Work package number [9]	WP6	Lead beneficiary [10]	1 - KU Leuven
Work package title	Ethical and legal framework		
Start month	1	End month	48

Objectives

• Ethics and data protection compliance: ensuring the project's compliance with ethics, data protection and other legal requirements at the European, national and local institutional level;
• Harmonization of data management procedures: devising a harmonized data governance framework for samples and data flows across the distinct partner institutions, in compliance with ethics, data protection, and other legal requirements;
• Ethical, legal and policy analysis: mapping the ethical, legal and policy requirements in view of the clinical application of the DMMH technology.
• Drafting a policy white paper laying down a policy template for the clinical implementation of DMMH technologies.

Description of work and role of partners

WP6 - Ethical and legal framework [Months: 1-48]
KU Leuven, CIMH, UEDIN, UK BA, UPJS, TMF
From an ethical and policy perspective, the IMMERSE project faces a threefold challenge: a) addressing ethics and data protection issues, which are raised by the very asset sustaining the project, namely the scope of data collection and analysis across the four national sites of intervention; b) harmonizing ethics and legal procedures across partner institutions; and c) prospectively identifying ethical, legal and policy requirements for the future clinical uptake of the technology developed in the project. To address these challenges, WP6 will provide robust ethics, legal and data governance guidance throughout the entire research process, through 'real-time ethics engagement'87 with the planned research activities (see task 6.1 and 6.2), while also conducting ethical, legal and policy analysis to prospectively identify relevant requirements for the clinical implementation of DMMH.

Task 6.1. Ethics, data protection and legal compliance (KU Leuven, UEDIN, CIMH, UK BA, UPJS, TMF)
Within the overall scope of this task, WP6 will monitor, during the whole project lifecycle, the compliance with the legal, ethical, and data protection requirements related to the research activities performed in the frame of the proposed project. WP6 will provide the necessary ethical and legal guidance, will liaise with project partners for the implementation of the necessary compliance measures, and will guarantee that ethics committees, the institutions' legal departments and regulatory bodies find a project internal, specialized contact point.

At the start of the project, WP6 will support project partners towards obtaining ethics approvals from the competent Ethics Committees for carrying out the proposed research activities, (which include qualitative interviews with end users as foreseen by WP5). It will provide guidance to align study protocols with a focus on data protection clauses, and, on the basis of local and national ethics requirements, it will elaborate a harmonized consent template covering the secondary use of the data across the different sites of intervention. In addition, WP6 will provide support to the implementation WPs (WP3, WP4, WP5 and WP7), which will carry out a Data Protection Impact Assessment (DPIA), as foreseen by art. 35 GDPR, to assess the potential risks for data subjects entailed by the planned data processing operations, and devise adequate safeguard measures. When required, WP6 will also facilitate the liaising with the Data Protection Officers (DPOs) of partner institutions.

Task 6.2. Harmonization of data management (KU Leuven, TMF)
Within the scope of this task, WP6 will oversee the establishment of an ethics-compliant, harmonized data governance framework that will underpin the processing and transfer of the datasets generated in the project. WP6 will provide guidance focused on ethics and data protection to the implementation WPs that will be tasked with establishing a Data Management Plan (DMP). Given the different regulatory requirements in place across the four national contexts of intervention, the underlying aim of the DMP will be to provide a harmonized and ethically consistent framework for data processing across a fragmented regulatory landscape. In addition, WP6 will develop a data governance framework in order to make data accessible within the Consortium in an ethically and legally compliant way. Moreover, conditions for sharing data with researchers beyond the Consortium will be defined in
compliance with the underlying consent of the participating patients.

