



Instituto de Investigación Sanitaria Gregorio Marañón



FUNDACIÓN INVESTIGACIÓN BIOMÉDICA
HOSPITAL GREGORIO MARAÑÓN

CONSORTIUM AGREEMENT

for a Research and Innovation action Project under the EU-LAC

**Project full title: Observatory for Genomic surveillance of Tuberculosis transmission
and migration in Europe and Latin America**

Project acronym: OBSERV-TB

Coordinator: Dr. Darío García de Viedma del Álamo

Fundación para la Investigación Biomédica del Hospital Gregorio Marañón

Instituto de Investigación Sanitaria Gregorio Marañón

THIS CONSORTIUM AGREEMENT is based upon the EU-LAC 5th EU-LAC Joint Call in STI 2025 within the EU-LAC Framework and is made on 01 January 2026, hereinafter referred to as the "Effective Date"

BETWEEN:

FUNDACION PARA LA INVESTIGACION BIOMEDICA DEL HOSPITAL GREGORIO MARAÑÓN, an entity organized under the laws of Spain, with legal address at Calle Doctor Esquerdo 46. 28007 Madrid (SPAIN) and tax identification number (CIF) G-83195305, duly represented by Mrs. Teresa Fernández Alonso, with DNI number 17.443.277-P, acting as Director of the entity (hereinafter "FIBHGM", or the "Coordinator").

UNIVERSIDADE FEDERAL DO RIO GRANDE, FURG, with legal address at Rua Visconde de Paranagua, 102, 96200190, Rio Grande (BRAZIL)

FACULTAD DE CIENCIAS UNIVERSIDAD DE LA REPÚBLICA DE URUGUAY, FCIEN, with legal address at Iguá 4225 casi Mataojo, 11400, Montevideo (URUGUAY)

INSTITUTO NACIONAL DE SALUD, INS, with legal address at Jirón Cápac Yupanqui 1400 - Jesús María, 15072, Lima (PERU)

UNIVERSIDAD DE ALMERÍA, UAL, with legal address at Carretera Sacramento, s/n, 04120, Almería (SPAIN)

UNIVERSITY OF WARSAW, UW, with legal address at Krakowskie Przedmiescie 26/28, 00-927, Warsaw (POLAND), represented by Vice-Rector of the University of Warsaw for Research – prof. dr hab. Zygmunt Lalak - authorization number BP-015-0-530/2024

MEDICAL UNIVERSITY OF WARSAW, WUM, with legal address at Zwirki i Wigury 61, 02-091, Warsaw (POLAND), represented by Professor Marcin Sobczak, MD, PhD, Vice Rector for Science and Technology Transfer, Medical University of Warsaw

ADMINISTRACIÓN NACIONAL DE LABORATORIOS E INSTITUTOS DE SALUD "DR. C. G. MALBRÁN", INEI, with legal address at Vélez Sarsfield 563, C1282AFF, Ciudad Autónoma de Buenos Aires (ARGENTINA)

hereinafter, jointly or individually, referred to as "Parties" or "Party" relating to the Action entitled "Observatory for Genomic surveillance of Tuberculosis transmission and migration in Europe and LatinAmerica", in short "OBSERV-TB", hereinafter referred to as the "Project".

WHEREAS:

The Parties, having considerable experience in the field concerned, have submitted a proposal for the Project to the Funding Authority as part of the EU-LAC 5th EU-LAC Joint Call in STI

2025. The Call selected this Collaborative Research Project (hereinafter referred to as "CRP") for funding.

The Parties are separately funded by their national Partners of EU-LAC- which are in charge to notify and wire the fundings following their own regulations.

The Parties wish to set up the rules concerning this CRP and the rights and obligations of the Parties.

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

1- DEFINITIONS

Words beginning with a capital letter shall have the following meaning:

"Access rights" means licenses and user rights to Background or Results.

"Background" means any and all data, know-how or information, software, material, intellectual property rights, needed to implement the action or exploit the results, which is (i) controlled by a Party prior to the Effective Date (ii) developed, conceived, licensed to or acquired by a Party during the term of the consortium agreement, independently from the work in this CRP, but solely to the extent that such data, information, know-how, material, software and/or IPRs are introduced into the consortium agreement by the controlling Party.

"Collaborative Board" means the decision-making body of the Collaborative Research Project.

"Collaborative Research Project (CRP)" means a project set up by two or more research groups that are funded by their respective national funding organizations (the Partners of EU-LAC) and organized in a transnational co-operation.

"Consortium" means all the Parties in the Collaborative Research Project.

"Consortium Agreement" means this agreement between the Parties in a CRP for its implementation.

"Consortium plan" means the description of the action which may be updated by the Collaborative Board.

"Dissemination" means the disclosure of Results by any appropriate means other than publication resulting from the formalities for protecting Results.

"Fair and Non-discriminatory Conditions" means fair market conditions.

