

Privacy Policy

Your Privacy

Your Privacy is important to us. We will respect your privacy through the protection of your Personal Information.

The following outlines our Privacy Policy:

Purpose and Consent

Before collecting Personal Information from you, we will explain to you the purpose of collecting it and we will only collect, use and disclose your Personal Information with your consent, except where otherwise permitted or required by law.

You may withdraw your consent to our collection, use and disclosure of your Personal Information at any time, subject to legal or contractual restrictions and reasonable notice. If you withdraw your consent, the implications of such withdrawal may be that we are not able to allow you to participate in a study. To withdraw your consent, simply contact us and advise us of what Personal Information you no longer wish us to collect, use or disclose.

Limiting Collection

Our collection of Personal Information is limited to what is reasonable under the circumstances and your information will be used only for the purpose for which it is collected.

Security

Cetero Research – Mississauga takes all reasonable precautions to ensure that your personal information is kept confidential and secure and is not disclosed to anyone outside our company without your consent, unless required by law. Our safeguards include physical measures (locked records rooms, restricted access to our office, alarm systems), technological tools (passwords, encryption, firewalls), and organizational controls (security clearances, limiting access on a 'need-to-know' basis, staff training, confidentiality agreements). We will ensure training of all Cetero-Research Mississauga employees that may have access to your personal information on our privacy policy and applicable regulations.

Despite having these controls in place, if it is discovered that your personal health information has been stolen, lost, or accessed by unauthorized persons, you will be notified at the first reasonable opportunity.

Access

You have the right to access your own Personal Information and to request that any inaccuracies be corrected.

What is Personal Information?

Personal Information is any information that identifies you, or by which your identity could be deduced. Data we collect with personal identifiers removed (so that it is impossible to determine the identity of the person to whom the information relates) is not considered Personal Information.

The 10 Privacy Principles

Since Cetero Research – Mississauga is committed to maintaining the confidentiality, accuracy and security of your Personal Information, we have adopted the 10 principles forming part of the Personal Information Protection and Electronic Documents Act (PIPEDA), which governs the collection, use and disclosure of Personal Information.

1. **Accountability:** All Cetero Research – Mississauga associates are responsible for maintaining and protecting all Personal Information under their control. Cetero Research – Mississauga has designated an individual to oversee our compliance with PIPEDA and our Privacy Principles.
2. **Identifying Purposes:** We will identify the purposes for which Personal Information is collected, either before or at the time of collection.
3. **Consent:** We will only collect, use and disclose your Personal Information with your consent, except where otherwise permitted or required by law.
4. **Limiting Collection:** We will limit the collection of your Personal Information to only those details which are necessary for the purposes identified.
5. **Limiting Use, Disclosure and Retention:** Your Personal information will only be used or disclosed for the purpose for which it was collected, unless you have otherwise consented, or when it is required or permitted by the law. We will only retain your Personal Information for the period of time required

to fulfill the purposes for which it was collected or for the period of time required by law.

6. Accuracy: We will keep Personal Information we collect as accurate, complete and up-to-date as necessary to fulfil the purpose for which it was collected.
7. Safeguards: We will protect the Personal Information we collect with security safeguards appropriate to the sensitivity of the information.
8. Openness: Information about our policies and practices relating to the management of Personal Information will be made readily available to you.
9. Access: You may request access to your Personal Information at any time to review its content and accuracy and have it amended as appropriate. If your information is not accurate or complete, please contact us to have it changed.
10. Challenging Compliance: You may contact us with any questions, complaints or suggestions with respect to our Privacy Principles.

Collecting Your Personal Information

Cetero Research – Mississauga may collect personal information, with your consent, when you:

- Complete a telephone questionnaire to participate in a research study
- Call into our recruiting department to register in our recruiting database
- Come in for a medical screening visit to participate in a research study
- Complete an emergency contact form when you participate in a research study with an in house confinement period
- Come in for a research study visit

This information could include but is not limited to: your name, phone #, address, date of birth, gender, race, height, weight, elbow breadth, childbearing potential, contraception used, participation in other trials, health lifestyle questions (re: past hospitalization, smoking history, past street drug use, alcohol consumption, caffeine consumption, dietary requirements, concomitant medication use), vital signs, in-house urine drug testing, ECG, pregnancy testing (if applicable), medical history, physical exam, Family Physician information (name, address, phone and fax numbers), and your OHIP number.

Access/Use of Personal Information

Those parties that will have access to your personal information include the study sponsor, Cetero Research – Mississauga, its employees, the law and the Ethics Review Board that reviewed the research study. Cetero Research – Mississauga may use your personal information, from time to time in order to:

- Identify you
- Determine your eligibility for possible study participation based on study protocol
- Respond to internal inquiries about your study information
- Meet any legal requirements
- To create statistics about our business. These statistics would not contain any information that could identify you personally.

Sharing of Personal Information

Your medical records relating to your participation are confidential to the extent permitted by the law (e.g. Government of Canada and the Government of the USA or other National Governments) and/or regulations and will not be made publicly available. Cetero Research – Mississauga will not sell, rent or trade personal information such as email addresses or phone numbers to any third party. We treat all information you provide as confidential.

