

# Towards an International Electronic Repository and Virtual Laboratory of Open Data and Open-Source Software for Telehealth Research: Comparison of International, Australian and Finnish Privacy Policies

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**Abstract.** Health data includes all content related to health in all data formats, document types, information systems, publication media and languages from all specialties, organisations, regions, states and countries. Capabilities to share, integrate and compare these data contents, clinical trial results and other evaluation outcomes together with telehealth applications for data processing are critical to accelerate discovery and its diffusion to clinical practice. However, the same ethical and legal frameworks that protect privacy hinder this open data and open-source code approach and the issues accumulate if moving data across national, regional or organisational borders. This can be seen as one of the reasons why many telehealth applications and health-research findings tend to be limited to very narrow domains and global results are lacking. The aim of this paper is to take steps towards establishing an international electronic repository and virtual laboratory of open data and open-source code for research purposes by comparing international, Australian and Finnish frameworks. The frameworks seem to be fundamentally similar; they apply the principles of accountability and adequacy to using and disclosing personal data. Their requirements to inform data subjects about the purposes of data collection and use before the dataset is collected, assure that individuals are no longer identifiable and to destruct data when the research activities are finished make sharing data and even secondary data difficult. Using the Internet or cloud services for sharing without proper approvals by ethics committees is technically not allowed if the data are stored in another country. The research community needs to overcome these barriers and develop a virtual laboratory, which operates on distributed data repositories. This empowers the community by enabling systematic evaluations of new technologies and research hypotheses on a rich variety of data and against existing applications, and subsequent tracking of quality improvements in time.

**Keywords.** Data mining, electronic health records, health Information technology, information dissemination, privacy

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## Introduction

Electronic recording of *health information* enables data to become better accessible through innovative information and communication technologies (ICTs) for the purposes of improving health and healthcare [1-4]. However, this promise holds only if the potential benefits outweigh the risks, in particular, the loss of privacy [5, 6]. This data contains *personal data* about patients and healthcare workers such as identifiers and information about a patient's health, healthcare, and other sensitive matters [7, 8]. In order to avoid compromise of privacy, storing and using personal data for research purposes - that is, *record* or *register research*, requires careful consideration and compliance with the appropriate governance, policy and legal frameworks.

The aim of this paper is to better understand the requirements for using health data in research internationally by comparing international, Australian and Finnish frameworks. The following research questions are addressed: What are the frameworks internationally, nationally, and regionally? How do they differ? How can the process of ethics approvals and research permissions be characterised? How can data be moved, combined or compared across geographical or jurisdictional borders? What happens to this data and derived resources after the research project is finished? The overall aim is to take steps towards an international electronic repository and virtual laboratory of open data and open-source code for researchers to evaluate research hypotheses and ICTs on a rich variety of data, develop these resources further and track quality improvements.

## 1. Results

International frameworks for privacy protection have an increasing role and harmonising impact over national, regional, and organisational regulations. Pioneering work towards today's privacy protection began in the late 1940s and early 1950s by recognising individuals' basic right to privacy [9]. In the early 1970s, some of the world's first laws for protecting electronic data privacy were established in Northern Europe and soon after, European governance, policy and legal frameworks on privacy protection addressed the consequences of electronic recording [10]. In 1980, the Organisation for Economic Co-operation and Development (OECD) adopted their guidelines, which address not only personal data and privacy protection but also movement of personal data across national borders [7]. The latest developments include the privacy framework by the Asia-Pacific Economic Co-Operation Organisation (APEC) in 2005, the directive by the European Commission in 1995 and its update as the regulation proposal in 2012 [11-13]. The proposal is intended to strengthen the protection of individuals with regard to the processing of personal data and to tackle the challenges of globalisation and new ICTs. These more general frameworks are supplemented with health specific ones, probably the most renowned being the Nuremberg Code for Human Experimentation (1947), Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects (1964), Belmont Report (1979), and Lisbon Declaration of the Rights of the Patient (1981) [14].

