WP6. Ethical and legal framework

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General Assembly meeting Edinburgh, 31/3/22

This project has received funding from the European Union's Horizon 2020 research and innovation Programme under grant agreement 945263 (IMMERSE)

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WP6 - Objectives

- Overseeing ethics and data protection compliance
  - **Amendment Phase I protocol**
  - **Involvment EAB Phase II**
- Harmonization of data management procedures (DPA, DGF)
  - **Overview DPA Phase I**
  - **DPA Phase II**
- Ethical, legal and policy analysis (ethics/governance white paper)
  - **Paper on normative discussion of contextual factors associated with participant enrollment in IMMERSE Phase I**

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WP6 – Items for discussion

Overview of allowed data processing operations IMMERSE (Phase I)

- https://docs.google.com/document/d/10VzfwOrWh6F_r0_PDfXoL-96Fpa6VGaO/edit

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WP6 – Items for discussion

Ethics, data protection compliance & harmonization

- **Amendment to Phase I ethics approval**
  - Workshop with clinicians (in July)
  - Definition of consent template [Luca/Irene revision – April 10]
  - Amendment template [Anita]
  - Procedures for amending protocol Phase I [Local sites – April 10]
  - Deadline for submission: **April 30, 2022**

Deadlines for local sites:
- **April 10: amendment procedures**
- **April 30: submission of Amendment**

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WP6 – Items for discussion

Ethics, data protection compliance & harmonization

- **Ethics and regulatory approval Phase II**
  - Sponsor: CIMH
  - Deadline for submitting ethics approval:
    - **Before end of May, 2022: submit to BfArM** → BfArM will submit the ethics file to EC
    - **After June 1, 2022: submit to EC** → EC will submit the file to BfArM
    - Other partners: submit ethics protocol to local EC [local sites – **check local requirements**]
    - Open issues to discuss?

Deadlines for local sites
May 18: finalization ethics documentation
Plan ahead for submission!

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WP6 – Items for discussion

Ethics, data protection compliance & harmonization

- **Data Processing Agreement (DPA) Phase II - *KUL Research & Development***
  - Study registration at CTC
  - Provision of supporting documents (GDPR tool / updated ‘Schedule 2’ (i.e. details of data flows))
  - On the basis of the provided documentation, ‘Clinical Trial Agreement’ and DPA
  - Ethics approval

When can study registration take place?

Alternative (quicker) route available?

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WP6 – Items for discussion

Ethics Advisory Board

- Feedback ahead of Phase II ethics submission
- Involvement in ethics paper project?

TBD:

- Date for (virtual) meeting (end of April?)
- Who needs/would like to be involved?

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WP6 – Items for discussion

Ethics paper

- Identification and normative discussion of contextual factors associated with participants' enrollment in IMMERSE Phase I [Luca, Maria, + …]
- **Twofold purpose:**
  - To **map contextual factors (barriers/facilitators) associated with participants enrollment** in the pre-trial study (questionnaire + interviews) conducted within the scope of the IMMERSE project (Phase I).
  - To identify **best practices** for future studies in the field, also in light of **established principles of research ethics**, such as autonomy and justice (normative analysis).

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WP6 – Deliverables

6.1	M3
1. Informed consent procedures 2. Templates of the informed consent/assent forms and information sheets (in local languages) 3. Copies of opinions/approvals by ethics committees and/or competent authorities	

6.2	M3
1. Declaration of compliance with respective national legal framework(s). 2. Appointment of DPO 3. Compliance with data minimization 4. Description of technical and organizational safeguards 5. Description of the anonymisation/pseudonymisation techniques 6. Declaration of compliance data transfers to outside EU 7. Declaration of compliance data transfers from outside EU	

6.3	M3
1. Description of security measures 2. Information on informed consent/assent procedures in regard to data processing 3. Templates of the informed consent/assent forms and information sheets (in local languages)	

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WP6 – Deliverables

6.4	M3
1. Risk assessment (e.g. distress, disrupting lives, dependence on mobile devices).	

6.5	M3
1. Clarification on direct potential for misuse.	

6.6	M3
1. Appointment of external independent Ethics Advisor	

6.6	M3
2. Report by the Ethics Advisor (at the end of each reporting period)	

6.7	M6
1. Copies of import/export authorisations, as required by national/EU legislation	

6.8, 6.9, 6.10, 6.13	M12, 24, 36, 48
Ethical monitoring	

6.11	M42
1. Report on the status of posting results in the study registry(s)	

6.12	M45
Policy White Paper	

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WP6 – Year 2

- Definition of DPA for Phase II
- Overseeing ethics approvals for Phase II
- Ethics paper
- …

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