Task 6.3. Ethical, legal and policy analysis (KU Leuven, UEDIN, CIMH, UK BA, UPJS)

Early on, this task will identify and distil the main ethical and legal requirements. During the evolution of the project, it will identify further ethical, legal and policy requirements that could impinge on the clinical implementation of the DMMH device. The specific steps that will be pursued within the scope of this task are the following:
• At the start of the project, this subtask will conduct an inventory and analyse relevant ethics and data protection requirements at EU, national, and local level, to implement a data protection by design approach and enable the obtainment of ethics approvals.
• This task will further elaborate on the main ethical and legal requirements distilled in the previous task, to prospectively identify further ethical, legal and policy requirements (at EU and national level) that may impinge on the future clinical uptake of the DMMH technology. Specific attention will be paid to: (i) data protection requirements as laid out in the GDPR and its national implementations in the three Member States and the UK; (ii) national digital health regulations and policies (which regulate the use of EHRs, PHEs, mHealth solutions in the healthcare context); and local soft laws and ethics requirements. Since both the data protection and digital health fields are rapidly advancing, new normative guidelines and recommendations from policymakers and regulators will be closely monitored. Finally, the insights gathered will be fed back into the project, to ensure timely and accurate implementation of the main legal and ethical requirements identified.
• Knowledge gathered from all the previous tasks will be incorporated to devise a policy white paper on the governance of DHHM technologies. The aim of the white paper will be to provide a policy template to navigate ethical, legal and policy requirements for the clinical implementation of this and other mHealth
initiatives unfolding at the four national contexts. The white paper will also provide a template for harmonized procedures facilitating data transfers across different European Member States and the United Kingdom for future mHealth interventions.

Participation per Partner

Partner number and short name	WP6 effort
1 - KU Leuven	32.80
2 - CIMH	4.00
3 - UEDIN	4.00
4 - UK BA	2.00
5 - UPJS	2.00
9 - TMF	5.88
Total	50.68

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D6.1	H - Requirement No. 2	1 - KU Leuven	Report	Confidential, only for members of the consortium (including the Commission Services)	3
D6.2	POPD - Requirement No. 4	1 - KU Leuven	Report	Confidential, only for members of the consortium (including the Commission Services)	3

List of deliverables

Deliverable Number[14]	Deliverable Title	Lead beneficiary	Type[15]	Dissemination level[16]	Due Date (in months)[17]
D6.3	POPD - Requirement No. 5	1 - KU Leuven	Report	Confidential, only for members of the consortium (including the Commission Services)	3
D6.4	OEI - Requirement No. 10	1 - KU Leuven	Report	Confidential, only for members of the consortium (including the Commission Services)	3
D6.5	GEN - Requirement No. 9	1 - KU Leuven	Report	Confidential, only for members of the consortium (including the Commission Services)	3
D6.6	NEC - Requirement No. 7	1 - KU Leuven	Report	Confidential, only for members of the consortium (including the Commission Services)	6
D6.7	Ethical monitoring (1)	1 - KU Leuven	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D6.8	Ethical monitoring (2)	1 - KU Leuven	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D6.9	Ethical monitoring (3)	1 - KU Leuven	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D6.10	H - Requirement No. 3	1 - KU Leuven	Report	Confidential, only for members of the consortium (including the Commission Services)	42
D6.11	Policy white paper	1 - KU Leuven	Report	Public	45
D6.12	Ethical monitoring (4)	1 - KU Leuven	Report	Confidential, only for members of the consortium (including the Commission Services)	48

Description of deliverables

-D6.1: H - Requirement No. 2
-D6.2: POPD - Requirement No. 4
-D6.3: POPD - Requirement No. 5
-D6.4: OEI - Requirement No. 10
-D6.5: M - Requirement No. 8
-D6.6: GEN - Requirement No. 9
-D6.7: NEC - Requirement No. 7
-D6.8: Ethical monitoring (1)
-D6.9: Ethical monitoring (2)
-D6.10: Ethical monitoring (3)
-D6.11: H - Requirement No. 3
-D6.12: Policy white paper
-D6.13: Ethical monitoring (4)

D6.1 : H - Requirement No. 2 [3]

1. The informed consent procedures that will be implemented for the participation of humans must be submitted as a deliverable. 2. Templates of the informed consent/assent forms and information sheets (in language and terms intelligible to the participants) must be submitted as a deliverable. 3. Copies of opinions/approvals by ethics committees and/or competent authorities for the research with humans must be submitted as a deliverable.

