## MUTUAL MULTIPARTY CONFIDENTIALITY AGREEMENT

## FOR PREPARING AN APPLICATION FOR AN IHI ACTION

**“[SHORT NAME PROJECT]”**

Between

**[XXX]**, having its offices at [ADDRESS] (hereinafter the “**Project Leader**”);

And

**[XXX]**, having its offices at [ADDRESS] (hereinafter the “[**First Subscribing Party/Coordinator]**” or “**[XXX]**”);

**WHEREAS**

(A) Each Party is in possession of certain commercial, financial, scientific, and or/ business-related information and any other material (in whatever form it exists) bearing or incorporating any information relating to the existence, scope and activities of its research, development, manufacturing, and/or commercial projects or products, including without limitation, data, methods, know-how, techniques, business plans, formulae, processes, methodology, designs, photographs, drawings, specifications, software programs, databases, source codes, object codes and samples (the **“Confidential Information**”);

(B) The Parties have agreed to exchange with each other Confidential Information for the purpose of preparing, negotiating and entering into an Innovative Health Initiative action, under Call [NUMBER], topic [NUMBER], entitled [FULL NAME PROJECT], in which **[XXX]** will act as Project Leader, referred to as the IHI-[SHORT NAME PROJECT] (the “**Project**”), and to further discuss the science of the Project, its application to the IHI JU call for proposals, and to work out their contributions to the Project and negotiate and prepare an acceptable grant and consortium agreement for the Project (the “**Purpose**”);

(C) This Agreement is intended to apply between all Parties who have signed this initial Agreement, and any additional Party acceding to it by signature of an Accession Form (the **“Acceding Party”**). Each proposed beneficiary to the above referred Project is expected to become an Acceding Party, and therefore to subscribe to the terms of this Agreement.

(D) This Agreement does not cover the exchanges of any patient data not being fully anonymized in accordance with applicable data protection laws and regulations. The Parties will enter into additional arrangements in case the sharing of such data is needed for the Purpose.

**NOW THEREFORE**, in order to protect each Party’s rights with respect to its Confidential Information, the Parties, intending to be legally bound, agree as follows:

**1. DEFINITIONS**

* 1. In this Agreement, unless the context otherwise requires, the following capitalized terms shall have the following meaning:

|  |  |
| --- | --- |
| “**Agreement**” | means this mutual, multiparty confidentiality agreement between the Parties; |
|  |  |
| **“Discloser”** | means the Party or Parties disclosing Confidential Information under the terms of this Agreement, either directly or through any of their respective Extended Affiliates; |
| **"Extended Affiliate"****“Party”/ “Parties”**“**Recipient**”**"Representatives"**"**Third Party**" | means any legal entity that is under the direct or indirect control of a Party or is under the same direct or indirect control as that Party, or is directly or indirectly controlling that Party. Control may take any of the following forms: (i) the direct or indirect holding of more than fifty percent (50%) of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity; or (ii) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned. However, the following relationships between legal entities shall not in themselves constitute controlling relationships: (i) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than fifty percent (50%) of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates; or (ii) the legal entities concerned are owned or supervised by the same public body.means the Project Leader, the First Subscribing Party as well as any Acceding Party to this Agreement;means the Party or Parties (or any of their Extended Affiliates) receiving Confidential Information under the terms of this Agreement.means the Recipient's personnel, other persons under the supervision and control of the Recipient, and its Extended Affiliates, and/or other Third Parties with which Recipient has an agreement at the time of disclosure to such Third Party and which need to know the Confidential Information for the Purpose. means a legal entity or person which is not a Party to this Agreement. |

* 1. Unless the context requires otherwise:
		1. any period of time from a specified date or day shall be calculated exclusive of that date or day;
		2. the words “include” or “including” are to be construed as meaning without limitation;
		3. words in the singular include the plural and vice versa and words for any gender shall include all genders;

**2. COMMENCEMENT DATE**

The Parties have been exchanging Confidential Information since [add date]. Therefore, the Commencement Date of this Agreement shall mean [add date], notwithstanding the date or dates of signature hereof.

