# IMMERSE

**Implementing Mobile MEntal health Recording Strategy for Europe**

**H2020 - 945263**

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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

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**List of abbreviations**

N/A

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## 1. Summary

This deliverable, to be read in conjunction with D6.2, further outlines key measures implemented in the IMMERSE project to comply with data protection requirements. It provides a description of the security measures that will be implemented with regard to the processing of personal data within the scope of the IMMERSE project, and outlines the procedures underpinning the provision of information and the use of explicit consent of data subjects as the legal basis for processing personal data in the project.

## 2. Deliverable report

### 2.1 A description of the security measures that will be implemented to prevent unauthorised access to personal data or the equipment used for processing must be submitted as a deliverable.

**Phase I (months 1-18)**

During phase I a self-administered questionnaire (part A) and semi-structured interviews (part B) will be implemented. The questionnaire will not contain personally identifying structured items, but will provide free-text fields into which participants could erroneously enter identifying data. Data entry for the part A questionnaires will be implemented through a centrally provided electronic data capture platform (REDCap). Free-text data items will be viewed and redacted by project staff members before data is exported into the research platform. For the semi-structured interviews (part B), a participant pseudonym will be assigned after informed consent has been obtained. Interview transcripts and raw data will be stored locally at the study sites in pseudonymized form. Transcripts from the semi-structured interviews (part B) will be processed locally at the study sites with a suitable qualitative data analysis software (e.g. NVivo, MaxQDA) to extract structured data elements. Structured data elements will be imported into the central research database in pseudonymized form.

With regard to the data processed during Phase I by the partner UHEI in the IMMERSE research platform, specific Technical and Organizational Measures (TOMs) will be put in place to protect the confidentiality, integrity and availability of personally identifiable data, which will include:

- physical access control:
  - access to server rooms hosting consortium servers will be restricted to authorized staff
- system access control:
  - access to systems will be restricted to authorized staff
  - user system passwords will have to satisfy a defined password policy regarding length & strength of passwords

    - two-factor authentication (e.g. cryptographic key or token) will be used when technically feasible
    - local and network-based firewalls
    - encryption of filesystems
    - timely installation of available updates to systems & applications
- application & data access control:
    - access to applications & datasets will be restricted to authorized staff with role-based permissions
    - user application passwords will have to satisfy a defined password policy regarding length & strength of passwords
    - two-factor authentication (e.g. cryptographic key or token) will be used when technically feasible
- transfer control:
    - restriction of data exports to authorized roles
    - audit log of data exports
    - policy for safely erasing physical media used for exports
- data entry control:
    - restriction of data entry to authorized roles
    - audit log of data entry, changes and deletions
- data availability:
    - backup policy with nightly encrypted backups
- data separation:
    - separation of identifying and medical data with pseudonymous storage of medical data

**Phase II (months 18-48)**

During the phase II trial, pseudonymized electronic data capture will be handled by a subcontractor that will adhere to the requirements defined in ISO 14155. In addition, experience sampling (ESM) and mobile sensing data will be captured through the Movisens platform. Measures to redact personally identifying data in free text fields and extraction of qualitative data will be implemented identically to phase I. Pseudonymized data from both sources (EDC, Movisens) will be imported into the IMMERSE research platform in a pseudonymized way.

The technical and organizational measures implemented for the research platform by UHEI for phase I will be applied identically in phase II.

The process to commission an EDC subcontractor for phase II is currently ongoing. Selection criteria for the subcontractor include strict adherence to GDPR requirements and implementation of adequate technical and organizational measures. This deliverable will be amended to include a detailed description of these measures after the subcontractor has been commissioned.

With regard to the data collected and processed by partner **Movisens**, specific Technical and Organisational Measurements (TOM) will be put in place, and will include:

- Entry control to the rooms and buildings to keep unauthorized persons from accessing data processing/storing systems which might handle or store personal data
- Access control to IT-Systems and Applications to keep unauthorized persons from using data processing systems.
- Access control to data to keep unauthorized persons from accessing data storing systems
- Transport control of data to keep unauthorized persons from eavesdropping on the data during transmission between systems

**2.2 Detailed information on the informed consent/assent procedures in regard to data processing must be submitted as a deliverable.**

Consent will represent the legal basis for both primary processing for scientific research purposes within the scope of the present project, as well as secondary uses of personal data for scientific research purposes, as it will be detailed in the study protocol for each phase that will be submitted for ethics approval, and in the information sheet/privacy notice and informed consent provided to research participants/data subjects. Data subjects will receive information, as described in what follows, and will be able to provide explicit consent for both primary and secondary uses of collected data for scientific research purposes.

