Ethics Board (EB)

Roles and Responsibilities

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Participant N°	Participant organisation name	Short Name	Type	Country
1	Amsterdam University Medical Centre	AMC	Clinical	Netherlands
2	IANUS Consulting Ltd	IANUS	SME	Cyprus
3	Telesto	TEL	SME	Greece
4	Saitama Medical Centre Hospital	SMCH	Clinical	Japan
5	Harokopio University	HUA	University	Greece
6	Innsbruck University	UIBK	University	Austria
7	Jurrisk	JUR	SME	Belgium
8	IMSPEX	IMSPEX	SME	United Kingdom
9	University of Cyprus	UCY	University	Cyprus
10	University of Pécs	UP	University	Hungary
11	RoboScientific	ROBO	SME	United Kingdom
12	Solgenium OG	SOL	SME	Austria
13	Ghent University	UGent	University	Belgium
14	Panou	PANOU	SME	Greece
15	Institute of International Sociology	ISIG	Research	Italy
16	Johanniter Österreich Ausbildung und Forschung gemeinnützige GmbH	JOAFG	First Responders	Austria
17	Bavarian Red Cross	BRK	First Responders	Germany
18	Bioxhale Ltd	BIOX	SME	United Kingdom
19	Municipality of Hasselt	HASS	Local Authority	Belgium
20	Hungarian Red Cross	HRC	First Responders	Hungary
21	Region of Western Greece	RWG	Local Authority	Greece
22	Gesellschaft für analytische Sensorsysteme mbH	GAS	SME	Germany

Version History

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V0.1	15-08-2023	Laurian Jongejan	Initial draft
V0.2	07/09/2023	Paola Lorenzoni (ISIG)	First document version outline
V0.3	20/09/2023	Olivia Ferrari (ISIG)	Review and integration of the document
V0.4	28/9/2023	Kathleen Van Heuverswyn (JUR); Laurian Jongejan (AMC)	Review and completion of the document
V0.5	02/10/2023	Olivia Ferrari (ISIG)	Integration of comments
V0.6	Nov/dec 2023	Laurian Jongejan, Paul Brinkman (AMC)	Final comments and additions
V1.0	29-12-2023	Laurian Jongejan	Final edits and submission

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Abbreviations

Abbreviation	Description
AI	Artificial Intelligence
CA	Consortium Agreement
D	Deliverable
DoA	Description of Action
DPIA	Data Protection Impact Assessment
EA	Ethics Advisor
EB	Ethics Board
EEB	External Ethics Board
EBC	Ethics Board Chair
EC	European Commission
DPO	Data Protection Officer
EU	European Union
GA	Grant Agreement
GDPR	General Data Protection Regulation
IEB	Internal Ethics Board
IPRs	Intellectual Property Rights
M	Month
NDA	Non-Disclosure Agreement
PC	Project Coordinator
PO	Project Officer
SAB	Security Advisory Board
T	Task
WP	Work Package

Executive Summary

The objective of this deliverable is to describe the ethics board, composed of external, independent members, free of any conflict of interest, that is appointed to oversee the ethics issues of the project, in particular those pertaining to the participation of humans and on data processing. This guarantees a trustworthy governance of the project and an effective check and balance. Furthermore, as it is mentioned in the proposal that there is risk of bio-surveillance at scale (p.11), this must remain justified and proportionate based on the evidence-based risk. The proportionality of the project must be carefully examined. This relates to preventive awareness.

The present document therefore outlines the roles and responsibilities of the ONELAB Ethics Boards (EB), providing details on the ethics management and compliance of the research and technological developments of the project.

A description of the composition, activities and procedures of both the Internal Ethics Board (IEB) and External Ethics Board (EEB) are provided in the document, defining clear responsibilities of the boards to monitor compliance of project activities with the ethics framework defined within the project, as well as with national and European regulations on privacy and data protection.

