1. *Purpose*

This guideline describes the process for initiating and obtaining Institutional approval for a research study at William Osler Health System (OSLER). The purpose of the Impact Assessment (IA) form is to obtain approval from departments or areas of the Institution where approval is required prior to initiating the study.

All studies involving human participants at OSLER will be required to obtain IA approval. It is the responsibility of the Principal Investigator/Study Team to notify the relevant department(s) when the research project may have an operational impact due to study activities.

2. *Scope*

This guideline applies to all studies involving human participants at OSLER. The IA process must be completed before other Institutional approval processes or requirements (e.g., REB, contracts, etc.) are initiated.

The impacted departments may include but are not limited to the OSLER Research Department, Pharmacy, Diagnostic Imaging (DI), Nephrology, Laboratory, Pathology, Nursing, and Cardiac Diagnostics.

3. *Responsibilities*

The Principal Investigator (PI) and Study Team are responsible to ensure completeness of the IA form. It is the PI's responsibility to ensure the IA form accurately reflects the impact on department(s) or resource(s) due to the research study.

4. *Definitions*

Primary Impacted Depts = Lab, DI, Pharmacy, Nursing, Cardiac Diagnostics
Secondary Impacted Depts = All areas impacted by research outside of primary impacted depts. (i.e. IT, Privacy, Legal, Risk, Registration, Organizational Performance).

Department Leadership = Chief of Department and Clinical Director

Study Team: refers to the individuals assigned to complete the study related research activities. This may include: Principal Investigator, Clinical Research Coordinator, Research Assistant, and Clinical Trials Pharmacist unless otherwise specified.

5. Process

The IA form will be available by emailing the Research Program (Research@williamoslerhs.ca). The IA presentation template will be available through the applicable Clinical Research Manager.

Steps to obtaining IA Approval are outlined in the attached workflow and detailed below:

1) Complete the IA Package along with supporting documentation

The assigned PI or Study Team will obtain the most up-to-date IA form from the Research Department website and in consultation with the PI, complete the IA form and indicate/describe any impact on departments.

A complete IA Package consists of the following required documentation:

- IA Form
- IA Presentation
- Relevant Study Documentation
- Statement of Services Rendered

If the following departments are indicated as being impacted on the IA form, along with the completed IA package and Protocol, the following documents must also be provided for review:

- **Pharmacy**: Investigators Brochure (IB) and/or Pharmacy Manual
- **Diagnostic Imaging and Lab:** Laboratory and Imaging Manuals
- **Organizational Performance Services:** Data Collection Form (DCF) or list of variables

2) Primary Impacted Departments Initial Approval Phase:

Present IA package to Department leadership where the study is taking place for initial IA approval (Obtain signatures on IA form or email approval).

Discuss IA package with pharmacy and nursing teams to ensure no roadblocks exist (no signature required). Contacts for initial

approval as defined in the current IA Workflow.

3) *Secondary Impacted Departments Approval Phase:*

   Present or circulate IA package to secondary impacted departments for approval. Obtain signatures on IA form or email approval.

4) *Primary Impacted Departments Final Approval Phase:*

   The Study Team to present the IA requirements and the study protocol (including all applicable documentation) at monthly IA meeting. Monthly IA meetings are attended by primary impacted departments only. Obtain signatures or email approval from the IA meeting panelists on both the IA form and the Statement of Services Rendered.

5) Once all required signatures are obtained and the PI confirms that the IA form accurately reflects the impact on departments and resources, the Study Team will send the completed IA form to the Research Manager.

6) The Research Manager will review the completed IA form to sign-off granting Institutional Approval. A fully signed copy of the IA form will be given to the Study Team and PI. A copy will also be placed on the secure J drive, along with the protocol and any other required material (IB, Pharmacy Manual, laboratory and imaging manuals, DCF).

7) Considerations:

   Note: in rare circumstances where the IA has not been finalized, an SIV can be scheduled and an invitation can be sent to the impacted departments. However, an approved IA (along with other approvals) is required prior to starting any research activities.

   The approved IA form will be used for a final review of the study's budget projection and to support any further negotiations with the Sponsors (if needed and/or requested by the OSLER impacted department). Once financial requirements for the conduct of the trial are met and agreed by the sponsors, final budget approval will be granted along with a fully executed contract.