**CONSORTIUM AGREEMENT for PPP PROJECTS**

**TKI-programme Life Sciences & Health 2023**

tHIS CONSORTIUM AGREEMENT for PPP PROJECTS (the “**Consortium Agreement**”) is signed on [date] (the “**Effective Date**”) by and between:

1. Stichting Amsterdam UMC, having its principal place of business at De Boelelaan 1117, 1081 HV Amsterdam, the Netherlands, hereby represented by its fully owned subsidiary AMC Medical Research BV, lawfully represented in this matter by J.J. Brand, CFO of AMC Medical Research BVhereinafter referred to as the “**Coordinator**” and/or “**Research Organization**”; and
2. **Company]**, incorporated under [nationality] law, having its statutory seat in [place, country] and its address [address] and registered with the [nationality] Chamber of Commerce under number [number], hereinafter referred to as the “**NAME**” and/or “**Industrial Party**”;

The parties hereinafter also referred individually as “a **Party**” and collectively as “the **Parties**”.

whereas:

1. The Dutch Top Sector Life Sciences and Health (‘*Topconsortium voor Kennis en Innovatie*’ or ‘*TKI*’ *Life Sciences and Health*) is represented by Stichting Life Sciences Health – TKI (also acting under its trade name Health~Holland, hereinafter referred to as “**Stichting LSH-TKI**”), tasked by the Dutch government to promote and stimulate new public-private partnerships to undertake research and development projects in the life sciences;
2. To promote such partnerships, the Minister of Economic Affairs and Climate Policy has allocated certain funds to Stichting LSH-TKI, to grant allowances to projects under the TKI-programme Life Sciences & Health;
3. Coordinator has applied for funding within the scope of the TKI-programme Life Sciences & Health 2023 and Stichting LSH-TKI has awarded such funding (“**PPP Allowance**”) to Coordinator, giving Coordinator the opportunity to identify Coordinator projects that qualify for PPP Allowance as set forth in the definitive award (In Dutch: Definitieve toekenning LSH PPS-toeslag TKI Programma 2023).
4. Coordinator has delegated the responsibility to identify projects that qualify for such funding to IXA Office Amsterdam UMC, and the responsibility to receive and distribute the PPP Allowance from Stichting LSH-TKI to the applicants to its subsidiary AMR (hereinafter referred to as “**Toeslagverstrekker**”). Furthermore, Stichting Amsterdam UMC has authorized AMR to be the contracting party for this Consortium Agreement on behalf of Stichting Amsterdam UMC, and to bind Stichting Amsterdam UMC to all contractual obligations under this Agreement (other than the receipt and distribution of the PPP Allowance which are AMR’s obligations).
5. IXA Office Amsterdam UMC has determined that the application with the title [*title*] as described in the full application and budget forms, which are based on the TKI-LSH Match Application Form (the “Project Application) and the LSH-TKI Match Budget Form (the “**Budget**”) respectively, qualifies for funding under the PPP Allowance;
6. The Parties accept the funding under the PPP Allowance subject to the conditions of the PPP Allowance Regulation (as defined below) and the terms and conditions of this Consortium Agreement which has been pre-approved by Stichting LSH-TKI.
7. The Parties desire to specify the binding commitments among themselves with regard to the Project and the work to be allocated thereunder as set out in the “**Project Application**” attached to this Consortium Agreement in Annex 1, all in accordance with the terms and conditions of this Consortium Agreement;

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

1. **Definitions**

Words beginning with a capital letter shall have the meaning defined herein.

* 1. “**Access Rights**” means any license and/or user rights to a Party’s Background or Foreground;
	2. “**Affiliate**” means the legal entity that is either the ultimate parent company of a Party or that is under the direct or indirect control of a Party, or under the same direct or indirect control as the Party, control taking any in the following forms:
1. the direct or indirect holding of more than 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;
2. the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.
	1. “**Background**” means all information or material held by a Party prior to its participation to this Consortium Agreement or that has been developed or obtained by a Party after the Effective Date of this Consortium Agreement independently from the Project, as well as any intellectual property rights pertaining to such information or material;
	2. “**Budget**” means the budget in the final budget form providing an estimate of the total cost to carry out the Project Application calculated in accordance with the Financial Guidelines and including an overview of the contributions of each Party, attached as Annex 2;
	3. “**Chairperson**” means the Coordinator’s representative;
	4. “**Confidential Information**” has the meaning as defined in Section 10.1.
	5. “**Completion Date**” means the date of receipt by Stichting LSH-TKI of the report as referred to under Section 2.1 (ii) of the PPP Allowance Terms.
	6. “**Consortium Agreement**” means this consortium agreement as well as all annexes hereto;
	7. “**Defaulting Party**” means a Party which is notified by the other Party to be in substantial breach of its obligations under this Consortium Agreement in accordance with Section 3.2.3 of this Consortium Agreement;
	8. “**Effective Date**” means the date first written in the pre-amble;
	9. “**Foreground**” means any (tangible or intangible) output, such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated under the Project, as well as any rights attached to it, including intellectual property rights;
	10. “**GDPR**” means the General Data Protection Regulation (EU) 2016/679;
	11. “**Member**” has the meaning assigned to it in Section 6.1;
	12. “**Option**” has the meaning assigned to it in Section 8.5 of this Consortium Agreement;
	13. “**PPP Allowance**” (in Dutch: PPS-toeslag) means the PPP Allowance awarded to Stichting Amsterdam UMC, for projects within the scope of the TKI-programme Life Sciences & Health 2023;
	14. “**PPP Allowance Terms**” means the PPP Allowance terms that apply to the PPP Allowance, attached to this Agreement as Annex 4;
	15. “**PPP Allowance Regulation**” means the Dutch regulation of the Minister of Economic Affairs of July 11, 2014, published in the Staatscourant 2014, nr. 20679 including any legislative instrument superseding, amending, or replacing this regulation (‘Regeling nationale EZ-subsidies’) and the corresponding legislation, including but not limited to the Dutch decision of the Minister of Economic Affairs of November 21, 2008 published in the Staatscourant 2008, nr. 499, (‘Kaderbesluit nationale EZ-subsidies’) including any legislative instrument superseding, amending, or replacing this decision.
	16. “**Principal Investigator**” means [NAME] of the department of [DEPARTMENT]
	17. “**Project**” means the research project titled [title] first set out in the Project Application;
	18. “**Project Application**” means the research (and development) project submitted to IXA Office Amsterdam UMC in the Amsterdam UMC-PPP application form (that is based on the TKI-LSH match application form), as attached to this Consortium Agreement as Annex 1;
	19. “**Project Committee**” has the meaning assigned to it in Section 6.1;
	20. “**Project Plan**” means the research (and development) Project and all work to be performed as part of this Project including the allocation of the work and Budget, as set out in the Project Application;
	21. “**Stichting LSH-TKI**” means the Stichting Life Sciences and Health, also acting under its trade name Health~Holland, having its statutory seat in The Hague, the Netherlands and its address at Wilhelmina van Pruisenweg 104, 2595 AN, The Hague and registered with the Dutch Chamber of Commerce under number 27380989.

