

Documented Institutional Ethics Requirements Ornge

Scope

Ornge's core business is providing timely patient transportation involving a range of paramedical services, by air and by land, including:

- Emergent and urgent interfacility transport
- Emergent scene response
- Repatriation of interfacility patients
- Non-urgent transport based on geographic and population needs
- Support for healthcare in remote communities through new and innovative approaches
- Provincial Transfer Authorization Centre (PTAC) authorization in support of public health objectives
- Transportation related to organ transplant

Missions and Values

Mission: to save lives, restore health, create capacity, and preserve dignity

Vision: the best care, wherever you may be

Values: kindness, respect, integrity, safety, professionalism

Privacy Considerations

Ornge's collection, use, retention and disclosure of personal information is regulated by two main Ontario statutes: the *Personal Health Information Protection Act, 2004* (PHIPA) and the *Freedom of Information and Protection of Privacy Act, RSO 1990* (FIPPA). For more information, please visit [Ornge - Privacy and Information](#) on our website.

Informed Consent Form Requirements

Informed consent (written/verbal) is obtained from patient/SDM for administration of blood products. It can be acquired by sending facility or Ornge crew (if possible).

Access to Medical Records and Obtaining Consent

As part of the requirements for research projects accessing medical records (e.g. chart review), data will not be collected, nor will it be transferred, until the research ethics board ("REB") or REBs of choice has/have: a) approved the Study protocol; and b) approved the Study informed consent forms or waived the requirement to obtain consent.

SRERS Administration Ornge

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.

Ornge has established a Research Approval Policy & Procedure to clarify the application, review and approval process for clinical research studies in which Ornge participates. Each study must include an Ornge-affiliated Physician or Ornge employee as part of the research team either as a Principal Investigator or a Site-Investigator:

- (1) Either the Principal Investigator for the study or the Site-Investigator who will be responsible for Ornge's participation in the study ("Researcher") must submit a brief description of the proposed study to **Research and Scholarly Activities Committee ("RSAC")** at research@ornge.ca.
- (2) Once received, the RSAC will review the submission and advise on the design and scientific merit of the study. Then RSAC will either ask the Researcher to revise his or her proposal or approve the study in concept.
- (3) If the RSAC approves a study in concept, it will also direct the Researcher on how to proceed to the next step of approvals:
 - a. If the study involves the alteration of an existing standard of care, Researcher must also seek Medical Advisory Committee (MAC) and Chief Medical Officer (CMO) approvals.
 - b. If the study involves Ornge employees or their personal information as subjects, Researchers must receive Chief Human Resource Officer (CHRO) and Chief Operations Officer (COO) approvals.
- (4) If required, Researcher works with Research Coordinator and/or Ornge Legal to enter into contracts regarding:
 - a. Clinical Research Data Sharing Agreement
 - b. Use of Ornge Personally-Identifiable Information for Research Agreement
 - c. Clinical Trial Agreements – for drugs
 - d. Publication & intellectual property rights
 - e. Funding agreements, etc.
- (5) Final RSAC approval will be granted after the completion of study protocol, receiving REB approval, and all other approvals – as mentioned above.

If you have any questions or need any further information regarding Ornge's Research Approval Policy and Procedure, please contact research@ornge.ca

CTO Stream

Collaborators:

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

Name: Bruce Sawadsky

Email: bsawadsky@ornge.ca

Role: Institutional Representative

Name: Brodie Nolan

Email: bnolan@ornge.ca

Role: Institutional Representative

Name: Mahvareh Ahghari

Email: mahghari@ornge.ca

Role: Institutional Representative

This access is automatically granted when the Centre Initial Application is created. **When Ornge is the Provincial Applicant site the research team should immediately create the CIA for Ornge (right after creating the PIA).**



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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.

Institution Representative in application forms

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

Title: Dr.
First Name: Bruce
Surname: Sawadsky
Corporate Title: Chief Medical Officer
Organization: Ornge
Address: 5310 Explorer Drive
City: Mississauga
Province/State: Ontario
Postcode/Zip: L4W 5H8
Telephone: 647.428.2033
Fax: 647.428.2006
Email: bsawadsky@ornge.ca

The Secondary Institution Representative field should be left blank.