"IPR Conditions" means special rules on Intellectual Property Rights for Collaborative Research Projects which are complementary to the national rules and are part of the conditions stated in the national funding contract or this consortium agreement.

"Legitimate interest" means a Party's interest of any kind, particularly a commercial interest which may be claimed in the cases provided for in these IPR Conditions. To this end the Party must prove that failure to take account of its interest would result in its suffering disproportionately great harm.

"Material" means any kind of material being a Background or Result not owned or co-owned by the receiving Party.

"MPDR" means Massively Produced Data or Resource being one of the followings:

- Data which are commonly stored and made available in databanks: Sequences or part of sequences for DNA, RNA, protein; Information and annotations concerning these sequences;
- Results from transcriptome, proteome, metabolome, or any other results of high throughput measurements of the accumulation of various classes of molecules in living organisms and related data;
- Newly designed Molecular Tests tailored for the detection of specific bacterial strains.
- Living organisms' collections, which may be stored and made available in resource centers:
 - Bacterial strains including banks of genomic DNA or cDNA;
 - Mutant bacterial collections obtained by high throughput mutagenesis (EMS, radio induced, tagging).

"Need" or "needed" shall mean that, without the grant of such Access rights

- In the case of Access rights granted for the execution of the CRP, carrying out the tasks assigned to the recipient Party would be impossible, significantly delayed, or require significant additional financial and human resources
- In the case of Access rights granted for Use, the Use of a defined and material element of the recipient Parties' own Results would be technically or legally impossible.

"Party" or "Parties" means any party or parties participating in this Collaborative Research Project. In certain cases where it is the researcher or a group of researchers who apply for funding from a Partner of EU-LAC, Party shall notwithstanding refer to the host institution to which the Partner of EU-LAC allocates the funding.

"Partners of EU-LAC" means the national funding organizations involved in the Coordination Action EU-LAC 5th EU-LAC Joint Call in STI 2025.

"Patent, Patenting, Patentable" means any term related to Patent in this Consortium Agreement shall include in addition to the patents any other intellectual property right which is submitted for its validity to registration in an official registry such as plant varieties, trademarks or internet domain names or registered to unofficial registry for managing proof such as for software and databases.

"Plan for using and disseminating the Results" means the report on the Parties' intentions for the protection, use and Dissemination of the Results generated under the CRP which was contained in the full proposal of the research

- 4 "Results" means the results, including information, whether or not they can be protected, arising from the Collaborative Research Project, as well as copyrights or rights pertaining to such results following applications for, or the issue of patents, designs, supplementary protection certificates or similar forms of protection.

"Third Party" means any party other than the Parties.

- 5 "Use" means the direct or indirect utilization of Results in any scientific research activities or for developing, creating and marketing a product or process or for creating and providing a service.

"Utilization Agency" means an organization that supports the exploitation and dissemination of Results into commercial use including the generation of intellectual and industrial property to be listed in the Consortium Agreement.

2- PURPOSE AND CONTENT OF THE AGREEMENT

2.1. Purpose of the Agreement.

The purpose of this Consortium Agreement is to set forth the basic principles concerning:

- Rights and duties of the Parties over the CRP, its results and their exploitation, notably access rights on Results and rules for publication and Dissemination
- Organization of the management of the CRP
- Performance of the CRP by the Parties
- Intellectual Property Rights

2.2. Content of the Agreement.

This Consortium Agreement and its annexes shall constitute the entire agreement among the Parties in respect of the CRP. Notwithstanding the foregoing, commitments previously undertaken through international instruments, institutional agreements, or national regulations applicable to the Parties, especially those of a public nature, shall remain in force to the extent that they do not conflict with this Agreement.

The Parties guarantee that nothing in the present Consortium Agreement is contrary to the conditions defined by their Partner of EU-LAC for the financing of their research.

In case of inconsistency between the different elements composing this Consortium Agreement, the provisions contained in the main text of this Consortium Agreement shall prevail over those contained in Annex 1 "IPR Conditions" which shall also prevail over those of Annex 2.

3- ENTRY INTO FORCE, DURATION AND TERMINATION

3.1. Entry into force

An entity becomes a Party to this Consortium Agreement upon signature of this Consortium Agreement by a duly authorized representative.

This Consortium Agreement shall have effect from the Effective Date identified at the beginning of this Consortium Agreement.

3.2. Duration and termination

This Consortium Agreement shall continue in full force and effect until complete fulfilment of all obligations undertaken by the Parties under this Consortium Agreement, and for a maximum period of 40 months, unless extended by the Collaborative Council and in accordance with the availability of financing and national regulations applicable to each Party.

3.3. Survival

The provisions relating to Access Rights, Dissemination and Confidentiality for the time period mentioned therein, as well as for Liability, Applicable law and Settlement of disputes shall survive the expiration or termination of this Consortium Agreement

Termination shall not affect any rights or obligations of a Party leaving the Consortium incurred prior to the date of termination, unless otherwise agreed between the Collaborative Board and the leaving Party. This includes the obligation to provide all input, deliverables and documents for the period of the leaving Party's participation in the Project.

