IMMERSE

Implementing Mobile MEntal health Recording Strategy for Europe

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[1] **Please choose the appropriate reference:**
PU = Public, fully open, e.g. web;
CO = Confidential, restricted under conditions set out in Model Grant Agreement;
CI = Classified, information as referred to in Commission Decision 2001/844/EC.

[2] **Use one of the following codes:**
R: Document, report (excluding the periodic and final reports)
DEM: Demonstrator, pilot, prototype, plan designs
DEC: Websites, patents filing, press & media actions, videos, etc.
OTHER: Software, technical diagram, etc

List of abbreviations

N/A

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1. Summary

This deliverable provides details as to the appointment of an external independent Scientific and Ethics Advisory Board (SEAB), tasked with monitoring the ethics issues involved in this project and how they are handled. The SEAB will be periodically consulted on key ethically-sensitive aspects of the project, including (but not limited to) patient recruitment, issues around informed/explicit consent, personal data protection, risk assessment of the proposed DMMH device.

2. Deliverable report

1. An external independent Ethics Advisor must be appointed to monitor the ethics issues involved in this project and how they are handled. The Advisor must be consulted at least on the following points: Patient recruitment, informed consent, personal data protection, ethics approvals, cross-border transfer of personal data and the potential for misuse and adverse effects in the study subjects.

The consortium has appointed an external independent Scientific and Ethics Advisory Board (SEAB), tasked with carrying out scientific and ethics advice functions. The decision to implement a single SEAB, rather than two distinct boards (tasked with providing distinct scientific and ethical advice) has been dictated both by the consideration that scientific/technical and ethical/legal aspects are deeply intertwined in the project (and thus may need to be discussed conjointly), and by the need to keep an agile governance system.

The SEAB is composed of the following individuals, who have been selected based on their distinct yet converging expertise in clinical psychology, digital mental health, bioethics and research ethics, public health, as well as their outstanding academic and professional achievements, which make them as ideally suited for providing high-level scientific and ethical advice to the project:

Dr. **Lucia Valmaggia**, Reader in Clinical Psychology and Digital Mental Health, King's College London, Lucia.Valmaggia@kcl.ac.uk

Prof. **Mario Alvarez-Jimenez**, Professor of Digital Mental Health and director of Orygen Digital, Melbourne, Australia, mario.alvarez@orygen.org.au

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Prof. **Tania Lincoln**, Professor of Clinical Psychology and Psychotherapy, Hamburg University, Germany, tania.lincoln@uni-hamburg.de

Specifically, Prof. Lucia Valmaggia, Prof. Mario Alvarez-Jimenez, and Prof. Tania Lincoln will be tasked with providing scientific advice (as **scientific advisors**), Prof. Els Maeckelberghe and Prof. Peter Schroeder-Baeck will be tasked with providing ethics advice (as **ethics advisors**). The SEAB has been formally introduced at the kick-off meeting of the project (May 27, 2021), where the *modus operandi* of the SEAB was defined, and a first round of consultation on relevant (ethical) issues in the project was carried out.

In general, consortium members and SEAB members expressed their preference and commitment for an ongoing dialogue, with sustained mutual interactions, rather than a mere formal engagement with activities carried out in the project. Specifically, it was agreed that, throughout the project, yearly online or in-person meetings will be organized to discuss pressing issues. Moreover, periodic short reports will be sent to the SEAB to keep SEAB members updated on relevant developments, and receive feedback as required.

In the meeting, ethical issues discussed revolved around patient recruitment, informed consent, and data sharing. A large consensus emerged around the need to use *broad consent* as a means to facilitate data sharing, while maintaining the possibility for research participants to exercise their autonomy over secondary uses of the data. Motives towards data sharing (or lack thereof) has been discussed, with a specific attention towards data sharing towards industrial entities, which is generally not opposed by participants as long as data are used for *bona fide* research purposes. Attention has been also devoted to the need to implement harmonized procedures throughout the consortium, in line with current discussions among project partners over the establishment of a data governance framework (which is due by M6).
As the project will submit a first ethics application (for phase I of the project) during the summer, SEAB members will be consulted over the definition of informed consent template and study protocol.

2. A report by the Ethics Advisor must be submitted as a deliverable at the end of each reporting period.

Ethics advisors within the SEAB have been alerted to this requirement, and will proceed accordingly.