In Australia and Finland, the general process of getting access to personal health data for research purposes is well guided (Table 1). It cascades furnishing the proper ethics approvals and research permissions at least from each healthcare jurisdiction

from where data originates (Figures 1 and 2). Permissions may be granted for a defined goal, specific data type and gathering interval and limited in time. The legislation does not permit organisations to use or disclose personal data unless data subjects have consented or this use or disclosure has been specifically authorised or required by another law. The data subject includes the patient and in Australia also the healthcare workers. Data for record research is usually gathered by the healthcare provider and thereby it may be subject to substantial fees and sometimes also delays. Also data de-identification, which is encouraged in Australia may be time consuming and subject to additional fees. Moving and combining data across geographical or jurisdictional borders is permitted only if it has been specifically requested in the ethics protocol and the proper approvals and permissions have been obtained. This may hinder comparative research and the use of cloud services for storage and computing. The requirement to inform data subjects about the purposes of data collection and use before the dataset is collected may raise issues if trying to release original data or derived resources. In Finland, difficulties may also arise from the requirement of destructing the dataset when the research activities are finished and assuring that individuals are no longer identifiable in the derived resources. The major challenge in Australia is to establish penalties for leakages of personal data (iappANZ Privacy Summit; Melbourne, VIC, Australia; 30 November 2011). Currently there is only a recommendation to inform the Office of the Australian Information Commissioner (and not the data subjects) if data subjects' privacy may have been compromised.

**Table 1.** Comparison of Australia and Finland

<b>Legal frameworks</b>	<b>Australia</b>	<b>Finland</b>
Harmoniser	Commonwealth of Australia	European Union (EU, member since 1995)
Highest national authority	Dep. of Health and Ageing, National Health and Medical Research Council	Ministry of Social Affairs and Health
Regional differences	Yes, for states/territories	No
Examples	Australia: Privacy Act ( <a href="http://www.privacy.gov.au/law/act">www.privacy.gov.au/law/act</a> ) New South Wales (NSW, <a href="http://www.legislation.nsw.gov.au">www.legislation.nsw.gov.au</a> ): - Health Records and Information Privacy Act 2002 (NSW), - NSW Health Privacy Manual, Version 2, 2005, - NSW Health Electronic Information Security Policy, Version 1, 2005, - NHMRC National Statement on Ethical Conduct in Human Research, 2007, and - Privacy and Personal Information Protection Act 1998 (NSW).	The EU directive <sup>13</sup> supplemented by - Act on Electronic Prescriptions 61/2007, - Act on Private Health Care 152/1990, - Act on the National Personal Data Registers for Health Care 556/1989, - Act on the Status and Rights of Patients 785/1992, - Act of Reading Health or Social care client information 159/2007, - Criminal Code of Finland 39/1889, 940/2008, - Decree of Ministry of Social Affairs and Health about Patient Records 298/2009, - Health Care Law 1326/2010, - Law on Medical Research 488/1999, 794/2010, and - Personal Data Act 523/1999 ( <a href="http://www.finlex.fi">www.finlex.fi</a> ).
<b>Ethics approvals</b>		
Projects subject to ethics approvals	Any health information acquisition or work with patients beyond routine care.	Any health information acquisition or work with patients beyond routine care.

Approving and guiding authorities	The Australian Health Ethics Committee supported by territorial and site specific committees	National Committee on Medical Research Ethics (TUKIJA) and its sub-committees for the five university hospital districts. TUKIJA gives statements on studies that involve patients and that are invasive in nature (either physically or mentally).
Application forms	The NEAF National Ethics Application Form is used for all projects but it may need to be supplemented with territorial applications.	Standardised forms of TUKIJA, dependent on the project type, are used for all projects. They may need to be supplemented with the standardised forms provided by the hospital districts.
Review times	Committees meet monthly	Committees meet once or twice a month
Review costs	0 – over 5,000 USD, depending on commercial sponsorships of the project.	0–3,000 USD, depending on commercial sponsorships of the project.

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**Informed consent**

Relevant legislation	Privacy Act	- Personal Data Act 523/1999 and - Act on the Status and Rights of Patients 785/1992
Data subject	Patient and healthcare workers	Patient
Required from	All data subjects	All data subjects
Exceptions	Specific authorisation or requirement by another law: health information can be used and disclosed for health and medical research purposes in certain circumstances, where researchers are unable to seek individuals' informed consent; if it is not practicable to consent data subjects, de-identified information should be used and if also this option is unavailable, identifying information may be used if the proposed medical project has been approved by a properly constituted Human Research Ethics Committee.	Personal data may be processed for purposes of historical or scientific research also for a reason, if: the research cannot be carried out without data identifying the person and the consent of the data subjects cannot be obtained owing to the quantity of the data, their age or another comparable reason; the use of the personal data file is based on an appropriate research plan and a person or a group of persons responsible for the research have been designated; the personal data file is used and data are disclosed therefrom only for purposes of historical or scientific research and the procedure followed is also otherwise such that the data pertaining to a given individual are not disclosed to outsiders; and after the personal data are no longer required for the research or for the verification of the results achieved, the personal data file is destroyed or transferred into an archive, or the data in it are altered so that the data subjects can no longer be identified.