All Annexes to this Consortium Agreement are incorporated as obligations under the Consortium Agreement. Any reference herein to the Consortium Agreement shall also include the obligations under the Annexes.

1. **Project and Purpose**
	1. Project Duration. The Project shall start on [date] and shall end on [date] ([x (x) months/years]).
	2. Purpose. The purpose of this Consortium Agreement is to specify with respect to the Project the relationship among the Parties, in particular concerning the organisation of the work between the Parties as set out in the Project Plan in Annex 1 and in accordance with the Budget set out in Annex 2, the management of the Project and the rights and obligations of the Parties.
	3. PPP Allowance Regulation. The Parties acknowledge that the PPP Allowance Regulation applies to the PPP Allowance and Parties agree to adhere to the terms and conditions of the PPP Allowance Regulation as applicable under this Consortium Agreement.
2. **Entry into force, duration and termination**
	1. Term. This Consortium Agreement shall enter into effect as of the Effective Date and shall continue in full force and effect until the earlier of (i) the Completion Date or (ii) earlier termination of this Consortium Agreement in accordance with this Article 3.
	2. Termination. Each Party is entitled to terminate the Consortium Agreement with immediate effect upon written notice to the other Party, in the following events:
		1. Insolvency. If the other Party is declared insolvent or granted suspension of payments, or if an application is filed to that end or its business is liquidated dissolved or discontinued;
		2. Force Majeure. If the other Party is in a situation of force majeure as described in Article 5.5, which has continued for a period longer than ninety (90) days.
		3. Breach. If the other Party is in breach of its obligations under this Consortium Agreement (*e.g.* improper performance or implementation of the Project) and has failed to remedy such breach within 30 (thirty) calendar days of notification of such breach by the Party terminating the Consortium Agreement.
	3. Compensation by Defaulting Party.

If the Consortium Agreement has been terminated pursuant to Section 3.2.3, the Defaulting Party shall bear all actual and reasonable costs incurred by the other Party under the Project as a result of the Defaulting Party’s breach of obligations, provided that the reimbursement of such cost towards the other Party shall be limited to the total Budget.

* 1. Survival. Sections 2.3, 3.4, 12.4 and Articles 8, 9, 10 and 13 as well as Sections 1.4, 1.5, 2.11 – 2.13 of the PPP Allowance Terms and any other terms intended by their nature to survive earlier termination or expiration of this Consortium Agreement shall survive earlier termination or expiration 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 Parties. This includes the obligation to provide all input, deliverables and documents for the period of its participation.
1. **Responsibilities of the Parties**
	1. General Principles. Each Party agrees to take part in the efficient implementation of the Project, and to cooperate, perform and fulfil, promptly and on time, all of its obligations under this Consortium Agreement as may be reasonably required from it and in good faith as required by Dutch law.
	2. Information Obligations. Each Party undertakes to promptly notify in the Project Committee any significant information, fact, problem or delay likely to affect the Project. Each Party shall promptly provide all information reasonably required by the Project Committee to carry out its tasks. Each Party shall take reasonable measures to ensure the accuracy of any information (including Background and Foreground) or material it supplies to the other Party.
	3. Involvement of Third Parties. A Party is only allowed to involve third parties in the execution of its work under the Project upon prior approval thereof by the other Party. A Party that involves third parties (including, but not limited to, Affiliates) in the Project shall at all times remain responsible for the execution of its relevant part of the Project and for such third party’s compliance with the provisions of this Consortium Agreement. Such Party shall ensure that the involvement of third parties does not affect the rights and obligations of the other Party under this Consortium Agreement and shall be fully liable toward the other Party for such Affiliates and third parties acting in compliance with this Consortium Agreement..
	4. Reporting. In connection with the conditions and reporting requirements as set out in the PPP Allowance Terms and with regard to the Foreground as referred to in Section 8.3 below, the Parties shall provide the Coordinator with financial, scientific and progress reports with regard to the Project.
	5. GDPR compliance. Any information containing personal data shall be handled in accordance with all applicable privacy laws and regulations, including without limitation the GDPR and equivalent laws and regulations. If for the performance of the Project it is necessary to exchange personal data, the relevant Parties shall determine their respective positions towards each other (either as controller, joint controllers or processor) and the subsequent consequences and responsibilities according to the GDPR as soon as possible after the Effective Date and where required implement these in a separate written agreement.
2. **Warranties and Liability**
	1. Warranties. Each Party represents and warrants to the other Party that it has full power, authority and legal capacity to execute and to perform its obligation(s) under this Consortium Agreement, and the conclusion of this Consortium Agreement does not violate any of its contractual or other obligations.
	2. No Further Warranties. In respect of information or materials, Background and Foreground supplied by one Party to another under the Project, no warranty or representation of any kind is made, given or implied as to the sufficiency, accuracy or fitness for purpose of such information, nor as to the absence of any infringement of any proprietary rights of third parties. The receiving Party shall be entirely and solely liable for its use of the information and materials, Background and Foreground provided by another Party under this Consortium Agreement.

Each Party shall be fully liable for the performance of any part of its part of the Project as set out in the Project Plan, in respect of which it enters into any contract with a third party (*i.e*. a subcontractor).

