**Confidentiality Agreement**

*Only the words highlighted in yellow should be edited/ updated.*

This confidentiality agreement (“**Agreement**”) effective as of [date] (“**Effective Date**”), is made by and among [SPONSOR/CRO] with a principal place of business at [ADDRESS], including its Affiliates, together “**Discloser**”), and **Santé Québec**, a legal person established under the Act respecting the governance of the health and social services system (CQLR, c. G-1.021), acting through the institution[NAME OF INSTITUTION], located at [ADDRESS OF INSTITUTION] , represented for the purposes hereof by [NAME OF SIGNATORY, TITLE OF SIGNATORY], duly authorized in accordance with Santé Québec’s by-laws (“**Institution**”) [**NTD: *If the institution is a university or is not a Santé Québec institution*, use the following:]** [INSTITUTION] located at [ADDRESS], represented by [NAME] (“**Institution**”) and [**NTD**: ***If the institution is a university/the employer of Investigator, delete the reference here to the Investigator and update the Agreement***] [INVESTIGATOR] having research privileges and an address at Institution (“**Investigator**”) (Institution and Investigator referred to as “**Recipients**”, provided that their rights and obligations remain several and not joint).

1. **Definitions and background**
	1. The Discloser is seeking investigators and sites to participate in a clinical trial entitled [INSERT] (the “**Clinical Trial**”) described in the protocol entitled: [INSERT] (“**Protocol**”) and, for this purpose, is willing to provide the Recipients with certain Confidential Information to assist them in evaluating and determining their respective interest in conducting the Clinical Trial. This Agreement shall govern the conditions of disclosure and use by each Recipient of such Confidential Information.
	2. In this Agreement, the following term shall have the meaning given to them hereunder:
		1. **“Confidential Information”** means: **(i)** the Protocol; and **(ii)** any confidential and proprietary information and material relating to the Clinical Trial or to Discloser’s products, business and operations generally, as relevant to the conduct of the Clinical Trial, including without limitation, business or scientific plans, reports, clinical data, memoranda, clinical, financial, technical and commercial information, know-how relating to the Clinical Trial and Clinical Trial compounds, disclosed by or on behalf of the Discloser to the Recipients: (a) in writing or other tangible form and marked as confidential by the Discloser, provided that Discloser’s failure to mark such information as confidential will not constitute a waiver of Recipient’s obligations under this agreement if such information falls under point (c) below; (b) orally and then reduced to writing and mark as confidential within 30 days of disclosure; or; (c) in writing, and which is evidently of a confidential nature by virtue of its character or the circumstances or manner of its disclosure. However, the term “Confidential Information” shall not include any of the information which a Recipient can show: **(i)** is already lawfully known to it/him/her at the date it was disclosed to it/him/her by the Discloser, or **(ii)** is or becomes generally known to the public, except by reason of any breach of its/his/her obligations hereunder, or **(iii)** is disclosed to it/him/her, free of restriction on the disclosure or use in question, by a third party who was entitled to make such unrestricted disclosure, or **(iv)** was independently developed by it/him/her without using or relying on the Information disclosed to it/him/her by the Discloser.
		2. “**Affiliate**” refers to any company, whether a corporation or other business entity, that is controlling, controlled by or under common control with such party, and “control” means the direct or indirect ownership of more than fifty percent of the equity interest in such corporation or business entity, or the ability in fact to control the management decisions of such corporation or business entity.
2. **Confidentiality obligations**
	1. Recipients agree to treat Confidential Information provided by or on behalf of Discloser as confidential. More particularly, the Recipients agree: **(i)** to maintain Confidential Information with the same degree of care they hold their own confidential information, which in no event shall be less than a reasonable standard of care; **(ii)** not to disclose or permit Confidential Information to be made available to any third party other than their Representatives (defined below), without the Discloser’s prior written consent, **(iii)** to ensure that each of their respective employees, Clinical Trial team members, contractors, agents and representatives and, as applicable, co-investigators students and advisors (each a “**Representative**”) who has a need to know is fully aware in advance of the Recipients’ obligations under this Agreement and is bound by obligations of confidentiality substantially similar to those in this Agreement, **(iv)** to notify Discloser if it becomes aware of any disclosure in breach of their obligations of this Agreement and to take, at the request of Discloser, all such steps, as are reasonably necessary to prevent further disclosure; and **(v)** upon request of Discloser (and at its expense), to promptly return to Discloser, or, at Discloser’s option, destroy, all Confidential Information, together with all copies and/or other forms of reproductions thereof of the Confidential Information, provided that the Recipients shall be entitled (a) to retain one copy of Information in their files in a secure location for the sole purpose of complying with their confidentiality obligations; and (b) shall not be obligated to destroy electronic copies of Confidential Information made as a matter routine information technology back-up which cannot be destroyed with reasonable efforts.
	2. In the event that the Recipients are required (whether by statute, regulation or law, or by judicial or administrative process) to disclose, during the term of the confidentiality obligations, any part of the Confidential Information, such disclosure will not be considered a breach of this Agreement so long as the Recipients comply with the following, to the extent authorized to do so under applicable laws: **(i)** promptly notify Discloser of each such requirement so that Discloser may seek an appropriate protective order or other remedy and/or waive compliance by the Recipients with the provisions of this Agreement **(ii)** at Discloser’s request, provide reasonable assistance to resist or narrow the scope of such disclosure; and **(iii)** furnish only that portion of the Information which is required to be disclosed if, in the absence of such a protective order, the Recipients are nonetheless legally required to disclose any part of the Confidential Information, and continue to maintain the confidentiality of that Confidential Information with respect to all other third parties.
	3. Recipients acknowledge that damages may be an inadequate remedy for breach of this Agreement and hereby consent to Discloser seeking injunctive or other relief in respect of the provisions thereof, in addition to any other rights and remedies it may have.
	4. Recipients agree that all Confidential Information is and shall remain the sole and exclusive property of the Discloser. This Agreement will not be construed as conferring to the Recipients any rights to the Confidential Information of the Discloser, or as an obligation to enter into any license or other agreement.
	5. If as applicable and during the term of this Agreement, Discloser gains access through site visits or otherwise to information relating to Recipients’ business or research operations, policies or procedures that Recipients identify to Discloser as proprietary and confidential or that is reasonably apparent to Discloser to be so, then Discloser will: **(i)** not copy or remove such information, **(ii)** not use such information for any purpose other than performance of this Agreement, **(iii)** not disclose such information to any third party; and **(iv)** comply with the provisions set forth herein, which shall apply *mutatis mutandis* to such information.
3. **Effective Date and term**
	1. This Agreement shall become effective as of the Effective Date and shall remain effective for one (1) year or until the parties enter into a *clinical trial agreement* regarding the Protocol and Clinical Trial, whichever occurs first.
	2. Despite the foregoing, the obligations of confidentiality set forth herein shall survive the expiration or any early termination of this Agreement for a period of ten (10) years.
4. **Miscellaneous**
	1. This Agreement represents the entire agreement among the parties with respect to all matters contained in this Agreement. In the event that any of the parties have previously entered into and signed another confidentiality agreement with the other(s), any and all rights and obligations arising from such other agreement shall survive and remain in full force and effect.
	2. If any provision of this Agreement is wholly or partially unenforceable for any reason, such unenforceability shall not affect the enforceability of the balance of this Agreement and the provisions of this Agreement shall, if alternative interpretations are applicable, be construed so as to preserve the enforceability of this Agreement.
	3. This Agreement shall enure to the benefit of and be binding on each of the parties and their Representatives, and their respective, successors and permitted assigns.
	4. The failure of any party to insist upon a strict performance of any of the terms and provisions in this Agreement shall not be deemed a waiver of any subsequent breach or default in the terms or provisions of this Agreement.
	5. No party may assign any of its rights or obligations under this Agreement without the prior written consent of the others; provided, however, that any party may without such consent assign this Agreement in connection with the sale or transfer of all or substantially all of its business or in connection with a merger or other consolidation with another entity.
	6. Any disclosure to a third party or other public announcement of any type whatsoever regarding the existence of this Agreement or the matters contemplated herein, will be made only with the prior approval of all parties, except as may be required under applicable law.
	7. This Agreement shall be governed by and shall be construed in accordance with the laws in force in the Province of Quebec without regard to any conflicts of law provisions or other principles, to the extent that this could lead or result in the application of another jurisdiction’s law. The parties consent to the exclusive jurisdiction of the courts of the Province of Quebec for the resolution of all disputes or controversies among the parties hereto that the parties are unable to settle amicably.
	8. This Agreement may be signed in two or more counterparts, which may be delivered by facsimile or electronic format, each of which shall be deemed to be an original and all of which shall together be deemed to constitute one agreement.
	9. This Agreement is draftedin English after considering the Charter of the French Language. **La présente entente est rédigée en anglais après avoir considéré la Charte de la langue française.**

[*the signature page immediately follows*]

**IN WITNESS WHEREOF**, the parties have executed this Agreement as of the Effective Date.

|  |  |  |
| --- | --- | --- |
| **[FULL LEGAL NAME OF SPONSOR/CRO]** |  | **Santé Québec, acting through [NAME OF INSTITUTION] OR [FULL LEGAL NAME OF INSTITUTION]** |
| By: |  | By: |  |
|  | Name: ⚫ |  | Name: ⚫ |
|  | Title: ⚫ |  | Title: ⚫ |
|  |  | **[DELETE IF THE INSTITUTION IS A UNIVERSITY/THE EMPLOYER OF THE INVESTIGATOR]** |
|  |  |  |  |
|  |  |  | Name: **[FULL NAME OF INVESTIGATOR]** |
|  |  |  | Title: Investigator |