1. Introduction

The ONELAB research activities aim to support effective, immediate, and targeted public health interventions. The project aims to develop modular RRML for rapid, flexible, scalable, multi-scenario deployments into the widest range of possible settings. Thus, simultaneously providing point-of-need disease detection, along with high-level situational awareness. ONELAB will also develop advanced measurement systems for a staged disease detection response, using acute viral infection biomarkers enabling early detection of disease during the asymptomatic incubation.

To achieve its objectives, the project will collect and generate different types of data and information from different sources. To this end, the project is tasked with the mission of establishing the ethical framework to guide the research activities. WP1, among others, is dedicated to the definition of the legal and ethical framework (compliance and impact), and the management of Intellectual Property Rights (IPRs). WP7 is dedicated to the Ethics Requirements, providing informed consent procedures (**D7.1**), DPO appointment (**D7.2**), health and safety procedures confirming to guidelines and legislation (**D7.3**) and the current document, the appointment of an external ethics board (**D7.4**).

As outlined here, the consortium will be supported by the expertise of an Ethics Board (EB), that has been established within the objectives of T1.4 and WP7, so to:

1. Ensure monitoring and compliance with both national and international laws and regulations related to safeguarding and respecting personal data privacy, including adherence to GDPR provisions.
2. Support oversight of ethical considerations throughout the entire project lifecycle, including aspects such as effectively incorporating gender-related perspectives into research and innovation activities, developing reliable AI systems, promoting human participation, and more. This monitoring is supported by dedicated checklists and self-assessment tools.
3. Support the identification of potential ethical issues, so to proactively address them.

As envisaged in the DoA, it is important to understand the ONELAB EB has a twofold role, and therefore it is crucial to distinguish between 2 entities: the Internal Ethics Board (IEB), involving members from the consortium, and the External Ethics Board (EEB), with external independent experts.

Ethics and legal compliance are ensured not only thanks to the monitoring role of the EB, but it is carried out in collaboration with other project bodies, such as: the Security Advisory Board (SAB), the Ethics Advisor (EA), the Ethics Board Chair (EBC), the project Data Protection Officer (DPO), and the Project Coordinator (PC).

The figure below provides a graphical visualisation of the Ethics and Data Management framework of the project, defining the 3 different pillars:

1. Conceptual and management framework.
2. Procedures.
3. Activities and Outputs.

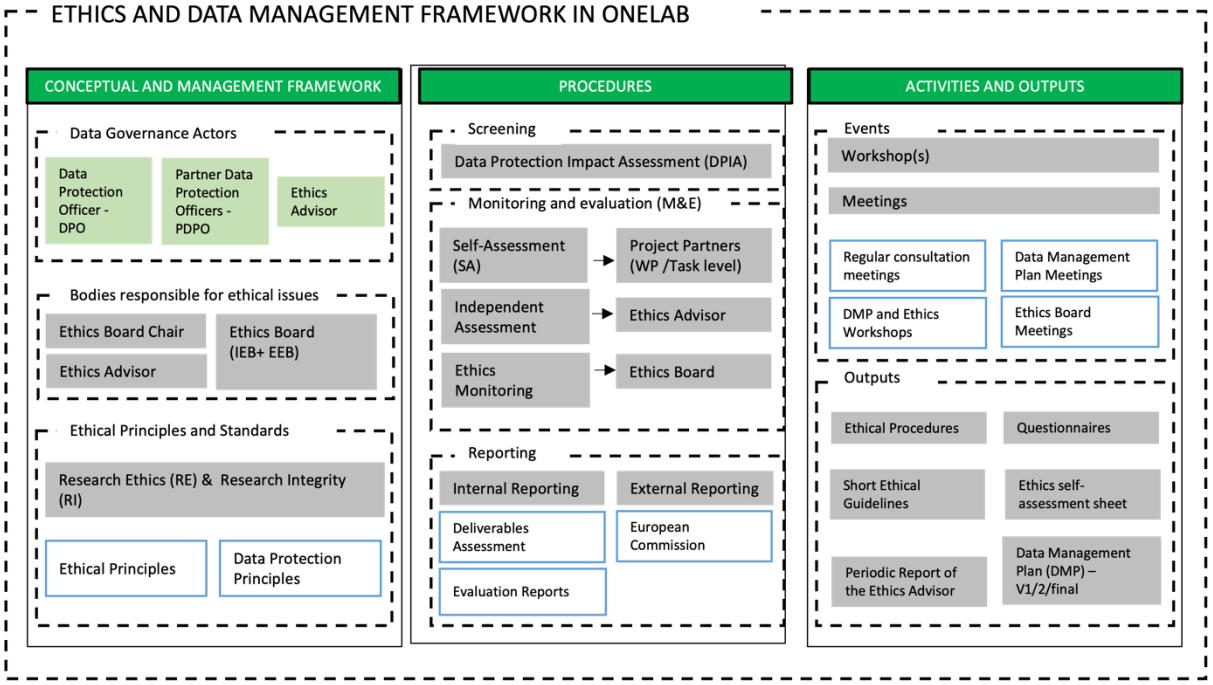

Figure 1: Ethics and Data Management Framework in ONELAB

1.1. Purpose and structure of this document

This document presents the roles and responsibilities of the IEB and EEB. It outlines the selection and appointment process performed for both entities, their activities and assessment procedures, as well as their reporting operations and relations with other project bodies.

The list of EEB members is presented in Annex 1 of this document. The list of IEB members will be presented in Deliverable D1.2 - Legal and ethical framework and data management plan.

2. The Internal Ethics Board (IEB)

The **Internal Ethics Board (IEB)** sees the participation of one representative per partner to ensure a continuous monitoring of ethics within the project.

2.1. IEB selection and appointment

The selection and appointment process of the IEB members is briefly described as follows and was carried out in the period September-November 2023. An internal process for the selection and appointment of the members of the IEB was performed within the Consortium. The activities of the IEB will be reported in D1.2 – Legal and ethical framework and data management plan at M36 (September 2025).

2.2. Activities

The IEB has the responsibility to:

- Support continuous monitoring and adherence to national and international laws and regulations, in terms of protection and privacy of personal data, including GDPR.
- Support continuous monitoring of ethical concerns such as: effective inclusion of sex/gender aspects within research and innovation activities, human participation, data processing.
- Support the identification of potential ethics issues, to be addressed and considered within the development of the project.

The IEB members perform such activities at partner's level, supervising the compliance of each partner organization to the overall project ethical framework and national and European laws and regulations.

The IEB is coordinated by the project Ethics Advisor (EA). The IEB meets regularly and on ad-hoc basis each time the project activities require support regarding ethics and privacy. Meetings can be convened by either the DPO or any IEB member, with a minimum notice of seven days. Meetings can take place either in-person or online, although online meetings will be the preferred choice to ensure all ethics and privacy-related concerns are discussed in an efficient and rapid way.

Communication exchanges within the IEB as well as for interaction with DPO, project coordinator, EA, and other entities, will be done through email, online conference meetings and web collaboration tools.

The IEB will perform the following activities:

- Collaborate closely with project tasks dealing with ethics aspects, in particular T1.4, T2.5, T3.1, WP4 and WP7 (Ethics Requirements), to apply ethical principles and internal operational procedures and protocols and to oversee and supervise the compliance to ethical requirements.
- Evaluate the ethical implications of individual research activities as they arise.
- Support the preparation and validation of documentation related to privacy and ethics, such as information sheets and informed consent forms.
- Report to the Project Coordinator (PC) and Ethics Advisor (EA) any ethical concern in order to identify mitigation actions.

2.3. Assessment procedures

The IEB is responsible for the assessment of research activities at partners' level within the project WPs.

The Assessment procedures imply: the implementation of self-assessments independently by IEB members, and the implementation of independent assessments performed by the IEB collectively.

The Assessment procedures of the IEB are defined as presented in the following points:

- The IEB requests documentation or further information regarding project activities to project partners, when deemed relevant for the work of the IEB.
- The IEB collaborates with the EEB, EA and DPO to assess research activities, evaluating each activity and deliverable that might raise ethical and/or privacy issues. When an activity is considered to be violating ethics and data protection principles, the

IEB notifies the PC and the WP coordinator. On the other hand, if the IEB, jointly with the EEB, EA and DPO, assess that activities or deliverables do not violate ethics and data protection principles, a positive notification is forwarded to the PC and WP coordinator.

