC's Pharmacy Services (Connell 0).

4.0 PROCEDURE

- Infusion pump units are designed to operate a maximum of four (4) infusion modules. One (1) module is used for saline and up to three (3) modules can be used for drugs.

- Infusion pumps **MUST** be mounted onto IV pole when in use.

- Infusion pumps **MUST** remain in the Clinical Investigation Unit and should not be moved to other areas within the WJHCPOR.

- When using the infusion pumps, whether for daytime and/or overnight stays of research participants, at least two users (one research nurse and one other research team member), possessing the following minimum qualifications, **MUST** be present at all times in the Clinical Investigation Unit in order to monitor research participants' safety:

  - One user must be (a) certified in advanced cardiovascular life support (ACLS), (b) able to activate a KHSC emergency response plan (i.e. CODE 99), and (c) competent in basic first aid.

  - A second user must be (a) certified in basic life support (BLS), and (b) able to activate a KHSC emergency response plan (i.e. CODE 99).

- Users **MUST** bring all required equipment and supplies (i.e. saline, drug, tourniquet, syringes, IV needles, alcohol wipes, gauze, tape, tubing, adapters and connectors) needed to operate the infusion pumps. KGHRI only provides the infusion pumps to users for usage.

- The principal investigator (clinician) **MUST** be accessible (located in KHSC-KGH site) and readily available at all times when a research participant is undergoing an intravenous drug infusion as part of a clinical trial in the Clinical Investigation Unit 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.

5.0 REFERENCES

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

6.0 SOP HISTORY

SOP Number	Date Issued	Summary of Revisions
SOP-IP-01	01-DEC-2017	Original version.
SOP-IP-01.1	01-FEB-2018	Infusion pump instruction manual added to policy. New appendix added to policy as "Appendix A". Section 4.0 "Procedures", last bullet changed to "The principal investigator (clinician) **MUST** be accessible (located in KHSC-KGH site) and readily available at all times when a research participant is undergoing an intravenous drug infusion as part of a clinical trial in the Clinical Investigation Unit within the WJHCPOR".
SOP-IP-02	01-MAY-2019	Bi-annual review of SOP completed. SOP header format updated. SOP version number updated. SOP effective date updated. Removed "Contacts" section from SOP. Updated section number for "References" and "SOP History". Under Section 1.0, under paragraph 1, within sentence 1,

		“Learning Management System (LMS)” changed to “learning management system “KnowledgeNow””. Under Section 1.0, a new second paragraph was created related to the use of cytotoxic drugs. Under Section 3.0, under “Users Responsibilities”, under bullet 1, “LMS” changed to “KnowledgeNow”. Under Section 3.0, under “Users Responsibilities”, under bullet 5, added quotations around “Disposal of Biohazardous and Sharps Waste”. Under Section 4.0, under bullet 6, added “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.” after last sentence. Updated “SOP History” section. No updates needed for Appendix A.