Research Ethics Board
William Osler Health System
2100 Bovaird Drive East
Brampton, ON L6R 3J7

PI Attestation and Agreement (PAA) - Resuming Research Activities

The plan to gradually restart clinical research activities must align with the approach taken by William Osler Health System. The hospital is following all applicable local, provincial and federal public health directives, and guidelines and direction from Ontario Health, which requires continued reassessment of activity based on local resources and regional COVID-19 activity. For more information about this form and who is required to complete the PAA prior to reopening, please visit our website for more details.

Please complete this form to resume research activities for 1) essential research studies placed on hold for new screening/recruitment; 2) non-essential research studies placed on hold; 3) studies under activation/have not started.

Please note: COVID-19 Research or research explicitly granted permission by the Osler REB to continue, do not need to apply to reopen.

I. STUDY INFORMATION	
Name of Principal Investigator	
Study Full Title:	
Sponsor:	
REB#	
Site	☐ William Osler Health System ☐ Headwaters Health Care Centre ☐ Central West LHIN
Is this study regulated by the FDA?	Yes ☐ No ☐
Is this study regulated by Health Canada	Yes ☐ No ☐
REB expiry date (based on your renewal approval letter)	
Planned restart date (if approved)	

II. CONDITIONS FOR RESUMING RESEARCH ACTIVITIES (Note: all requirements must be met)	
☐ Yes ☐ No ☐ N/A	Adequate and stable supply of PPE, including research personnel in **direct contact** with subjects, face masks AND face shields will be made available
☐ Yes ☐ No ☐ N/A	Adequate training of research personnel to ensure compliance with Osler guidelines (see updates on OslerNet's COVID-19 Resources section)
☐ Yes ☐ No	Adequate and stable supply of necessary medications in support of the clinical trial.

☐ N/A	
☐ Yes ☐ No ☐ N/A	Adequate capacity of clinic space, beds, waiting areas, hospital resources. Note: no research participants should be in unconventional spaces (e.g., hallways).
☐ Yes ☐ No ☐ N/A	Have other Departments where resources required beyond standard of care that are involved in the study (i.e., lab, pharmacy, imaging, etc.) agreed to resume study enrollments and activities? Please obtain signatures from impacted Departments on the Study Impact Signature Page.
☐ Yes ☐ No ☐ N/A	Adhere to other program, department, division policies or directives for resuming research.
☐ Yes ☐ No ☐ N/A	All temporary modifications made to the study protocol or consent form have been reported to the REB using the Planned Protocol Deviation Form for acknowledgement. This includes consideration for conducting the study while maintaining social distancing. For example, amending the consent process to eliminate research staff contact with patients, study activities be completed either remotely, etc.
☐ Yes ☐ No ☐ N/A	For research personnel where distancing (>6 feet) is not possible, then face masks MUST be worn
☐ Yes ☐ No ☐ N/A	Will ensure appropriate sanitation of all materials, equipment and area. Stable supply of Osler approved sanitation supplies e.g., wipes and hand sanitizer.

III. CONSIDERATIONS FOR RESUMING RESEARCH ACTIVITIES

I confirm that when resuming research acuities, the study will:

☐ not compromise patient or staff safety
☐ where feasible, allow for physical distancing between patients and staff who would not otherwise have contact, when feasible
☐ have appropriate PPE and staff have been trained on its use
☐ allow for REB approved verbal or remote consent models where feasible (note modifications must ensure adequate privacy protections are in place and require notification and acknowledgement by the REB prior to implementation).
☐ will not be affected should a patient/participant need to isolate for 14 days with interruption in clinical trial therapy/procedures
☐ have sufficient resources to follow participants/patients throughout the trial, OR, do not involve additional clinical visits, resources and/or investigations beyond standard of care procedures (e.g. medical imaging, labs, pharmacy etc.)
☐ involve fewer than standard of care procedures (e.g. less frequent chemotherapy infusions)
☐ are time sensitive
☐ allow remote monitoring if needed
☐ have sufficient funding to complete the study
☐ can comply with applicable ethics, regulations, policies and guidelines

This signature attests that the PI is aware and meets all requirements outlined in Section 2, and that Section 3 has been reviewed and considered.

Principal Investigator:

_____	_____	_____
Name	*Signature*	*Date*

Institutional Approval (Department Chief or Clinical Lead):

_____	_____	_____
Name	*Signature*	*Date*

STUDY IMPACT SIGNATURE PAGE

If any departments are will be impacted by resuming study activity, please complete the form below. Note: due to COVID-19, priorities for some departments may have shifted and to expect longer than normal wait times.
Does the study impact on other hospital departments or services? Yes ☐ No ☐
If yes, provide signature to indicate protocol has been submitted to appropriate department.

Departments/Committees	Impact	Departmental/Divisional Signature
Pharmacy **Patricia Mosnia** ext: 57833	Yes ☐ No ☐	
Director Diagnostic Imaging (DI) and Laboratory Medicine **Aimee Langan** ext: 33539	Yes ☐ No ☐	
Cardiac Diagnostics **Anne Marie Graham**	Yes ☐ No ☐	
Nursing **Tiziana Rivera**	Yes ☐ No ☐	
Health Records **Janet Smit** ext: 58860	Yes ☐ No ☐	
Decision Support Services **Desa Martin** Ext: 50449	Yes ☐ No ☐	
Other: _____		

Approved to re-open by, REB Chair, Co-Chair or Delegate (Note: please submit this form to WOHSREB@williamoslerhs.ca to obtain approval):

_____ _____ _____
Name *Signature* *Date*