WINDSOR REGIONAL HOSPITAL
OUTSTANDING CARE – NO EXCEPTIONS!

WINDSOR REGIONAL HOSPIAL RESEARCH ETHICS BOARD
GUIDANCE ON CASE REPORTS

All research projects carried out at all sites within Windsor Regional Hospital require the approval of the Research Ethics Board (REB). The purpose of this document is to provide guidance and differentiate when a case report meets the criteria for REB exemption or constitutes human subjects research and thus requires a REB Review.

A case report describes the course of medical treatment, a unique outcome, or a unique case. Whereas research, as defined by TCPS 2 Chapter 2, is defined as "an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation." In general, case reports are unique accounts of individual cases noted during regular practice. These reports are not initiated as inquiry/investigation, nor are these cases meant to be generalizable.

Key Eligibility for REB Exemption:

- Three or less participants are involved; AND
- The case report(s) will not be used to answer a research question. There is no intent to conduct research/answer a research question/hypotheses from the outset of case report; AND
- The results will not be generalized and no statistical analysis will be performed; AND
- There is no intention to test various therapies/treatments/interventions prospectively or retrospectively.
- Teaching cases (i.e. academic rounds, presentations, requiring teaching notes, written as a "story") are exempt from ethics review if the 'intent or purpose' of a teaching case report study is for educational or learning purposes rather than research.

If all of these requirements are not met, a REB review would be required.

Additional Key Requirements for Case Reports

- In line with WRH and WRH REB policies, the WRH REB expects that the patient or their family member/substitute decision maker will be informed of, and consent to, the investigator's plans to create and publish (if applicable) a case report.
- Assent will be obtained for those that have the capacity to assent, where the family members/substitute decision maker has already obtained consent.
- No direct personal information (PI) or Personal Health Information (PHI) should be used (i.e. direct includes name, address, MRN or any other information unique to the patient) and indirect PI and PHI should be VERY limited (i.e. indirect includes age, gender, occupation, or any other information that can be used in combination to re-identify the patient). All measures will be taken to minimize the risk of re-identification through publication.
- All images/photographs will be de-identified (i.e. redacted name, medical record number, DOB etc.) and do not include pictures with faces/facial features.
- Data related to case reports will not be shared outside of report team members.

- Students/Residents/Fellows ensure that case reports are co-authored by a qualified physician, who has appropriate credentials and is aware of, and shall make all reasonable efforts to, comply with the applicable laws, guidelines, policies, and professional obligations.

Case Report vs. Research

	CASE REPORT (REB approval NOT needed)	**RESEARCH** (REB approval needed)
Medical Record Review	Three or fewer patients	Reviewing four or more patient records would meet the definition of research (disciplined inquiry or systematic investigation to extend knowledge or a case series).
Clinical Treatment	Each patient is treated as clinically indicated - treatment is not directed by a research protocol nor are specific research interventions/interactions required.	**Clinical Trials:** Research protocol dictates how all patient/subjects are treated. Specific research interventions/interactions scheduled. **Other research (e.g. retrospective review of clinical records):** treatment occurs clinically or as part as part of REB approved protocol.
Generalizability	NOT GENERALIZABLE or scientifically rigorous. Information is considered to be educational by sharing a very limited number of interesting cases (3 or less) and how they were treated. No statistical analysis.	GENERALIZABLE. Hypotheses can be proved/disproved. Data is collected and analyzed in a rigorous manner (may include statistics).

Should there be any uncertainty or concerns, investigators are advised to consult with the WRH REB. Inquiries should be emailed to research.ethics@wrh.on.ca.

Should a journal require documentation of REB exemption/waiver of review prior to publication for a case report of three or less patients, please provide the journal with a copy of this guidance document.

References:
1. TCPS 2: https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter2-chapitre2.html#a