Standard Operating Procedure **Use of Clinical Investigation Unit**			
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1.0 POLICY

Testing and/or monitoring as part of any clinical research project or clinical trial is under the medical supervision/oversight of the principal investigator at **ALL** times. All clinical research projects and clinical trials contain a level of risk. This risk **MUST** be assessed and managed at each stage of a study by the principal investigator to ensure the safety, rights and well-being of research participants and research staff personnel and the integrity and successful completion of the study. Only trained research personnel **MUST** work with research participants within the Clinical Investigation Unit (CIU) located within the W.J. Henderson Centre for Patient-Oriented Research (WJHCPOR). All users of the CIU are required to undergo hands-on training prior to using the area within the WJHCOPR.

2.0 PURPOSE

To standardize the training required when research participants are undergoing testing and/or monitoring as part of any clinical research project or clinical trial in the CIU located within the WJHCPOR.

3.0 RESPONSIBILITY

Users are responsible for:

- Completing the WJHCPOR “General Orientation” course and participating in hands-on training. For users using the cardiac monitors and/or infusion pumps, additional courses and hands-on training required.
- Operating and maintaining all CIU equipment in accordance with manufacturer’s instructions for safe usage and professional best practice procedures.

- Reporting any damage to the CIU equipment to the designated Kingston General Health Research Institute (KGHRI) staff member **immediately** so equipment repairs can be made.

- Wearing appropriate personal protective equipment in the CIU when working with research participants. See Personal Protective Equipment SOP.

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

- Ensuring the safety of other users of the CIU. Incidents (i.e. spills, accidents, exposure) are reported immediately. See Accidental Occupational Exposure and Reporting Workplace Incidents SOP and Spill Control Procedures SOP.

- Familiarizing themselves with all the emergency codes while conducting research within the CIU. See Emergency Procedures SOP and Calling Codes SOP.

- Ensuring proper use of spot monitors, cardiac monitors, infusion pumps, otoscopes and ophthalmoscopes, and height and weight scales in the CIU. See Spot Monitors SOP, Cardiac Monitor SOP, Infusion Pump SOP, Otoscopes and Ophthalmoscopes SOP, and Use of Height and Weight Scales SOP.

- Wiping down all CIU equipment and furniture surfaces with Oxivir® wipes provided after each research participant.

- Ensuring that they have in place with their direct supervisor a buddy system, a check-in procedure, and an effective means of communication when working alone in the CIU. See Working Alone Safely SOP.

KGHRI is responsible for:

- Ensuring all CIU equipment is in good working condition and labelled with appropriate contact information for maintenance and repair.

- Providing users with access to research treatment areas in the CIU through an online booking system: 3 beds, 4 recliners (one chair is bariatric), and a procedure room.

    - Each bed area is equipped with a procedure stretcher, Philips® cardiac monitor (NBP, pulse, SpO_2, ECG), Alaris® infusion pump, digital timer, stool, over bed table, oxygen, and suction.

    - Each chair area is equipped with a reclining chair with side table, Alaris® infusion pump and stool.

    - The procedure room is equipped with a surgical stretcher, Philips® cardiac monitor (NBP, pulse, SpO_2, ECG), Alaris® infusion pump, digital timer, otoscope and ophthalmoscope, surgical/procedure light, oxygen, and suction.

  - The CIU also allows users and research participants with access to cable TV, computer workstations, access to security cameras within WJHCPOR, intercom system for answering the doorbell at main entrance, clocks, spot monitors, otoscopes and ophthalmoscopes, height and weight scale, storage cupboard for personal items of research participants, and a bathroom with shower.

- Contacting KHSC's Clinical Engineering to arrange for routine inspections and/or repair of all CIU equipment.

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

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

- Providing appropriate personal protective equipment (PPE) for users in the CIU (i.e. disposable gloves).

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

4.0 PROCEDURE

- When users are accessing CIU, whether for daytime and/or overnight stays of research participants, at least two users (research nurse or clinician **and** one other research team member (preferred) **OR** two research team members who meet qualifications), possessing the following minimum qualifications, **MUST** be present at all times in the CIU in order to monitor research participants' safety. If the risk assessment is high for a possible adverse event, more users present in the CIU is recommended:

  - 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, gauze, tape, tubing, adapters and connectors, procedure kits, diagnostic kits) needed to carryout the clinical research project or clinical trial. KGHRI only provides the CIU equipment to users for usage and limited supplies (i.e. disposable gloves, disposable masks for research participants and users, ECG electrodes, razors, alcohol wipes, paediatric adhesive wraps for cardiac monitors, disposable speculas for otoscopes, Oxivir® wipes, Oxivir® bottles for clean-up, thermometer probes for spot monitors).

- When using the procedure room in the CIU, users **MUST** only carry out the approved procedures listed in Appendix A. If a procedure is not listed, please contact the designated KGHRI member. For additional procedures to be added to Appendix A, formal approval from KHSC's Director of Health Sciences Research and KHSC's Infection Control Department is required.

- 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 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.

- All CIU equipment and furniture **MUST** remain in the CIU and should not be moved to other areas within the WJHCPOR.

5.0 CONTACTS

Research Administration Facilitator (Designated KGHRI Staff Member):

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6.0 SOP HISTORY

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SOP-UCIU-01	01-APR-2018	Original version.