Queen’s REB Guidelines on Case

Purpose

The purpose of this guideline is to:

A research case report and chart review studies are required to be submitted for approval from the REB before the case report/chart review begins (i.e. before consenting the participant).

Types of case report studies that do not require REB approval

Teaching case report studies:

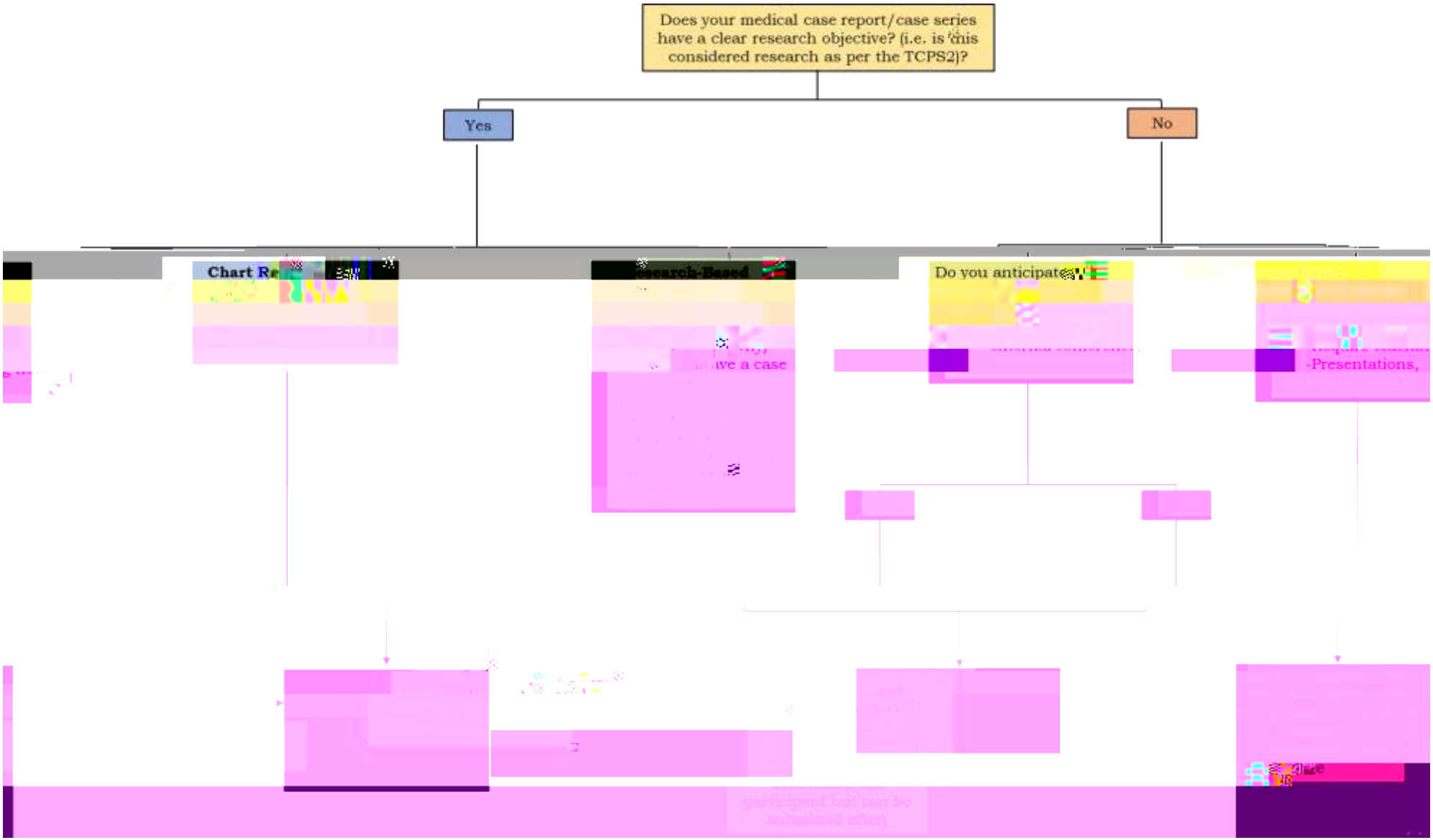
Teaching cases are exempt from ethics review based on the TCPS2, Article 2.5. The 'intent or purpose' of a teaching case report study is for educational or learning purposes rather than research and, therefore, does not fall under the scope of the TCPS 2. A teaching case report will satisfy the following:

- It would be written as a "story."
- It would be written to support problem-based learning.
- It would require teaching notes.
- It would value practical implications more than theoretical knowledge.

Decision Tree for determining what requires REB approval

Please see the decision tree below to determine if submission to the REB is required. Note: Queen's REBs will not issue a retroactive approval. If REB review is required, submission and approval by the REB are required before the participant consents and data is collected. If REB exemption is required, ideally this application is submitted prior to consenting and collecting data, but may be submitted after for an exemption letter.

Any non-


Does your medical case report/case series have a clear research objective? (i.e. is this considered research as per the TCPS2)?
Yes
No
Chart Re
Research-Based
ve a case
Do you anticipate
-Presentations,

Critical considerations for research case report studies

Consent will be obtained from the participant, parent/legal guardian/substitute decision maker. Use of the Queen's REB consent form template for case studies is required. The case report consent form template will be used to obtain consent (a qualified physician must also sign the consent form if the report is being authored by students/residents/fellows).

There is no intention to test various therapies/treatments/interventions prospectively or retrospectively.

Assent will be obtained for those who can assent, where consent has already been obtained by the parent/legal guardian/substitute decision maker.

The consent/assent process will be documented and kept on file for 5 years per Queen's University guidelines.

Justification of personal information/Personal Health Information (PHI) is required. It is best practice to limit the information collected (e.g., age, gender) (i.e., not using the full date of birth (DOB)/date of death (DOD) or any other information used in combination could lead to the identification of individuals). All measures will be taken to minimize the risk of re-identification through publication from the participant/friends/family members.

All images/photographs will be de-identified (i.e., do not include name, medical record number, DOB) and do not include pictures with faces/facial features.

The investigator, sub-investigators, or anyone connected to them through their interpersonal relationships (including their partners, family members, or former or current professional associates) will not receive any personal financial benefit from the report.

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

A TRAQ DSS form has been submitted to obtain hospital approval.

Approval has been obtained from your departmental res-Ő