



RESEARCH VERSUS QUALITY IMPROVEMENT GUIDELINE & CHECKLIST

The SHN Research Ethics Board (REB) primary purpose is to protect the rights, safety and wellbeing of human participants involved in research at the hospital. The REB is also responsible for ensuring research protocols meet the current safety, scientific, ethical and privacy standards and to ensure all research activities are aligned with the best interest of SHN.

In order to maintain those responsibilities, all research and QI should be submitted to the SHN Research office, which will ensure that proper procedures are maintained. Research must be submitted to the REB for approval through the REB application process. For QI, the summary of the project should be submitted and the research office will provide a REB waiver for projects that meet the QI criteria.

PURPOSE:

There is quite often confusion about what is considered a quality improvement initiative (QI) and what is considered research that requires Research Ethics Board (REB) approval. In order to address this confusion and ensure the ongoing protection of our patients and their personal health information, the SHN REB has developed this guideline and checklist to assist innovators and researchers to determine if their project is QI or Research.

RESEARCH AND QUALITY IMPROVEMENT:

The key difference is QI is applied intervention while in research you are looking at the safety and efficacy of the intervention. QI is more administration and research is clinical. In addition, QI projects and clinical research are treated differently under PHIPA, which states QI projects don't need to go to REB for approval

Research is any systematic investigation to establish facts, principles or generalizable knowledge which involves human participants (including patient data), biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells (from living and deceased individuals).

Quality Improvement is “an activity where the primary purpose is to monitor, evaluate or improve the quality of health care delivered by a health care provider (an individual, a service or an organization).”¹

CHECKLIST: DOES YOUR PROJECT REQUIRE REB REVIEW? ²

Questions	Yes	No	Comments
1. Is the project being referred to as research or a research project by anyone else? Do you consider it research?	<input type="checkbox"/>	<input type="checkbox"/>	
2. Is the project funded in anyway? Is there any money being given for this project? Either by a grant/award or sponsor?	<input type="checkbox"/>	<input type="checkbox"/>	
3. Does the project involve the use of an experimental medical device, drug or natural health product which requires approval from Health Canada or another regulatory body?	<input type="checkbox"/>	<input type="checkbox"/>	
4. Does the project involve randomization of participants into different groups to compare interventions?	<input type="checkbox"/>	<input type="checkbox"/>	
5. Is there a risk to the participants beyond the standard of care (SOC) and/or best evidence that they are receiving?	<input type="checkbox"/>	<input type="checkbox"/>	
6. Does the project involve the collection and retention of tissue or blood samples, DNA beyond SOC?	<input type="checkbox"/>	<input type="checkbox"/>	
7. Does the project involve participants receiving interventions beyond SOC?	<input type="checkbox"/>	<input type="checkbox"/>	
8. Is the purpose to publish in a peer-reviewed research journal?	<input type="checkbox"/>	<input type="checkbox"/>	

¹ National Health & Medical Research Council, *When does quality assurance in health care require independent ethical review?* Endorsed 20 February 2003, Australia.

² Adapted from St. Joseph's Health Center, *Research versus Quality Improvement Checklist*, 2014 and the Ottawa Health Science Network Research Ethics Board, *Is your project Research or Quality Improvement? Checklist*, 2016

Checklist Results:

Upon completion, if yes is checked for any of the questions above, then the project



requires REB review.

All projects should be sent to the Research Office for review. The final authority on whether a project requires REB approval always lies with the REB Chair.

QI projects will be given a letter from the REB chair stating that their project is considered to be QI and therefore does not require REB review.

References:

Alberta Research Ethics Community Consensus Initiative (ARECCI) Network, *ARECCI Ethics Screening Tool*, 2005, revised 2013.

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement 2 (TCPS2), Ethical Conduct for Research Involving Humans*, December 2010.

Casarett; Jason H.T. Karlawish; Jeremy Sugarman. *Determining When Quality Improvement Initiatives Should Be Considered Research: Proposed Criteria and Potential Implications*. Journal of American Medical Association. 2000;283 (17):2275-2280.

Ottawa Health Science Network Research Ethics Board, *Is your project Research or Quality Improvement? Checklist*, 2016

National Health & Medical Research Council, *When does quality assurance in health care require independent ethical review?* Endorsed 20 February 2003, Australia.

St. Joseph's Health Center, *Research versus Quality Improvement Checklist*, 2014