4- RESPONSABILITIES OF THE PARTIES

4.1. Scope and financial resources of the CRP

The description, allocation and performance of tasks in the CRP tasks will be carried out in accordance with the projects approved by the EU-LAC Partners, respecting the technical, administrative, and budgetary autonomy of each Party, as well as the limitations arising from their respective national regulations. Its content is hereafter annexed under Annex 2.

4.2. General Principles

Each Party undertakes to take part in the efficient implementation of the Project, and to cooperate, perform and fulfill, promptly and on time, all of its obligations under this Consortium Agreement as may be reasonably required from it.

Each Party undertakes to notify promptly any significant information, fact, problem or delay likely to affect the Project.

Each Party shall provide the information reasonably required by the Coordinator, provided that such delivery does not contravene confidentiality obligations, data protection, institutional regulations or legal restrictions applicable to the Party.

Each Party shall take reasonable measures to ensure the accuracy of any information or materials it supplies to the other Parties. The Parties acknowledge that all such information and materials are provided on an "as is" basis, without prejudice to liability for willful misconduct or gross negligence in providing incorrect or misleading information.

Each Party shall ensure that its work on the Project complies fully with all applicable local, government and international laws, regulations and guidelines which are effective during the period of the Consortium Agreement, including those governing health and safety, data protection, and where relevant, the use of human or animal subjects and good clinical practice. In this regard, each Party shall maintain the confidentiality, in accordance with the applicable laws, regulations and guidelines, of all samples and data relating to the use of human subjects, which is created or used in the course of the Project.

Each Party shall secure all necessary approvals from the relevant research ethics committees and/or Institutional Animal Care and Use Committee before undertaking any part of the Project requiring ethics committee approval and shall, if required, obtain properly signed informed consent and acknowledgement forms from any human subjects, or their legal guardians, who they will involve in the Project. Where any part of the Project takes place in a hospital, the Party involved shall first obtain all necessary approvals, indemnities and agreements from that hospital.

When a Party (the "Provider") sends biological material to another Party (the "Recipient") in respect of the Project, a material transfer agreement (MTA), shall be concluded between such Parties to specify the conditions applying to such transfer of material. The material shall only be used for the purpose of the Project and only for as long as is necessary for that purpose. The Recipient will be entirely responsible for the use of the biological material and the Provider shall have no obligation or liability for the material, except for gross negligence or willful misconduct. Material provided in the performance of the Project shall remain the property of

the Provider. The Recipient shall not be entitled to transfer the material to any third party (including another Party) without the Provider's prior written consent.

Each Party is responsible for ensuring that the MTA is adapted to the relevant situation and that it complies with this Consortium Agreement and all applicable rules, laws or regulations.

A draft of MTA is attached as Annex 2.

4.3. Breach

In the event that the Collaborative Board identifies a breach by a Party of its obligations under this Consortium Agreement (e.g. improper implementation of the Project), the Coordinator or, if the Coordinator is in breach of its obligations, the Party appointed by the Collaborative Board will give formal notice to such Party requiring that such breach be remedied within 30 calendar days. If such breach is substantial and is not remedied within that period or is not capable of remedy, due process shall be followed, guaranteeing the right of defense of the Party involved, to determine the consequences, which may include termination of its participation.

4.4. Involvement of third parties

A Party that enters into a subcontract or otherwise involves third parties (including but not limited to Affiliated Entities) in the Project remains solely responsible for carrying out its relevant part of the Project and for such third party's compliance with the provisions of this Consortium Agreement. It has to ensure that the involvement of third parties does not affect the rights and obligations of the other Parties under this Consortium Agreement.

5- LIABILITIES TOWARDS EACH OTHER

No Party shall, without prior written consent of the other Parties assign or otherwise transfer partially or totally any of its rights or obligations under this Consortium Agreement.

5.1. General Principles

Except as provided below (article 5.2), each Party shall be liable for damage resulting from the performance of its work, subject to the conditions of this Consortium Agreement. A Party's aggregate liability towards the other Parties collectively shall be limited to the amount of the Party's funds actually received by that Party for the Project, except in cases of willful misconduct or gross negligence costs

Each Party is in charge of its own personnel insurance coverage according to its national applicable law including social security law and accident at work and occupational diseases regulations. Each Party is liable for any damages caused by its own personnel. Each employer performs its own formalities.

Self-insured public bodies will assume themselves the financial consequences of their liability.

5.2. Exclusion of indirect damages

No Party shall be responsible to any other Party for indirect or consequential loss or similar damages such as loss of profit, loss of revenue, or loss of contracts or a similar loss or damage, provided such damage was not caused by a willful act or by a breach of confidentiality related to the project.

5.3. Liability towards Third Parties

Subject always to such other undertakings and warranties as are provided for in this Consortium Agreement, each Party shall be solely liable for any loss, damage or injury to Third Parties resulting solely from the performance or non-performance of its work.

