Decision support for prediction and management of LCS

PROJECT NO

101057553

PROJECT ACRONYM

Long COVID

PROJECT TITLE:

Decision support for prediction and management of Long Covid Syndrome (LCS)

CALL/TOPIC:

HORIZON-HLTH-2021-DISEASE-04-07

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DELIVERABLE D7.5

Creation and composition of the independent ethics advisory board

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Associated Task	Task 1.2 HUS Clinical cohort
Deliverable Lead Partner	HUS
Main author(s)	Helena Liira
Internal Reviewer(s)	Francesca Carraro (CHINO), Malin Tverin (SPINVERSE)
Version	1.0

DISSEMINATION LEVEL		
PU	Public	X
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

CHANGE CONTROL

DOCUMENT HISTORY

VERSION	DATE	CHANGE HISTORY	AUTHOR(S)	ORGANISATION
V0.1	20.11.2022	First draft completed and shared with the internal reviewers	Helena Liira	HUS
V0.2	23.11.2022	Document sent back to HUS with comments from Spinverse	Malin Tverin	SPV
1.2V0.3	25.11.2022	Document sent back to HUS with comments from Chino	Francesca Carraro	CHINO
V1.0	30.11.2022	Final revision submitted to the EC	Helena Liira	HUS

Funded by the European Union

longCOVID
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EXECUTIVE SUMMARY

This deliverable presents the creation and composition of the independent Ethics advisory board in the Long COVID EU Consortium. The mission of the Ethics advisory board is to offer advice and assistance with the ethical aspects that are needed in the project. The task of the Ethics advisory board is to assess the ethics reviews made by HUS on each of the three reporting periods. In addition to three reporting periods, for month 23 there is an additional review to assess the issues raised in the project review process.

The Ethics advisory board will also answer the potential ethics question that may arise in the research work and within the consortium.

HUS as Coordinator has organized the creation of the ethics advisory board. It was decided that a member from each country that provides clinical data to the consortium will be invited. Members from Finland, the Netherlands and Switzerland have been nominated.

TABLE OF CONTENT

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1 INTRODUCTION

Although ethics assessment is part of the work of each work package in this EU project, to ensure the role of ethics, an external Ethics advisory board (EAB) is nominated. The mission of the EAB is to offer advice and assistance with the ethical aspects that are needed in the project.

Chino is the responsible partner of ethics in WP7 and has a lot of expertise in this area, being involved as responsible of Ethics in other European Projects (Aiccelerate, Resq+). An overall report on Ethics is due on M36 under Deliverable D7.3.

Also, HUS as Coordinator has responsibilities with regards to ethics. The consortium has decided to work so that ethics is on the agenda in all consortium meetings and this way the consortium gathers questions, discussions, and other material continuously. This ongoing reporting forms the basis of ethics reviews that are a task of HUS as Coordinator.

The role of the ethics advisory board is to assess the ethics reviews made by HUS on each of the three reporting periods.

2 COMPOSITION OF THE ETHICS ADVISORY BOARD

Following the guidelines provided in “Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects” published by the European Commission, the Consortium has asked the Partners to nominate candidates to cover a range of ethics and topic-relevant expertise and EU states involved in the Project.

In particular, the Consortium has asked all the clinical partners (HUS, UMCG and UNIBAS) to nominate a member to the EAB.

Members guarantee their independence by not being involved directly in the Project, even if part of or being connected in the same organization.

The following experts have given their consent to participate in the work of the EAB:

Country	**Member**	**Email**	**University**
FIN	Prof Veikko Launis	vlaunis@utu.fi	University of Turku
NL	Dr Els Maeckelberghe	e.l.m.maeckelberghe@umcg.nl	University of

			Groeningen
SUI	Dr Julia Amann	julia.amann@careum.ch	ETH Zurich

Professor Veikko Launis is the only Professor of Medical Ethics in Finland at the University of Turku. He specializes in moral philosophy, bioethics and research ethics. Launis wrote his doctoral thesis on Multidimensional Bioethics at the University of Turku in 2001. In addition, he has written numerous articles for scientific and popular periodicals in Finland and abroad. Launis has served as a member and chairman of several national and regional ethical commissions and advisory boards. His more recent production includes, among other things, the work Ihmisarvo (Vastapaino 2018) about the ethics of humanity.

Dr Els Maeckelberghe is Associate Professor in Bioethics and Research Ethics and a Confidential Advisor of Scientific Integrity. She has ample experience with European projects.

Dr. Julia Amann is a health services researcher with extensive experience and training in qualitative and participatory research methods. A broad range of topics at the intersection of digital health technologies, bioethics, and Ethics of Big Data and Medical AI is in Dr. Amann´s field of expertise.

3 TASKS OF THE ETHICS ADVISORY BOARD

The board is tasked with providing detailed advice and guidance on all ethical matters. This includes providing feedback on planned deliverables and on guidelines to be followed during the Project.

More precisely, the Board's tasks are:

a) to assist the Partners with task 7.3 Delivering an ethical project, offering advice and assistance on any ethical aspects that are needed and providing feedback on D 7.3 Report on Ethics;

b) to report on four ethics reviews written by the Coordinator HUS:

1. Report from the Independent EAB for reporting period 1 (M18)
2. Report on the issues raised by the EthSR (M23)
    a. *HUMANS - the project plans to carry out 6 cohort clinical studies and 2 interventional studies. One of them is already approved, but it is not clear whether the project will then obtain separate approval or will use samples and data from this already approved study. The involvement of vulnerable populations is acknowledged, but details on their recruitment and protection are not presented. The policy on incidental findings, as well as the insurance policies of the two interventional studies, are not available.*
    b. *HUMAN BIOLOGICAL SAMPLES - one study is already approved; it is unclear whether the use of biological samples from this study constitutes secondary use.*
    c. *PERSONAL DATA - it is unclear whether there will be secondary use of personal data*

from the already approved study. In addition, there is lack of clarity as to whether the consortium partners will be acting as joint data controllers, i.e. the role and interaction of controller/joint controller and data processor among consortium partners (as envisaged in the Data Management Plan). In particular, in case of joint controllership, the consortium should clarify if and how Article 26 of the GDPR would be implemented. The project lacks details on the evaluation of the ethics risks related to the data processing activities.

d. *ANIMALS - details on the ethics issues related to research involving animals are not provided.*

e. *ENVIRONMENT, SAFETY AND HEALTH - the handling of infectious samples should be monitored."*

3. Report from the Independent EAB for reporting period 2 (M36)
4. Report from the Independent EAB for reporting period 3 (M48)

4 CONCLUSIONS

The independent EAB board is a guarantor of the ethics processes in the Long COVID consortium. Its tasks will be to provide an external evaluation of the project's ethics.

In particular, the EAB is asked to assess the ethics reviews written by the Coordinator HUS and to give four reports on them during the project. In addition, the Ethics advisory board may serve as consultant for specific ethics questions. To the board of three experts, members from Finland, the Netherlands and Switzerland have been nominated.

5 REFERENCES

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4. European Commission, DG Research and Innovation, Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects, 2021 Jul. , available here: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/roles-and-functions-of-ethics-advisory-ethics-advisory-boards-in-ec-funded-projects_he_en.pdf