

Disclaimer: We kindly ask to acknowledge that due to the diverse and heterogeneous nature of the questions and dynamic situations they pertain to, some of the information might be incomplete or only correct for the time being. Thus, please consider the date and date of last update with the below information. All available information was provided by a country representative from the PHIRI network during or in connection to the respective meeting.

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Table 1: Country responses – Ethical, Legal and Social Issues (ELSI) on Health Data Processing

Country	Topic: Ethical, Legal and Social Issues (ELSI) on Health Data Processing Q1: Are there any best practices or specific limitations? Q2: Are there efforts for more coherent ELSI principles? Q3: Which enablers or which barriers do you experience? Q4: Current changes in legislation (e.g. in light of upcoming EHDS regulation)?
Austria	Q2: Some parts of the system can be seen as best practice examples (e.g. the system for individual consent management, or the linkage of many public registries), but to make full use of it the overall coherence and smooth interaction of all parts has to be improved. Currently, several changes to national legislation are being negotiated to reduce administrative and legal barriers. Q4: There are a lot of dynamics on the legislation side, also in regard of the EHDS, Austria is working on defining which institution will be appointed as Data Access Body
Croatia	Q4: There have been current proposals to the change of legislations (based on the COVID recommendations) in our country; <ol style="list-style-type: none"> 1. Law on primary and secondary occupation 2. Amendments to the law on the amendments of general data administration 3. New procedure for the data protection agency 4. Mandatory application of privacy design (user privacy) – so there has been some analysis done <p>Based on Active citizens fund Croatia's „Analysis of practices for data collection and processing during the COVID pandemic - the case of Croatia.“ the key recommendations are:</p> <ul style="list-style-type: none"> - Amendments to the Law on the Protection of the Population against Infectious Diseases in accordance with Recital 52 of the Regulation, defining a legal basis for exceptions to the prohibition of processing special categories of data for the purpose of preventing or controlling infectious diseases. - Amendments to the Law on the Protection of the Population against Infectious Diseases (or other national regulations, such as the Law on Primary and Secondary Education or the Law on Occupational Safety), in accordance with Recital 45 of the Regulation, to ensure that the legal framework contains all the necessary elements as prescribed by Recital. - Amendments to the Law on the Implementation of the General Data Protection Regulation, eliminating the exemption from the application of administrative fines for public bodies. - A more proactive role for the Data Protection Agency, along with an expansion of the technological capabilities of the body and the implementation of a new procedure for appointing the head of the independent supervisory institution. - Mandatory application of the "privacy by design" principle, the design and development process of digital solutions in which user privacy is the fundamental rule of solution development and the most basic functional pillar, especially when such solutions are commissioned by public authorities. <p>The aim of this analysis is to eliminate unlawful pandemic data collection practices and establish principles of good governance and transparency among institutional actors shaping public privacy policy. The analysis is intended for institutional actors responsible for shaping public privacy policy, independent institutions protecting citizens' human rights, civil society organizations, as well as citizens and the general public.</p>

Czech Republic	Q4: There has been a recent legislation change, so we can provide health data (as our institute is responsible to provide health data), currently we are oriented mainly on open data (for processing and providing), which we are publishing on our homepage (as discussed with our GDPR experts), so it is not clear yet who is going to be the health data access body. But most probably UZIS.
Hungary	Q4: There are no significant law amendments. The EU legislation and recommendation of the instruments, regarding the questions, who is going to be the health data access body (for secondary use) was implemented. The national data protection office will most probably be the national health data access body, but it is not sure yet.
Ireland	Will reply in written.
Italy	<p>Q1: Italy moves in the framework of Europe and Italy has accepted the European GDPR regulation. The scientific research/studies which have access and can use health personal data are implemented under an ad hoc decree (in Italian language only): https://www.epicentro.iss.it/politiche_sanitarie/DpcmSorveglianze2017 https://www.gazzettaufficiale.it/atto/serie_generale/caricaDettaglioAtto/originario;jsessionid=cKSknd1IbT2dY-9SDiNhmA...ntc-as3-guri2a?atto.dataPubblicazioneGazzetta=2017-05-12&atto.codiceRedazionale=17A03142&elenco30giorni=true</p> <p>Recently, a survey regarding the need of health data interoperability in the research studies was launched among researchers of the National Institute of Health. This initiative is going forward the issue related to the secondary use of health data and related ELSI.</p> <p>Q2: However, all the scientific studies collecting personal health data directly on patients and general population, need to collect informed consent signed by the participant; the informed consent, according to the specific study, are becoming as much as complex and comprehensive according to the ELSI issues and the GDPR regulation.</p> <p>Q3: Even though the National Institute of Health-ISS is the scientific arm of the Ministry of Health, researchers do not have access to individual personal and health data, except for studies under ad hoc laws/regulations/programs; two examples: - the COVID-19 integrated surveillance system was set up under a special law related to the 'national emergency status' that expired on March 2022; - the national Health Examination Survey is included in the National Statistical Programme; thanks to that, the study has access to mortality individual data including identifier, but only to anonymised Hospital Discharge Records.</p> <p>Q4: Italy is collaborating in preparing the proposal for the European Health Data Space (EHDS) (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52022PC0197) with the aim of establishing the European Health Data Space (EHDS) in order to improve access to and control by natural persons over their personal electronic health data in the context of healthcare (primary use of electronic health data), as well as for other purposes that would benefit the society such as research, innovation, policy-making, patient safety, personalised medicine, official statistics or regulatory activities (secondary use of electronic health data).</p>
Poland	Q4: The works on the legislative framework are still an ongoing process, because Poland has submitted many comments to the regulation to the proposal, the regulation is still perceived as something positive (ePrescription will definitely make the system better), biggest data owner is the ministry of health, the national public health institute. More recent information with an update will follow.
Portugal	Q4: Ministry of health is holding all the data, they have issued a document with the portugal strategy (end 2022) – one of the major challenges is to integrate the digital ethics – she will send it also for the minutes. Link to the National Strategy for the Health Information Ecosystem: https://www.spms.min-saude.pt/wp-content/uploads/2019/10/ENESIS2022_Version-for-Public-Consultation_Out2019.pdf
Serbia	Q4: There are interesting articles about data in Serbia health system: Article 'Privacy and Data Protection in Serbian Law: Challenges in the Digital Environment': http://real.mtak.hu/163740/1/CEA-ProfNet_07_Wielec_Right%20to%20Privacy_CH6.pdf Article 'Impact of the European General Data Protection Regulation (GDPR) on Health Data Management in a European Union Candidate Country: A Case Study of Serbia': https://medinform.jmir.org/2020/4/e14604/
The Netherlands	Will reply in written.



United Kingdom	<p>Welsh Government funds the SAIL (Secure Anonymised Information Linkage – www.saildatabank.com) system for the ethical and legal sharing of data for research purposes whilst protecting privacy through design and the implementation of the five safes. On the social side members of the public (SAIL Consumer Panel) are involved in all decisions on whether a proposed project should be approved (also need to show it is in the public interest and protects the privacy of individuals data). This system works very well, for example we were able to link up to 54 different databases to answer policy relevant questions on responding to the COVID-19 pandemic.</p> <p>Some links to papers with more detail: https://link.springer.com/article/10.1186/1472-6947-9-3 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8142954/</p>
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