**3. UNDERTAKINGS OF THE RECIPIENT**

* 1. Each Discloser shall disclose to the Recipient only such of its Confidential Information as the Discloser, in its sole discretion, deems necessary or desirable for the Purpose. The Recipient may, in its sole discretion, refuse to receive any Confidential Information offered to be disclosed by the Discloser. In case an Extended Affiliate of a Party acts as Discloser or Recipient under this Agreement, such Party will ensure that such Extended Affiliate complies with all terms and conditions of this Agreement with respect thereto and will be liable towards the other Party for such compliance.
	2. The Recipient hereby agrees, binds and obliges itself that from the Commencement Date and for a period of seven (7) years after the termination of the Agreement according to Clause 7 of this Agreement, it shall:
		1. maintain and shall procure that any of its Representatives shall maintain in confidence the Confidential Information of the Discloser; and
		2. not, and shall procure that any of its Representatives shall not, publish or disclose nor in any way directly or indirectly permit the disclosure of, the existence, source, content or substance of the Confidential Information of the Discloser to a Third Party other than to the extent a disclosure is permitted by Section 5.1.3; and
		3. not, and shall procure that any of its Representatives shall not, use the Confidential Information for any purpose, whether commercial or non-commercial, other than the Purpose; and
		4. not, and shall procure that any of its Representatives will not, use, rely upon or duplicate or in any way profit from or take advantage of in any manner the Confidential Information of the Discloser without the prior written consent of the Discloser.

**4. EXCEPTIONS TO CONFIDENTIALITY OBLIGATIONS**

4.1 Notwithstanding any other provisions of this Agreement, the Recipient may use and disclose any Confidential Information of the Discloser which is:

 4.1.1 at the time of disclosure already lawfully in the possession of the Recipient or any of its Extended Affiliates without confidentiality obligations, provided that the Recipient can prove by written evidence such prior possession;

 4.1.2 at the time of disclosure, or becomes after such disclosure generally and publicly available, without any breach by the Recipient of this Agreement;

 4.1.3 received by the Recipient or its Extended Affiliates without confidentiality obligations from a Third Party (other than to the extent such Third Party made the disclosure on behalf of the Discloser) who did not acquire such information directly or indirectly from the Discloser and who is entitled to disclose such information;

 4.1.4 independently created or developed by or on the behalf of the Recipient or any of its Extended Affiliates without the access to, the reliance to, or the use of Discloser’s Confidential Information; or

 4.1.5 permitted to be so disclosed by prior written consent of the Discloser.

4.2 Notwithstanding anything to the contrary contained herein, the Recipient shall be permitted to disclose (and such Party shall not be required to destroy) any Confidential Information that it is and only to the extent that it is obliged to disclose by operation of law or by a requirement of a regulatory or judicial body, provided, however, that the Recipient shall (i) provide the Discloser with prompt notice of such event, to the extent legally feasible, so that the Discloser may take appropriate steps, including intervening, to protect the confidentiality of the Confidential Information, (ii) take all reasonable and lawful actions to avoid or minimize the degree of such disclosure and to obtain assurance that confidential treatment will be afforded to the Confidential Information, and (iii) use reasonable efforts to cooperate with the Discloser in the Discloser's efforts, at the Discloser's written request and expense, to apply for an appropriate protective order or similar legal remedy. In the event that such legally compelled disclosure is made, the Recipient shall continue in all other ways to maintain the confidentiality obligations and use restrictions herein with respect to such Confidential Information and shall disclose only that portion of Confidential Information as is legally required to be disclosed.

4.3 Without prejudice to the generality of Clause 4.1.2 hereof, information shall not be deemed to be publicly available by reason only that it is known to only a few of those people to whom it might be of commercial interest, and a combination of two or more portions of the Confidential Information shall not be deemed to be publicly available by reason only of each separate portion being so available.

4.4 Information shall not be considered Confidential Information unless it is reduced to writing (e-mail notification is sufficient) and marked “CONFIDENTIAL” or in the normal course of business can be considered of a confidential nature. An oral disclosure shall be considered Confidential only if it is so confirmed at the time of disclosure and is subsequently reduced to writing and confirmed to the receiving Party within 30 (thirty) days after its oral disclosure.