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**Trans-border aspects**

Relevant legislation	Privacy Act	- Personal Data Act 523/1999, - Act on the National Personal Data Registers for Health Care 556/1989, - Act on the Status and Rights of Patients 785/1992, and - Directive 95/46/EC
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Feasibility of transfers and responsibilities	<p>If an agency or organisation in Australia or an external territory transfers personal information about an individual to a recipient who is outside Australia and an external territory, the agency or organisation remains accountable for that personal information, unless: the agency or organisation reasonably believes that the recipient of the information is subject to a law, binding scheme or contract which effectively upholds privacy protections that are substantially similar to these principles; individual consents to the transfer, after being expressly advised that the consequence of providing consent is that the agency or organisation will no longer be accountable for the individual's personal information once transferred; or agency or organisation is required or authorised by or under law to transfer the personal information.</p>	<p>Personal data may be transferred across territorial and national borders not only within the EU and the European Economic Area but also out of these areas if the country in question guarantees an adequate level of data protection, this protection of the privacy and the rights of individuals is guaranteed by means of contractual terms or data subjects have been consented. If combining or correlating Finnish data across municipalities, public and private sectors and employed and self-employed healthcare professionals, additional permissions from the Ministry is needed.</p>
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#### A. Initialising the project

1. Initial discussions take place.
2. Research plan is developed.
3. Research group is formed and its leader is named.

#### B. Developing the ethical protocol, which encompasses:

1. studying the governance, policy, and legal frameworks
2. assuring that the proper permissions are furnished and legislation is followed
3. monitoring that the permissions cover all aspects of project
4. specifying the purposes of data collection, including justifications for the relevance of the data to the research plan and the amount of data to be collected
5. specifying data collection, storage and protection which includes data access, destruction, use, modification and disclosure
6. preparing user agreements
7. educating the data users on research ethics
8. answering to questions on research ethics
9. monitoring that good research practice is conformed
10. intervening in problems.

#### C. Obtaining the ethics approvals and research permissions

1. The study is accepted by chief officers of the jurisdiction.
2. Ethics approvals are obtained from the approving authority.
3. Research permissions are obtained from the jurisdictions (and in some cases from the highest national health-authority).

#### D. Collecting the data

1. Data are collected for the purposes specified above.
2. Typically, informed consent forms are required from patients and healthcare workers.
3. Typically, data, or at least its structured parts are de-identified.

