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

# Documented Institutional Ethics Requirements
# Mehren Kidney Research Inc.

## Scope

Mehren Kidney Research Inc. is an independent clinical research organization specializing in nephrology and related therapeutic areas. The site conducts both industry-sponsored and investigator-initiated clinical trials, with a focus on advancing treatments for kidney disease and complement-mediated conditions. Our scope includes Phase II–IV interventional studies, observational research, and patient registry projects.
Research activities are carried out by a qualified multidisciplinary team led by experienced investigators, with full adherence to Health Canada regulations, ICH-GCP guidelines, and Research Ethics Board (REB) requirements. Our site infrastructure supports participant recruitment, clinical trial management, regulatory compliance, and data integrity, ensuring that high-quality research contributes to both patient care and scientific advancement.

## Missions and Values

**Mission**
Our mission is to improve the lives of patients living with kidney disease and related disorders by conducting ethical, high-quality clinical research that advances access to innovative therapies. We are committed to bridging clinical practice with scientific discovery while safeguarding participant rights, safety, and well-being.

**Values**

- **Integrity:** We uphold the highest standards of ethical conduct, scientific rigor, and regulatory compliance.
- **Respect:** We treat all participants with dignity and ensure their rights and privacy are protected.
- **Excellence:** We deliver accurate, reliable research through trained, qualified staff and robust clinical practices.
- **Collaboration:** We partner with patients, families, healthcare providers, sponsors, and regulators to advance research in nephrology.
- **Innovation:** We embrace new scientific and clinical approaches that can accelerate discovery and improve outcomes.

## Privacy Considerations

Mehren Kidney Research Inc. complies with Ontario's *Personal Health Information Protection Act* (PHIPA) and all applicable privacy regulations. Personal Health Information (PHI) is accessed, collected, used, and disclosed only as necessary for study purposes and always through REB-approved processes. Safeguards include:

- Limiting access to PHI to authorized study staff.
- Password-protected, encrypted, and auditable electronic systems.
- Locked and access-controlled storage for paper records.
- Separation of identifiers from study data.
- Mandatory training for all staff in confidentiality and privacy protection.

## Informed Consent Form Requirements

The informed consent forms used at this site are developed in accordance with Health Canada regulations, ICH-GCP guidelines, and applicable institutional and privacy requirements. All ICFs undergo review and approval by the Research Ethics Board (REB) prior to use.
The REB-approved ICFs:

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- Clearly describe the purpose of the study, study procedures, potential risks, and possible benefits in plain language.
- Emphasize voluntary participation and the right to withdraw without impact on clinical care.
- Outline protections for confidentiality and privacy.
- Disclose any compensation, conflicts of interest, and provide emergency contact information.
- Require signatures from the participant (or Substitute Decision Maker, if applicable) and the individual obtaining consent before any study activities begin.

Participants and/or SDMs will always be given adequate time to review the ICF, ask questions, and consult with family or advisors before providing consent.

## Access to Medical Records and Obtaining Consent

Authorized study personnel will access participants' medical records only for eligibility screening, study conduct, and safety monitoring, as approved by the REB and in compliance with Ontario's *Personal Health Information Protection Act (PHIPA)*. Access will be limited, documented, and restricted to individuals on the Delegation of Authority Log.

Informed consent will be obtained using REB-approved consent forms in a private setting by the Principal Investigator, a Sub-Investigator, or a delegated Clinical Research Coordinator. Consent discussions will be conducted respectfully and without coercion, and participants/SDMs will be provided sufficient time to decide. Documentation of consent will be maintained both in the study file and participant source records as required.

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# SRERS Administration
# Mehren Kidney Research Inc.

**Reminder: Institutional Research Administration Requirements**

Mehren Kidney Research Inc. ensures that all required institutional authorizations, contracts, and study-specific agreements are fully executed prior to study initiation. The Principal Investigator and site administration are responsible for confirming that regulatory approvals, site agreements, and financial contracts with the sponsor are in place before research activities begin. No study-related procedures will be conducted until these requirements are satisfied.

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 the initial study-wide application, called the Clinical Trial Initial Application (CTIA), or Observational Study Initial Application (OSIA) and the Participating Site Initial Application (PSIA):

Email: andrew@tkmrp.com
Role: Institutional Representative

Email: hitmehta@yahoo.com
Role: Institutional Representative

This access is automatically granted when the Participating Site Initial Application is created. **When Mehren Kidney Research Inc. is the Lead Applicant site the research team should immediately create the PSIA for Mehren Kidney Research Inc. (right after creating the new study)**. This will ensure that access is automatically granted as required above, otherwise the research team will need to manually add these roles to the CTIA/OSIA 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: | Hitesh |
| Surname: | Mehta |
| Organization: | Mehren Kidney Research Inc. |
| Address: | 215 Delta park Blvd. Unit 8 |
| City: | Brampton |
| Province/State: | Ontario |
| Postcode/Zip: | L6T 0H9 |
| Telephone: | 416-254-3030 |
| Fax: | 289-498-1925 |

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Email: hitmehta@yahoo.com

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

Title: Mr.
First Name: Andrew
Surname: Hussain
Organization: Mehren Kidney Research Inc.
Address: 215 Delta park Blvd. Unit 8
City: Brampton
Province/State: Ontario
Postcode/Zip: L6T 0H9
Telephone: 416-456-8970
Fax: 289-498-1925
Email: andrew@tkmrp.com