Standard Operating Procedure **Administrative Management of Standard Operating Procedures**			
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Subject:	**Administrative Management of Standard Operating Procedures**		

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Approved By:	Veronica Harris-McAllister	29/Nov/17 dd/mmm/yy

1.0 POLICY

This standard operating procedure (SOP) describes the process for the development, review, approval, and maintenance of all W.J. Henderson Centre for Patient-Oriented Research (WJHCPOR) written SOPs.

2.0 PURPOSE

SOPs are controlled documents designed to give instructions for performing routine and essential procedures to ensure that these measures are performed consistently and in a manner upholding safety, quality and integrity. SOPs must be in compliance with the applicable regulations, guidelines, requirements, and related documents. Please refer to the "References" section of each SOP for these documents. All users of the WJHCPOR MUST adhere to all SOPs.

3.0 RESPONSIBILITY

Kingston General Health Research Institute (KGHRI) is responsible for developing and maintaining all written sets of SOPs and will follow this SOP when reviewing, preparing, and revising any new or current SOPs. KGHRI must identify a person(s) responsible for the preparation of SOPs and implement a development and approval/authorization process to adopt. It is the responsibility of each user of the WJHCPOR to review, be familiarized with, and follow all SOPs while conducting clinical research in the WJHCPOR.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

5.1 General Information

- If users of the WJHCPOR require additional SOPs for their clinical research beyond the written SOP sets provided by KGHRI, users should follow a similar format outlined below for creating their additional user-specific SOPs. **IMPORTANT NOTE**: Changes to any content of the SOPs belonging to the WJHCPOR may invalidate the compliance status of the SOPs. Any required deviations MUST be made as a "Note to File" by users of the WJHCPOR.

5.2 SOP Style

- Describe each operation in a procedure as a separate step. Make instructions explicit enough so that a user of the WJHCPOR could perform the procedure by following the instructions during routine work. The SOP may also be used as a training tool.

- Use clear, concise, unambiguous instructions so that users of the WJHCPOR can understand the requirements. Do not use qualifiers and vague terms such as "usually", "sometimes", "normally", "regularly" or "try to".

- Use titles and/or functions, not individual names.

- Flow charts may be included, as they are an excellent way of communicating the sequential steps of a process. Equipment diagrams and scanned images can also help users of the WJHCPOR understand equipment, and are useful aids during hands-on training sessions.

5.3 SOP Format and Content

- Write the SOP using the same formatting, font (Arial 12 for main headings, Arial 11 for sub-headings and body text) and writing styles as shown in this SOP.

- The "Effective Date" refers to the date that the approved SOP is to be implemented by users of the WJHCPOR. The format is the date spelled out (i.e. December 1, 2017). "Prepared By" and "Approved By" dates refer to the edits to the existing SOP that were competed and approved by the designated KGHRI staff members. The date format is day (DD), month (MMM), and year (YY).

- An SOP Table of Contents should be created to list all of the approved SOPs. This table needs to be updated when amendments occur.

- Title Section: Include the following:

    - The complete SOP title, without any abbreviation. The title should clearly describe the SOP.

- SOP Abbreviation: use "SOP"', followed by dash (-), followed by the corresponding title abbreviation, followed by dash (-), followed by the SOP version in two digits. For this original SOP, the SOP abbreviation would be "SOP-AMSOP-01". A major revision to any existing SOP would move the version of the SOP up by one full digit (i.e. SOP-AMSOP-02). The effective date needs to reflect the new date that the SOP was approved for implementation. Minor revision updates are only used for minor typographical errors/clarification or other small administrative changes. The effective date remains the same as the last major revision but the number digit moves up by "0.1" unit (i.e. SOP-AMSOP-01.1).

- Format headers and footers, with described information, as shown in this SOP. For the header include the complete title and SOP abbreviation. For the footer include the version date in the bottom left corner, page number in the bottom centre, and SOP abbreviation in the bottom right corner of the footer.