* 1. Liability to Third Parties. Subject to such other undertakings as are provided for in this Consortium Agreement, each Party shall be solely liable for any loss, damage or injury to third parties resulting from its carrying out its parts of the Project and from its use of the Access Rights to the Background and Foreground, unless such liability on the use of Access Rights is expressly agreed upon between the Parties in writing.
	2. Limitation of Liability. No Party shall be liable for any indirect or consequential loss or similar damages such as but not limited to loss of profit, loss of revenue, loss of contract or the like. For any remaining contractual liability, each Party’s total aggregate liability under this Consortium Agreement towards the other Party in respect of any and all such claims shall not exceed that Party’s budget contribution (in cash and/or in kind) as foreseen in the Budget, except for and to the extent that such damage was caused by a willful act or gross negligence. The terms of this Consortium Agreement shall not be construed to amend or limit any Party’s statutory liability.
	3. Force Majeure. No Party shall be considered to be in breach of this Consortium Agreement if such breach is caused by force majeure. Each Party will promptly notify the Coordinator of any force majeure. If the consequences of force majeure for the Project are not overcome within 90 (ninety) days after such notification, the Coordinator may decide on transfer of tasks of the Party in breach or terminate such Party’s participation in accordance with Section 3.4.
1. **Governance**
	1. Project Committee. The Project Committee is responsible for strategic and scientific management of the Project. The Project Committee shall consist of one representative from each Party (hereinafter referred to as “**Member**”). Each Member shall be deemed to be duly authorised to deliberate, negotiate and decide on behalf of its organization all matters listed in Section 6.5 of this Consortium Agreement. The Coordinator shall chair all meetings of the Project Committee, unless decided otherwise by the Project Committee. A member of the IXA staff may join the Project Committee meetings but shall not have any voting rights as per Article 6.3.2.

If the Parties cannot come to a unanimous decision in the Project Committee, the decision may be escalated to senior management of both Parties in order to try and come to a mutually acceptable solution. If senior management is not able to come to such mutually acceptable solution, the Parties may submit the dispute for resolution in accordance with the provisions of settlement of disputes in Article 13 of this Consortium Agreement.

* 1. Operational procedures for the Project Committee
		1. *Representation in meetings.* Any Member shall use its best efforts to be present or represented at any meeting, and may appoint a substitute or a proxy to attend and vote at any meeting and shall participate in a cooperative manner in the meetings.
		2. *Preparation and organisation of meetings*. The Chairperson shall convene ordinary meetings of the Project Committee at least once every 6 (six) months and shall also convene extraordinary meetings at any time upon written request of any Member.
		3. *Notice of a meeting*. The Chairperson shall give notice in writing of a meeting including an agenda, to each Member as soon as possible and no later than 14 (fourteen) calendar days preceding an ordinary meeting and 7 (seven) calendar days preceding an extraordinary meeting.
		4. *Agenda*. Any agenda item requiring a decision by the Members must be identified as such on the agenda. Any Member may add an item to the original agenda by written notification to all of the other Members no later than 7 (seven) calendar days preceding the meeting. During a meeting of the Project Committee the Members can unanimously agree to add a new item to the original agenda, provided that all Members are present or represented.
		5. *Decision outside the Meeting*. Any decision may also be taken without a meeting if the chairperson circulates to all Members a written document which is then signed by the unanimity or the defined majority of Members.
		6. *Binding Decisions*. Decisions will only be binding once the relevant part of the minutes has been accepted according to Article 6.4 of this Consortium Agreement.
	2. Decision-making by the Project Committee
		1. *Voting rules and quorum.* Decisions shall be taken by unanimity of the votes validly cast at a meeting where all of the Members are present or represented subject to Section 6.3.2. below.
		2. *Votes.* Each Member or its representative shall have one vote.
	3. Minutes of Meetings.
		1. *Minutes of meetings.* The Chairperson shall produce written minutes of each meeting which shall be the formal record of all decisions taken. The Chairperson shall send draft minutes to the Member of the other Party within 14 (fourteen) calendar days of the meeting.
		2. *Corrections.* The minutes shall be considered as accepted if, within 14 (fourteen) calendar days from sending, the Member of the other Party has not objected in writing to the Chairperson with respect to the accuracy of the draft of the minutes.
	4. Decisions of the Project Committee. The following decisions shall be taken by the Project Committee:
1. changes to the Project Application set out in Annex 1;
2. changes to the Budget set out in Annex 2;
3. changes to this Consortium Agreement;
4. withdrawals or adjustments to the Background set out in Annex 3;
5. determine whether certain Background or Foreground falls within the scope of the Access Rights granted under Section 9.3;
6. suspension of all or part of the Project;
7. termination of the Project and the Consortium Agreement.

Any changes to the Project Application, the Budget or this Consortium Agreement as discussed in the Project Committee shall require prior written consent of the IXA Office AMC.

* 1. Stichting LSH-TKI, IXA Office Amsterdam UMC and Project Committee. Each year IXA Office Amsterdam UMC shall inform Stichting LSH-TKI on any decisions by the Project Committee pursuant to Section 6.5 (a) to (c).
	2. Coordinator. The Coordinator coordinates and manages the Project and represents the Parties towards Stichting LSH-TKI. Parties appoint Stichting Amsterdam UMC as Coordinator and authorize …[name Amsterdam UMC researcher}……. to carry out the tasks set forth under this Section 6.7 and Section 6.8.
	3. In particular, the Coordinator shall be responsible for:
1. preparing the meetings, proposing decisions and preparing the agenda of Project Committee chairing the meetings, preparing the minutes of the meetings and monitoring the implementation of decisions taken at meetings;
2. monitoring compliance by the Parties with their obligations;
3. collecting and reviewing information on the progress of the Project and submitting outline scientific reports and other deliverables (including financial statements and related certification), if required, to IXA Office Amsterdam UMC and other Party;
4. transmitting promptly documents and information connected with the Project;
5. administration of the Budget and fulfilling the financial tasks, all as described in Article 7;
6. providing, upon request, the Parties with official copies or originals of documents which are in the sole possession of the Coordinator when such copies or originals are necessary for the Parties to present claims.
7. informing IXA Office Amsterdam UMC of meetings of the Project Committee in writing at least 10 (ten) days before the day of the meeting, in order for an IXA Office Amsterdam UMC representative to be able to participate in the meeting. Minutes of the meetings of the Project Committee will be made by the Coordinator and sent to each Party and IXA Office Amsterdam UMC after each meeting.