Ethical risks are to be strictly managed on a confidential level among IEB, EEB, EA, DPO, PC and all Consortium members.

2.4. Reporting

To report its activities to relevant project bodies, the IEB will use project standard templates. Furthermore, the IEB members will maintain proactive communication and provide timely information to all project partners concerning any issues on privacy and ethics.

3. The External Ethics Board (EEB)

The **External Ethics Board (EEB)** is composed of 3 external, independent experts, free of any conflict of interest, and has the responsibility to oversee the ethics issues of the project, in particular those pertaining to the participation of humans and data processing. The EEB ensures a trustworthy governance of the project and an effective check and balance.

The members of the EEB have an expertise covering the following topics:

1. Data management.
2. Clinical trials.
3. Any other relevant ethical aspect related to ONELAB activities.

3.1. EEB selection and appointment

The selection and appointment process of the EEB members is briefly described as follows:

- June-November 2023: identification of experts with the support of project partners, it appeared to be difficult to find experts that were willing to free time to take a seat in the board.
- October-December 2023: Invitation of the experts, appointment of one external expert and invitations to two others are pending.

We are in the process of finalizing agreements with three independent ethics experts. As soon as all documents are signed, we will release their full names, for now we can provide a description of their expertise:

· Member 1: Foreign relations on issues of technology and security policy.

· Member 2: Medical scientific research involving human subjects.

· Member 3: Social Integrity, communication & engagement, decision making and crises management.

If due to unexpected issues the envisioned members are not able to join, we will ask other ethics experts to take seat in this board.

The intended composition of the EEB is reported in annex 1, while its activities will be reported in D1.2 – Legal and ethical framework and data management plan at M36 (September 2025).

The invitation letter to the ONELAB ethics board and the non-disclosure agreement (NDA) are enclosed as Annex 2 &3.

3.2. Activities

The EEB has the responsibility of:

- Supporting the consortium in its efforts to ensure a continuous monitoring of ethical issues and adherence to national and international laws and regulations, in terms of protection and privacy of personal data, data processing and participation of humans.
- Provide guidance and advise the Project Coordinator, the Ethics Board Chair - EBC, the Ethics Advisor, the Data Protection Officer and Consortium partners on actions or mitigation measures related to ethics and data protection issues.

The EEB is independent and free of any conflict of interest, and operates in autonomy, with the collaboration of the EBC, EA, DPO and IEB. The EEB members are remunerated by the project and are not employed by any of the Consortium partners. The EEB meets regularly and on ad-hoc basis each time the project activities require support regarding ethics and privacy. Meetings can be convened by either the EBC, EA, PC, DPO or any IEB member, with a minimum notice of seven days. Meetings will mostly take place online, so to ensure all ethics and privacy-related concerns are discussed in an efficient and rapid way.

Communication exchanges within the EEB as well as for interaction with EBC, DPO, PC, EA, and other project entities, will be done through email, online conference meetings and web collaboration tools.

The EEB will perform the following activities:

- Participation to at least 1 periodic online meeting/ethics workshop per year.
- Participation to ad hoc meetings whenever an ethics issue is raised.
- Preparation of a total of 2 written reports (1 per project year).
- Provide feedback on draft deliverables, presenting ethical concerns, before submission.

3.3. Monitoring and assessment procedures

Monitoring and assessment procedures of the EEB are defined as follows:

- The EEB will oversee the ethics issues of the project, in particular those pertaining to the participation of humans and on data processing and support the consortium in ensuring a continuous monitoring and independent assessment of research activities at project level.
- The EEB can request documentation or further information regarding project activities to project partners, when deemed relevant for its work.
- The EEB collaborates with the IEB, EA, EBC and DPO to monitor and assess research activities, evaluating each activity and deliverable that might raise ethical and/or privacy issues.
    - When an activity, following a preliminary assessment by the IEB, is considered to raise ethical/privacy concerns, the EEB is consulted.
    - When an activity is considered to be violating ethics and data protection principles, the EEB notifies the PC and the WP coordinator.

