

STUDY SUBMISSION CHECKLIST

Before a research project can begin, approval from BOTH the Research Ethics Board (REB) and the Office of Research & Innovation (ORI) is required.

PLEASE SUBMIT A TYPED SIGNED HARD COPY OF THIS FORM TO THE REB OFFICE AND THE ORI.

STUDY INFORMATION (PLEASE TYPE)			
Study Title:			
Type of Research Study:			
<input type="checkbox"/> Clinical Trial	<input type="checkbox"/> Prospective Observational Study		
<input type="checkbox"/> Retrospective Chart Review	<input type="checkbox"/> Qualitative –Focus group/Surveys		
<input type="checkbox"/> Registry	<input type="checkbox"/> Research involving First Nations, Inuit or Metis		
<input type="checkbox"/> Student/Resident Project	<input type="checkbox"/> Other (Please Specify):		
Name of the funding source:			
Name of NYGH Investigator:			
Contact email address:			
Employee/Affiliation/Credentialing status @NYGH:			
Department/Program of NYGH Investigator:			
Is this a multi-site study?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>If "Yes", Name the Lead Study Site:</i>			
Will participants for this study be recruited at NYGH?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>If "No", Specify the location of recruitment:</i>			
Will the study involve collection/analysis of Personal Health Information?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Will the study require access to health record /power chart?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Will the study involve transfer of data/biological materials to or from NYGH?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>If "Yes", Specify transfer location:</i>			
Will the study require research ethics review by NYGH REB?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>If "No", Specify the REB of Record:</i>			
Will this study require a Contract/ Agreement Review?		<input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No
Will you be hiring study personnel / students for conducting this study?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Will you be purchasing equipment/devices for this study?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Will you be requiring resources from other NYGH departments?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>If "Yes", is Resources Required for Research form attached?</i>		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Is the study funded?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Will any study funds be administered by NYGH?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Will you require a research account at NYGH?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
Will the funder cover the REB fee? *		<input type="checkbox"/> N/A	<input type="checkbox"/> Yes <input type="checkbox"/> No
<i>*An administrative fee of \$3000/-CAD is invoiced for all Industry- sponsored/Supported Studies applying for NYGH REB Initial Review. REB administration fees are due within 30 days of submission.</i>			

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STUDY PERSONNEL INFORMATION (PLEASE TYPE)

- Please list all study team personnel, their assigned study role, study tasks involved in conducting research activities at NYGH. The information regarding the mandatory ethics education requirements is available at REB website - <http://www.nygh.on.ca/Default.aspx?cid=3571&lang=1>
- Please Note: The external (non-NYGH) study staff performing research study at NYGH or accessing NYGH patient records/personal information/personal health information, is required to have appropriate signed permissions and designations as a research visitor/volunteer. For additional information, please contact the Office of Research and Innovation, email - Research.Innovation@nygh.on.ca

Study Personnel Name	NYGH Affiliation	Study Role*	Study Task(s)**	Access to PHI?	TCPS2	Privacy
	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

***Study Role:** PI, Co-PI, Research Coordinator, Statistician, Research Student, Trainee, Fellows etc.

****Study Tasks:** Chart Review, Data Analysis, Data Collection, Data Entry, Obtain Informed Consent, Participant Recruitment, Protocol Development etc.

DECLARATION BY NYGH PRINCIPAL INVESTIGATOR

I affirm that all individuals listed above have completed the TCPS2 training and education in accordance with NYGH institutional requirements.

Name of NYGH Site PI

Signature

Date

STUDY SUBMISSION CHECKLIST

If you answered "Yes" to any of the questions below, please submit the following documents to the Research Ethics Board Office (Rm. GS-70), email: reb@nygh.on.ca If you have any questions, please phone 416-756-6000 Ext. 3485

RESEARCH ETHICS BOARD SUBMISSION CHECKLIST	
Study Submission Checklist	<input type="checkbox"/>
Completed TAHSN Application Form with Signatures	<input type="checkbox"/>
Study Protocol	<input type="checkbox"/>
Study Budget	<input type="checkbox"/>
NYGH Specific Informed Consent/Assent Documentation	<input type="checkbox"/>
Recruitment Materials (Advertisements, flyers, etc.)	<input type="checkbox"/>
Data Collection Instruments(Surveys, Questionnaires)	<input type="checkbox"/>
REB Approvals from other sites (If Applicable)	<input type="checkbox"/>
TCPS2 training tutorial for protection of human research participants	<input type="checkbox"/>
Privacy & Security Fundamentals for Researchers Module Attestation	<input type="checkbox"/>
Investigator's Brochure (If Applicable)	<input type="checkbox"/>
Health Canada NOL/ITA/NOA (If Applicable)	<input type="checkbox"/>
CTO REB Board of Record Agreement (If Applicable)	<input type="checkbox"/>
Other (Please list):	

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REB #	CTO BOR Agreement
Date Submitted	Health Canada NOL
Need ORI Approval	Clinical Trial Reg. #
Date of REB Review	Investigator Brochure
REB Review Type	Informed Consent Form
REB Decision	REB Fee Invoice #
Comments:	

STUDY SUBMISSION CHECKLIST

If you answered “Yes” to any of the questions below, please submit the following documents to the Office of Research & Innovation (Rm. LE-140), email: Research.Innovation@nygh.on.ca along with the study submission checklist.

RESEARCH AND INNOVATION SUBMISSION CHECKLIST	
Will this study require a Contract/ Agreement Review?	<input type="checkbox"/>
Will any proprietary data/ information/ biological materials (e.g., tissues, cell lines) be transmitted to or from NYGH?	<input type="checkbox"/>
Will you need a research account at NYGH?	<input type="checkbox"/>
Will you be hiring study personnel or students for conducting this study?	<input type="checkbox"/>
Will you purchase equipment/devices for this study?	<input type="checkbox"/>
Will you need resources from other NYGH departments?	<input type="checkbox"/>
<i>If “Yes”, is Availability of Resources for Research form attached?</i>	<input type="checkbox"/>
Signed Study Personnel Information sheet attached?	<input type="checkbox"/>
For Clinical Trial studies- Health Canada No-Objection Letter is obtained?	<input type="checkbox"/>

For ORI USE ONLY

Contract/Agreement Review	
Privacy/Risk Assessment	
Budget Review	
Availability of Resources Form	
Study Personnel Sheet	
Research Account Set Up Required	
REB Approval Status	
Comments:	
ORI recommends Institutional Approval for this study	