D6.2 : POPD - Requirement No. 4 [3]

1. The beneficiary must check if special derogations pertaining to the rights of data subjects or the processing of genetic, biometric and/or health data have been established under the national legislation of the country where the research takes place and submit a declaration of compliance with respective national legal framework(s)." 2. The host institution must confirm that it has appointed a Data Protection Officer (DPO) and the contact details of the DPO are made available to all data subjects involved in the research. For host institutions not required to appoint a DPO under the GDPR a detailed data protection policy for the project must be submitted as deliverable. " 3. The beneficiary must explain how all of the data they intend to process is relevant and limited to the purposes of the research project (in accordance with the 'data minimisation 'principle). This must be submitted as a deliverable. " 4. A description of the technical and organisational measures that will be implemented to safeguard the rights and freedoms of the data subjects/research participants must be submitted as a deliverable. " 5. Description of the anonymisation/ pseudonymisation techniques that will be implemented must be submitted as a deliverable. 6. In case personal data are transferred from the EU to a non-EU country or international organisation, confirmation that such transfers are in accordance with Chapter V of the General Data Protection Regulation 2016/679, must be submitted as a deliverable. " 7. In case personal data are transferred from a non-EU country to the EU (or another third state), confirmation that such transfers comply with the laws of the country in which the data was collected must be submitted as a deliverable.

D6.3 : POPD - Requirement No. 5 [3]

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. 2. Detailed information on the informed consent/assent procedures in regard to data processing must be submitted as a deliverable. 3. Templates of the informed consent forms and information sheets (in language and terms intelligible to the participants) must be submitted as a deliverable.

D6.4 : OEI - Requirement No. 10 [3]

1. A risk assessment must be provided as a deliverable to describe as to how the DMMH device could adversely affect the lives of the patients, particularly the risk of causing distress, disrupting their lives and the dependence on mobile devices.

D6.5 : GEN - Requirement No. 9 [3]

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

D6.6 : NEC - Requirement No. 7 [6]

1. Copies of import/export authorisations, as required by national/EU legislation must be submitted as a deliverable.

D6.7 : Ethical monitoring (1) [12]

At the end of each year, we will submit a report on the activities carried out within the previous reporting year to ensure that the project is consistently ethically and legally compliant.

D6.8 : Ethical monitoring (2) [24]

At the end of each year, we will submit a report on the activities carried out within the previous reporting year to ensure that the project is consistently ethically and legally compliant.

D6.9 : Ethical monitoring (3) [36]

At the end of each year, we will submit a report on the activities carried out within the previous reporting year to ensure that the project is consistently ethically and legally compliant.

D6.10 : H - Requirement No. 3 [42]

1. For each clinical study, a report on the status of posting results in the study registry(s) must be submitted as a deliverable, including timelines if/when final posting of results is scheduled after end of funding period.

D6.11 : Policy white paper [45]

Knowledge gathered from all the previous tasks will be incorporated to devise a policy white paper on the governance of DHHM technologies. The aim of the white paper will be to provide a policy template to navigate ethical, legal and policy requirements for the clinical implementation of this and other mHealth initiatives unfolding at the four national contexts. The white paper will also provide a template for harmonized procedures facilitating data transfers across different European Member States and the United Kingdom for future mHealth interventions.

D6.12 : Ethical monitoring (4) [48]

At the end of each year, we will submit a report on the activities carried out within the previous reporting year to ensure that the project is consistently ethically and legally compliant.

Schedule of relevant Milestones

Milestone number[18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS3	Establishing a data governance framework	1 - KU Leuven	6	
MS6	First analysis of regulatory requirements, feeding insights back into the project	1 - KU Leuven	12	
MS13	Second analysis of regulatory requirements, feeding insights back into the project	1 - KU Leuven	24	
MS19	Third analysis of regulatory requirements, feeding insights back into the project	1 - KU Leuven	36	