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Ethical-Legal Framework for the Secondary Use of Health-related Data

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06.10.2023

Background

HealthyCloud consortium partners analysed the ethical-legal framework governing secondary use of health-related data. The work was carried out across multiple activities, resulting (among other output) in the following public reports:

- Framework of modular contract clauses under the GDPR
- Report on a workshop dedicated to Secure Processing Environments (SPEs)
- Guideline on Ethically and Legally Compliant Governance Models

Lessons Learned

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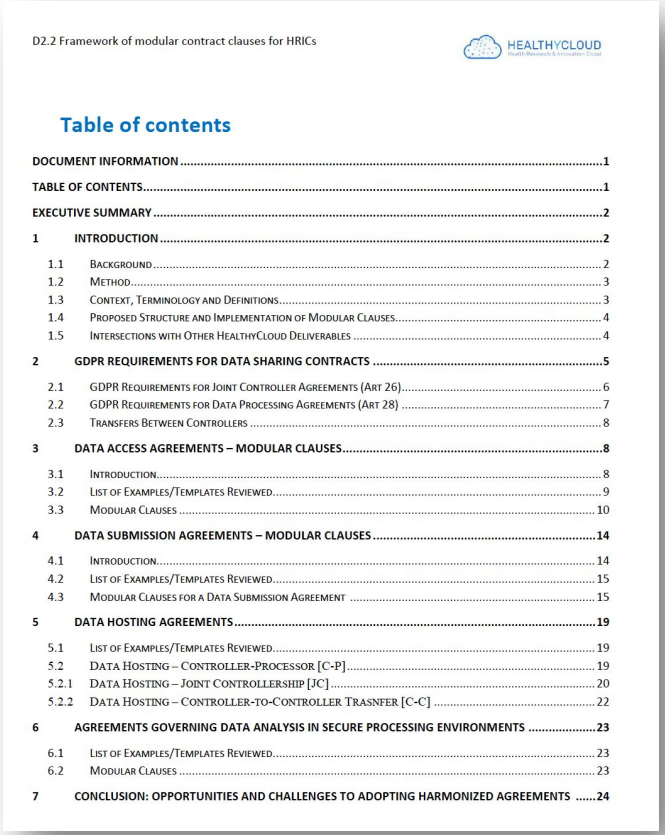
Framework of modular contract clauses

- The value of standardising or harmonising contracts, to provide clarity, certainty and predictability, and to facilitate negotiations is understood

  In practice, however, institutions and their legal departments typically have their own templates in place.

- Many of the challenges of achieving harmonisation have to do with different data sharing contexts: different data types, types of actors (e.g., academic v industry v healthcare institutions), jurisdictions involved (and applicable laws), different relationships between the parties, different sectoral norms (proprietary vs open science).

- There are still competing GDPR interpretations. **The GDPR has also significantly increased the due diligence surrounding contract execution** – before (due diligence, negotiation, signing), and after (monitoring of obligations).



D2.2 Framework of modular contract clauses for HRICs

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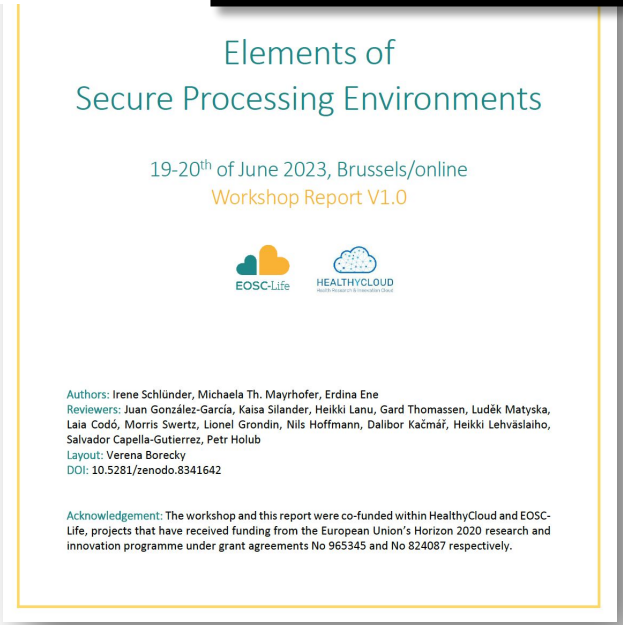
Workshop: Elements of SPEs

