OFFICE OF RESEARCH INTAKE FORM

IMPORTANT INFORMATION FOR RESEARCHERS: The Research Intake Form is the first point of contact for researchers wishing to conduct research at Erie Shores Health Care (ESHC). The purpose is to ensure the institution is aware and supportive of all research being conducted within our population of patients. We will provide directions on how to move forward to the next steps required to conduct research at the ESHC, and items to consider such as budgets. It is important that all researchers understand however that there are other committees and considerations, which may not permit the research project to move forward in the future, even if the Research Assessment process provides no objection. Examples are the Research Ethics Board review, and clinical committee review.

Name of the applicant	
Contact Information	
Proposed protocol title/name	
ESHC Physician Affiliate's Name (If Applicant is not ESHC Professional staff, required to have a clinical staff investigator affiliated with project if research involves patients)	

Actions Required for Submission:

- Please submit this completed application to the Office of Research either online through ESHC Intranet, or by email: research@eshc.org
- Please submit a BUDGET if available; if not available or assistance with budgeting needed, please indicate in your submission.
- Please submit the UWindsor REB Ethics Submission Form for Research Involving Humans and any supporting documents required for REB Review (research project PROTOCOL or project outline, any Informed Consent documents etc.)

- ALL applications must have the ESHC Departmental Impact forms completed and attached for all impacted departments – i.e., Laboratory, Diagnostic Imaging, Program Area (e.g., Renal, Mental Health).

Upon receipt of the above, the Research Assessment review will take place, and feedback will be provided in the form of directions to move forward, a request for clarification, or reasons why the project cannot be conducted at ESHC as submitted.

1. Please indicate the type of Research you are applying for:

- WRH Patient Population **Interventional** (Prospective) Clinical Trial
  - Outpatient only
  - Inpatient only
  - Both
- ESHC Patient Population **Non-Interventional** (Prospective) Clinical Trial
  - Outpatient only
  - Inpatient only
  - Both
- ESHC Patient Population Retrospective Chart Review

*No Resources needed for retrospective reviews; Skip to Question #3 ESHC Research with NO Patient participation

2. Please indicate the type of Resources you will require from ESHC:

- **Regulatory Support** Only (e.g., Ethics Submissions, Management of Investigator Site File, Health Canada Application assistance etc.)
  - Please attach Budget if available
- **Enrollment/Patient Access Procedures** Only (e.g., Non-interventional, Identifying/Consenting participants and minimal data collection only)
  - Please attach Budget if available
- **Laboratory Processing/Shipping** Only (outside of Standard of Care)
  - Please attach Budget if available
- **Full Study Support** (e.g., Enrollment, Data Collection, Participant assessments and Case Report Form Entry)
  - Please attach Budget if available
- **No Study Support** Needed (e.g., Student work only)

3. What is the approximate number of participants to be included in the research project (90% Confidence interval)? _____

4. What is the approximate start date of the research? __Day__/___Month____/____Year___

5. Approximately, how long is the recruitment/data collection period? _____

6. Please provide a concise description of the Research Project Proposal (maximum 250 words), including a description of all the service areas listed above and how the research will impact ESHC Departments. Please also include any rationale for benefit to ESHC participants, especially if the project is underfunded.

Feasibility Factors for your Consideration:

Population		**Comments**
	Do you have access to the right patient population?	
	Is the proposed enrollment goal and timeline realistic?	
	Are inclusion/exclusion criteria overly restrictive? (Consider the screen failure ratio and the number of screen failures)	
	Do you expect a considerable number of adverse events? (How sick is this population?)	
Protocol		
	Is the protocol well designed? Is the protocol ethical? Will the REB have problems with it?	
	Is the study question important?	
	Will patients benefit from participating in the study?	
Staff		
	Does the Principal investigator (PI) have adequate time to devote to the protocol?	
	Are additional specialists needed? (Pathologist, radiologist etc.)	
	Is the PI a qualified investigator (the minimum qualification is being an Adjunct Faculty at an accredited university)	
	Does the study team including PI have required certifications for clinical research (e.g., ICH-GCP, TCPS2)	
Budgets		
	If the study is canceled prior to enrollment, will you be able to pay for pre-study activities, e.g., REB submission?	
	Any other protocol required equipment or procedure etc.	

Additional Comments:

_____
_____
_____
_____

ESHC USE ONLY:

Date received		
Date reviewed by Office of Research		
Follow-up information requested (please circle the appropriate response)	**Yes** **No**	
	If **yes** who is responsible for request and Date completed	
Research request outcome	Approved to Move to Next level of Review; specify	
	Conditional – comments attached	
	Declined – comments attached	