Waiver of Informed Consent

Article 5.5A

This study qualifies for a waiver of consent according to Article 5.5A of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans—TCPS 2 (2022) because:

A. Identifiable information is essential to the research;
    a. No directly identifiable information will be collected. Only the ***quantitative codebook variables*** will be exported from the NB Trauma Registry. These variables are essential to answering the research question, conducting the inclusion and exclusion criteria, and capturing the outcome variables. Moreover, this information will be presented as aggregate data and not as a "patient profile" or on a patient-by-patient basis.
B. The use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
    a. The use of this information will not adversely affect the individuals to whom the information relates because it will be presented as non-identifiable information.
C. The researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable information;
    a. All information collected in this study will be exported into an excel file that will be stored on the Q Drive of a Horizon laptop that is password protected and requires a closed network or VPN connection for the file to be accessed. The Excel file will be accessible to the Horizon employees developing this project. The data will continue to be stored in this manner for a minimum of seven years. These data protection and storage steps will ensure all information is appropriately managed and stored while fulfilling our commitment to our confidentiality obligations.
D. The researchers will comply with any known preferences previously expressed by individuals about any use of their information;
    a. There are no known preferences expressed by the included individuals.
E. It is impossible or impracticable to seek consent from individuals to whom the information relates;
    a. It is impossible to seek consent from individuals included in this study as there is no contact information for the patients in the NB Trauma Registry.
F. The researchers have obtained any other necessary permission for secondary use of information for research purposes.
    a. It is within Trauma NB's mandate and policies to use the Trauma NB Registry for research purposes, for which this study satisfies those requirements.