- On the other hand, if the EEB, assess that activities or deliverables do not violate ethics and data protection principles, a positive notification is forwarded to the PC and WP coordinator.

Ethical risks are to be strictly managed on a confidential level among IEB, EEB, EBC, EA, DPO, PC and all Consortium members.

3.4. Reporting

The EEB provides an annual report to the PC. The PC is responsible for the reporting procedures of the project, while the EA, supported by the EEB and IEB, is responsible to coordinate activities on ethics and data protection, and consult national data protection authorities.

To report its activities to relevant project bodies, the EEB will use project standard templates. Furthermore, the EEB members will maintain proactive communication and provide timely information to all project partners concerning any issues on privacy and ethics.

4. The Ethics Board Chair (EBC)

In order to oversee and ensure alignment between the internal and external activities related to ethics, an Ethics Board Chair (EBC) is appointed.

The EBC will act as the contact person for the external advisors and will ensure an alignment between the IEB and EEB.

5. Conclusions

The present document provides information to all members of the EB and project partners in general on the main activities, roles, and responsibilities of the board. The activities performed by the EB will be reported in D1.2 – Legal and ethical framework and data management plan at M36 (September 2025).

6. Annexes

Annex 1 – List of EEB members

Name	Expertise	Affiliation (domain of work***)
-***	Foreign relations on issues of technology and security policy.	Governmental
-***	Medical scientific research involving human subjects.	University Hospital
-***	Social Integrity, communication & engagement, decision making and crises management.	SME

***(dec'23): We are in the process of finalizing agreements with three independent ethics experts; As soon as all documents are signed, we will release their full names, for now we provide a description of their expertise and domain of work.

Annex 2- Invitation letter to the ONELAB Ethics board

Dear _____,

We are contacting you on behalf of the **ONELAB** project consortium.

ONELAB is a project funded by the European Commission under the **Horizon Europe Programme**. The project aims to design and coordinate mobile laboratory operations for the detection and identification of infectious agents enabling enhanced situational awareness through integrated data communication that supports multi-agency decision-making and leadership.

The Consortium brings together **22 partners** from 10 countries. To effectively carry out the 36 months project, the Consortium is composed of end-users, small and medium enterprises (SMEs) and research institutions.

Within the project development and implementation, strong attention is given to the **compliance** of all solutions and activities to **ethics, privacy and legal** requirements and regulations. To ensure this, the project has foreseen the establishment of an **External Ethics Board (EEB)**, which is composed of **2 external independent experts**.

Based on our research, you have been selected as a potential candidate for such position. We are therefore writing you to ask if you would be available to assume the role of external independent ethics expert to ONELAB. The project started in October 2022 and the estimated end date is 30 September 2025. Therefore, we envisage an engagement of approximately **24 months**.

The role and responsibilities of the independent experts would be those of:

- Supporting the consortium in ensuring a continuous monitoring of **ethical issues** and adherence to **national and international laws and regulations**, in terms of protection and privacy of personal data, data processing and participation of humans.
- Provide guidance and advise to the Project Coordinator, Ethics Advisor, Data Protection Officer and Consortium partners on actions or mitigation measures related to ethics and data protection issues.

In order to do so, we envisage the following effort:

- Participation to at least 1 periodic online meeting/ethics workshop per year (2024, 2025).
- Participation to ad hoc meetings whenever an ethics issue is raised.
- Preparation of a total of 2 written reports (1 per project year: 2024, 2025).
- Review and feedback on draft deliverables (presenting ethical concerns) before submission.
- Assessment and validation of documentations regarding privacy and ethics: information sheet and informed consent form templates.

The available budget for such activity is set at **max 450 euros/day** and we envisage approximately a 10-day commitment. We kindly ask you to **let us know of your acceptance** for the above-mentioned activities **no later than ___ January 2024.**

Shall you need any further information and/or clarification, please do not hesitate to contact us.