**Phase I**

Participants will be approached by the research team via service-specific email lists, by mail shots to service-specific postal mailing lists, and by adverts and leaflets in clinics. For Part A (Questionnaire), participants will be sent a copy of the participant information sheet as part of the recruitment email, if recruited by email; otherwise, they will be provided with a paper copy of the participant information sheet for their own records. For questionnaires that are completed on paper, participants will be required to provide a signature on the consent form; the consent form will be separated from the actual questionnaire after the paper questionnaire has been received by the research team. For questionnaires that are completed online, following established practice in online interviews, participants give consent by completing a series of yes/no statements establishing consent. For Part B (interviews), the recruitment and informed consent procedure will be as in Phase II.

**Phase II**

The following procedures will be implemented with regard to the provision of explicit consent for the processing of personal (sensitive) data. Different categories of data subjects will be approached in different ways.

**(i) Service users** will be approached by their treating clinician and provided with information about the study using a participant information sheet that describes the study. If the individual is interested in the study, the treating clinician will ask for permission to forward their contact details to the research team. If the person agrees, a graduate researcher (e.g., with a degree in psychology) will contact the potential participant by phone, email or in person and provide both oral and written information of the study (written information is forwarded by email, sent by mail or handed out in person).
Information will be provided in line with the principle of transparency, as enshrined in Art. 5(1)(a) GDPR (personal data are "processed lawfully, fairly and in a transparent manner in relation to the data subject"). Such principle requires that individuals are made aware, in a form "easily accessible and easy to understand," that "personal data concerning them are collected, used, consulted or otherwise processed and to what extent the personal data are or will be processed" (Recital 39). As such, transparency is the principle that informs the right of the individual to receive adequate information regarding the processing of personal data (Chapter III, Section 1 GDPR). In this vein, specific attention will be paid to the wording of the information sheets / privacy notices, to make them attuned to the special needs of the vulnerable population to which they are provided. Notably, details of how the data will be used for the purposes of the present project and, potentially, secondary research activities will be provided; it will be emphasized that participation is voluntary, potential participants can withdraw from the study at any time without giving any reason, and withdrawal from the study or refusal to take part will not involve any consequences for the potential participant. After this first contact, potential participants (and, in the case of adolescents, their parent/guardian/legally authorised representative) will have sufficient time (i.e. 1 week) to decide whether they want to take part in the study. If interested, a qualified investigator will schedule a first session with the potential participant. The privacy notice and consent form will be handed out at the beginning of this session. Explicit consent is only signed after all questions of the participants (and, where applicable, their legal guardians) are answered and the procedures of the study and related data processing activities are entirely clear. This will include informing participants about the circumstances in which the research team are obliged to disclose participants' personal information (including information that can pose a likely immediate threat to themselves or to others). If required, participants will be granted more time to decide whether or not they want to participate after this first personal contact.

**(ii) Clinicians, service user support network, health care system administrators and managers** will be approached by the research team and provided with information about the study using a specific participant information sheet / privacy notice for healthy volunteers that describes the study. It will be emphasized that participation is voluntary, potential participants can withdraw from the study at any time without giving any reason, and withdrawal from the study or refusal to take part will not involve any consequences for the potential participant. After discussing all relevant information, a specific informed consent for healthy volunteers will be provided.

Informed consent is only signed after all questions of the participants are answered and the procedures of the study are entirely clear.

**3. Templates of the informed consent forms and information sheets (in language and terms intelligible to the participants) must be submitted as a deliverable.**

To ensure a high degree of harmonization, the consortium is currently finalizing a template for consent and information sheet (in English), which will be then translated to local languages and adapted to the requirements of the local ethics committees.

Such a template is geared to address both ethics requirements related to participation of research subjects in research, and data protection requirements related to the processing of personal data.

Templates of the informed consent forms and information sheets in local languages will thus be submitted as part of Deliverable 6.1, which is due at M9.