5.4. Liability for Subcontractors, Third Parties

Each Party shall remain fully responsible for the performance of:

- a) any part of its work;
- b) its obligations under this Consortium Agreement: by any subcontractor.

by Third Parties which contribute to the CRP on the basis of an agreement between itself and such Third Party.

Therefore, said Party shall ensure that (i) such subcontract or agreement fully complies with the requirements of this Consortium Agreement; (ii) the other Parties' Access Rights are fully preserved; and (iii) subcontractors and Third Parties shall have no access to any other Party's Results or Background without the latter's prior written consent.

5.5. Force Majeure

No Party shall be considered to be in breach of this Consortium Agreement if it is prevented from fulfilling its obligations under the Consortium Agreement by Force Majeure.

Each Party will notify the Collaborative Board of any Force Majeure without undue delay. If the consequences of Force Majeure for the Project are not overcome within 6 weeks after such notification, the transfer of tasks - if any - shall be decided by the Collaborative Board.

6-GOVERNANCE STRUCTURE:

The Parties shall establish a Collaborative Board led by the coordinator (who can't be substituted) composed of authorized representative(s) (principal researcher) of each Party.

Each Party may change its representative to the Collaborative Board at any moment, but will have to inform the other Parties of this change in writing (including email) and the change must be approved by the coordinator. Nonetheless the Parties shall use all reasonable endeavors to maintain the continuity of their representation.

The members of the Collaborative Board will nominate one of them as Chairman of the Collaborative Board no later than the day of their first meeting. He/she will be nominated for the whole duration of the CRP.

Each Collaborative Board member, upon request to the Chairman, may be assisted by a representative from its organization/institution or by an external expert as advisor after these advisors have been bound by confidentiality under the same terms as those described in this Consortium Agreement. The Collaborative Board will meet: in principle at request of its Chairman, or at any other time, when necessary, at request of one of the Party. Meetings shall be convened by the Chairman.

The regular meetings will be proposed by the coordinator and held, subject to the previous agreement of an agenda and the items dealt on them, by all the Parties.

The meetings may take place via teleconference and decisions and/or advices on urgent matters may be agreed by electronic means (such as exchange of emails). Decisions will preferably be adopted by consensus. If consensus is not reached, they will be adopted by simple majority, except for those affecting the Parties' substantial, financial, or intellectual property rights, which will require unanimity.

7. FINANCIAL PROVISIONS

Each Party supports its own costs and is funded by its national Partner of EU-LAC.

8. RESULTS

Rules about IPR contained in Annex 1 should apply.

8.1. Dissemination of Results: Publication

Rules related to publication described under article 2.3 of the IPR Conditions shall apply. The following provisions are complementary to them.

The composition and order of the authorships for the articles produced within the Project will be determined after having been discussed and agreed by all the involved Parties. The discussion will be led by the Coordinator of the Project. To be an author a significant contribution to the study should have been done. The same will be applied for oral or poster communications to scientific meetings or congresses.

All information, Results and data generated within the Project must be kept confidential and shall not be published, disclosed or otherwise made publicly available prior to the assessment of their protectability and, where appropriate, the filing of relevant intellectual property protection applications, including patent applications, by the owning Party or Parties.

The usage of the information, Results and data obtained in the Project as part of PhD thesis has to be previously authorized in writing by the Coordinator, who may not deny such authorization without justification, respecting the academic rights of the Parties.

The distribution of a scientific and/or financial activity report by a Party, if requested from its State, its administrative organization and/or its Partner of EU-LAC or if requested in order to comply with applicable laws, regulations or with a court or administrative order, shall not constitute a public disclosure, but an internal communication. The Party will then have the responsibility to take the appropriate measures in order to ensure the maintenance of confidentiality of these reports. However, prior to such distribution, the disclosing Party shall notify the other Parties in writing of the intended disclosure at least 7 calendar days in advance.

8.2. Publication of Results of the CRP

Any publication or communication, whether written or oral, in connection with Results is shall be submitted to the Collaborative Board.

To this end, the full text of the proposed publication or communication shall be submitted to the Collaborative Board at least 30 calendar days before the submission to publication/communication date. The Collaborative Board may object within 15 calendar days, and the objection has to include the reason and the proposal for overcoming it. The Collaborative Board may request a delay of the publication or communication for a period not exceeding sixty (60) calendar days in order to address the objections raised. Publication or communication shall be permitted only once the objections have been resolved.

An objection is justified if:

- a) the protection of the objecting Party's Results or Background would be adversely affected, or
- b) the objecting Party's legitimate interests in relation to its Results or Background would be significantly harmed, or
- c) the proposed publication includes Confidential Information of the objecting Party.

The objection has to include a precise request for necessary modifications.

Communications to Conferences will be notified at least 30 calendar days beforehand.

This obligation, nonetheless, should not prevent the application of a Patent in accordance with the provisions of this Consortium Agreement, nor should it unnecessarily prevent a possible commercial use.

