WP6. Ethical and legal framework

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WP6 – Outline

- **Items for discussion re: ethics / data protection compliance**
- **Preparation evaluation meeting**
- **EAB meeting**
- **WP6 research line on data governance (white paper, D6.12)**

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WP6 – Items for discussion

- **DPA Phase II**
- **JCA**

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WP6 – Items for discussion

- **Preparation evaluation meeting:**
  - Share ethics package (approvals, etc.) phase II

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WP6 – Items for discussion

- **EAB meeting**
  - Role of EAB?
  - Suggested period for next yearly meeting: mid-December 2022

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WP6. White paper on data governance

Analysis of proposed Regulation on the **European Health Data Space**

- EHDS is the first domain-specific common European data space (European Data Strategy, 2020), it is intended to address health-specific challenges to health data access and sharing.
- Two main stated objectives: (i) Facilitate **primary use of health data (EHR)** by patients across the continent; (ii) Enhance **seconday data uses** by researchers, innovators, etc.
- Direct relevance for the field of digital health (mHealth data made available, integration with EHRs)

- **Interdisciplinary Expert Rountable** in Leuven, 25.10.2022 (including all WP6 members)
- **Position paper** (target journal: *Policy Forum*, Science)

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WP6. White paper on data governance

Critical issues: *too big to succeed*

- **Too big to implement:**
  - Data quality
  - Missing data infrastructures
- **Too big to govern**
  - On a collision course with existing (European, national) rules
  - Establishment of Health Data Access Boards: unclear decision-making prerogatives, lack of public accountability
- **Too big to produce public value**
  - No guarantee of equitable returns for society
  - Data harvesting by commercial actors (Big Tech platforms)
  - Exacerbating digital divides

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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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