Best regards,

Annex 3- NDA for Ethics board members

NON-DISCLOSURE AGREEMENT

This NON-DISCLOSURE AGREEMENT ("**NDA**") is for the members of the Ethics Board Members (the "**EB**") of the project **ONELAB – Orchestrating next-generation mobile modular laboratories for pandemic monitoring preparedness,** identified in the corresponding **Grant Agreement** as **Project 101073924** (the "**Project**") and it is entered into by and between:

[Insert name of the Ethics Board member] with ID [insert XXXX], currently working as [insert job title} at [insert professional address] (hereinafter, the "**EB Member**").

and

the Project consortium:

1. ACADEMISCH MEDISCH CENTRUM BIJ DE NL UNIVERSITEIT VAN AMSTERDAM (AMC), established in Meibergdreef 15, 1105 AZ, Amsterdam, The Netherlands, the Coordinator,
2. IANUS CONSULTING LTD (IANUS), established in SPYROU KYPRIANOU 85 ELENEION BUILDING 4TH FLOOR FLAT/OFFICE 401, LARNACA 6051, Cyprus,
3. TELESTO TECHNOLOGIES PLIROFORIKIS KAI EPIKOINONION EPE (TEL), established in Imitou 62 Cholargos, Greece,
4. INCORPORATED EDUCATIONAL INSTITUTION SAITAMA MEDICAL UNIVERSITY (SMHC), established in 38 Morohongo, Moroyama-cho, Iruma-gun, Saitama Prefecture, Japan,
5. CHAROKOPEIO PANEPISTIMIO (HUA), established in El. Benizeloy 70, Kallithea, Attiki, GR Kallithea 17676, Greece,
6. UNIVERSITAET INNSBRUCK (UIBK), established in Innrain 52, 6020 Innsbruck, Austria,
7. JURRISK (JUR), established in Tichelstraat 126/1, 3540 Schulen, Belgium,
8. UNIVERSITY OF CYPRUS ("UCY"), established in 1, University Avenue, Aglantzia, 2109, Nicosia, Cyprus,
9. PECSI TUDOMANYEGYETEM - UNIVERSITY OF PECS (UP), established in Vasvári Pál str. 4, Pécs, 7622, Hungary,
10. SOLGENIUM (SOL), established in Gstöttnerhofstraße 8, 4040 Linz, Austria,
11. UNIVERSITEIT GENT (UGENT), established in B-9000 Gent, Sint-Pietersnieuwstraat 25, Belgium,
12. PANOU ELECTRONIC TELECOMMUNICATION DEFENCE EQUIPMENT & SECURITY SERVICES RENDERING PRIVATE ENTERPRISE HANDICRAFT AND COMMERCIAL SOCIETE ANONYME (PANOU), established in Efstathiou 15, 115 24 Athens, Greece,
13. ISTITUTO DI SOCIOLOGIA INTERNAZIONALE DI GORIZIA ISIG (ISIG), established in VIA MAZZINI 13, GORIZIA 34170, Italy,

14. JOHANNITER OSTERREICH AUSBILDUNG UND FORSCHUNG GEMEINNUTZIGE GMBH (JOAFG), established in Ignaz-Köck-Straße 22, 1210 Wien, Austria,
15. BAYERISCHES ROTES KREUZ (BRK), established in Garmischer Str. 19-21, 81373 München, Germany,
16. STAD HASSELT (HASS), established in Limburgplein 1, 3500 Hasselt, Belgium,
17. MAGYAR VOROSKERESZT (HRC), established in Arany Janos utca 31, Budapest, 1051, Hungary,
18. PERIFEREIA DYTIKI ELLADA (RWG), established in Patron National Rd, 32 Athinon & Amerikis, Patra, 26441, Greece,
19. G.A.S. GESELLSCHAFT FUR ANALYTISCHESENSORSYSTEME M.B.H (GAS), established in Otto Hahn 15, 44227 Dortmund, Germany,
20. BIOXHALE LTD (BIOX), established in 17 Woodlands Court, Oadby, Leicester, England,
21. IMSPEX DIAGNOSTICS LIMITED (IMSPEX), established in Ty Menter, Navigation Park, Abercynon, RCT, CF45 4SN, United Kingdom,
22. ROBOSCIENTIFIC LIMITED (ROBO), established in Espace North, 181 Wisbech Road, Littleport, Cambridgeshire, United Kingdom,