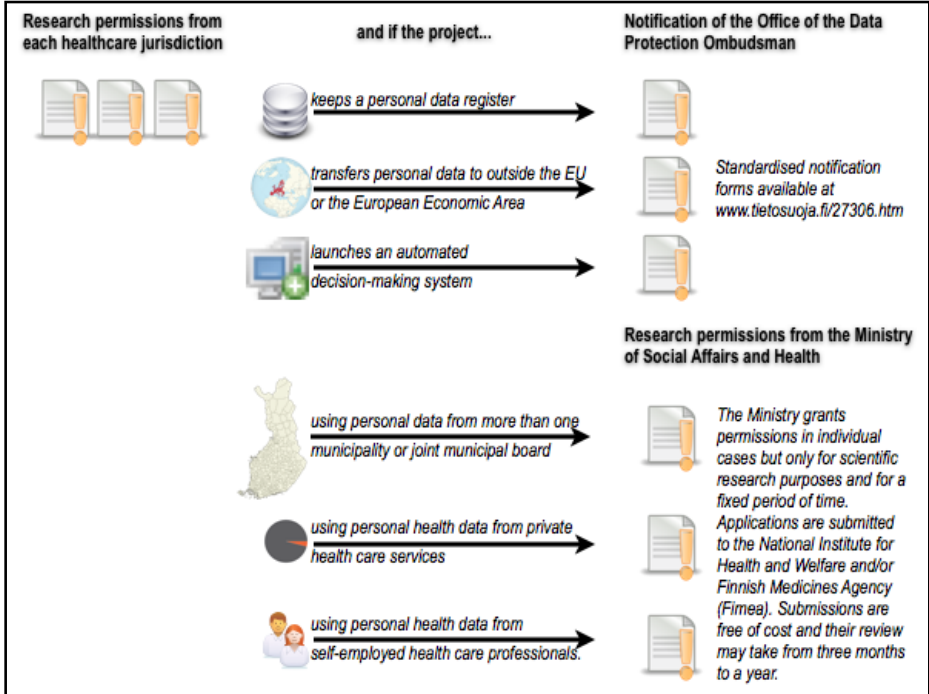
#### E. Studying the data

1. The ethical protocol of the step B is followed.
2. Research takes place and data is used only for the purposes specified above.
3. If data were wanted to use for other purposes, steps A-D would be repeated.

#### F. Closing the project

1. All data are destructed (typically returned to the jurisdiction or deleted) as specified in the study protocol.

**Figure 1.** The general process of getting access to authentic health information for academic research purposes from a single public-health organisation/jurisdiction



**Figure 2.** Research permissions in Finland as stated in the Finnish Personal Data Act 523/1999, Act on the National Personal Data Registers for Health Care 556/1989, and Act on the Status and Rights of Patients 785/1992

## 2. Conclusions

The results of this study contribute to a better understanding of the requirements for using health data in research internationally. In summary, the governance, policy and legal frameworks differ between countries, regions and organisations in Australia and Finland. They mostly apply the principles of *accountability* and *adequacy* and are thereby fundamentally similar [15]. In the accountable principle, used for example in the APEC and Australian frameworks, the original creator of the personal data register is accountable for regulatory compliance or the accountabilities are specified separately [11, 16]. In the adequacy principle, used for example in the EU and Australian frameworks, the subsequent receiver of the data register must protect privacy adequately [12, 17].

In Australia, the Australian Centre for Health Record Linkage has collected, since 2006, authentic health information and created from it de-identified data for projects that are for the benefit of the Australian public. This activity addresses not only using

and disclosing information during the lifetime of a given project but also allows this in other projects. Moreover, opening in 2012 the Personally Controlled Electronic Health Record for Australians to access, record and share their health information is likely to contribute to the availability of health information for development and evaluation of health informatics resources and solutions. Finally, BioGrid Australia is a secure research platform and infrastructure that provides access to real-time clinical, imaging and biospecimen information across Australia. The platform is web-based, protects both privacy and intellectual property and includes both health information and ICTs for information collection, analysis, integration and linkage across multiple organisations. Authorised users can access information and solutions, develop them further and use their own solutions. In March 2012, the amount of information on the platform was over 200,000 records and they covered over 15 specialties.

In Finland, trans-border information dissemination has been addressed not only by legislation but also via the KanTa National Archive of Health Information. Since 2007, the Ministry of Social Affairs and Health, Finland has been obligated by law to develop KanTa. It has been used since 2010 and today it encompasses national information systems for the electronic prescribing and archiving of health records, online access by citizens to their prescriptions and archives and online access by healthcare workers to the national pharmaceutical database. More widely in the Nordic and Baltic countries, the HHealth teXt Analysis network has been sharing personal data since 2010 for health, computer science and health informatics research.

Probably the first steps towards international sharing of health data and software have been taken by the Computational Medical Centre, Cross-Language Evaluation Forum, Informatics for Integrating Biology and the Bedside, Text REtrieval Conference and many other international challenges with dedicated shared tasks for health ICTs. Even though the challenges have had limited environments for the participants to download data and upload their solutions, they have resulted in freely available sets of carefully de-identified health information for research and rigorous evaluations of the state-of-the-art in these ICTs on specific tasks. Today, the iDASH NLP Ecosystem, established in 2011 in the USA is the most comprehensive work towards an international electronic repository and virtual laboratory for research purposes. It is a webpage with a focus on textual health information and the related resources, ICTs and educational materials. On the webpage, people can easily access links to the existing materials, information, resources and solutions. Authorised users can also access a virtual machine, which has a suite of installed health informatics solutions and download the suite from the webpage. However, the major challenge of complying all up-to-date governance, policy and legal frameworks related to using and disclosing personal data remains. A timely approach to address the challenge is to build ICTs, which minimise the possibility of accountability and adequacy for violations as well as enforce and audit the regulatory compliance [18].

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