1. *Purpose*

This guideline describes the process for initiating and obtaining Institutional approval. 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 William Osler Health System (WOHS) will be required to obtain IA approval. It is the responsibility of the Principal Investigator/Research Staff 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 WOHS. The IA process can be conducted simultaneously with other Institutional approvals (e.g., REB, contracts, etc.).

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

3. *Responsibilities*

The Research Staff and the Principal Investigator (PI) are responsible to ensure completeness of the IA form. It is the PIs responsibility to ensure the IA form accurately reflects the impacted on department(s) or resource(s) due to the research study.

4. *Procedure*

The IA form will be available on the Research Department website.

Steps to obtaining IA:

1) The assigned Research Staff or PI will obtain the most up-to-date IA form from the Research Department website.

2) The Research Staff in consultation with the PI will complete the IA form and indicate any impact on departments.

3) The Research Staff will circulate the IA form to the impacted departments along with the study protocol. The managers of all impacted departments including the Research Manager should be copied on the email circulation. Approval from the identified personnel must be obtain via e-signature or a scan of wet ink signature. In rare circumstances (e.g., on holidays) when an e-signature or wet ink signature cannot be obtained, email approval can be used instead.

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

   a) **Pharmacy**: Investigators Brochure (IB) and/or Pharmacy Manual
   b) **Diagnostic Imaging and Lab:** laboratory and imaging manuals
   c) **Decision Support Services:** Data Collection Form (DCF) or list of variables

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

5) 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 Research Staff 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).

6) 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.

7) The Research Contract Specialist will review the approved IA form in consultation with the PI for a final review of the study's budget projection and initiate any further negotiations with the Sponsors (if needed and/or requested by the WOHS 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.

8) Note: the Research Staff is required to keep a fully signed copy of the IA and finalized budget projection (along with other required material, e.g., fully executed contract) in the regulatory binder.

5. Definitions

Research Staff: refers to the individual assigned to complete the research activities. This may include: Clinical Research Coordinator, Clinical Trials Assistant, Clinical Trials Pharmacist and/or Clinical Coordinator unless otherwise specified.