The Coordinator shall not be entitled to act or to make legally binding declarations on behalf of the other Party. The obligations of Coordinator towards IXA Office Amsterdam UMC apply to the Principal Investigator.

1. **Financial provisions**
	1. Contribution. The contribution in cash and/or in kind (other than the Background) provided by each Party is set out in Annex 2 (hereinafter referred to as the “**Budget**”). The Budget shall be valued in accordance with the usual accounting and management principles and practices of the respective Parties. The in-cash contributions shall be paid to AMR in accordance with the PPP Allowance Terms.
	2. Obligations Coordinator. Parties acknowledge that any PPP Allowance by Toeslagverstrekker will be allocated to the Coordinator and that AMR (on behalf of the Coordinator) shall distribute the PPP Allowance between the Parties, if applicable, as set out in the Project Budget in Annex 2 and the PPP Allowance Terms, after actual receipt of the TKI-Allowance. The Coordinator shall undertake to keep the PPP Allowance for the Project separated from its normal business accounts, its own assets and property. The Coordinator shall perform diligently its tasks in the proper administration and distribution of the Budget and in maintaining financial accounts. The Coordinator shall provide Toeslagverstrekker each year with an overview of the actual payments made under this Consortium Agreement, including a copy of the relevant bank account transaction or an audit certificate prepared and certified by an independent auditor, before April 1 of the following year.
	3. Accounting. Each Party is solely responsible for the administration and accounting of the cost incurred with respect to the Project. In the event that an audit certificate is required, such certificate by an independent auditor shall be provided at the Party’s own cost.
2. **Foreground**
	1. Ownership. Any Foreground generated under or in connection with the Project that is conceived solely by one Party shall be exclusively owned by that Party and that Party shall be responsible for securing ownership of such Foreground from its employees, students and other agents.
	2. Joint Ownership. Any Foreground generated under or in connection with the Project that is conceived by more than one Party and for which Foreground it is not possible to (i) establish the respective contribution of each Party, or (ii) separate their contribution for the purpose of applying for, obtaining or maintaining protection of the Foreground, shall be jointly owned by such Parties.
	3. Disclosing the Foreground. Each Party shall promptly disclose in confidence to the other Party all Foreground generated by it under the Project, during the term of this Agreement. The Coordinator shall further disclose such Foreground to IXA Office Amsterdam UMC and shall include it in the progress reports and final report.
	4. Exploitation of Foreground. Subject to Section 8.5 and 8.6, each Party shall have the right to exploit such Foreground solely owned by it, and each owner of joint Foreground shall be entitled to use the jointly owned Foreground, unless otherwise agreed in a joint ownership agreement to be concluded between the joint owners before any exploitation of Foreground takes place:
		1. for non-commercial purposes such as academic research and third party research, as well as training and teaching activities, on a royalty-free basis, and without requiring the prior consent of the other joint owner(s); and
		2. to grant nonexclusive licences to third parties (without any right to sublicense) for commercial purposes, if the other joint owners are given (i) at least 45 (forty-five) days advance notice and (ii) fair and reasonable compensation taking into account each joint owner’s relative intellectual contribution to the joint Foreground.
	5. Option. In the event of Foreground generated by the Research Organization (“**RO Foreground**”), the Research Organization shall grant the Industrial Party, if the Industrial Party has contributed substantially to the Research Organization’s activities under the Project, an option to negotiate an exclusive license to such RO Foreground (the “**Option**”). A contribution in cash and/or in kind that equals at least 5% (five percent) of the Budget shall be considered ‘substantial’.
	6. Exercise of the Option. Subject to clause 8.5, the Industrial Party may exercise the Option at any time within three (3) months after the date of disclosure by the Coordinator of such RO Foreground, after which period the Option will lapse.

The Option shall be deemed to be declined if the Industrial Party has not informed the Coordinator within the aforesaid Option term. If the Option is exercised within the Option term, the Industrial Party and Research Organization shall negotiate in good faith for a period of up to 90 (ninety) calendar days, or such longer period as may be agreed upon between the Parties, all necessary commercial arrangements taking into account the stage of development and the relative contribution of the Research Organization to the RO Foreground and subject to the minimal conditions set out in Section 8.7. If the Parties fail to reach agreement, the Option shall lapse, and the Research Organization shall be free to exploit the RO Foreground

* 1. Minimum Conditions. Any license agreement shall contain the following minimal conditions:
1. the Industrial Party shall pay the Research Organization a fair market price in respect of access to the RO Foreground. The Industrial Party is entitled to deduct an amount from the fair market price equal to the value of its contribution under the Project as set out in the Budget;
2. an anti-shelving clause for the Industrial Party (*i.e.* use of best endeavours to effectively commercialise or apply the RO Foreground);
3. a non-exclusive license for the Research Organization for the use of the RO Foreground for academic research and teaching purposes;
4. an indemnification obligation by the Industrial Party to the Research Organization against any third party claims for damages resulting from the use of the RO Foreground;
5. a warranty from the Industrial Party to respect the Access Rights of the other Party granted under this Consortium Agreement with respect to the Foreground pursuant to Section 9.3, including a warranty that these Access Rights will not be affected by a subsequent license of the Foreground; and
6. a warranty from the Industrial Party that it will use diligent efforts to ensure effective and affordable access to any products or services implementing the RO Foreground or for which the RO Foreground has been used for the development of those products or services, including but not limited in developing countries.
	1. Maintenance and Prosecution. Each Party is responsible for any protection of the Foreground that it owns pursuant to this Consortium Agreement and shall have the right to file patent applications for such Foreground in their own name and at its own expense. If the Research Organization and/or the Industrial Party are joint owners of Foreground the owning Parties shall discuss which Party will be in the lead of patent prosecution and how the associated costs will be shared.
	2. Publication. Pursuant to the publication obligations set out in Section 2.12 of the PPP Allowance Terms, the Parties must ensure open access (free of charge, online access for any user) to all scientific publications relating to its Foreground under the Project subject to the conditions hereunder. In particular, the Parties shall ensure open access to the deposited publication at the latest: (i) on publication, if an electronic version is available for free via the publisher, or (ii) within six months of publication in any other case.