8.3. Mandatory mention on publications

Any publication or communication as authorized in application of article 8.1 must acknowledge EU-LAC by a mention such as: "Results have been achieved within the framework of the EU-LAC 5th EU-LAC Joint Call in STI 2025, with funding from....".

9- ACCESS RIGHTS

In Annex 1, the Parties have identified and agreed on the Principles of Access rights.

Each Party shall carry out its tasks in accordance with the Consortium Plan and shall bear sole responsibility for ensuring that its acts within the Project do not knowingly infringe third party property rights. Where the need to safeguard intellectual property rights is identified, any related measures shall be agreed in advance in writing between the Parties involved in the Project.

10- NON-DISCLOSURE OF INFORMATION

10.1. Confidentiality. General Principle

All information ,including Background and Results, in whatever form or mode of communication, disclosed by a Party (the "Disclosing Party") to any other Party (the "Recipient") in connection with the negotiation, execution and implementation of this Consortium Agreement and the Project, and which is explicitly marked as "confidential" at the time of disclosure, or when disclosed orally, identified as confidential at the time of disclosure and confirmed in writing within 15 calendar days thereafter, shall be considered "Confidential Information".

The Recipients hereby undertake, for a period of 4 years or such longer period as may be required by the national regulations applicable to each Party, after the end of the Project:

- not to use Confidential Information for any purpose other than that for which it was disclosed;
- not to disclose Confidential Information without the prior written consent of the Disclosing Party;
- to ensure that internal distribution of Confidential Information by a Recipient shall take place on a strict need-to-know basis; and

- to return or destroy, upon request, all Confidential Information, including all copies thereof, and to delete all electronic copies to the extent reasonably practicable. Copies may be retained only where required by applicable law or regulation or for evidence of ongoing obligations, provided that confidentiality obligations continue to apply. The recipients shall be responsible for the fulfilment of the above obligations on the part of their employees or third parties involved in the Project and shall ensure that they remain so obliged, as far as legally possible, during and after the end of the Project and/or after the termination of the contractual relationship with the employee or third party.

The above shall not apply for disclosure or use of Confidential Information, if and in so far as the Recipient can show that:

- the Confidential Information has become or becomes publicly available by means other than a breach of the Recipient's confidentiality obligations;
- the Disclosing Party subsequently informs the Recipient that the Confidential Information is no longer confidential;
- the Confidential Information is communicated to the Recipient without any obligation of confidentiality by a third party who is to the best knowledge of the Recipient in lawful possession thereof and under no obligation of confidentiality to the Disclosing Party;
- the disclosure or communication of the Confidential Information is foreseen by provisions of the Consortium Agreement;
- the Confidential Information, at any time, was developed by the Recipient completely independently of any such disclosure by the Disclosing Party;
- the Confidential Information was already known to the Recipient prior to disclosure; or
- the Recipient is required to disclose the Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, subject to the provision below.
- 'The confidentiality obligations shall not apply if and in so far as **the Disclosing Party or the Recipient** can show that the disclosure or communication of the Confidential Information is foreseen by provisions of the Grant Agreement.

The Recipient shall apply the same degree of care with regard to the Confidential Information disclosed within the scope of the Project as with its own confidential and/or proprietary information, but in no case less than reasonable care.

Each Party shall promptly advise the other Party in writing of any unauthorized disclosure, misappropriation or misuse of Confidential Information after it becomes aware of such unauthorized disclosure, misappropriation or misuse.

If any Party becomes aware that it will be required, or is likely to be required, to disclose Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, it shall, to the extent it is lawfully able to do so, prior to any such disclosure

- notify the Disclosing Party, and
- comply with the Disclosing Party's reasonable instructions to protect the confidentiality of the information.

Where the communication of any data, Results, Background or other document is needed in performing the work in the CRP, the Parties shall first satisfy themselves that the recipient will keep it confidential and use it only for the purpose for which it is communicated taking into account that this does not substitute the rules concerning the Material Transfer Agreements defined under this Consortium Agreement.

The confidential information must be maintained confidential until the time when the results are published.

11- MISCELLANEOUS

11.1 Annexes

- Annex 1- IPR Conditions
- Annex 2- Collaborative Research Project.
- Annex 3- Material Transfer Agreement.

11.2 Language

This Consortium Agreement is drawn up in the English language, which shall govern all documents, notices and meetings, for its application and/or extension or in any other way relative thereto.

11.3. Notices and other communication

Any notice to be given under this Consortium Agreement shall be in writing to the addresses and recipients as listed in the most current address list kept by the Coordinator.

If it is required in this Consortium Agreement that a formal notice, consent or approval shall be given, such notice shall be signed by an authorized representative of a Party and shall either be served personally or sent by mail with recorded delivery or telefax with receipt acknowledgement.

Other communication between the Parties may also be affected by other means such as e-mail with acknowledgement of receipt, which fulfils the conditions of written form

Any change of persons or contact details shall be notified immediately by the respective Party to the Coordinator. The address list shall be accessible to all concerned.

11.4. Mandatory statutory law.

Nothing in this Consortium Agreement shall be deemed to require a Party to breach any mandatory statutory law under which the Party is operating.

11.5 Applicable law.

This Consortium Agreement shall be construed in accordance with and governed by the laws of Belgium, without prejudice to the mandatory application of the internal public law rules of each Party, where applicable. a Public Body), by reason of its legal nature, applicable national law, or internal legal limitations, is prevented from submitting to international arbitration, that Party shall duly notify the other Parties. In such case, disputes involving that Party shall be resolved through the mechanisms provided for in its national legislation or, by mutual agreement between the Parties, through other alternative dispute resolution mechanisms that are compatible with such limitations. Notwithstanding the foregoing, the Parties may resort to the competent judicial authorities to request precautionary or provisional measures that may be necessary for the protection of their rights or legitimate interests.

11.6 Settlement of disputes.

The Parties shall endeavor to settle their disputes amicably. All disputes arising out of or in connection with this Consortium Agreement, which cannot be solved amicably, shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one arbitrator appointed in accordance with the said Rules. However, should any Party (e.g. a Public Body) show that certain provisions of its national law or other applicable domestic limitations prevents it from submitting the relevant dispute to arbitration, then the concerned Parties will submit the dispute to the Courts of Brussels.



Instituto de Investigación Sanitaria Gregorio Marañón



FUNDACIÓN INVESTIGACIÓN BIOMÉDICA
HOSPITAL GREGORIO MARAÑÓN

12. SIGNATURES

Mrs. Teresa Fernández Alonso (Director)
FUNDACIÓN PARA LA INVESTIGACIÓN HOSPITAL GREGORIO MARAÑÓN
Date:



Instituto de Investigación Sanitaria Gregorio Marañón



FUNDACIÓN INVESTIGACIÓN BIOMÉDICA
HOSPITAL GREGORIO MARAÑÓN

Name:



UNIVERSIDADE FEDERAL DO RIO GRANDE

Date:



Instituto de Investigación Sanitaria Gregorio Marañón



FUNDACIÓN INVESTIGACIÓN BIOMÉDICA
HOSPITAL GREGORIO MARAÑÓN

Name:

FACULTAD DE CIENCIAS UNIVERSIDAD DE LA REPÚBLICA DE URUGUAY

Date:



Instituto de Investigación Sanitaria Gregorio Marañón



FUNDACIÓN INVESTIGACIÓN BIOMÉDICA
HOSPITAL GREGORIO MARAÑÓN

Name:

INSTITUTO NACIONAL DE SALUD

Date:

Inscrita en el Registro de Fundaciones de la Comunidad de Madrid. Hoja Personal 285. Inscripción 1ª, Tomo XXXVIII, Folios 302 y siguientes - C.I.F. G-83195305

FUNDACIÓN PARA LA INVESTIGACIÓN BIOMÉDICA HOSPITAL GREGORIO MARAÑÓN

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Instituto de Investigación Sanitaria Gregorio Marañón



FUNDACIÓN INVESTIGACIÓN BIOMÉDICA
HOSPITAL GREGORIO MARAÑÓN

Name:

UNIVERSIDAD DE ALMERÍA

Date:



Instituto de Investigación Sanitaria Gregorio Marañón



FUNDACIÓN INVESTIGACIÓN BIOMÉDICA
HOSPITAL GREGORIO MARAÑÓN

Name:

UNIVERSITY OF WARSAW

Date:



Instituto de Investigación Sanitaria Gregorio Marañón



FUNDACIÓN INVESTIGACIÓN BIOMÉDICA
HOSPITAL GREGORIO MARAÑÓN

Name:

MEDICAL UNIVERSITY OF WARSAW

Date:



Instituto de Investigación Sanitaria Gregorio Marañón



FUNDACIÓN INVESTIGACIÓN BIOMÉDICA
HOSPITAL GREGORIO MARAÑÓN

Name:

ADMINISTRACIÓN NACIONAL DE LABORATORIOS E INSTITUTOS DE SALUD "DR. C. G. MALBRÁN"

Date:

Annex 1 - IPR Conditions

I. General Principles

These rules shall promote the protection of intellectual property and the use and dissemination of results. They should ensure that Parties have mutual access to Background and to Results arising from research work to the extent necessary to conduct the research work or to use the resulting Results. At the same time, they should guarantee the protection of the Parties' intellectual and industrial assets.

These IPR Conditions set out the rules governing the dissemination and use of results from Collaborative Research Projects carried out under the Joint Calls established by Partners of EU-LAC.

