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6	University of Innsbruck	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
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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
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Abbreviations

Abbreviation	Description
METC	Medical Ethical Committee
WMO	Medical Research Involving Human Subjects Act, WMO, in Dutch
BROK	Basic course on Regulations and Organisation for clinical investigators in The Netherlands



Executive Summary

Details are submitted that demonstrate appropriate health and safety procedures conforming to relevant local/national guidelines/legislation are followed for staff involved in this project before the start of the relevant activities.



1. Introduction

This deliverable was added by the EU as a result of the ethical appraisal report, with the objective to add details demonstrating that appropriate health and safety procedures conforming to relevant local/national guidelines/legislation are followed for staff involved in this project and are submitted as a deliverable before the start of the relevant activities.

For the 4 centers involved in the clinical studies (University of Pécs, Hungary; Universität Innsbruck, Austria; Amsterdam UMC, The Netherlands; Saitama Medical Center Hospital, Japan) we have collected this information below.

2. Institutes

University of Pécs, Hungary

The University must comply with the rules of the highest national authority, the Medical Research Council, on ethical issues. (<https://ett.okfo.gov.hu/en/codex-of-bioethics/>)

Staff at the University must attend and pass an annual online training course on fire safety, occupational health and safety and environmental protection. No other related yearly qualifications are required.

Activities at the University are governed by the University's organizational and operational rules, in accordance with the law.

(https://adminisztracio.pte.hu/sites/adminisztracio.pte.hu/files/files/Adminisztracio/Szabalyzatok_utasitasok/PTE_SZMSZ/pte_szmsz_20230701.pdf).

University of Innsbruck, Austria

University:

All new employees are expected to familiarise themselves with the University regulations on Health and Safety: <https://www.uibk.ac.at/arbeitssicherheit/>

Documents on Health and Safety are stored (provided by the Health and Safety Department): <https://sp.uibk.ac.at/sites/SiGe/SitePages/Homepage.aspx>

Sub-group employee protection:

<https://www.uibk.ac.at/arbeitssicherheit/arbeitnehmerinnenschutz/>

Institute for Breath Research, University of Innsbruck:

Health and Safety instructions are provided to all new staff members, after which a document is signed. By way of example, we attach the document that has just been signed by a new post-doctoral fellow, who started working at 100% on the project from the 1st October 2023. (Annex 1:IAA H&S Form)

Amsterdam UMC, The Netherlands

All new employees are expected to familiarize themselves with the University regulations on Health and Safety and complete an e-learning course on these subjects. Before being allowed to participate as a researcher involved in clinical studies, in The Netherlands a BROK certificate is required. The BROK® is a basic course about regulations and organization for WMO-project research (Medical Research Involving Human Subjects Act, WMO, in Dutch). The BROK certificate for the Dutch PI is added in Annex 2.

Saitama Medical Center Hospital, Japan



A certificate of completion of web-learning (on-line course) on research ethics (Valid for 1 year) is required for every researcher involved in the ONELAB studies, as approved by the institutional Ethics Committee.

3. Conclusions

All researchers involved in the ONELAB clinical studies undertake the appropriate Health and Safety procedures conforming to relevant local/national guidelines/legislation before the start of the relevant activities.



4. Annexes

Annex 1: IUBK-IAA H&S Form







Annex 2: BROK-certificate Dutch PI (Paul Brinkman)