A Party or Parties that intend to publish on the Foreground (jointly) owned by it shall provide the other Party or Parties with the draft publication at least 30 (thirty) calendar days before publication and at least 15 (fifteen) calendar days before submission of an abstract. Any objection to the planned publication shall be made in writing to the Coordinator and the Party or Parties proposing the publication within 30 (thirty) calendar day upon receipt of the draft publication and within 15 (fifteen) calendar days upon receipt of the abstract. If no objection is made within these time limits stated above, the publication is permitted.

* 1. Objections to publication. An objection has to include a precise request for necessary modifications and shall be considered justified only, if:
1. the proposed publication includes another Party’s Background, Foreground or other Confidential Information; or
2. the proposed publication includes patentable Foreground and the objecting Party anticipates that it wishes to exercise the Option.

Upon receipt of an objection, the Parties involved shall discuss a solution in good faith. Within the time limits stated in Article 8.9, the objecting Party may request removal of its Background, Foreground or other Confidential Information, or, if the objection is based on (b) above, a publication delay of at most 60 (sixty) calendar days, in which event the intended publication will be delayed to allow a patent application to be filed. Upon expiration of the term, the publishing Party will be entitled to publish the proposed publication.

The Parties acknowledge that if the Project consists of the performance of clinical research that is subject to the Dutch Medical Research Involving Human Subjects Act (WMO), publication arrangements under Sections 8.9 and 8.10 are subject to the Revised CCMO Directive on the Assessment of Clinical Trial Agreements of 30 August 2011, and that in case of any conflict, the latter shall prevail.

* 1. Use of Names, Logos or Trademarks. Nothing in this Consortium Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Parties or any of their logos or trademarks without their prior written approval.
	2. License for non-commercial research. Each Industrial Party hereby grants, which the Research Organization(s) hereby accept, the Research Organization(s) a worldwide, perpetual, royalty-free and non-exclusive license for the use of such Industrial Party’s Foreground for non-commercial research and educational purposes.
1. **Ownership Background and Access Rights**
	1. Background identification. Each Party has identified in Annex 3 to this Consortium Agreement certain of its Background that it is willing to grant Access Rights, if any, to and has also indicated, where relevant, whether the Access Rights to specific Background are subject to legal restrictions or limits. Anything not identified in Annex 3 shall not be the object of Access Right obligations with respect to the Background. Background remains the sole property of the Party disclosing Background under the Project. Unless expressly agreed otherwise in writing, the disclosure of any Background does not imply the grant of Access Rights by the disclosing Party. Each Party will have the right to add Background to Annex 3 by written notice to the Coordinator, who will be responsible to inform the other Party of such addition. In the event that a Party desires to withdraw or modify any Background or restrict the Access Rights provided under this Agreement, such Party will request the Project Committee to do so by written notice. For the avoidance of doubt, any withdrawal of Background may not negatively impact the execution of the Project.
	2. Request for Additional Background.A Party is entitled to request another Party to add certain Background to Annex 3 if, without Access Rights to such Background, carrying out the tasks assigned to the recipient Party would be technically or legally impossible, significantly delayed, or require significant additional financial or human resources. The Party receiving such request may decide to add such Background in its sole discretion.
	3. Standard Access Rights. Each Party hereby grants to the other Party such non-exclusive Access Rights as required for the execution of the Project and the Project Plan and for this purpose only, for the term of this Consortium Agreement and subject to the restrictions set out in Annex 3 with regard to the Access Rights to a Party’s Background. Any Access Rights granted under this Section 9.3 shall exclude any obligation to pay royalties and/or the right to sublicense.

If a Party requires Access Rights as set out in this Section, such Party shall request the relevant Party in writing to make such Background or Foreground under the Access Rights available. The Party receiving such request shall provide the requesting Party with the relevant Background and/or Foreground within fourteen (14) calendar days of the receipt of such notice. If the Party receiving such request disagrees with the requesting Party that the requested Background or Foreground falls within the Access Rights, the requesting Party shall have to show its need for such Access Rights. Access Rights shall be free of any administrative transfer costs.

* 1. Access Rights for Use or Exploitation. Each Party shall have the right to request Access Rights to the other Party’s Background and/or Foreground in addition to the Access Rights granted under Section 9.3: (i) if without the Access Rights the use of a Party’s own or jointly owned Foreground would be technically or legally impossible or (ii) for the commercial exploitation of a Party’s (or that other Party’s) own or jointly owned Foreground.

A request for Access Rights shall be made in writing ultimately within six (6) months after expiration or termination of this Consortium Agreement. The granting of Access Rights will be at a Party’s own discretion and may be made conditional on the acceptance of specific conditions aiming at ensuring that these rights will be used only for the intended purpose and that appropriate confidentiality obligations are in place. Any Access Rights under this Section 9.4 shall be granted on fair and reasonable market conform conditions. Each Party hereby grants to the other Party the royalty free right to use its Foreground for internal and/or non-commercial research and education purposes.

* 1. Use of Access Rights. Background AND Foreground shall be used only for the purposes for which Access Rights to it have been granted.
	2. Parties leaving the Consortium Agreement. Access Rights granted to a Defaulting Party and such Party's right to request Access Rights shall cease immediately upon receipt by the Defaulting Party of the formal notice by the non-Defaulting Party.
1. **Non-disclosure of Confidential Information**
	1. Non-disclosure of information. All information in whatever form or mode of communication, which is disclosed by a Party (the “**Disclosing Party**”) to any other Party (the “**Receiving Party**”) in connection with the Project during its implementation and (i) which has been explicitly marked as “confidential” at the time of disclosure, or (ii) when disclosed orally has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within 15 calendar days from oral disclosure at the latest as confidential information by the Disclosing Party or (iii) when the confidential or proprietary character is or should reasonably have been known to the receiving Party is “**Confidential Information**”.