II. Rules For Ownership, Access Rights, Dissemination and Use

I. Ownership of Results

- 1.1. Results arising from work carried out under a Collaborative Research Project shall be owned by the Party that generates them.
- 1.2. Where several Parties have jointly carried out work resulting in such Results and their respective contributions cannot be ascertained, the Results shall be jointly owned. The Party shall agree on the allocation of ownership and the terms governing the exercise of such ownership in accordance with these IPR Conditions and applicable national funding rules. Ownership shares shall be determined based on the respective intellectual contributions of each Party.
- 1.3. In case of joint ownership, the Parties shall use best efforts to conclude a joint ownership agreement within six (6) months from the date on which such Results has been generated. Until such agreement is concluded:
 - Any form of commercial exploitation of the Jointly Owned Results, including the granting of licenses to third parties, will require the prior, express and written consent of all co-owners, which may not be arbitrarily or unjustifiably denied, and the corresponding compensation conditions must be established by agreement between the Parties.
- 1.4. Where employees of the Parties or Utilization agencies are entitled to claim rights to Results, the relevant Party shall ensure that such rights are transferred or otherwise arranged in a manner consistent with this Agreement, applicable funding rules, and the rights of the other Parties.
- 1.5. Each Party may identify specific third parties it intends to transfer the ownership of its Results. The transferring Party shall, however, at the time of the transfer, inform

the other Parties of such transfer at least 30 calendar days before the transfer and shall ensure that the rights of the other Parties under this Agreement and the Funding Agreement will not be affected by such transfer and that previously set rules regarding the exercise of joint ownership of Results will be respected by such specific third parties who will acquire such right. Where a Party transfers ownership of Results, it shall take steps or conclude agreements with the other Parties to pass on its obligations to the assignee. The Collaborative Board or other Parties in the CRP may object within 30 days of notification to such a transfer of ownership if this would adversely affect their Access rights and/or Legitimate Interest. Furthermore, the transferee shall expressly assume all obligations arising from this Consortium Agreement.

The Partners of EU-LAC concerned with that CRP may object to any transfer of ownership to Third Parties, in particular to those not established in a Member State or an associated State, if such a transfer is not in accordance with the interests of developing the competitiveness of the dynamic, Results-based European economy, or is inconsistent with ethical principles.

2. **Protection of Results**

- 2.1. The Party that is the sole owner of any Results shall be solely responsible for deciding on, managing and implementing the protection of such Results, including the choice of form and scope of intellectual property protection.
- 2.2. In the case of jointly owned Results, the Parties concerned shall enter into a separate written co-ownership agreement without undue delay, governing in particular the allocation of rights, shares, and obligations with respect to such Results, including their protection, maintenance, exploitation, and enforcement.
- 2.3. The allocation of ownership shares in jointly owned Results shall be determined in proportion to the respective intellectual contribution of each Party to the creation of such Results.
- 2.4. Until the co-ownership agreement is concluded, the Parties shall cooperate in good faith and shall not take any actions that would prejudice the protection or exploitation of the jointly owned Results.
- 2.5. A Party may publish or allow the publication of any data relating to Results generated within the Project, provided that due consideration has been given to the protection of intellectual property rights, confidentiality, and the legitimate interests of the other Parties.

- 2.6. The Collaborative Board and the other Parties in the same CRP shall be given prior written notice of any intended publication.
- 2.7. The Collaborative Board will review the proposed publication of Results.
- 2.8. It is understood that Results solely owned by a Party (i.e. not jointly owned Results) may be published only by the owning Party.

3. Plan for using and disseminating the Results

The plan for using and disseminating the Results, which is part of the full proposal, shall be revised every 12th month.

4. Principles for Access rights

Access rights shall be granted on written request. The granting of Access rights may be made conditional on the conclusion of specific agreements, aimed at ensuring that they are used only for the intended purpose, and the giving of appropriate undertakings as to confidentiality. Parties may also conclude agreements with the purpose, in particular, of granting additional or more favorable Access rights, including Access rights to Third Parties or specifying the requirements applicable to Access rights, but not restricting the latter. Such agreements shall comply with the applicable competition rules. The Partners of EU-LAC concerned with this CRP may object to any grant of Access rights to Third Parties, in particular to those not established in a Member State or an Associated State, if such a grant is not in accordance with the interests of developing the competitiveness of the dynamic, Results-based European economy, or is inconsistent with ethical principles. Each Party shall bear sole responsibility for ensuring that its acts within the Project do not knowingly infringe third party property rights.

- 4.1. Access Rights to Background shall be granted provided that the granting Party is entitled to grant them.
- 4.2. No right to sublicense shall be granted unless otherwise expressly agreed in the Consortium Agreement.
- 4.3 The Consortium Agreement shall include an Annex 4 entitled "Background" which shall list all Background necessary for the performance of the Project and made available by each Party to the other Parties.
- 4.4 Parties in the same CRP shall be informed as soon as possible by the Party required to grant Access rights of any limitations to the granting of Access rights to Background, of any obligations to grant rights to Results, or of any restriction which might substantially affect the granting of Access rights, as the case may be. The requesting Party must show that the Access rights are needed.
- 4.5 A Party may explicitly exclude specific Background from Access Rights obligations by written agreement between the Parties prior to the entry of a new Party into the CRP.

