Sunnybrook
HEALTH SCIENCES CENTRE

ETHICS REVIEW- SELF ASSESSMENT TOOL
ER-SAT

INTRODUCTION
A project that entails "*research on human subjects*" requires that it be reviewed by the institution's research ethics board (REB) for approval prior to its initiation. However, not all projects are "research" in their intent or design, and therefore they may be exempt from the requirement of having a formal REB review prior to initiation. Projects that are properly deemed to be either: Quality improvement (QI), educational assessments, or performance review of a specific program or system- are examples of work not requiring REB review.

PURPOSE
The following tool is intended to facilitate an individual's self assessment of their work to help determine if their project fits either a QI, Educational Assessment, or Performance Review design- and therefore not requiring a separate REB review.
Note: If your intent is to publish or present findings that are QI, Educational, or Performance in nature- this does not automatically mean the project needs REB Review. Please refer to the SQUIRES Guidelines for assistance related to the publication requirements of QI papers.

INSTRUCTION
Fill in this form by answering the questions in each section- if you require support in determining how best to answer one of these questions, please contact either the Ethics Centre (ext 4818) for support and make the appropriate notation in the review/comments box provided. Please keep a copy of this assessment tool in your project file.

Project title: Reducing the duration of post-operative antibiotics for surgical prophylaxis in lower limb arthroplasty. A quality improvement project.

Project leader name: Dr. Tosan Okoro **Date of assessment:** 25th September 2018

	Yes	No	Review/comments
A.1 Does the activity involve living human beings and/or information (data) collected from or about them?	☒	☐	
A.2 Does the activity involve human remains, cadavers, tissues, biological fluids, embryos or foetuses ***other than*** those that are commercially available?	☐	☒	

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If you answered *YES* to either question A.1 or A.2 the activity described involves human subjects but may not require review. Please proceed to section B. If you answered *NO* to both of the questions in Part A, then your project does not involve human subjects or their information, and does not require research ethics review.			
	YES	NO	**Review/comments**
B. Is the ***primary consideration*** of your project to contribute or add to a body of generalizable knowledge in the academic community? The term generalizability means that you specifically structured your project such that the results you obtained would be applicable to programs outside of the local area you did your research.(i.e. The results of your QI project are meant to apply to areas outside of the local area it was initially intended to be used. This does NOT apply to projects that will be implemented in other areas of the same organization after an initial pilot or testing phase).	☐	☒	
If you answered Yes to B- your project is probably research and you will need to apply to the REB If No, proceed to section C			
	YES	NO	**Review/comments**
C1 Is the ***primary*** intent of the activity to assess the performance of an organization, its medical staff, employees or students?	☐	☒	
C2 Is the ***primary*** goal of the activity to improve process of care or to create an intervention to meet known/accepted standards of care? (This could be a project that is mandated by your department- or part of the terms and condition of your employment)	☒	☐	
C3 Would the activity take place, regardless of whether or not the research is disseminated to those outside of the organization and other direct stakeholders?	☒	☐	
C4 Does the activity involve testing/evaluating within normal/established educational requirements? (Example- you created an educational event and you also developed an assessment tool to give to participants to help evaluate how well the event did- this would be considered an evaluation within normal educational requirements)	☐	☒	

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If you answered Yes to any question in section C your project may be considered a QI/Education or Performance Review project please complete question D below. **If you answered No to all the questions in section C-please submit your project for REB review**			
	YES	NO	**Review/comments**
D 1 Will you be randomizing participants to intervention-specific groups?	☐	☒	
D2 Will you be requiring additional testing of subjects?	☐	☒	
D3 Are subjects being exposed to non standard of care treatments or interventions?	☐	☒	
D4 Might your intervention result (directly or unintentionally) in any potential risk or harm to patients/staff?	☐	☒	
D5 Are you sampling from a larger community than your local area of responsibility (i.e. City wide, Provincial, etc sampling)?	☐	☒	
D 6 Will your project involve the use of an untested: piece of equipment, medical device or drug that is not yet supported with suitable evidence to support its use in the specific application you are proposing?	☐	☒	
If you answered Yes to any of the questions in section D, your project will need REB review **Otherwise your project will not require REB review**			
If this assessment tool indicated that your project does not require REB review, it is recommended that you print and save a copy of this document for your files. On completion of your project, and in the event that you are interested in having your project published- a notation of this assessment process can be referred to in the methodology section of your paper and submitted for review (if the journal requests further documentation).			

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Additional Consideration Not all research projects require REB review. If your research is based on one of the following (Answering Yes to any question below) conditions it is exempt from formal review.

Criteria	YES	NO	Review/comments
1 Is the activity based ***solely*** on obtaining information that is generally available to the public? Are you able to access this information by website, brochures, booklets, etc. without being a member of a group or organization, or any other formal or informal requirement? (This entails stored documentary material, records or publications which may or may not include identifiable information and that has no restrictions on its use or distribution, or that may be released under certain legal conditions)	☐	☒	
2 Does your project involve only the observation of people in public places without an intervention? (The study of behavior in a natural environment in which people involved in their normal activities are observed whether with or without their knowledge, No interaction with participants is involved, the targeted group have no reasonable expectation of privacy and the results do not allow for identification of specific individuals) [By example: A hallway, visiting room, and foyer would be considered public places. A patient's room, staff offices, surgical suites, etc. would be considered private spaces]	☐	☒	
3 Does your project rely exclusively on data 1) that was initially collected for a different purpose than your current project (i.e. your project would involve "secondary use" of the data)? **And** 2) Was the data given to you as anonymous information or anonymous human biological materials (Anonymous information refers to information that from your perspective never had identifiers associated with it- and also that the collected information will not be linked with other data sets that may render the information identifiable in the future).	☐	☒	