Notwithstanding the foregoing, Confidential Information of a Party shall not include information that the other Party can establish by written documentation:

1. to have been publicly known prior to disclosure of such information by the Disclosing Party to the Receiving Party;
2. to have become publicly known, without the fault of the Receiving Party, subsequent to disclosure of such information by the Disclosing Party to the Receiving Party;
3. to have been received by the Receiving Party at any time from a source, other than the Disclosing Party, rightfully having possession of and the right to disclose such information;
4. to have been otherwise known by the receiving Party prior to disclosure of such information by the Disclosing Party to the receiving Party; or
5. to have been independently developed by employees and/or agents of the Receiving Party, on its behalf, without access to or use of such information disclosed by the Disclosing Party to the Receiving Party.
	1. Non-Disclosure.During the term of this Consortium Agreement, and for a period of three (3) years following the expiration or termination of this Consortium Agreement, each Party shall maintain in confidence all Confidential Information disclosed by the other Party, and agrees:
6. not to use the Confidential Information for any other purpose for which it was disclosed;
7. not to disclose Confidential Information to any third party without the prior written consent by the Disclosing Party;
8. to ensure that internal distribution of Confidential Information by a Recipient shall take place on a strict need-to-know basis; and
9. to return to the Disclosing Party on demand all Confidential Information which has been supplied to or acquired by such Recipient including all copies thereof. If needed for the recording of on-going obligations, such Recipient may however keep a copy for archival purposes only.

Each 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.

* 1. Mandatory Disclosure. If any Party is required to disclose Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, nothing herein shall restrict the Recipient from disclosing Confidential Information, but only to the extent of such order, law or regulation and it shall, to the extent it is lawfully able to do so, prior to any such disclosure (i) promptly notify the Disclosing Party, and (ii) comply with the Disclosing Party’s reasonable instructions to maximally protect the confidentiality of the information.
	2. Obligations Recipient. Notwithstanding Section 10.2 (c), Parties will have the right to disclose Confidential Information of another Party to any of its Affiliates, provided that prior consent of the Disclosing Party is obtained and such Affiliates are bound by confidentiality obligations not less stringent than the ones of the Consortium Agreement. Each Recipient shall further be responsible for the fulfilment of the above obligations on the part of its employees and its Affiliate employees and shall ensure that its employees remain so obliged, as far as legally possible, during and after the end of the Project and/or after the termination of employment.
	3. Unauthorized Disclosure. Each Party shall promptly advise the other Party in writing of any unauthorized disclosure, misappropriation or misuse by any person of Confidential Information as soon as practicable after it becomes aware of such unauthorized disclosure, misappropriation or misuse.
	4. *Transfer of Material*.
		1. If any Materials are transferred for the performance of the Project from one Party (including through its Affiliated Entities or third parties) (“**Providing Party**”) to another Party (“**Recipient Party**”), or to its Affiliated Entities or third parties, each Recipient Party shall be bound by the following provisions and shall be responsible for ensuring that its Affiliated Entities and third parties comply with such provisions:
1. The Recipient Party needs to have all the required authorisations under all applicable laws and regulations to perform the allocated work using the Materials.
2. The Materials shall be used by Recipient Party in full compliance with all applicable laws and regulations.
3. The Materials shall be used solely for performance of the Project in accordance with this Consortium Agreement. The Materials will under no circumstances be administered to humans, unless this is specifically required in accordance with the Project Application.
4. The Materials shall not be analysed or modified except as necessary for the purpose of the Project.
5. The Materials shall not be transferred or made by the Recipient Party available to any individual other than those under the supervision and control of the Recipient Party, its Affiliates or third parties. Upon completion of the Project, or the expiry or termination of this Consortium Agreement, any unused Materials will be either returned to the Providing Party at its written direction, which made them available, or disposed of/destroyed in accordance with all applicable laws and regulations and provide Providing Party with a written confirmation of such disposal or destruction.
6. All Materials are transferred with no warranties, express or implied, of merchantability or fitness for a particular purpose or otherwise. In particular, no Providing Party represents or warrants that the use of the Materials will not infringe or violate any patent or proprietary rights of third parties.
7. The Materials are to be used with caution and prudence in any experimental work, since not all of the characteristics are necessarily known. The Recipient Party using the Materials shall bear all risk to it and/or any other risks resulting, directly or indirectly, from its use, application, storage or disposal/destruction of the Materials.
8. In case that a Providing Party requires more stringent clauses in order to protect its Materials to be transferred under the Project, the relevant Parties may agree to enter into a separate material transfer agreement. Such a material transfer agreement may not contain provisions contradicting this Consortium Agreement or limiting any usage rights already granted under this Consortium Agreement. In case of contradicting clauses the Consortium Agreement shall prevail.
9. This Agreement shall not be construed by the Recipient Party, its Affiliates and third parties to convey an assignment by the Providing Party of any of its rights in the Material except the right to use the Material as provided for hereunder.
	1. Clinical Trials. If the Project consists of the performance of clinical research, the relevant Parties shall make appropriate additional contractual arrangements regarding the rights and obligations in respect of the performance of such clinical research in accordance with applicable law and consistent with the PPP Allowance Grant and this Consortium Agreement. The initiator of the clinical trial will act as Sponsor (“Verrichter“ in the terms of the Dutch Medical Research Involving Human Subjects Act (Wet Medisch-wetenschappelijk Onderzoek met Mensen or WMO) of the clinical trial. In case of conflict between such clinical contractual arrangements and the PPP Allowance Grant and/or Consortium Agreement, firstly the PPP Allowance Grant and secondly the Consortium Agreement shall prevail over any such additional contractual arrangements, except in case where this is not in the best interest of subjects included in the clinical research.
10. **Notice and contact persons**

11.1 Any legal notices required or permitted by the terms of this Agreement shall be given by e-mail followed by registered mail, prepaid and properly addressed or delivered by hand or by other recognized express carrier to the relevant Party at their respective addresses as included in **Annex 6** or at such other address as either Party hereto may designate by notice pursuant hereto. If mailed, any such notice shall be deemed to have been given when received; and if delivered by hand, when received.

