In May 2018, the General Data Protection Regulation (GDPR) was implemented as a European Union law on the protection of data and privacy for all individuals within the EU. The aim of the GDPR is to give control to individuals over their personal data. Controllers or custodians of personal data must implement appropriate data protection principles and obtain consent to process personal data. This has implications for Canadian research participants because EU-based sponsors are held to the GDPR standards regardless of participant location if data is subsequently transferred to the EU.

The HSREB supports sponsors in their compliance with GDPR.

**New Studies**
Requisite GDPR language may be included in the main LOI provided it is clear, concise, and does not contradict or repeat current HSREB Consent Form Guidance Document language with respect to privacy and confidentiality. Participants should be directed to the REB reviewing the study, or Patient Relations Office of the appropriate hospital (LHSC or SJHC) for questions about how their data is handled. This entity would then further coordinate any contact with the data controller (sponsor) as necessary. The HSREB will not approve material where participants are directed to contact the sponsor, data protection officer, or European data protection office directly. Principal Investigators are asked to assure that study staff who will be conducting informed consent are sufficiently trained in the GDPR language to respond to participant questions.

**Amendments**
Participants should not be required to re-consent to an LOI amendment solely for purposes of including language about the GDPR. Instead, the following template language for a separate letter to be given to participants for acknowledgement is recommended.
Additional Information on Data Privacy

Study Title:

Protocol Number:
EudraCT number:
IND number:

Sponsor Name and Address
Study Drug:

Dear Patient

The Sponsor’s head office, [sponsor name], conducts this study globally and is responsible for how the data collected from you is handled. [sponsor name] is in Europe and is therefore governed under European regulation (General Data Protection Regulation or GDPR). Even though you do not live in Europe, the GDPR provides you with rights that were not mentioned in the Informed Consent Form (ICF) you signed as part of the Study. Please read further below.

Your consent provided in the LOI/C is required by law for the Sponsor to handle study data collected from you. You do not have to consent or provide your data, but it is necessary if you wish to take part in the study.

You have the following data privacy rights in addition to those listed in the ICF:

1. **Special categories of personal data**

The European privacy law applies to all of the data collected from you for the study as specifically mentioned in the LOI/C as well as:
- your age, sex and racial background
- your health and medical conditions including your past medical history
- your treatments and your response to treatments
- your sex life and sexual orientation
- your biological samples e.g. blood, tissue and the results learned from analysing them
- your medical images e.g. scans, X-Rays and the results learned from evaluating them
- your information collected by the wearable health tracker used in this study such as heartbeat
- in case of unintended pregnancy, data on pregnancy and the birth
- Important note: During this study pregnancy must be avoided for safety reasons (see full patient informed consent form)

2. **Your data privacy rights**

For the study data that is collected from you provided to the Sponsor, you have the following data privacy rights:
• You can **request information** about the handling of the study data collected from you. However, to protect the scientific integrity of the study you may not be able to receive access to some of the data before the study ends.

• You can **request correction** of study data collected from you if it is incorrect or incomplete. During the assessment of this request, you have the right to restrict the processing of the data.

• You can **request transfer** of study data collected from you to you or someone else in a commonly used and accessible format, such as a computer-readable format.

• You can **file a complaint** with a data protection authority. If you would like to make a complaint related to the study data collected from you and provided to the Sponsor, please contact the Patient Experience Office at London Health Sciences Centre at (519) 685-8500 ext. 52036, where you will be told how you can exercise your rights.

• You can **withdraw your consent** for the processing of your data, but please note that your original consent allows for the processing of your data that occurred up to the time you withdraw your consent. After this withdrawal, no further data will be collected from you.

• Along with your withdrawal, you have the right to **request the deletion** of data about you if your data are no longer needed or there is no other legal requirement for their use.

If you wish to apply any of your data privacy rights with respect to your data, including those listed above, please inform your study doctor*.

3. **Transfer and Retention of encoded data**

As indicated in your LOI/C, the study data that has been collected from you may be transferred to or handled in countries outside of Canada. This may include countries whose data protection level has not been confirmed as adequate by the European Commission. In such cases appropriate safety measures will be taken in order to protect your data privacy rights. If you have further questions please ask your study doctor.

The study data collected from you will be stored for at least 25 years after the end of the study, or longer, if needed for legal requirements.

*Instead of any direction to contact a data protection officer, the sponsor, or European agency about questions regarding how the sponsor processes personal information, participants should be directed, as they are in main Letters of Information, to contact the Patient Relations department at the applicable institution who would then coordinate any further contact with sponsor or regulatory entities.