We may share your personal information with:

- The Study Sponsor's staff or their representative(s)
At these visits, your medical records and study source documentation will be made available for review for validity verification. A copy of your written informed consent form will be available for collection by the staff or sponsor. To retain confidentiality, your name will be blacked out of the Sponsor's copy. All documentation collected by the Sponsor will be kept confidential.

At the conclusion of the study, copies of the source documents will be provided to the Sponsor and may be submitted as part of a submission to the applicable regulatory authorities. These document copies will not contain information that could identify you.

- Other Clinical Investigators
Information from the research study will be used by the Sponsor in connection with the development of the study formulation and, therefore, may be disclosed as required to other clinical Investigators and to regulatory agencies. In order to allow the use of the information derived

from the research study, it is understood that there is an obligation to provide the Sponsor with complete test results and all data generated in the study. If results of the study are published, a number only will identify you. If photographs of study subjects are published, the identity of the subjects will be protected.

- **Government Regulatory Agencies**
Data (which will not contain any identifiable information about you) from studies may be submitted to government regulatory authorities (e.g., in the USA, Canada, European Union, Brazil etc.) to obtain approval to market the sponsor's product. Regulatory inspectors that visit Cetero Research – Mississauga will have access to all study documents. Some of these documents will contain your identity.
- **Ministry of Health or your Family Physician**
Any positive infection results (HIV and Hepatitis) from screening labs will be forwarded to the Ontario Ministry of Health. A copy of the positive results will either be (a) forwarded to your family physician for follow up and consultation, or (b) if you do not have a family doctor or if you choose for the results not to be forwarded to your family doctor, the results will be forwarded to Cetero Research – Mississauga's Senior Medical Director, Dr. Deepen Patel, for follow up and consultation. Test results will become a part of your medical record. If in the future, you sign waivers to release medical information to insurance companies, employers or any other third party, then the Ministry of Health or your physician/Dr. Patel would be obligated to release a positive HIV antibody result to those third parties.

Can I Access, Update or Delete My Information

You may access and verify the accuracy of your personal information upon written request. We will respond to your request to access, update, or delete your information within 30 days of receiving the request. We may ask you to verify your identity in a secure manner in order to help us respond to your request.

There may be instances when we will not be able to provide you with the Personal Information that you request. An example of such an instance would be if the information you request contains references to other individuals, or if it can not be disclosed for legal reasons.

We encourage you to notify us in writing of inaccuracies or corrections to your Personal Information. We will make the proper changes unless restricted by law, regulatory, or audit purposes. You may also send us a written request that we delete personally identifying information stored in our database that we actively use for recruiting purposes. Unless restricted by law, regulatory, subject safety,

or audit purposes we will take all reasonable steps to functionally delete or de-identify such information from our database. More precisely, the de-identification process will remove all mention of the following information: Your name; address; any telephone or fax numbers; all elements of dates, including your date of birth, except the year; electronic mail address; any other information that may identify you. De-identified information may be used for statistical or research purposes.

Retention of Personal Information

It is a regulatory requirement that Investigators maintain the following records until; (1) written notification is received from the Sponsor; or (2) a minimum of 25 years:

- a signed consent form of each subject
- completed source data forms of each subject

The information captured on the emergency information form is for emergency purposes only. Upon completion of the study this information will be destroyed. (name, address, OHIP #, emergency contact name, number). We destroy our records in a way that protects subject privacy. Our shredding is conducted by bonded contractors, who must adhere to contractual privacy obligations.

Standard Operating Procedures at Cetero Research – Mississauga indicate that all medical records obtained for each subject are kept indefinitely in a medical file specific for that subject.

Communicating With You

Our concern with the privacy of your health information is reflected in how we communicate with you, and we protect your personal health information regardless of its format.

By Phone: Unless you indicate otherwise, we will only leave our name and phone number on any message for you.

By Fax: Our fax machines are located in a secure area and we use pre-programmed numbers to send transmissions. All transmissions are sent with a cover sheet that indicates the information is confidential. We take reasonable steps to ensure that health information is received only by a secure fax machine.

By Email: Any confidential information that we send via email over public or external networks is encrypted. We employ a firewall and virus scanning

software to mitigate against unauthorized modification, loss, access or disclosure.

By Mail: When health information is transferred to another location, it is placed in a sealed envelope, marked as confidential, and directed to the attention of the authorized recipient.

Whom Can I contact if I have Questions or Concerns?

Cetero Research – Mississauga has a procedure in place in order to receive and respond to complaints or inquiries about its policies and practices relating to the handling of personal information. Individuals with inquiries or complaints will be informed of these procedures once contact is made with Cetero Research – Mississauga in one of the following ways:

1. By Mail: Privacy Officer
Cetero Research – Mississauga
4520 Dixie Road
Mississauga, ON
L4W 1N2
2. Email: MIS-privacyofficer@cetero.com
3. Phone: 905-238-0599

We will investigate all complaints in a timely fashion and if the complaint is found to be justified, Cetero Research – Mississauga will take appropriate measures including amending its policies and practices.

As permitted by law, we reserve the right to amend or modify our privacy policies and practices.