as well as possible future members of the Project consortium, hereinafter referred as "**Project Partners**" or individually as "**Project Partner**";

represented by dr. Paul Brinkman, ONELAB project coordinator.

(Hereinafter the EAB Member and the Project Partners jointly referred as "**Parties**" or individually referred as "**Party"**).

WHEREAS:

a. Project Partners have elected to institute an Ethics Board (EB), as part of the requirements of the Grant Agreement (GA).

b. The purpose of the EB Member participation in the EB is to contribute to the EB objectives: the EB will support the identification of ethics principles and define operational procedures, ensure a continuous and independent monitoring and adherence to national and international laws and regulations, monitor and oversee the application of the defined ethics standards and requirements, in particular those pertaining to the participation of humans, data processing and risk of bio-surveillance, supervise the protection and privacy of personal data, provide support and recommendations on ethical procedures and potential mitigation measures (hereinafter the "**Purpose**"). For this Purpose, the Project Partners may disclose to the EB Member information which the Project Partners regard as confidential and the EB Member is willing to undertake to restrict the use and further disclosure of such Confidential Information.

NOW THEREFORE IT IS HEREBY AGREED:

1. "Confidential Information" shall mean any data or proprietary information received by the EB Member from a Project Partner whether orally, in writing, or in electronic or any other form that is not generally known to the public or has not yet been revealed, whether in tangible or intangible form, whenever and however disclosed, including, but not limited to:

   a. any scientific or technical information, invention, design, process, procedure, formula, improvement, technology or method;

   b. any concepts, samples, reports, data, know-how, works-in-progress, designs, drawings, photographs, development tools, specifications, software programs, source code, object code, flow charts, and databases;

   c. any marketing strategies, plans, financial information, or projections, operations, sales estimates, business plans and performance results relating to the Project Partner's past, present or future business activities, or those of its affiliates, subsidiaries and affiliated companies;

   d. trade secrets; plans for products or services, and customer or supplier lists;

   e. any other information that should reasonably be recognized as Confidential Information by the Project Partner.

   Confidential Information shall be identified either by marking it, in the case of written materials, or, in the case of information that is disclosed orally or written materials that are not marked, by notifying the EB Member of the confidential nature of the information. Such notification shall be done orally, by e-mail or written correspondence, or via other appropriate means of communication.

2. The EB Member hereby undertakes from the date of signature and until five (5) years after the end of the Project (which is foreseen at 30/09/2025) to keep strictly confidential all Confidential Information received by it hereunder with the same degree of care as is used with respect to the EB Member's own equally important confidential information to avoid disclosure to any third party, but at least with reasonable care, and neither disclose Confidential Information received by it hereunder to third party nor use it for any purpose other than the above-mentioned Purpose without the prior written permission of the disclosing Project Partner.

   The EB Member shall not, except as and to the extent required to enable it to carry out the Purpose, make any copies or reproduce the disclosed Confidential Information except copies of electronically exchanged Confidential Information made as a matter of routine information technology backup (cf. Section 6 below). Such copies or reproductions shall be subject to the terms of this NDA. The EB Member shall take such steps as are reasonably necessary to restrict access to and protect the confidentiality of such copies or reproductions of the NDA.

3. The foregoing obligations shall not apply to any Confidential Information which:

   a. is in the public domain at the time of disclosure or later becomes part of the public domain through no fault of the EB Member; or

   b. was known to the EB Member prior to disclosure hereunder without any obligation of confidentiality to the disclosing Project Partner, under evidence of reasonable proof or written record of such disclosure; or

c. is disclosed to the EB Member by a third party who, to EB Member's best knowledge, is in lawful possession thereof and under no obligation of confidentiality to the disclosing Project Partner or any other third party; or

d. was developed by the EB Member completely independently of any disclosure of Confidential Information hereunder under evidence of reasonable proof or written record of such disclosure.