- **Goal:** to discuss elements of Secure Processing Environments (SPEs)
- This hybrid workshop was jointly organised by the EU Projects EOSC-Life and HealthyCloud on 19-20th of June 2023 in Brussels/online. It attracted more than 150 participants.
- Brought together experts from academia, industry, and policy makers to exchange on the basic technical and organisational requirements, best practices, and their relevance for the realisation of the European Health Data Space (EHDS) and in connection with recent developments within the European Open Science Cloud (EOSC)



Elements of
Secure Processing Environments

19-20th of June 2023, Brussels/online
Workshop Report V1.0

EOSC-Life HEALTHYCLOUD

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Layout: Verena Borecky
DOI: 10.5281/zenodo.8341642

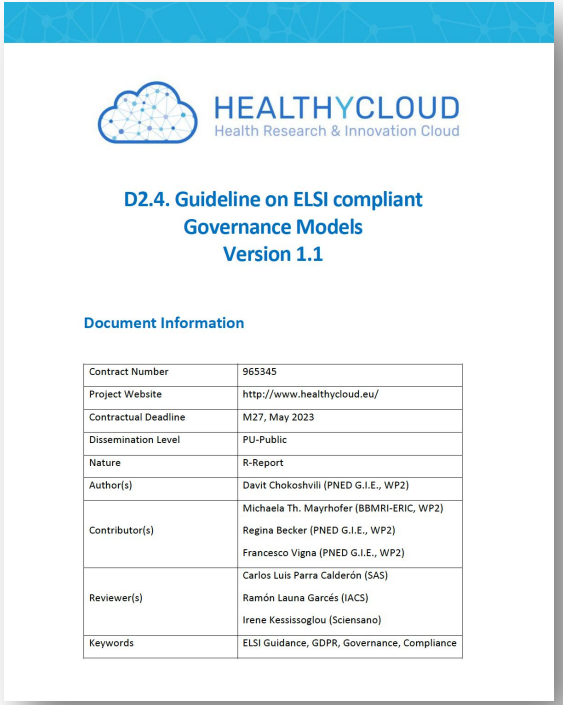
Acknowledgement: The workshop and this report were co-funded within HealthyCloud and EOSC-Life, projects that have received funding from the European Union's Horizon 2020 research and innovation programme under grant agreements No 965345 and No 824087 respectively.

Key Findings

- Agreement that many elements are indeed in place
- A regulatory roadmap is needed
- Retaining a plurality of SPE providers is critical (interoperability)

Guideline on Compliant Governance Models

- Overall, the providers of the key infrastructural components of the HRIC defined by the HealthyCloud consortium are well-positioned to meet their compliance obligations as processors in the sense of the GDPR.
- Several potential areas of improvement, such as implementing appropriate Metadata standards, and enhanced capabilities for supporting data subjects in exercising their GDPR rights, have been proposed.
- **Compliance challenges stem from the complex, fragmentary, and uncertain legal framework under which controllers operate. The challenges are further exacerbated by the inherent compliance interdependencies among the controllers involved at different steps throughout the data lifecycle.**
- Ambitious vision of the EHDS Regulation has the potential to resolve these systemic challenges, although feasibility and timeframes remain uncertain



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D2.4. Guideline on ELSI compliant Governance Models
Version 1.1

Document Information

Contract Number	965345
Project Website	http://www.healthycloud.eu/
Contractual Deadline	M27, May 2023
Dissemination Level	PU-Public
Nature	R-Report
Author(s)	Davit Chokoshvili (PNED G.I.E., WP2)
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Keywords	ELSI Guidance, GDPR, Governance, Compliance

Conclusions

Outlook and Next Steps

- Need to leverage existing resources and best practices (‘don’t reinvent the wheel’)
  - Numerous high-quality template agreements, contractual tools, and guidance documents are available. While there are no perfect templates/guidance (no one-size-fits-all), existing resources provide a good starting point for most actors in the health data ecosystem.
  - Several European data-sharing infrastructures have adequate technical safeguards in place to be GDPR compliant (**as processors**)
- What is lacking is internal expertise and/or adequate resources to cover personnel costs required by **controllers** (i.e., data providers, data users) to meet their own compliance obligations
  - This unmet need has guided the design of the **HRIC Legal/Regulatory Guidance Service**

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Thank you!

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The HealthyCloud project has received funding from the European Union's Horizon 2020 research and innovation programme under the grant agreement № 965345.