UHN REB GUIDANCE ON CASE REPORTS

Background

The purpose of this document is to provide guidance on when publication/presentation of case report(s) constitutes human subjects research and requires prospective REB review. The Tri-Council Policy Statement defines *research* as "an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation." A case report is a description of (a) the course of medical treatment with one or more patients that has a unique outcome or (b) the handling of a unique clinical case; which in either case did not involve the investigator having any research intent at the time of the intervention [i.e., no prospective plan to systematically evaluate the outcome for purposes other than treating the particular patient(s)]. A case report simply describes the course of medical treatment, a unique outcome, or a unique case. In an academic teaching hospital it is not unusual for unique and interesting clinical cases to be written up as case reports for publication in medical journals or presentation at medical or scientific meetings.

UHN REBs' Position on Case Reports

A case report with three or fewer patients does not meet the definition of research on the basis that the information in the case report has not been obtained through a systematic investigation and was not collected with a prior research intent. Furthermore, the information presented in a case report is not considered to be generalizable. Therefore, case studies that involve three or fewer patients do not require UHN REB review.

Conversely, if anything was done in the course of care with a research intent, the case report becomes research. If more than three patients are included in the project, it becomes a case series, is considered research, and requires UHN REB review and approval.

The UHN REB expects that patients will be made aware that the author / investigator plans to create a report which may be published, about their case. Patients or their family members/substitute decision makers should provide written consent to have the patients' personal health information included in a case report. Clinicians should be sensitive to the "small cell problem": the existence of individuals with such unique or unusual diagnoses or illnesses, that it might be possible for others (or patients and families themselves) to identify the individuals in case reports or medical text books based upon limited information, such as city of residence, age and diagnosis.

The UHN REB does not grant "retroactive" approval after research is done. Researchers are advised to consult with the REB when uncertainty exists and when formal and systematic collection of human subjects' research will be occurring.

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).
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.
Generalizable?	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).

NOTE: Investigators asked by a journal to provide documentation of REB approval or REB waiver for approval prior to publication for a case report of three (3) or less patients should provide the journal with a copy of this UHN REB guidance document.