➢ Complete the SOP History section following the first approval to implement the SOP using the following information. All revisions need to be documented in this table:

- SOP Number: SOP abbreviation, including correct new version number reflecting if revisions are classified as major or minor;

- Date Issued: the effective date of the new version of the SOP in the format day (DD), month (MMM), and year (YYYY);

- Summary of Revisions: a brief description of any changes in the new version compared to old version.

5.4 Section Numbering

➢ Number SOP sections and include header specific information. SOP section examples include the following:

- Policy: describe what the SOP is about.

- Purpose: why SOP required and which individuals is the SOP applicable.

- Definitions: optional. Include if you have a glossary of terms. Ensure language is consistent across SOPs for all definition terms.

- Responsibility: documents the users of WJHCPOR responsibilities and KGHRI responsibilities related to the SOP.

- Procedures or Description of Specific Equipment: describes how a procedure is done or how to use a specific piece of equipment. Use active/assertive verbs and sentences, if possible (i.e. "obtain signature", "complete CRF", "file document").

- o Contacts: list of designated KGHRI staff members to contact regarding any questions or issues related to an SOP.

- o References: optional. Include regulatory references, if required to be reviewed or helpful for users of the WJHCPOR.

- o SOP History: describes all changes made to the SOP since the original SOP was implemented. Use a table format to present this information.

5.5 Developing New or Revising Existing SOPs

- Any user of the WJHCPOR and/or KGHRI staff members can identify the need for new or revised SOPs, based on findings from a scheduled SOP review, audit, or changes to regulations, guidelines, research practices, or changes to hospital and/or university institutional policies. See Appendix A ("SOP Change Request Form").

- A designated KGHRI staff member will write the new original SOP or amend the existing approved SOP, following the standard format outlined in this procedure. For SOPs that are specific only to a user/user group of the WJHCPOR, the user/user group will write the new SOP or amend the existing user-specific SOP, following the standard format outlined in this procedure.

- A designed KGHRI staff member will write all new or amend all existing SOP "Appendices".

- All existing SOPs and Appendices that are amended will have their version number and effective date updated as outlined within this SOP. The SOP Table of Contents will need to be updated whenever existing SOPs and Appendices are amended.

5.6 Review and Approval of SOPs

- SOPs need to be reviewed once every two years (biannual review), but more frequently if regulatory and/or institutional changes have occurred and warrant immediate changes to SOPs. A "SOP Review Record" (See Appendix B) should be completed for each SOP.

- All identified revisions to any SOPs MUST also be documented in the SOP History section of each SOP as outlined within this SOP. If no revisions are required, a statement "no revisions needed" still needs to be documented. Remember to update the version number and effective date and document approvals.

5.7 SOPs Distribution, Communication and Training

- Users of the WJHCPOR MUST be notified of all new and/or revised SOPs. If needed, documentation of the rationale for the new SOP or SOP changes should be provided. See Appendix C ("SOP Distribution Record").

- KGHRI MUST ensure that current SOPs (paper or electronic) are readily available to all user of the WJHCPOR. For electronic versions of the SOPs, the final approved SOP should be posted in a format that cannot be altered (i.e. PDF format). Ensure that all electronic files are checked regularly and only current SOPs are distributed to users of the WJHCPOR.

- As required, a designated KGHRI staff member will provide training for the new and/or revised SOPs. To provide training, the designated KGHRI staff member should be qualified by a suitable combination of education, experience, and skills.

- All training MUST be documented and training records MUST be retained by KGHRI.

5.8 SOPs Storage

- KGHRI should create and maintain a central SOP folder that contains the most up-to-date SOPs in electronic format. A paper copy version should also be readily available for quick review, if needed, by users of the WJHCPOR.

- Outdated SOPs, SOP Appendices, SOP Table of Contents, and SOP review/distribution records MUST be archived by KGHRI. All documents MUST be retained for the longest retention period requirements (i.e. research ethics boards, Health Canada, FDA).

6.0 Contacts

Research Administration Facilitator (Designated KGHRI Staff Member):

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7.0 SOP HISTORY

SOP Number	Date Issued	Summary of Revisions
SOP-AMSOP-01	01-DEC-2017	Original version.