1. **Miscellaneous**
	1. Inconsistencies and severability. If conflicts appear between the annexes and the body text of this Consortium Agreement, the latter shall prevail. Should any provision of this Consortium Agreement become invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of this Consortium Agreement. In such a case, the Parties concerned shall be entitled to request that a valid and practicable provision be negotiated which fulfils the purpose of the original provision.
	2. No representation, partnership or agency. The Parties shall not be entitled to act or to make legally binding declarations on behalf of any other Party. Nothing in this Consortium Agreement shall be deemed to constitute a joint venture, agency, partnership, an offer by, or creating any obligation of either Party to enter into any form of agreement other **than** stated in this Consortium Agreement or interest grouping or any other kind of formal business grouping or entity between the Parties.
	3. Assignment. Except as allowed under this Consortium Agreement, no rights or obligations of the Parties arising from this Consortium Agreement may be assigned or transferred, in whole or in part, to any third party without the other Party prior formal approval.

AMC Medical Research BV and VUmc research BV are working towards a full legal merger into a new legal entity. Parties agree that when the Agreement, including any specific clauses that survive the termination or expiration thereof, is still effective at the moment of the legal merger, Coordinator shall have the right to assign all its rights and obligations arising out of and/or related to the Agreement, to the new legal entity without requiring any prior consent and/or prior or further notice.

* 1. Amendment. Pursuant to the PPP Allowance Terms, any amendments or modifications of the text of this Consortium Agreement approved by all Parties require the prior written approval of IXA Office Amsterdam UMC if, and to the extent that the PPP Allowance is still in effect. For the avoidance of doubt, any amendment of this Consortium Agreement without the prior written consent of IXA Office Amsterdam UMC is null and void, if and to the extent that the PPP Allowance is still in effect.
	2. Invalid or Unenforceable Provisions. If part of this Consortium Agreement is or becomes invalid or unenforceable, the Parties shall remain bound to the remaining part. The Parties shall replace the invalid or unenforceable part by provisions which are valid and binding and the effect of which, given the contents and purpose of this Consortium Agreement, is, to the greatest extent possible, similar to that of the invalid or unenforceable part.
	3. Position AMR. AMR is a limited liability company fully owned by Stichting Amsterdam UMC. For the purpose of this Consortium Agreement the task of AMR is to manage the administration and financial aspects of the PPP Allowance. AMR represents and warrants that it shall perform and/or have performed all its activities within the facilities of Stichting Amsterdam UMC, using the required Stichting Amsterdam UMC staff. AMR shall perform all its activities in direct co-operation with the Stichting Amsterdam UMC. All stipulations regarding liability, confidentiality and insurance in favor of the AMR in this Consortium Agreement shall also apply to Stichting Amsterdam UMC. AMR shall have the right to assign this Consortium Agreement and all of its obligations thereof to Stichting Amsterdam UMC upon written notice.
1. **Governing Law and Dispute Resolution**
	1. Governing Law. This Agreement is governed by, and is to be construed exclusively in accordance with the laws of the Netherlands without regard to the conflict of laws provisions thereof.
	2. Dispute Resolution. In the event of any disputes arising out of or in connection with this Agreement, including disputes concerning the existence and validity thereof, the Parties shall first make reasonable efforts to settle the dispute between themselves. Any legal actions or proceedings arising out of this Agreement which cannot be settled by good faith efforts and shall be brought exclusively to the court of Amsterdam, the Netherlands.

**IN WITNESS WHEREOF**, the Parties hereto have signed this Consortium Agreement with separate signing pages signed by their authorized representatives.

 Each Party agrees that this Agreement will be executed in electronic PDF format only and each Party explicitly acknowledges and agrees that its signature in such format shall be regarded as an original signature and that this Agreement shall be effective upon delivery by electronic mail to the other [Party/Parties] and thereafter shall be deemed an original signed agreement, irrespective of whether the signatures are on the same page or on separate pages.

On behalf of **AMC Medical Research B.V.**

Place Amsterdam

Date ………………………………

Signature ………………………………

Name J.J. Brand

Position CFO

Read and acknowledged by:

Principal Investigator

Signature ………………………………

Name ………………………………

On behalf of **Industrial Party**

Place

Date …………………………..

Signature …………………………..

Name

Position

**Annex 1 – Project Application (including the Project Plan)**

*The Project Application is attached separately*

**Annex 2 – Budget**

*The Budget is attached separately*

**Annex 3 – Background**

**Academisch Medisch Centrum**

As to AMC, it is agreed between the Parties that, to the best of their knowledge (*please choose)*,

Option 1: The following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

|  |  |  |
| --- | --- | --- |
| Describe Background | Specific limitations and/or conditions for implementation of the Project; | Specific limitations and/or conditions for exploitation of the Foreground |
|  |  |  |
|  |  |  |

Option 2: No Background of AMC shall be Needed by another Party for implementation of the Project or exploitation of that other Party’s Foreground.

This represents the status at the time of signature of this Consortium Agreement.

**Industrial Party**

As to [**Industrial Party**], it is agreed between the Parties that, to the best of their knowledge (*please choose)*

Option 1: The following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

|  |  |  |
| --- | --- | --- |
| Describe Background | Specific limitations and/or conditions for implementation of the Project; | Specific limitations and/or conditions for exploitation of the Foreground |
|  |  |  |
|  |  |  |

Option 2: No Background of [**Industrial Party X]** shall be needed by another Party for implementation of the Project or exploitation of that other Party’s Foreground.

This represents the status at the time of signature of this Consortium Agreement.

