

## Quality Improvement in Healthcare Certificate

Centre for Quality, Innovation, and Safety  
Schulich School of Medicine & Dentistry, Western University

### QI ETHICS EXEMPTION PROCEDURE: WESTERN UNIVERSITY

#### *CQUINS Procedure to Apply for QI Ethics Exemption at Western University*

1. Fill out the Western Research Ethics Manager QA/QI/PE form as usual - <https://applywesternrem.uwo.ca/Account/Login?ReturnUrl=%2fActivityForm%2fIndex> - noting the suggested approach to specific sections below.
2. For section 1.6, fill in and upload the QI REB Template (pg 3-4 below).

#### *Suggested Approach to Specific Sections (in blue)*

<b>Section 1.5</b>	
Provide a thorough summary of your project. Additionally, ensure to ALSO include a comprehensive explanation of: what the current standards are, what the issues are with the current standard [a.k.a Why is this project needed?] and what this project intends to improve).	This is your literature review which should capture what the current standards are, what the issues are with the current standard [a.k.a Why is this project needed?] and what this project intends to improve.
<b>Section 1.6</b>	
Upload your project plans that detail what is being done.	*The example on the WREM is very much structured for classic research.  Upload your project plan using the template that follows (below). Essentially, it forces you to truly plan the QI project. (It's work that needs to be done anyway, so no extra work required.)
<b>Section 2.4</b>	
Does the project involve a comparison to different groups, protocols, sites, or interventions, and/or control groups?	This is a yes/no question. If you answer "yes" (as many QI projects nowadays compare one team to another, for example), it excludes the project from being considered QI as per REB. *We discussed this at length with Daniel and he agrees that this comparison is essentially a

	<p>PDSA cycle (ramping towards full implementation); therefore, we propose (if your project does include a comparator) to include the following blurb at the end of the uploaded project template (1.6) until such time when the electronic form is updated, and we can make it part of the electronic version of 2.4.</p> <p><i>“Please note that Section 2.4 does not yet apply to this project; however, depending on the results of the Diagnostics phase of this project, it is likely that the impact of any proposed change ideas being trialled using Plan-Do-Study-Act (PDSA) cycles on [CTU Team 2] will be compared to the standard-of-care being provided on [CTU Team 1]. The impact of change ideas will be measured using standing quality improvement strategies and displayed as statistical process control charts. It is foreseeable that successful change ideas will be scaled up such that there are no comparator groups in the final implementation PDSA.”</i></p>
<p><b>Section 3.7</b></p> <p>Please clearly state why this project has been deemed QA/QI by the investigator.</p>	<p>According to REB, this (and 3.8 below) is a key important question. The REB's goal is to distinguish between researchers who really understand what QI is and those trying to sneak a project past as QI to avoid full ethics review. Thus, we think that it's important that this (and question 3.8) be relatively standardized across submissions. We suggest using the following:</p> <p><i>“The fundamental aim of this project is to drive immediate improvement in the safe delivery of healthcare (in this case, administration of IDSA recommended dosing of Vancomycin) within a particular setting (the Medicine Clinical Teaching Unit at University Hospital). The QI project proposed will continually evaluate and adapt in an iterative manner during each Plan-Do-Study-Act for any and all proposed change ideas. Data will be continually collected and analyzed with the intention of comparing the performance of the existing process or system to our established performance target.”</i></p>
<p><b>Section 3.8</b></p>	

Please state how the results will be used.	<i>"The results of this study will be used to enhance the quality of care proved on [Unit]. Given that there are similarities between this particular setting and those at other hospitals, this data may be of interest to other healthcare providers; however, this research would be conducted to improve the delivery of care at [London Health Sciences Centre] regardless of generalizability to other centres."</i>
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### **QI REB Work Plan**

Version 2.0 (02/13/2020)

Re Section 1.6: Upload your project work plan using the following template.

Problem Statement:
AIM Statement:
What is the justification for your target? E.g. national benchmark, institutional benchmark, care gap, local consensus
Family of Measures:  Outcome measure:  Process measures (if already defined):  Balancing measures:
Outline how you will collect this data (outcome, process, balancing measures).
Do you or your supervisor have access to software capable of developing Statistical Process Control (SPC) charts as part of your statistical analysis plan? E.g. QI Macros  Yes <input type="checkbox"/> No <input type="checkbox"/>  *If not, please contact the Centre for Quality, Innovation, and Safety (CQUINS) for assistance ( <a href="mailto:cquins@uwo.ca">cquins@uwo.ca</a> ).

Please outline your planned diagnostic tools and how you plan to execute this phase of your QI project.