Inclusion of Pediatric Patients

Article 3.9

For research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB shall ensure that, as a minimum, the following conditions are met:

A. The researcher involves participants who lack the capacity to decide on their own behalf to the greatest extent possible in the decision-making process.
    a. While receiving ongoing patient consent and involving participants in the decision-making process is a fundamental ethical requirement in most research studies, it is impractical to seek and involve participants who lack the capacity to decide on their own behalf in the decision-making process of the research study for two reasons. 1. No directly identifiable information is collected, and 2. Patient contact information does not exist in the NB Trauma Registry.
    b. Additionally, this study satisfies the requirements 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:
        i. 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 answer the research question, conduct the inclusion and exclusion criteria, and capture 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.
        ii. 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.
        iii. All information collected in this study will also 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 ensure all information is appropriately managed and stored.
        iv. There are no known preferences expressed by the included individuals.
        v. 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.
        vi. 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.
    c. It is also worth noting that 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.
B. The researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned.
    a. It is impractical to seek and maintain participant consent from authorized third parties in accordance with the best interest of the persons concerned in the context of this study, as this study satisfies the requirements 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:
        i. 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 answer the research question, conduct the inclusion and exclusion

criteria, and capture 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.

ii. 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.

iii. All information collected in this study will also 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 ensure all information is appropriately managed and stored.

iv. There are no known preferences expressed by the included individuals.

v. 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.

vi. 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.

C. The authorized third party is not the researcher or any other member of the research team.

a. Under no circumstances will participant's data be shared with a third party that is not the researcher or any other member of the research team. If a need for this arises, an amendment to this ethics approval will be sought before moving ahead.

b. Additionally, 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:

i. 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 answer the research question, conduct the inclusion and exclusion criteria, and capture 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.

ii. 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.

iii. All information collected in this study will also 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 ensure all information is appropriately managed and stored.

iv. There are no known preferences expressed by the included individuals.

v. 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.

vi. 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.

D. The researcher demonstrates that the research is being carried out for the participant's direct benefit, or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the

participant to only a minimal risk and minimal burden and demonstrate how the participant's welfare will be protected throughout the participation in research.

a. The research being carried out is not for the participants direct benefit but rather for the benefit of other persons in the same category. The only threat to participants' is the unlikely event of a data breach. In the instance a data breach occurs, participants are exposed to a minimal risk and minimal burden. Importantly, however, directly identifiable information is not exported from the NB Trauma Registry. This information will be presented as aggregate data and not as a "patient profile" or on a patient-by-patient basis; therefore, in the unlikely event of a data breach, it would not adversely affect the individuals to whom the information relates because it will be presented as non-identifiable information.
b. To maintain the protection of the data and protect the welfare of participants, 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 the commitment to the confidentiality obligations.

E. When authorization for participation was granted by an authorized third party, and a participant acquires or regains decision-making capacity during the course of the research, the researcher shall promptly seek the participant's consent as a condition of continuing participation.

a. Under no circumstances will authorization for participation be granted by an authorized third party, nor will a participant acquire or regain decision-making capacity during the research. Moreover, the researcher will not promptly seek the participant's consent as a condition of continuing participation. If a need for this arises, an amendment to this ethics approval will be sought before moving ahead.
b. Additionally, 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:
    i. 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 answer the research question, conduct the inclusion and exclusion criteria, and capture 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.
    ii. 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.
    iii. All information collected in this study will also 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 ensure all information is appropriately managed and stored.
    iv. There are no known preferences expressed by the included individuals.
    v. 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.

vi. 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.

Article 3.10

Many individuals who lack legal capacity to make decisions may still be able to express their wishes in a meaningful way, even if such expression may not fulfill all the requirements for consent. Prospective participants may be capable of verbally or physically assenting to, or dissenting from, participation in research. Those who may be capable of assent or dissent include:

a. Those whose decision-making capacity is in the process of development, such as children whose capacity for judgment and self-direction is maturing.
b. Those who once were capable of making an autonomous decision regarding consent but whose decision-making capacity is diminishing or fluctuating; and
c. Those whose decision-making capacity remains only partially developed, such as those living with permanent cognitive impairment.

It is impractical to involve individuals who lack legal capacity in the decision-making process of the study, as this study satisfies the requirements 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:

Article 4.6

Subject to applicable legal requirements, individuals who lack capacity to decide whether to participate in research shall not be inappropriately excluded from research. Where a researcher seeks to involve individuals in research who do not have decision-making capacity, the researcher shall, in addition to fulfilling the conditions in Articles 3.9 and 3.10, satisfy the REB that:

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 answer the research question, conduct the inclusion and exclusion criteria, and capture 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 this information will not adversely affect the individuals to whom the information relates because it will be presented as non-identifiable information.
c. All information collected in this study will also 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 ensure all information is appropriately managed and stored.
d. There are no known preferences expressed by the included individuals.
e. 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. 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.
g. The research question can be addressed only with participants within the identified group;
h. The research does not expose the participants to more than minimal risk without the prospect of direct benefits for them; or
i. Where the research entails only minimal risk, it should at least have the prospect of providing benefits to participants or to a group that is the focus of the research and to which the participants belong.

The research being carried out is not for the participants direct benefit but rather for the benefit of other persons in the same category. As such, data of participants within the identified group is needed to address the research question. The only threat to participants' is the unlikely event of a data breach. In the instance a data breach occurs, participants are exposed to a minimal risk. Importantly, however, directly identifiable information is not exported from the NB Trauma Registry, only the ***quantitative codebook variables*.** This information will be presented as aggregate data and not as a "patient profile" or on a patient-by-patient basis; therefore, in the unlikely event of a data breach, it would not adversely affect the individuals to whom the information relates because it will be presented as non-identifiable information. To maintain the protection of the data and protect the welfare of participants, 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 the commitment to the confidentiality obligations.