661 University Avenue, Suite 460
MaRS Centre, West Tower
Toronto, Ontario
M5G 1M1 Canada
www.ctontario.ca

Documented Institutional Ethics Requirements
Bruyère Research Institute

Informed Consent Form Requirements (not applicable to studies reviewed by OCREB)

REMOVE CURRENT LANGUAGE AND ADD THE FOLLOWING:

1. **Reproductive Risks**

   If there are potential or known reproductive risks associated with the research, the following text must be used as the template for the centre consent forms in the 'What are the reproductive risks" section:

   If there are risks related to being or becoming pregnant or getting someone pregnant:

   The effects that the study drug(s) may have on eggs (ova), sperm, or on an unborn baby (fetus) are unknown/detail the known risks. You should not become pregnant or get someone pregnant while taking the study drug(s).

   Participants who are able to become pregnant or produce sperm must agree to both of the following while taking the study drug(s) and for length of time afterward: i) not to get pregnant or get someone pregnant and ii) to use an appropriate family planning method as discussed and decided upon in consultation with a study investigator.

   If you become pregnant or get someone pregnant while taking the study drug(s) or for length of time afterward, you should immediately notify the study investigators, who will discuss next steps with you.

   If there are risks related to being or becoming pregnant:

   If you are able to become pregnant, a study investigator will order a blood/urine pregnancy test prior to the start of your participation in this study to confirm that you are not pregnant. To confirm that you have not become pregnant during the study, blood/urine pregnancy tests will be done throughout your participation in the study.

   If the participant will be asked to consent to allow the study team to follow a pregnancy that occurs during this study:

   If you become pregnant or get someone pregnant while you are taking the study drug, the study team may ask if you/the person who is pregnant would be willing to provide information about the pregnancy as part of this study. A separate consent document will be used to request permission to collect this information. You/The person who is pregnant may choose not to give consent for the collection of this information or may withdraw consent at any time without giving a reason. This decision will not affect your participation in this study and will not affect the health care that any person receives at Unity Health Toronto.

   If there are risks to a nursing infant:

   You should not nurse (breastfeed or chestfeed) an infant while in this study because the study drug(s) may be present in your milk and could be harmful to a nursing infant.

   If there are risks to future reproductive ability:

   The drug(s) used in this study may affect your ability to reproduce (become pregnant or produce sperm) in the future. A study investigator will discuss this with you.

2. **Participant questions**

   If you have any ethical concerns about the study, or the way it is conducted, please contact the Bruyère REB: REB@bruyere.org.

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Patient Enrollment

Studies to establish a database/registry/biobank should not be submitted through CTO Stream. These types of studies require local REB review and approval.

Research sites under Bruyère Research Institute's Auspices:

- Elisabeth Bruyère Hospital – 43 Bruyère St, Ottawa, ON K1N 5C8
- St. Vincent Hospital - 60 Cambridge St. N. Ottawa, ON K1R 7A5
- Bruyère Village
  - Besserer Place and The Villas - 889 Hiawatha Park Rd. Orléans, ON K1C 0A9
  - Saint-Louis Residence - 879 Hiawatha Park Rd. Orléans, ON K1C 2Z6
- Greystone Transitional Care Unit -225 Scholastic Dr. Ottawa, ON K1S 5W2

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SRERS Administration
Bruyère Research Institute

Reminder: Institutional Research Administration Requirements

The CTO Streamlined System provides a streamlined approach to research ethics review. Each participating site must ensure that all necessary institutional authorizations and contracts/agreements are in place prior to beginning the research.

CTO Stream

Collaborators:

The following collaborators must be given a role on all Provincial Initial Application (PIA) forms and Centre Initial Application (CIA) forms.

Email: hniezgoda@bruyere.org
Role: Institutional Representative

This access is automatically granted when the Centre Initial Application is created. **When Bruyère Research Institute is the Provincial Applicant site the research team should immediately create the CIA for Bruyère Research Institute (right after creating the PIA)**. This will ensure that access is automatically granted as required above, otherwise the research team will need to manually add these roles to the PIA prior to submission.

Department Approver in application forms

The Department Approver on the CIAs for Bruyère Research Institute must be indicated as follows:

Title:	Ms.
First Name:	Trish
Surname:	DeFazio
Organization:	Bruyère Research Institute
Address:	43 Bruyère Street
City:	Ottawa
Province/State:	Ontario
Postcode/Zip:	K1N 5C8
Telephone:	613-562-6262 ext. 2902
Fax:	N/A
Email:	TDeFazio@bruyere

Institution Representative in application forms

The Primary Institution Representative must be indicated as follows in the applications within CTO Stream:

Title:	Ms.
First Name:	Helen
Surname:	Niezgoda
Organization:	Bruyère Research Institute
Address:	43 Bruyère Street
City:	Ottawa
Province/State:	Ontario
Postcode/Zip:	K1N 5C8
Telephone:	613 562-6328

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Fax: N/A
Email: hniezgoda@bruyere.org

The Secondary Institution Representative should be left blank.