**Annex 4 – PPP Allowance Terms**

1. **Grant of the PPP Allowance**
	1. The PPP Allowance is granted to the Project subject to the conditions of the PPP Allowance Regulation and the terms and conditions of this Consortium Agreement.
	2. The Parties agree to use the funding under the PPP Allowance solely for the purpose of the Project in accordance with the Project Application, the Budget and the Consortium Agreement and the conditions of the PPP Allowance Regulation. The Parties acknowledge that the Project Application and/or the Budget and/or the Consortium Agreement may change as result of the experimental nature of the Project.
	3. A change to the Project Application and/or the Budget that affects the cost estimate for the Project cannot result in an increase of the funding under the PPP Allowance as granted to the Parties under Section 1.1 above.
	4. If the Principal Investigator, the Research Organization or the Industrial Party do not comply with any of its obligations under the PPP Allowance Regulation and/or the terms and conditions of this Agreement, the PPP Allowance may be reduced by Toeslagverstrekker.
	5. The definitive amount of funding under the PPP Allowance made available to a Party, depends on the actual extent to which the Project has been executed in accordance with the conditions of the PPP Allowance Regulation and this Consortium Agreement and the approval of the final report (including financial justification of costs) by Toeslagverstrekker. After such approval by Toeslagverstrekker and final reporting by Toeslagverstrekker to Stichting LSH-TKI, Toeslagverstrekker shall calculate the definitive amount of PPP Allowance.
2. **Obligations of the Parties**
	1. The Principal Investigator shall provide IXA Office AMC:
3. within 6 (six) weeks after the start of each project year, with a periodic report including an explanation of the work carried out by the Parties, an overview of the progress of the Project and explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and work that was actually carried out. [In the event that a Project runs 18 months or less, only the final report is required].
4. within 8 (eight) weeks upon completion of the Project, an integrated final report providing an overview of the progress and results of the entire Project and a specific update on those parts of the Project that have been performed by use of the PPP Allowance.
5. (only for Projects receiving € 125.000 PPP Allowance or more) within 8 (eight) weeks upon Completion of the Project a final audit of the Project costs including an audit certificate prepared and certified by an independent auditor. The PPP Allowance may not be used to cover audit costs.
	1. All reports (regular and financial reports, including financial statements) must be submitted in the English language.
	2. The Coordinator shall keep accounts of the in-cash and in-kind contributions that have been made for the purpose of the Project.
	3. The Coordinator shall further keep accounts of any and all cost (as defined in the Financial Guidelines) made by each Party for the purpose of the Project. The accounts shall ensure the transparency and traceability of the costs.
	4. The Coordinator shall initiate and enforce adequate management of the Project.
	5. The Principal Investigator shall be responsible for informing IXA Office AMC with regard to any actions by one or both of the Parties in respect of the results arising from the Project outside the scope of the Consortium Agreement (such as unauthorized publication and/or transfer).
	6. The Principal Investigator shall be responsible for informing IXA Office AMC with regard to any event materially affecting or delaying the performance of the work under the Project.
	7. The Parties hereby authorize the Principal Investigator to conduct all communication and correspondence with IXA Office AMC concerning this Project on their behalf.
	8. Each Party undertakes reasonable endeavours to perform and fulfil, promptly, actively and on time, all of its obligations with respect to the Project under this Agreement and within the applicable rules set by the PPP Allowance Regulation.
	9. Each Party agrees to keep an accurate and up-to-date time registration in respect of the work performed under or in connection with the Project. Following this obligation, each Party shall provide to the Coordinator an annual progress report of the work performed under the Project and its financial contribution or contribution in kind to the Project in order to allow the Principal Investigator to provide IXA Office AMC with the reports required under Section 2.1 above. In case the Project runs 18 months or less, only a final report is required.
	10. Each Party must ensure open access (free of charge, online access for any user) to all scientific publications relating to its results under the Project. In particular, the Parties shall ensure open access to the deposited publication at the latest: (i) on publication, if an electronic version is available for free via the publisher, or (ii) within six months of publication in any other case.
	11. Unless Stichting LSH-TKI agrees otherwise or unless it is impossible, any dissemination of results of the Project (in any form, including electronic) must include the following text:

“The collaboration project is financed by the Ministry of Economic Affairs by means of the PPP Allowance made available by the Top Sector Life Sciences & Health to stimulate public-private partnerships”

Any dissemination of results of the Project must indicate that it reflects only the author's view and that Stichting LSH-TKI or the Ministry of Economic Affairs is not responsible for any use that may be made of the information it contains.

* 1. The Parties agree to cooperate to produce and upon request deliver data for controls, audits and communication purposes during and up to 5 (five) years after termination of the Project.
1. **Payment of Contributions and the PPP Allowance**
	1. Each of the Parties shall contribute to the Project, as follows:
2. Company shall contribute € xxx in cash. The in-cash contribution shall be paid according to the schedule included in the Budget, or, if no such schedule is included, within sixty (60) days after the Effective Date.

The Industrial Party’s contribution in kind shall represent a value of € yyy.

1. Coordinator’s contribution in kind shall represent a value of € yyy
	1. The in cash contributions set forth in Article 3.1 shall be made by wire transfer by the Industrial Party to AMR’s bank account, the details of which are included in Annex 5.

**Annex 5 – AMR Bank details**

Company name : AMC Medical Research B.V.

Street address : Meibergdreef 9

P.O. Box : Postbus 22660

Zip code : 1100 DD

City : Amsterdam

Telephone (general) : +31 (0)20 – 566 5558

Email : fs-amr@amc.uva.nl

Website : www.amr.nl

Chamber of Commerce : 33284074 (Amsterdam)

VAT number : NL8052.70.826.B01

Bankrelation : ING Bank regio Noord-West

 De Entree 201 Postbus 23432

 1101 HG Amsterdam 1100 DX Amsterdam

BIC/SWIFT : INGBNL2A

Accountnumber EUR : NL98 INGB 065 067 2801

**Annex 6 – Notices and contact persons**

**For AMC**

|  |  |
| --- | --- |
| For the project  | Attn. [projectleider] Attn.e-mail: ………..@amsterdamumc.nlMeibergdreef 9/De Boelelaan 11171105 AZ/1081 HV AmsterdamThe Netherlands |
| For financial details/reports | AMR Attn. …………. (AMR project controller)e-mail: tel: +31 20 …………… |
| For update and final project reports | IXA Office Amsterdam UMCAttn. ……………. (business developer)e-mail: ………@amsterdamumc.nltel: |
| For legal notices | Attn. Legal Research Support e-mail: lrs@amsterdamumc.nlAcademic Medical CenterMeibergdreef 91105 AZ/1081 HV AmsterdamThe Netherlands |
|  |  |

**For Industrial Party**

|  |  |
| --- | --- |
| For the project  | Attn. Attn.e-mail: |
| For financial details/reports | Attn. e-mail: tel:  |
| For update and final project reports | Attn. e-mail:tel: |
| For legal notices | Attn. e-mail: Address: |