**5. CONFIDENTIALITY MEASURES**

5.1 To maintain the confidentiality of the Confidential Information of the Discloser, the Recipient shall:

 5.1.1 protect the Confidential Information in the same manner it protects its own Confidential Information of a similar nature, which shall be at least a reasonable standard of care;

 5.1.2 store all Confidential Information of the Discloser and all information based thereon generated by the Recipient in a location and under such security systems utilized in respect of its own confidential and proprietary information to prevent unauthorized access;

* + 1. allow access to the Confidential Information of the Discloser exclusively to those Representatives who have reasonable need to know it for the Purpose and who are bound by obligations of confidentiality at least equivalent to those set forth herein, and be responsible for any breach by its Representatives of the obligations of non-disclosure and non-use as set forth in this Agreement;
		2. make only such limited number of copies of the Confidential Information as is strictly required for the Purpose;
		3. on request of the Discloser made at any time, and at the choice of the Recipient destroy in the manner reasonably prescribed by the Discloser or deliver to the Discloser all documents and other material in the possession, custody or control of the Recipient that bear or incorporate any part of the Confidential Information of the Discloser, including for the avoidance of doubt any copies and thereafter certify to the Discloser that it has complied with the terms of this sub-clause; provided, however, that the Recipient (i) may retain one (1) copy for the sole purpose of monitoring its compliance with this Agreement , (ii) may maintain copies of Confidential Information which must be stored by the Recipient according to mandatory law and (iii) shall not be obliged to destroy automatically created backup copies kept on backup media, provided that for (i), (ii) and (iii) the confidentiality and non-use obligations set forth in this Agreement continue to apply for an unlimited period of time; and
		4. not attempt to decompile, disassemble, reverse engineer, or use any other process to gain access to the physical or circuit design or source code of any software that may be disclosed by the Discloser to the Recipient under the terms of this Agreement.
	1. All Confidential Information belonging to the Discloser shall remain the property of the Discloser. In no event shall the Recipient be deemed to have acquired any right, title or interest in or to the Confidential Information of the Discloser, or related information or technology possessed by the Discloser by virtue of this Agreement.

5.3 For the avoidance of doubt, the Parties agree that the documents or information (whether Confidential Information or otherwise) made available for the purposes of this Agreement shall not constitute an offer by one Party to any other or form the basis of any contract.

5.4 The Confidential Information is disclosed “as is”. Nothing contained within this Agreement or in any Confidential Information shall constitute any express or implied warranty of any kind, including without limitation, any warranty of satisfactory quality or fitness for a particular purpose or a warranty regarding non-infringement of any patent, copyright or other third party intellectual property rights.

**6. ASSIGNMENT**

This Agreement may not be assigned by any Party without the prior written consent of the other Parties. No Party shall publicly announce or otherwise disclose the existence or content of this Agreement or make any advertisement, disclosure or publicity based thereon without the prior written consent of the other Parties.

**7. TERMINATION**

7.1 This Agreement shall come into effect on the Commencement Date. It may be terminated with respect to further disclosures upon thirty (30) days’ prior written notice by each of the Parties.

 This Agreement shall either (i) be terminated and (for those Parties who have entered into a consortium agreement for the Project (the “**Consortium Agreement**”)) be superseded automatically at the signature of the Consortium Agreement, which terms will replace those of this Agreement with effect as from the Commencement Date and will govern all Confidential Information disclosed after the Commencement Date, or (ii), expire, if the Project is not entered into or the grant not awarded, one (1) year from its Commencement Date, it being expressly acknowledged that the obligations set forth in Clause 3 shall survive the termination pursuant to (ii) above.

7.2 Termination of this Agreement shall not affect the rights or claims of any Party against any other Party(ies) in respect of the period up to the date of termination.

7.3 Termination of this Agreement shall not affect the rights and obligations of the Parties to maintain confidentiality and non-use with regard to the Confidential Information, unless to the extent such Agreement is superseded by the Consortium Agreement, and in that case only for those Parties who have entered into such superseding Consortium Agreement. For the other Parties the terms of confidentiality and non-use shall continue to survive under this Agreement in accordance with the terms hereof.

**8. AMENDMENTS**

Any amendments to the Agreement shall only be effective if in writing and signed by all Parties.

**9. WAIVER**

The failure of any Party to exercise or enforce any right conferred upon it by this Agreement shall not be deemed to be a waiver of any such right or operate so as to bar the exercise or enforcement of such right at any time or times thereafter. No waiver or discharge shall be valid unless in writing and signed by all Parties.

