**RESEARCH CONSENT FORM FOR PROCESSING PERSONAL DATA OF EUROPEAN UNION (EU) / EUROPEAN ECONOMIC AREA-BASED (EEA) AND UNITED KINGDOM (UK) DATA SUBJECTS**

|  |  |
| --- | --- |
| **STUDY TITLE** |  |
| **SPONSOR** |  |
| **PRINCIPAL INVESTIGATORS** |  |
| **FUNDER** |  |

**1. OVERVIEW**

This consent form provides information for potential research participants to understand how the processing of their personal data will be conducted for the purposes of this research study, which is subject to the General Data Protection Regulation (GDPR) and/or the UK General Data Protection Regulation (UK GDPR). This consent form outlines the personal data we will collect, how we intend to use and protect this information, and your rights with respect to your personal data for purposes of the GDPR and/or UK GDPR (herein referred to as the ‘GDPR consent form’).

Please note the GDPR and/or UK GDPR applies to personal data that you provide while physically located in the EU/EEA and UK. It does not apply to information provided while located outside of the EU/EEA and UK (e.g., while in Canada). The data protection requirements do not apply to your personal data that is rendered anonymous such that you are not identifiable or can no longer be identified.

You can find additional information related to the purpose of the research study, how it will be conducted, risks and benefits, and by whom it will be conducted from the study informed consent form, which you will receive as a separate document.

All research is voluntary – you do not have to participate, and **you can withdraw your consent for the processing of your personal data at any time** by contacting the Contact Person listed below.

It is important that you read the information in this GDPR consent form. It includes details we think you need to know in order to decide if you wish to take part in this study. If you have any questions, please ask a study team member.

Should you decide to consent to the processing of your personal data for this research study, please review and initial the consent clauses on the last page and sign at the bottom to indicate that you have read and understood how your personal data will be processed and your related rights.

**2. DATA CONTROLLER**

The data controller of your personal data collected as a part of this research study is Unity Health Toronto (Unity Health) located at 30 Bond Street, Toronto, Ontario M5B 1W8.

**3. LEGAL BASIS FOR PROCESSING STUDY DATA**

Unity Health Toronto will process your personal data and sensitive personal data in accordance with your explicit consent as provided through your signature to this document, which is supplemented by the study informed consent form to which this GDPR consent form is attached.

**4. COLLECTION, USE AND DISCLOSURE OF STUDY DATA**

**Collection of Study Data**

Unity Health Toronto will collect and process the following categories of personal data about study participants (“**Study Data**”):

* Name
* Contact information
* Date of birth
* Health information relating to [*insert information about the type of health information collected*]
* [*complete with any other information collected from participants*]

Sensitive Data:

*[Instructions: Only include this if you will process personal data that are considered special category data. Otherwise, delete this section.]*

We will also collect and process the following special category data about you:

* Race and/or ethnicity
* Health data
* Religion or philosophical beliefs
* Sex life information
* Sexual orientation
* Political opinions
* Trade Union membership
* Genetic data
* Biometric data

Personal Data from Other Sources:

*[Instructions: Only include this if you obtain personal data from other sources than what you observe directly and what the subject is providing to you. Otherwise, delete this section.]*

We obtain additional personal data related to you from third party sources, as follows:

* *[Copy list of sources from ICF]*

**Purposes for Using Study Data**

Unity Health Toronto will use Study Data for the following purposes:

* To determine whether you meet the eligibility criteria for the study;
* To carry out the study;
* To link your data to other sources, as described above;
* To confirm the accuracy of the data;
* To monitor and audit whether the study complies with applicable laws as well as standards developed by the research community;
* To pseudo-anonymize and/or anonymize the Study Data;
* To make results available outside of the research team; and
* To re-contact you for your consent for future uses of the identifiable or pseudonymized Study Data.

**Recipients of Study Data**

*[Instructions: Include information about all entities that have access to the personal data, including service providers that are contracted for handling data (e.g., app developer) or any other party who will handle data (e.g., collaborator who will provide a service, such as translation or data analysis, without or without a contract). Please indicate the name of the service provider. Please include the appropriate recipients listed below where applicable.]*

The following individuals and organizations may process your Study Data in connection with the study:

* *[insert study sponsor*], as the study sponsor.
* The Principal Investigator and the study team who conduct the study at Unity Health, as well as the organizations [insert organizations] that support the study team.
* The Unity Research Ethics Board committee or other Independent Ethics Committees.
* Canadian, domestic, and other foreign regulatory agencies and government officials who have a duty to monitor or oversee studies like this one, including, but not limited *[insert oversight bodies].*
* Data processors that act on our behalf: *[insert processor e.g., a cloud service provider, an image processor, collaborator doing analysis].*
* To parties where the disclosure is required by law.
* To other researchers for reuse.

**Future Use of Study Data**

Where the Study Data will be used for other purposes or disclosed to another party, we will anonymize your data, rendering it non-identifiable, wherever possible. Where we cannot anonymize your data, or apply other controls permitted by the GDPR and or UK GDPR, we may re-contact you for your explicit consent.

**Retention of Study Data**

We will retain the Study Data for [*insert longest retention period or criteria used to determine that period*].

We will delete your personal data or render the data anonymous after the retention period, when it is no longer needed for the study, or if you withdraw your consent, provided such deletion does not render impossible or seriously impair the achievement of the objectives of the research study. However, some of your informationmay be retained as necessary to comply with legal or regulatory requirements.

**International Transfer of Study Data**

By consenting to the research study’s processing of your Study Data, you agree that your Study Data will be hosted on a secure server at Unity Health Toronto in Ontario, Canada. Where we are collecting data from an organization that holds your data in the EU/EEA/UK, we rely on the standard contractual clauses issued by the European Commission in Decision (EU) 2021/914 to transfer your personal data from your country to Canada. You may obtain a copy of the standard contractual clauses by contacting the Contact Person listed below.

Furthermore, Unity Health may use and disclose your Study Data for processing for the purposes stated in this form to entities and individuals located in Canada or in other countries where the laws do not protect your privacy to the same extent as the laws the country in which you are located. Unity Health and the study team will take reasonable steps to protect your privacy in accordance with the applicable data protection laws.

**5. YOUR RIGHTS**

The GDPR/UK GDPR provides you with control over your personal data and how it is processed when you agree to your information being processed for research purposes. However, some of those rights may be limited in order for the research to be reliable, accurate, and to maintain integrity. With regard to your data, you have the following rights:

* **Rights of Access and Portability**: You have the right to request a copy of the personal data that has been collected from or about you within the research study. Requests must be made through the study doctor within your country of residence. You also have the right receive the personal data that you have provided to us in a structured, commonly used, and machine-readable format.
* **Right to Rectification (Correction):** You have the right to have incorrect or incomplete personal data concerning you corrected, subject to restrictions under Member State law. Requests must be made through the study doctor within your country of residence.
* **Right to be Forgotten (Erasure):** You have the right to request to have your personal data deleted. You are reminded that personal data will only be retained for the period of time specified in this GDPR consent form.
* **Right to Withdraw Consent:** You can withdraw your consent at any time. Note that this does not affect the legality of the processing carried out on the basis of the consent up to the point of revocation.
* **Right to Limit Processing:** You have the right to request that any processing of your data be restricted or limited in certain circumstances.
* **Right to Object**: If there are reasons that arise from your particular situation, you have the right to object to specific decisions or measures to process your personal data.
* **Right to Lodge a Complaint with Supervisory Authority:** You have the right to lodge a complaint with a supervisory authority if you believe that our privacy practices of processing your personal data violates the GDPR/UK GDPR.

**6. UNITY HEALTH DATA PROTECTION OFFICER CONTACT INFORMATION:**

If you have any questions or concerns about the processing of your personal data for this study or would like to withdrawal your consent, please contact the Contact Person:

**EU Representative:**

Adam Brogden

Email: contact@gdprlocal.com

Telephone: +35315549700

INSTANT EU GDPR REPRESENTATIVE LTD

Office 2, 12A Lower Main Street, Lucan Co. Dublin

Ireland

K78 X5P8

**UK Representative:**

Adam Brogden

Email: contact@gdprlocal.com

Telephone: +44 1772 217800

1st Floor Front Suite

27-29 North Street, Brighton

England

BN1 1EB

If you would like to exercise your rights, please contact the Unity Health Data Protection Office at +1-416-864-6088 or email at privacy@unityhealth.to.

If you will not be satisfied with our reply and how we protect your personal data, you can contact the data protection authority in your home country or in another relevant jurisdiction for this processing activity, pursuant to the conditions of Article 77 of the GDPR/UK GDPR.

**7. PARTICIPANT CONSENT FOR THE PROCESSING OF PERSONAL DATA FOR THE RESEARCH STUDY**

Upon review of this consent form, I acknowledge that I have read the consent form, understand the information provided, and have had the opportunity to ask questions for clarification and received satisfactory responses.

I understand that my participation is voluntary, and I am free to withdraw my consent for the processing of my personal data at any time. I understand that I am not waiving any of my legal rights as a result of signing this consent form.

I agree to the study’s processing of my personal data for the following activities, as outlined in this form: *(please initial the box corresponding to each data processing activity to acknowledge your consent).*

|  |  |
| --- | --- |
| **Data Processing Activity** | **Initial** |
| I agree to the purposes for processing my personal data as outlined in this consent form. |  |
| I agree to the purposes for processing my sensitive data as outlined in this consent form.  |  |
| I agree to the study team’s linkage of my personal data with data provided by the third-party sources listed in this consent form.  |  |
| I agree to the transfer of my personal data to those organizations listed above to facilitate the research study. |  |
| I agree to provide access to my pseudonymized data to regulatory authorities, authorised individuals from Unity Health and [insert other study-related organizations], funding bodies, regulatory authorities or public health agencies.  |  |
| I agree to the storage of my personal data at the location listed above. [If linkage may occur, I agree to the storage of the linked data at [insert location]. |  |
| I agree to the future use of my personal data as outlined above and understand that Unity Health will apply the appropriate controls to protect my personal data.  |  |
| I agree to be re-contacted by Unity Health where my explicit consent may be required for the re-use of identifiable or pseudonymized data. |  |
| I agree to the rights provided to me by this research study and understand how I can exercise them.  |  |

**Declaration:** I acknowledge that I agree to participate in the study and consent to the collection and processing of personal data in accordance with this GDPR consent form.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Participant name (print) |  | Participant signature |  | Date |