- 4.6 Except where the Party granting Access Rights so agrees, such rights shall confer no entitlement to grant sublicenses.

5. **Access rights for the execution of CRPs**

- 5.1. Parties in the same CRP shall have Access Rights to the Results arising from work carried out under the concerned CRP and to the Background, if that Results or Background is needed to carry out their own work under that CRP. Access rights to Results shall be granted on a royalty-free basis. Access rights to Background shall also be granted on a royalty-free basis, unless otherwise agreed in the Consortium Agreement.
- 5.2. Subject to its Legitimate interests, the termination of the participation of a Party shall in no way affect the obligation to grant Access rights to the other Parties in the same CRP until its end.

6. **Access rights for Use**

- 6.1. Parties in the same CRP shall have Access Rights to the Results arising from work carried out under the relevant CRP and to Background, if that Results or Background is needed to deliver their Results under this Project only. Access rights to Results shall, for bona-fide non-commercial research purposes be granted on royalty free basis, and in all other cases be granted under Fair and Non-discriminatory Conditions, unless otherwise agreed in the Consortium Agreement. Access rights to Background shall be granted under Fair and Non-discriminatory Conditions to be agreed in writing.
- 6.2. Subject to the Parties' Legitimate interests, Access Rights may be requested up to two years after the end of the CRP or for the longer period permitted by the national regulations applicable to each Party, whichever is more favorable.

7. **Incompatible or restrictive commitments**

- 7.1 Parties shall make no commitments incompatible with the obligations provided for in the national funding rules.



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Annex 2 - Material Transfer Agreement

The following Parties:

[Name of Sending Party] [Legal statute]

Having its registered office at: [address line 1]

[address line 2]

[country]

Represented by: [Name of the responsible scientist]

Function: [Function of the representative and name of its laboratory] Hereinafter referred to as the "Sending Party"

AND

[Name of Receiving Party] [Legal statute]

Having its registered office at: [address line 1]

[address line 2]

[country]

Represented by: [Name of the responsible scientist]

Function: [Function of the representative and name of its laboratory] Hereinafter referred to as the "Receiving Party"

WHEREAS

The Sending Party and the Receiving Party collaborate or have collaborated in the Consortium Agreement [name of the Consortium] signed the [date] in which they agreed for modalities of exchange of Material as defined in this Consortium Agreement.

NOW THEREFORE in application of the said Consortium Agreement, the Sending Party agrees to send Material to the Receiving Party in the terms defined below.

The receiving Party especially agrees to the following conditions:

- To use the Material transmitted for the sole purpose(s) expressly authorized within the framework of the Project, and in accordance with applicable national and international regulations, including provisions on biosafety, biodiversity and access to genetic resources, where appropriate;
- Not to use the Material transmitted outside its laboratory (on the address specified in the MTA), and not to transfer, assign or make available the Material, in whole or in part, to any Third Party, without the prior, express and written consent of the sending Party and, where appropriate, the competent national authorities.;
- To limit access to the Material to those of its personnel involved in its part of the CRP and oblige them to comply with the provisions hereof;
- To handle Material in compliance with all national laws of the Sending Party and international laws, regulations and guidelines which are applicable at the time of use. Material shall be handled only by those with sufficient skill, Results, experience and ability to use the Material;
- The receiving Party does not acquire any proprietary rights on Material or its derivatives, unless expressly agreed otherwise between the Parties;
- The results derived from the use of the Material shall be the property of the Party that generates them, without prejudice to the rights of the Transferring Party when such results are substantially based on the transferred Material. The conditions of use, protection, and exploitation of such results must be agreed upon in advance between the Parties;
- Not to commercialize, Patent, protect, claim any title, deed or restrictive rights on the Material without the prior written permission of its owner(s);
- The sending Party do not warranty the sufficiency, accuracy or fitness for purpose of such Material, or the absence of any infringement of any proprietary rights of Third Parties by the use of such Material (provided however obligation for the sending Party to inform on any possible limitation to use) and the receiving Party will be responsible for the use of the Material, without prejudice to the Sending Party's liability in cases of willful misconduct or gross negligence;
- The Parties shall comply with applicable national and international regulations regarding access to genetic resources, associated traditional knowledge and fair and equitable sharing of benefits, where appropriate;
- The Receiving Party undertakes to comply with all applicable biosafety and bio protection standards, ensuring the safe handling of the Material.



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Note: The aforementioned conditions are the minimum conditions to be considered for a Material Transfer Agreement. The specific conditions shall be agreed between the Sending and the Receiving Party.

1 Description of Material:

[Describe here the Material which will be transmitted]

2 Use of the Material

[Complete as needed]

3 Document and technical information provided by the Sending Party to

the Receiving Party

[Complete as needed]

4 Price of the Material

[Complete as needed if the transfer is royalty free or royalty bearing, accordingly to the conditions of the Consortium Agreement]

Date of signature: xxxxx

[Sending Party]

[Name of representative]

[Function of representative]

[Receiving Party]

[Name of representative]

[Function of representative]