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COMMITMENT TO CONFIDENTIALITY

Access to the clinical information system OACIS

Title :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Birth Date : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title and Number of the Protocol :

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(hereinafter « the Study »).

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(your name in print characters), monitor, auditor or inspector for \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(name of the company or the regulatory authority on behalf of whom you are doing a monitoring, audit or inspection visit) is carrying out a monitoring, audit or inspection visit for a Study that is performed at the CIUSSS de l’Est-de-l’île-de-Montréal, in compliance with the research agreement signed with the CIUSSS de l’Est-de-l’Île-de-Montréal, if applicable.

In the course of my duties, I will have access to documents and personal information of sensitive and confidential nature of Study participant(s) throught OACIS’ software. I will limit my monitoring, audit or inspection only to the research file and medical file of such participant(s) of the Study (hereinafter « Study paticipant(s) ») in compliance with their signed informed consent form, if applicable.

I undertake:

1. not to make any copy, photograph, video, document sharing, screenshot, (nor print) any information from the research file and the medical file of a Study participant(s).

Additionally, if this is a remote visit, I undertake to :

1. keep my access codes confidential during the period allocated for the remote access period and not share them with any third party;
2. immediately notify the CIUSSS de l'Est-de-l'Île-de-Montréal in writing if, during the access period, I no longer perform work for my employer or for the sponsor needing the confidential information, and immediately cease all use of my access codes.

By executing this commitment, I undertake to respect the confidential nature required during and after the monitoring, audit or inspection and to comply with the laws and regulations applicable for the protection of personal and medical information including, but without limitation to, sections 19 and following of the *Act respecting health and social services*, RLRQ, c S-4.2.

I undertake to promptly send a written notification to the Information Security Office of the CIUSSS de l’Est-de-l’Île-de-Montréal for any violation or possible violation, that come to my knowledge, by me or by any person of the obligations related to personal and confidential information to which I had access during the performance of my monitoring or audit. This notice shall be sent at the following : Direction de la qualité, évaluation, performance et éthique, CIUSSS de l’Est-de-l’Île-de-Montréal, Stéphane Gagnon, 5689 boulevard Rosemont, Montréal (Québec), H1T 2H1,

stephane\_rsi.gagnon.cemtl@ssss.gouv.qc.ca.

I understand and agree that my usage of OACIS’ software may, at any time, be audited by the CIUSSS de l’Est-de-l’Île-de-Montréal.

In addition to any action in damages, against me and/or the company or the regulatory authority for which I perform the monitoring or audit, to remedy any prejudice that may result from a breach of this Agreement, I agree and understand that the CIUSSS de l’Est-de-l’Île-de-Montréal and any Study participant may seek injunctive relief or any other remedy applicable and available at law.

**IN WITHNESS WHEREOF**, I have executed this commitment, in \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(City) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(Province ou State), on this \_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, 20\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Signature