**10. NOTICES**

10.1 Any notices, request or consent under this Agreement shall be in writing and in English. Any notice sent shall be deemed to have been served when personally delivered or delivered by internationally recognized courier service or, if transmitted by fax, electronic or digital transmission, at the time of such transmission, provided that such transmission is confirmed by receipt of a successful transmission report and thereafter confirmed by surface/air mail or delivered by internationally recognized courier service within five (5) days..

10.3 If any Party changes its address, then it shall as soon as possible give the other Parties written notice of the new address (e-mail notification is sufficient).

**11. ENTIRE AGREEMENT**

* 1. If any provision of this Agreement shall for any reason and to any extent be determined to be invalid or unenforceable under applicable law, then such invalidity or unenforceability shall not affect the remainder of this Agreement. The Parties agree to replace any such invalid or unenforceable provision with a valid and enforceable provision designed to achieve, to the extent possible, the purposes and intent of such invalid and unenforceable provision
	2. This Agreement constitutes the whole agreement between the Parties and supersedes all previous agreements between them relating to its subject matter.
	3. Each Party acknowledges that, in entering into this Agreement, it has not relied on, and shall have no right or remedy (other than for breach of contract) in respect of, any statement, representation, assurance or warranty (whether made negligently or innocently) other than as expressly set out in this Agreement.
	4. From the moment the two initial Parties have signed this Agreement, it shall be binding upon those two initial Parties. It shall thereafter apply *mutatis mutandis* versus any additional Acceding Party after it has acceded to this Agreement by signature of an accession form (a template of which is attached to this Agreement).

**12. GOVERNING LAW AND DISPUTE RESOLUTION**

* 1. This Agreement and all disputes or claims arising out of or in connection with it or its subject matter (including non-contractual disputes or claims) shall be governed by and construed in accordance with the laws of Belgium.
	2. All disputes arising out of or in connection with this Agreement that cannot be settled amicably between the Parties shall be finally settled under the Rules of Conciliation and Arbitration of the International Chamber of Commerce, by three Arbitrators appointed in accordance with the said rules. The language of the arbitral proceedings shall be the English language and shall take place in Brussels, Belgium.

**14. SIGNATURE**

Parties explicitly agree to execute this Agreement by way of an electronic signature, and agree this shall constitute a valid and enforceable agreement between the Parties.

**IN WITNESS WHEREOF** the Parties have caused this Agreement to be executed by their duly authorized representatives, on the date set below, each party acknowledging receipt of an (electronically) signed copy.

For and on behalf of **[XXX]:**

**(Project Leader)**

Date:

Name:

Function:

Authorized signature:

For and on behalf of **[XXX]:**

**([First Subscribing Party/Coordinator])**

Date:

Name:

Function:

Authorized signature:

**Accession Form - to the Mutual Multiparty Confidentiality Agreement for preparing an application for an IHI Action for [add reference to project name]**

*(template)*

*Accession of a new Party to the IHI-[SHORT NAME PROJECT] Multiparty Confidentiality Agreement (hereinafter referred to as “****Agreement****”) with Commencement Date [DATE] between [XXX] and [XXX].*

**xxxxxxx**, newly acceding party to the [add reference to project name], having its offices at \_\_\_\_\_\_\_\_\_\_\_, duly represented by \_\_\_\_\_\_\_\_\_\_\_\_\_\_, (hereinafter also referred to as “**Acceding Party**”);

hereby represents it has received an executed copy of the Agreement;

hereby consents to become a Party to the Agreement and accepts to be bound by the terms and conditions set forth in such Agreement as from the last signature date of this accession form;

**IN WITNESS WHEREOF** the Acceding Party and the Project Leader of [add reference to project name] have caused this accession form to be executed by their duly authorized representatives, the Acceding Party acknowledging receipt of a true copy of the Agreement it is acceding to.

The Acceding Party and the Project Leader may expressly intent to sign electronically this Agreement. None of them may oppose or dispute the validity and/or probative force of this accession form signed electronically.

For and on behalf of the Acceding Party**, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_:**

Date:

Name:

Authorized signature:

For and on behalf of the Project Leader, **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_:**

Date:

Name:

Authorized signature: