

QUALITY IMPROVEMENT (QI) ASSESSMENT CHECKLIST

Please submit a typed signed hard copy of this form to the REB office

PROJECT INFORMATION (PLEASE TYPE)		
Project Title:		
Name of NYGH Investigator:		
Contact email address:		
Employee/Affiliation/Credentialing status @NYGH:		
Department/Program of NYGH Investigator:		
Is this a multi-site project?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>If "Yes", Name the Lead Project Site:</i>		
Will the project involve collection/analysis of Personal Health Information?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Will the project require access to health record /power chart?	<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
REMINDER: Shared health systems such as ConnectingOntario, OLIS, cCHN, HDIRS and IAR are not permitted to be used for quality improvement, service evaluation or research.		
<i>If "Yes", is Resources Required for Research form attached?</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>Is Project Proposal or Protocol outline enclosed?</i>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Is the project funded?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<i>If "Yes", Name of the Source of Funding:</i>		

SECTION A: PRELIMINARY QUESTIONS			
A1	Is there a requirement for review of this project by a Research Ethics Board as part of its funding arrangements?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	Comments:		
A2	Is this a student-led project?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	Comments:		
<ul style="list-style-type: none"> If you answered Yes to any of the questions in section A, your project will require a review by the REB. If you answered No to both questions in section A, proceed to the following section. 			

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SECTION B: QUESTIONS ABOUT YOUR PROJECT			
B1	Does this project involve an evaluation of an organization, its processes, or staff to improve its performance, practices, costs, or productivity?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Comments:			
B2	Has this project been initiated by decision makers within your organization to make improvements to an existing process or policy?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Comments:			
B3	Is the primary audience of this project internal stakeholders and customers at NYGH?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Comments:			
B4	Will this project continue, if the project findings are not shared outside of the organization?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Comments:			
<ul style="list-style-type: none"> If you answered Yes to all of the questions in section B, your project is likely a Quality Improvement project and may be exempt from an REB review. Otherwise, you will need to submit your project for review by the REB. 			

SECTION C: QUESTIONS ABOUT YOUR PROJECT			
C1	Will this project involve an assessment of any equipment, device, or drug not currently supported by evidence in that application?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Comments:			
C2	Will this project involve a practice/ intervention that <u>does not fall</u> within the current standard of care?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Comments:			
C3	Will the project data be provided to an outside entity that will analyze the data and send results back to NYGH (e.g. aggregated with data results from other institutions)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Comments:			

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SECTION C: QUESTIONS ABOUT YOUR PROJECT			
C4	Will the results be shared with an outside entity (governmental agency/sponsor) that is providing financial support for the project?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Comments:			
C5	Will the results be shared for publication or presentation?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Comments:			
C6	Will the outcomes of the project be of interest or benefit to other institutions/organizations?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Comments:			
<ul style="list-style-type: none"> If you answered Yes to any of the questions in section C, your project is project may require an REB review. If you answered No to all of the questions in section C, your project is a QI project. 			

<u>PRINCIPAL INVESTIGATOR DECLARATION:</u>		
On behalf of myself and all my project team members:		
<input type="checkbox"/> I acknowledge that the information provided in above project assessment form is true and accurate.		
<input type="checkbox"/> I understand that based on my current assessment the proposed project is classified as Quality Improvement/ Quality Assurance (QI/QA) project and will not review and oversight by NYGH REB.		
<input type="checkbox"/> I understand that should any changes be made to the original project as outlined above, I should contact the Research Ethics Office for advice on whether or not the project qualifies for QI/QA project and may need a re-assessment /re-evaluation.		
<input type="checkbox"/> I acknowledge that all the members of the project team will adhere to the relevant institutional data protection, privacy and confidentiality policies and guidelines for conduct of this quality improvement project.		
Principal Investigator Name	Signature	Date

Research Ethics Office Use Only:

QI Project Number:

Project Title :

Date Submitted :

Date Reviewed:

Review Type:

Review Details:

Based on the information provided with this assessment tool, the NYGH REB review has determined that

This is a Quality Improvement /Performance Improvement / Quality Assurance project.

This appears to be a human subject research project and warrants an application to the NYGH REB.

Please provide following additional information

Chair, Research Ethics Board/ Designate

Date (dd/mm/yyyy)

Common Questions:

- **Can I access Personal Health Information for the QI projects?**

Yes, As long as you are authorized legal custodian or agent of health data used for QI project and adhere to the relevant institutional data protection, privacy and confidentiality policies and guidelines for conduct of the quality improvement project.

- **Can I access data from Shared Health Systems for the QI projects?**

NO. Shared health systems such as ConnectingOntario, OLIS, cCHN, HDIRS and IAR are **not permitted** to be used for quality improvement, service evaluation or research.

- **Can a project be both QA and Human Subjects Research?**

Yes. For example, a researcher implements a new test or treatment or new evidence based interactions to introduce change in practice. *(This is quite verbose, we need simple example)*

- **I'm not sure if my project is QA or research. Can I determine this after I begin my project?**

No. Research requires REB review and approval before the research begins. You must determine the purpose of your project at the beginning of your project. If a researcher knows at the outset that the project will be done for both QI and research purposes, REB approval is required BEFORE project starts.

- **If I intend to publish results of a true QI project, do I require approval from NYGH REB?**

No. If a journal requests ethics approval documentation, you would explain that these activities do not require institutional ethical review under Article 2.5 of the TCPS. You may use the REB issued acknowledgement reply of above assessment tool if you had approached the REB BEFORE the start of your QI project.

- **I collected data for a QA project. I now would like to use the data for research. Can I use it?**

No. This would be considered secondary use of information and may require REB review in accordance with TCPS. Please complete a NYGH REB application before proceeding with research.