The EB Member may disclose Confidential Information received hereunder if the EB Member is required to do so by any final ruling of a governmental or regulatory authority or court or by mandatory law, provided that written notice of such ruling is given without undue delay to the disclosing Project Partner so as to give the disclosing Project Partner an opportunity to seek a protective order or equivalent or to obtain a written assurance from the competent judicial or governmental entity that it will afford the Confidential Information the highest level of protection afforded under the applicable law or regulation, and provided further that the EB Member uses reasonable efforts to obtain assurance that the Confidential Information will be treated confidentially. Confidential Information which is disclosed in such a manner must be marked as "Confidential".

4. The EB Member shall not make any publicity on, press release of or any reference to Confidential Information received hereunder without the prior written permission of the corresponding Project Partner/s.

5. This Confidentiality Undertaking shall come into force upon signature by the EB Member.

6. The disclosing Project Partner may at its discretion request at any time in writing from the EB Member that the EB Member either return or destroy all Confidential Information received from such disclosing Project Partner and stored electronically and/or on record-bearing media as well as any copies thereof. The EB Member shall confirm in writing such destruction or return the Confidential Information as well as any copies thereof to the disclosing Project Partner within fifteen (15) calendar days after receipt of the disclosing Project Partner´s request.

   The provisions of the paragraph above of this Section 6 shall not apply to copies of electronically exchanged Confidential Information made as a matter of routine information technology backup and to Confidential Information or copies thereof which must be stored by the EB Member according to provisions of mandatory law, provided that such Confidential Information or copies thereof shall be subject to an indefinite confidentiality obligation according to the terms and conditions set forth herein.

7. No license to the EB Member, under any trademark, patent, copyright or any other intellectual property right is either granted or implied by the conveying of Confidential Information to the EB Member. None of the Confidential Information disclosed shall constitute any representation, warranty, assurance, guarantee or other inducement to the EB Member of any kind, and, in particular, with respect to the non-infringement of trademarks, patents, copyrights or any other intellectual property rights, or other rights of third Project Partners.

8. The EB Member shall not reverse engineer, disassemble or otherwise attempt to reconstruct any physical embodiments or prototypes provided hereunder to the Member.

9. This NDA may not be modified or amended except by written amendments duly executed by the Parties. This requirement of written form can only be waived in writing.

10. This NDA shall be construed and interpreted in accordance with the laws of Belgium, excluding its rules for choice of law.
11. All disputes directly arising under this NDA, which cannot be settled amicably, shall be subject to the jurisdiction of the competent court in Brussels, Belgium.

    The foregoing shall be without prejudice to the right of any Party to seek injunctive relief or other non-monetary relief before the competent Court of Brussels, in case it were not competent, before any court in any place where any unauthorized use of its Confidential Information occurs or threatens to occur.
12. Any communication regarding changes and/or modification of addresses/contacts or of any of the above, should be done by written means directly with the project manager at the following contact details: L.Jongejan (l.zuidmeer@amsterdamumc.nl)

This NDA may be executed by means of a scan or digitization of the whole page containing the original signature (e.g. a scan in PDF format) or an advanced or qualified electronic signature meeting the requirements established in Regulation 910/2014 (“EU eIDAS”) or equivalent (e.g.UK eIDAS), issued by a trusted legally authorized certification authority, or using remote signing services (like, including but not limited to, AdobeSign, Docusign etc.), counting as an original signature with the same validity, enforceability and permissibility.

The transfer of this copy by e-mail or via an electronic signature system will have the same legal force and legal effect as the transfer of the original copy of this NDA.

SIGNATURE for ONELAB	**SIGNATURE Expert**
Date:	Date:
Place:	Place:
_____	_____
Name:	Name: