Responsible Data Processing in Health Research

REPORT

Mandated by
the Swiss Academy of Medical Sciences

(25.8.2017)

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ETH Zurich

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Introduction

1.1 Aim of this report

In December 2016, the Swiss Personalized Health Network (henceforth, SPHN) required the ELSI Advisory Group (henceforth, ELSIag) to propose a set of principles that shall be adopted by the SPHN and shall appear in the first call for proposals of the initiative. To corroborate such activity, the Swiss Academy of Medical Sciences (henceforth, SAMS) mandated the Health Ethics and Policy Lab of the University of Zurich (now at ETH Zurich) to realize a study on national and international principles for responsible access to personal data for research purposes. The present report illustrates the methodology and the findings of the study, including a section analyzing the compatibility of internationally accepted normative standards and practices of data access with relevant Swiss laws. Moreover, this document also includes the "**Ethical Framework for Responsible Data Processing in the Swiss Personalized Health Network**" (version 1) that has been publicly released on June 12, 2017. The principles laid down by the framework, albeit not legally binding, have to be fulfilled by successful grantees in order for research projects to be funded and to continue to be supported through the grant scheme of the SPHN.

This project was supported by the SAMS and conducted by the Health Ethics and Policy Lab at the University of Zurich (now at ETH Zurich). The research was led by Dr. Alessandro Blasimme (University of Zurich – now ETH Zurich) and by Dr. Ania Sitek (University of Zurich) under the supervision of the ELSIag chair, Prof. Effy Vayena (University of Zurich – now ETH Zurich).

1.2 The importance of sharing data

The availability of extensive arrays of health-related data is a precondition for the development of personalized and precision medicine[1]. Moreover, the notion of health-related data is expanding to include clinical data from electronic health records, genetic and genomic data – generated in clinical, research or even in commercial settings – and also lifestyle data produced through smartphones and other sensor-equipped devices. Such diverse data are typically not interoperable and several barriers prevent them from being available for research purposes.

Increasing accessibility to health-related data for precision medicine faces many ethical and policy hurdles. Major challenges hinder the seamless integration of health-related data and set limits to data sharing. Among them, data security, data ownership and privacy play a prominent role. Furthermore, current informed consent practices do not easily accommodate the need of making data available for use, reuse and sharing. This casts doubts on the capacity to generate public trust around data sharing practices.

For these reasons, over the last two decades, public policy organizations, research funders and scientific institutions have been engaged in a sustained effort to promote data sharing as an ethically robust practice. Numerous policies and guidelines have been issued internationally, restating the need to share data and calling attention on the impediments and challenges that such need entails.

Recent interest in precision medicine has revamped the debate on the opportunities and challenges of data sharing – in Switzerland and abroad. The reliance of precision medicine on huge amounts of data recalls the need for acceptable policy principles governing the collection, flow, analysis and sharing of data for research purposes. Moreover, the expanding notion of health-related data in this domain calls for sustained scrutiny of how new data types fit into existing ethical and regulatory categories.

The SPHN is a conscious effort at tackling current technical barriers to data sharing, so as to promote the development of personalized medicine in Switzerland. For this effort to produce its expected outcomes, responsible processing of personal health-related data is a precondition.

[1] Alessandro Blasimme and Effy Vayena, "Becoming Partners, Retaining Autonomy: Ethical Considerations on the Development of Precision Medicine," *BMC Medical Ethics* 17 (2016): 67; Alessandro Blasimme and Effy Vayena, "'Tailored-to-You': Public Engagement and the Political Legitimation of Precision Medicine," *Perspectives in Biology and Medicine* 59, no. 2 (2017): 172–88.

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Methods

2.1 Scope of the study

The study offers an overview of **existing normative standards** for the use and sharing of personal data in the context of scientific research. In particular, we have focused on human biomedical research – that is, research involving human subjects, human biological material and data. For the purposes of the present study, **human biomedical research** includes:

- Basic research on the molecular basis of physio-pathological processes;
- Observational studies involving either healthy volunteers or patients, including longitudinal, case-control and cross-sectional studies;
- Interventional studies (i.e. clinical trials in all their forms and phases);
- Studies conducted on existing cohorts, including those involving the collection and analysis of genetic material, such as in the case of population genetics studies;
- DNA and RNA sequencing studies;
- All other studies based on the use of high-throughput technologies to analyze a variety of biological substrates and physiological functions (e.g. studies in proteomics, metabolomics, lipidomics, nutrigenetics and nutrigenomics, pharmacogenetics, pharmacogenomics, toxicogenomics, and so on);
- And finally, data produced through the use of qualitative research methods, such as interviews, surveys and ethnographic observations.

While we have considered issues emerging from both prospective and retrospective studies, the study only focuses on the collection, use and circulation of **personal data** – that is, data and measurements issued from the observation or the analysis of human subjects or of biological material derived from them. Both data originally collected and used for research purposes and data issued from clinical practice have been considered. Furthermore, the study takes into account both identifiable data and non-identifiable data, that is, data protected by available means of encryption, pseudonymization, anonymization and the like. It should be noticed that, in some jurisdictions, non-identifiable data are not considered as personal data from a legal point of view. In this study, "personal data" will refer also to non-identifiable data.

On the other hand, issues relative to the collection, processing, sharing and use of human biological *material* will not be covered in the version 1 of the framework, if not incidentally.

The study focused in particular on the issue of **further research use** of collected data. This expression refers to the possibility of making data available for analysis to researchers that were not originally involved in the collection, curation and initial analysis of the data. Henceforth, the term **secondary users** will be employed to designate researchers that re-analyze data produced by others. It is important to notice that data access does not imply data sharing, since data can be re-analyzed by secondary researchers without being transferred to them, nor, in principle, without providing them with a copy of the data. Yet, *data sharing* is commonly used to designate any activity implying the re-analysis of already collected data.

Given the sensitive nature of personal data and of health-related information that can be extracted from them, there exist universal consensus that such data should be processed with special caution. As a consequence, a wide number of institutions and governments have issued principles and recommendations regarding data processing in the context of scientific research. Most of these documents also contain guidance relative to the issue of further research use in human biomedical research. Although there is no consensus on a clearly identifiable set of principles and recommendations in this specific area, some of them are more recurrent. The most frequently recalled principles and recommendations can be considered the normative standards in the field.

The present study offers a comprehensive overview of national and international guidance and recommendations in the domain of data sharing. Relevant documents have been collected, screened for inclusion in the study and analyzed (see below). In particular, we aimed at retrieving the principles most frequently invoked as ethical cornerstones of data sharing. Those standards have then been studied from a legal point of view to analyze their consistency with the Swiss legal environment.

The normative standards for data use and sharing in human biomedical research may not all possess the same ethical importance. Moreover, there may be important principles to be respected in this domain that have not been captured by our study. While we do not consider the most frequently cited principles as the most compelling from an ethical point of view, they are the more likely to be recognized as valid by a broad array of stakeholders in different national contexts. However, attempting a normative ordering of the principles and values for data use and data sharing falls beyond the scope of this study.

Principles and recommendations for responsible data accessibility, unless contained in legal texts, are not legally binding. Rather, the kind of normativity that the principles express is ethical. More specifically, for the purposes of this document, it will be assumed that the relevant form of ethical normativity for the issue at stake will be that developed in bioethics over the course of the last four decades. Although bioethics nowadays comprises a number of different schools and approaches, in its canonical form bioethical analysis has proceeded along four axes: (1) respect for autonomous choices; (2) minimization and management of risks; (3) promotion of welfare; (4) fair allocation of resources (Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics (Principles of Biomedical Ethics*, 6th ed. (OUP USA, 2008)).

These four dimensions of bioethical analysis define the normative perimeter of this discipline. The principles usually invoked in the context of data access can, broadly speaking, be grounded into such dimensions. However, foundational issues with respect to those principles have not been addressed in this study, as that would exceed the scope of its mandate.

Rather, the function of this study is to aid the ELSIag in the decision-making process leading to the proposed **Ethical Framework for Responsible Data Processing in the Swiss Personalized Health Network.** In this respect, the study provides indications as to which principles and recommendations should be taken into account by the ELSIag. To this aim, the present report includes:

- An analysis of existing declarations and guidelines on data access in the context of human biomedical research;
- A summary of the most frequently invoked principles for responsible data access based on the previous analysis;
- A legal analysis of the fit between those principles and relevant legally binding regulations in Switzerland;
- An "Ethical Framework for Responsible Data Access to Health-Related Data in the Context of Scientific Research" (in the form of an Annex to the Report);
- The data used for the study (in the form of annexes to the Report).

2.2 Description of the study

This study looked primarily at texts (recommendations, policies, guidance, statements and the like) issued by organizations directly linked to science governance, and thus interested in shaping practices of data sharing for scientific purposes. We have thus initially identified relevant organizations in this field and then searched on their respective websites for documents about data sharing. In particular, we have only included texts issued by:

- National or international public policy organizations;
- Scientific societies, research platforms or consortia, expert groups;
- Professional organizations.
- Research funders;
- Governmental organizations.

Table 1. *List of organizations included in the study. All the organizations in the table have issued at least one document concerning data sharing policy. Other organizations were considered but not included.*

Type	Name
International public policy organizations	Council for International Organizations of Medical Sciences (CIOMS) Global Alliance for Genomics and Health (GA4GH); International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH); Organization for Economic Co-operation and Development (OECD); Public Population Project in Genomics and Society (P3G); United Nations Educational, Scientific and Cultural Organization (UNESCO).
National public policy organizations	Comité d'Éthique du Centre National de la Recherche Scientifique (France); Deutsche Ethikrat (Germany); Nationale Ethikommission / Commission Nationale d'Éthique dans le Domaine de la Médicine Humaine (Switzerland); Nuffield Council on Bioethics (United Kingdom); Office for Science and Technology Policy (United States); President's Council of Advisors on Science and Technology (United States); Swiss Clinical Trial Organization (Switzerland).
Scientific societies, professional organizations, and expert groups	European Federation of Pharmaceutical Industries and Associations (EFPIA); European Society of Human Genetics (ESHG); Human Genome Organization (HUGO); The Royal Society (United Kingdom); World Medical Association (WMA); 3 expert groups.
Research institutes and platforms	Institute National de Santé et Recherche Médicale – Inserm (France); International Cancer Genome Consortium (ICGC); Wellcome Trust Sanger Institute (United Kingdom);
Research funders	Cancer Research UK (United Kingdom); Horizon 2020 EU Framework Programme (European Union). Medical Research Council (United Kingdom); National Health and Medical Research Council (Australia); National Institutes of Health (United States); National Science Foundation (United States); Public Health Research Data Forum; Research Councils UK (United Kingdom); The Wellcome Trust (United Kingdom).
Governmental organizations	Council of Europe; European Commission; G8 Science Ministers;

The initial selection of the relevant organizations was based on the authors' personal knowledge of the field. Relevant suggestions also came from the Chairwoman and members

of the ELSIag. See **Table 1** for the complete list of selected organizations. We considered international organizations or organizations based in: Switzerland, Germany, France, Italy, United Kingdom, Australia, United States and the European Union (as a single entity).

Documents included in the study belong to at least one of the following categories:

- Policy declaration;
- Declaration of ethics principles;
- Public statement;
- Policy analysis;
- Expert report;
- Guideline;
- Best practices.

Included documents can be both specific to healthcare and medical research data and unspecific, that is, relative to all data produced in the course of publicly funded scientific research. See **Table 2** for the complete list of included documents.

The documents were retreived based on extensive Internet-based searches in the websites of the relevant organizations; more were included based on general Internet-based searches and suggestions from both the Chairwoman and other members of the ELSIag. The analysis of the documents initially included for review, provided furhter indications as to other documents to be included.

Each document included in the list of relevant texts has been analyzed with the aim of collecting information relative to:

- Year of publication;
- URL;
- Type of organization (see list of categories above);
- Type of document (see list of categories above);
- Nature of the data considered (e.g. genetic, clinical etc.);
- Ambit of application (e.g. research, clinical practice, public health);
- Stated goals of the document;
- Principles;
- Recommendations.

For this step, a working definition of 'principle' and 'recommendation' had to be created *ad hoc*, so as to make data collection consistent and replicable – see **Box 1** and **Box 2**. Of all the principles and recommendations that can be found in the documents, those who are either directly or indirectly relevant to data access in the context of human biomedical research are summarized in a unique table for further reference and analysis. It shall be noticed that there is no linear correspondence between principles and recommendations. This means that not all principles translate into specific recommendations in the texts analyzed, nor all recommendations are of direct relevance to one specific principle alone.

The retrieved principles have been analyzed from a legal perspective. In particular, in this phase, relevant Swiss legal texts have been identified. The normative standards for data use and sharing were compared with the requirements of Swiss law in this domain.

Box 1. Definition of "Principles"

Principles correspond to value statements having any of the following forms:

- Someone has a right
- Something is a right
- A given value should be protected or promoted
- A given state is valuable
- A given state of affairs should be achieved
- A given activity should be promoted or encourged or is valuable
- A given activity is key to promote something (implying that that 'something' is valuable)

Box 2. Definition of "Recommendations"

Recommendations correspond to requested or prescribed actions having any of the following forms:

- A given actor should act in a certain way
- Someone should do act in a certain way [this counts as a "generic recommendation", i.e. there is no explicit indication of the actor, but the latter can be inferred]
- A given activity should be done in such and such way
- A given activity shall be prohibited

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Analysis

3.1 Description of the dataset

Following our inclusion criteria, the search for policy and guidance documents on data sharing allowed us to retrieve 50 texts issued by 35 different organizations between 1996 and 2017 (see **Table 2**). Such documents are mainly specific to health and medical research data (40), but also include policies for data collected, produced and used in the course publicly funded research in general (10). Research funders and international public policy organizations figure as the most active type of entities involved in producing data sharing policies (with 14 and 13 documents respectively), followed by scientific societies, professional organizations and expert groups (9 documents).

3.2 The normative standards of data sharing

The analysis of data sharing policies and guidelines reveals overlap on a restricted set of principles.

List of included documents	
Specific to healthcare and medical data	
Type of organization	*Document title (publishing organization, date)*
International Public Policy Organizations	International Ethical Guidelines for Health-Related Research Involving Humans (CIOMS, 2016)
	Framework for Responsible Sharing of Genomic and Health-Related Data (GA4GH, 2014)
	Genomic Sampling and Management of Genomic Data (ICH, 2015)
	Best Practice Guidelines for Biological Resource Centers (OECD, 2007)
	Guidelines on Human Biobanks and Genetic Research (OECD, 2009)
	Health Data Governance (OECD 2015)
	Recommendation of the OECD Council on Health Data Governance (OECD, 2016)
	New Health Technologies (OECD, 2017)
	Data Sharing Code of Conduct for International Genomic Research (P3G, 2011)
	Universal Declaration on Human Genome and Human Rights (UNESCO, 1997)
	International Declaration on Human Genetic Data (UNESCO, 2003)
National Public Policy Organizations	Human Biobanks for Research (Deutsche Ethikrat, 2010)
	Biobanks for Research (NEK, 2015)
	The Collection, Linking and Use of Data in Biomedical Research and Health Care (Nuffield Council, 2015)
	Research with Human Subjects: a Manual for Practitioners (Swiss Clinical Trial Organizations And Swissethic, 2015)
Scientific societies, professional organizations, and expert groups	Principles for Responsible Clinical Trial Data Sharing (EFPIA, 2014)
	Data Storage and DNA Banking for Biomedical Research (ESHG, 2003)
	Statement on Benefit Sharing (HUGO, 2000)
	Statement on Human Genomic Databases (HUGO, 2002)
	Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks (WMA, 2016)
	Bermuda Principles (Expert Group, 1996)
	Amsterdam Principles (Expert Group, 2008)
	Toronto Statement (Expert Group, 2009)
Research funders	Data Sharing Policy (Cancer Research UK, 2009)
	Policy And Guidance On Sharing Research Data From Population And Patient Study (MRC, 2011)
	Data Sharing Policy (MRC, 2016)
	Policy on Open Research Data from Clinical Trials and Public Health Intervention Studies (MRC, 2016)

	Statement on Data Sharing (NHMRC, 2016)
	Data Sharing Policy and Implementation Guidance (NIH, 2003)
	Final Statement on Sharing Research Data (NIH, 2003)
	Genomic Data Sharing Policy (NIH, 2014)
	Dissemination and Sharing On Research Results (NSF, 2010)
	Sharing Research Data to Improve Public Health (Public Health Research Data Forum, 2010)
	Policy on Data Management and Sharing (The Wellcome Trust)
	Fort Lauderdale Principles (The Wellcome Trust, 2003)
Research institutes and platforms	Policies and Guidelines (ICGC, 2008)
	Data Sharing Policy (WTSI, 2014)
	Towards a Sustainable Sharing of Data and Samples (Inserm)
Governmental organizations	Additional Protocol to the Convention of Human Rights and Biomedicine (Council of Europe, 2005)
	Recommendation on Research on Biological Material of Human Origin (Council of Europe, 2006)
Relative to all data types produced through public funding	
Type of organization	*Document title (publishing organization, date)*
International Public Policy Organizations	Declaration on Access to Research Data from Public Funding (OECD, 2004)
	Principles and Guidelines for Access to Research Data from Public Funding (OECD, 2007)
National Public Policy Organizations	Increasing Access to the Results of Federally Funded Scientific Research (OSTP, 2013)
	Big Data and Privacy Report (PCAST, 2014)
	Avis du Comité d'éthique (CNRS, 2015)
Research Funders	Common Principles on Data Policy (Research Councils UK, 2015)
	Guidelines on FAIR Data Management (H2020, 2016)
Scientific societies, professional organizations, and expert groups	Science as an Open Enterprise (The Royal Society, 2012)
Governmental organizations	Recommendations on Access to and Preservation of Scientific Information (European Commission, 2012)
	Science Ministers' Statement (G8 Science Ministers, 2013)

***Table 2**. List of analyzed documents.*

Overall, the documents that have been analyzed clearly stress the importance of data sharing as a practice that promotes scientific progress and increases the potential for societal benefits being generated through scientific knowledge. In what follows, we list and illustrate all the normative standards that we have retrieved in form of principles. We present the principles from the most to the least frequently encountered. Yet we would like to stress once again that this order does not rank them in terms of ethical importance.

Principle 1. Maximal availability

Maximizing the availability of research data is the most often cited principle in the reviewed documents. This principle has a wide scope and serves as the basis for a number of valued practices. In a broad sense, the principle encourages data sharing and re-use, guaranteeing that research data and research outputs are promptly made available to the rest of the scientific community.

As to primary data, the principle of maximal availability emerges in particular in the context of policies regarding genetic and genomic data. In concomitance with international efforts such as the Human Genome Sequencing Consortium or the International HapMap Project, consensus emerged as to the opportunity of releasing publicly genetic data and genomic sequences as soon as they were generated. This is supported by the idea that cooperative efforts of this type amount to 'community resource projects' that is projects "specifically devised and implemented to create a set of data, reagents or other material whose primary utility will be as a resource for the broad scientific community"[2].

The principle of maximal availability intends to counteract the effects of the interests individual researchers or institutions can have in retaining data for the sake of publication. For this reason, it is frequently recommended that data from community resource projects be released prior to publication and therefore made available to all interested scientists.

Another element that is frequently recalled regarding the availability of primary data is the importance of accurately describing good practices adopted to generate the data themselves. This is intended to maximize data usability providing further users with high quality data and enabling them to fully exploit their scientific potential.

Principle 2. Data utility

Numerous documents affirm that promoting data sharing should be understood as a way to serve the common good. In this respect, *prioritizing data utility* emerges as a principle that orients all activities related to data processing and management.

Very much resonating with the ideals of 'open data' movements, this principle encourages openness, but it also factors in the importance of legitimate social, scientific and economic interests that could be affected by widespread data circulation. Public beneficence should be the ultimate goal of data sharing, but this does not entail that periods of exclusive data use or IP protection on data resources are always unreasonable. Quite to the contrary, the principle of data utility pays due attention to the dis-in-

[2] The Wellcome Trust, "Sharing Data from Large-Scale Biological Research Projects: A System of Tripartite Responsibility. Report of a Meeting Organized by the Wellcome Trust and Held on 14–15 January 2003 at Fort Lauderdale, USA.," 2003, https://www.genome.gov, pages, research, wellcomereport0303.pdf.

centivizing effects of openness and thus recognizes the legitimacy of practices aimed at attributing full recognition (both in terms of academic credit and in terms of due financial reward) to the efforts of those who initiate data collection.

One frequently cited mechanism for ensuring a balance between openness and equitability is the existence of well-functioning access review procedures.

Principle 3. Accountability

Policy and guidance documents on data sharing frequently emphasize the need for formal governance structures to help track down responsibility for how data are used, re-used and shared. This recommendation translates into a *principle of accountability* that is common to most reviewed documents.

The principle prescribes that governance bodies should be transparent and auditable. Also, data access policy should be cleared – so as to facilitate data users – and constantly monitored.

Adequate training should be provided to those who are in charge of monitoring and reviewing data access requests. Moreover, those who process research data should comply with professional standards in their respective domains, including ethical codes of conduct when appropriate.

Moreover, all accountability mechanism should be aligned with relevant regulations – both legal and ethical.

Principle 4. Respect for persons

When human personal data are at stake, special attention is devoted to ensure *respect for the dignity and the central moral interests of data donors*.

A major articulation of this principle prescribes respect for individual autonomy, and the primary mechanism to ensure autonomy is informed consent – to the use of one's data.

Taking a broader perspective, some documents mention respect for human rights as a key normative framework under this rubric. In particular, this is spelled out by the claim that individual rights shall always prevail over purely scientific interests.

One right in particular is recognized by some of the analyzed documents, that is, right to withdraw from a study and the corresponding right to have one's data removed from a database – when feasible.

Other important articulations of the principle of respect for persons include the right of data donors to decide whether or not they want to be informed of the findings of studies conducted using their data. Such findings could reveal medically relevant information (e.g. an increased risk for a given disease), or personally relevant information (such as uncovering genetic bonds with other people).

The right not to be discriminated against, or harmed, together with the right to exert some form of control over personal data are also acknowledged, albeit by a small portion of the analyzed documents.

Principle 5. Privacy and confidentiality

According to most documents, preventing inappropriate or unauthorized access to donors' data is a precondition to *protect privacy and confidentiality*.

In particular, access to sensitive data, such as identifiable health and genetic data should

only take place under strictly overseen conditions.

Respect for individuals privacy is often associated with stripping personal data of all identifiers before sharing them for research purposes. State-of-the-art techniques for de-identification, pseudnymization and full anonymization through cryptography are cited as means to minimize the risk of unauthorized re-identification of data.

Other confidentiality safeguards are represented by limiting data access to trusted users, that is, users that possess a series of pre-requisites for processing data in a reliably secure way.

In general, there is consensus in the documents regarding the fact that whereas identifiable data should be available only under controlled access conditions, aggregate data can be made publicly available.

Other values

A number of other values and principles are cited in the analyzed documents albeit with less frequency. Among them, it is worth mentioning that some documents stress the importance of anticipating public concerns by eliciting the opinion of lay publics and engaging them in the rollout of large-scale data-driven projects.

Data transparency through making metadata easily accessible is also invoked, along with the need to foster *interoperability* across different data platforms. *Adequate investment* in the sustainability of databases is also recalled.

Finally, fostering *public trust*, enhancing *coordinated policy* initiatives, and following ideals of *reciprocity* and *solidarity* in the design of data initiatives are also mentioned, although only sparsely in the analyzed documents.

3.3 Legal analysis

3.3.1 Identification and analysis of relevant legal texts in Switzerland

Patient data generated in cantonal and community hospitals are covered by *cantonal health acts* as well as *constitutional personality rights* (Art. 10 Para. 2 of the *Swiss Federal Constitution of 18th of April 1999*, FC)[3]]. Patient data collected in a private hospital or healthcare centre in general are covered by the *Federal Act on Data Protection of 19th of June 1992 (FADP)*[4] (Art. 2 Para. 1 lit. a FADP).

Privacy protection in Swiss private law is covered by *personality rights* (Art. 27 *et seq.* of the *Swiss Civil Code of 10th of December 1907*)[5] and *contract law*. Moreover, the *Right to privacy* is also recognized at a constitutional level (Art. 13 FC) and in the specific constitutional provisions regarding *research on human beings* (Art. 118b Para. 1 FC), *reproductive medicine and gene technology involving human beings* (Art. 119 Para. 2 FC) and *transplant medicine* (Art. 119a FC). In Swiss medical law the right of *self-determination* (based on *Art. 10 FC* and *Art. 28 of the Swiss Civil Code)* is of central importance.[6] The Swiss Federal Court derives a fundamental right to informational self-determination

[3] Bundesverfassung der Schweizerischen Eidgenossenschaft, Constitution fédérale de la Confédération Suisse, Costituzione federale della Confederazione Svizzera, SR 101.

[4] Bundesgesetz über den Datenschutz, Loi fédérale sur la protection des données, Legge federale sulla protezione die dati, SR 235.1.

[5] Schweizerisches Zivilgesetzbuch, Code civil Suisse, Codice civile svizzero, SR 210.

[6] Büchler Andrea, Gächter Thomas, Medical Law in Switzerland, 2nd ed., Alphen aan den Rijn 2016, No. 328.

from Art. 10 Para. 2 FC (Right to personal freedom) and Art. 13 Para. 2 FC (Right to privacy); it implies that every person has the right to decide whether her personal data is being processed or saved by private or governmental proponents and to determine what purpose the processing or saving of personal data may have.[7] The principle of human dignity (Art. 7 FC) which is being referred to in every specific biomedical constitutional provision mentioned above (Art. 118b *et seq.* FC) should also serve as further source of rights[8].

According to Art. 118b Para. 2 SFC the Confederation shall legislate on research on human beings where this is required in order to protect their dignity and privacy. In doing so, it shall preserve the freedom to conduct research and shall take account of the importance of research to health and society.

Specific federal acts define the legal entitlements of patients and research participants with respect to the processing of their data:

Human Research Act (HRA)

The *Federal Act on Research involving Human Beings* (Human Research Act, HRA of 30th of September 2011)[9] applies to research concerning human diseases and concerning the structure and function of the human body (Art. 2 Para. 1 HRA); the scope of the law therefore in general does not include clinical care. If existing biological material or personal health-related data collected in clinical care is further used for research, Art. 32 - 35 HRA (Chapter 4: Further Use of Biological Material and Health-Related Personal Data for Research) apply; in terms of data protection, further use of patient data is a change in purpose which needs to be covered by the informed consent of the person concerned (Art. 4 Para. 3 FADP).[10] Per Art. 24 lit. d of the *Human Research Ordinance of 20th of September 2013, HRO*)[11] *further use* is defined as the handling of already extracted biological material and generated data notably by giving access, providing or transmitting it.[12] The HRA does not apply to anonymously collected or anonymised health-related data (Art. 2 Para. 2 lit. c HRA). Anonymised biological material and anonymised health-related data means biological material and health-related data which cannot (without disproportionate effort) be traced to a specific person (Art. 3 lit. I HRA). Pseudonymised (coded) biological materials and coded health-related personal data means biological material and data linked to a specific person via a code (Art. 3 lit. h HRA). The Federal Council has specified the requirements for correct and secure anonymization and coding and furthermore the conditions for breaking the code (Art. 35 HRA, Art. 25 *et seq.* HRO): Biological materials and health-related personal data is considered correctly coded (Art. 32 Para. 2

7 "Der Anspruch impliziert, dass jede Person gegenüber fremder, staatlicher oder privater Bearbeitung und Speicherung von sie betreffenden Informationen bestimmen können muss, ob und zu welchem Zwecke diese Informationen über sie bearbeitet und gespeichert werden.", BGE 140 I 2, 22, E. 9.1.

8 Schweizer Rainer, van Spyk Benedikt, Art. 118b BV, in: Ehrenzeller Bernhard, Schindler Benjamin, Schweizer Rainer J., Vallender Klaus A. (Hrsg.), Die schweizerische Bundesverfassung, St. Galler Kommentar, 3. Aufl., St.Gallen 2014, Art. 118b N 18 with further references.

9 Bundesgesetz über die Forschung am Menschen, Loi fédérale relative à la recherche sur l'être humain, Legge federale concernente la ricerca sull'essere umano, SR 810.30.

10 Rudin Beat, Art. 32 - 35 HFG, in: Rütsche Bernhard (Hrsg.), Stämpflis Handkommentar zum Humanforschungsgesetz (HFG), Bern 2015, Introduction to Arts. 32 - 35 N 4.

11 Verordnung über die Humanforschung mit Ausnahme der klinischen Versuche, Ordonnance relative à la recherche sur l'être humain à l'exception des essais cliniques, Ordinanza concernente i progetti di ricerca sull'essere umano ad eccezione delle sperimentazioni cliniche, SR 810.301.

12 Cf. Schläpfer Lea, Clinical Data Sharing: Nutzen, Risiken und regulatorische Herausforderungen, recht (2016), 136 *et seq.*, 140.

and Art. 33 Para. 2 HRA) when from the perspective of a person not in charge of the key it can be qualified as anonymised (Art. 26 Para. 1 HRO). Re-identification is lawful if aimed at safeguarding the rights of the person concerned, namely the right to withdrawal their consent (Art. 27 lit. c HRO).

The conditions for further use of anonymised, coded and non-coded biological material and data as well as genetic data are regulated differently because according to the dispatch of the Federal Council the further use of certain data bear a higher risk for infringements of the personality rights of the person concerned than other data.[13] The provisions regulating the further use in the HRA are complex (see **Table 3**).

Concerning coded genetic and personally identifying non-genetic data, general consent to further use for research projects is possible.[14] The further use of personally identifying genetic data is restricted to specific research projects; general consent is not possible.[15] Non-genetic health-related personal data in coded form may be used for further research purposes if the person concerned or the legal representative or next of kin have been informed in advance and have not dissented (Art. 33 Para. 2 HRA, Art. 32 HRO). Arts. 22 - 24 HRA apply *mutatis mutandis*. The same information process may apply to the anonymization of genetic data (and biomaterial) (Art. 32 Para. 3 HRA, Art. 30 HRO).

Types of data	*Further research use of biological material and **genetic data** (Art. 32 HRA)*	*Further research use of **non-genetic health-related personal data** (Art. 33 HRA)*
Personally identifying	1) Informed consent to specific research projects is needed (Art. 32 Para. 1 HRA, Art. 28 HRO)	4) Broad consent to research projects in general is possible (Art. 33 Para. 1 HRA, Art. 31 HRO)
Coded	2) Broad consent to research projects in general is possible (Art. 32 Para. 2 HRA, Art. 29 HRO)	5) Data can be used for research purposes in general (Art. 33 Para. 2 HRA, Art. 32 HRO)

13 Cf. Dispatch of the Federal Council on the Human Research Act of 21st of October 2009, BBl 2009, 8045 *et seq*., 8121 f.; the distinction is contentious cf. Rudin Beat, Art. 32 - 35 HFG, in: Rütsche Bernhard (Hrsg.), Stämpflis Handkommentar zum Humanforschungsgesetz (HFG), Bern 2015, Introduction to Arts. 32 - 35 N 2 and Opinion of the Swiss National Advisery Commission on Biomedical Ethics (NEK-CNE), Biobanks for research No. 24, Bern 2015, No.141: "An unconvincing aspect of the legislation is the differentiation between genetic and other health-related personal data. In both cases, the data in question is highly sensitive. Donors' privacy can be jeopardised just as much – if not more so – if what falls into the wrong hands are medical records stored in biobanks, from which more intimate information may emerge than from a tissue or blood sample." For that reason, NEK-CNE 2015 criticises the current regulation for further use of coded non-genetic health-related personal data (Art. 33 Para. 2 HRA) and states that it should be regulated like genetic data (Art. 32 Para. 3 HRA) and informed consent must be obtained.

14 Cf. the specific Requirements for general consent regarding research in embryos and fetuses from induced abortions, spontaneous abortions and stillbirths in Art. 39 and 40 HRA, Art. 16 HRA, Art. 44 HRO, van Spyk Benedikt, Art. 7, in: Rütsche Bernhard (Hrsg.), Stämpflis Handkommentar zum Humanforschungsgesetz (HFG), Bern 2015, Art. 7 N 14.

15 Rudin Beat, Art. 32 - 35 HFG, in: Rütsche Bernhard (Hrsg.), Stämpflis Handkommentar zum Humanforschungsgesetz (HFG), Bern 2015, Art. 32 N 5.

Anonymized	3) Data can be used for research purposes in general, but data subjects have to be informed about anonymization and they should not object to it (Art. 32 Para. 3 HRA, Art. 30 HRO)	Not in the scope of the HRA (Art. 2 Par. 2 lit. c HRA)

***Table 3**. Legal consent requirements for the further research use of genetic and non-genetic health-related data in Switzerland*

Arts. 28 - 31 HRO specify the information that needs to be provided in accordance with Arts. 32 - 34 HRA:

1) Informed consent for further use of biological material and genetic personal data in non-coded form *for a research project* (Art. 28 HRO): The person concerned must receive written and oral information concerning the nature, purpose and duration, and procedures of the research project (lit. a); their right to withhold or to revoke their consent at any time without giving reasons (lit. b); the consequences of revocation of consent for the biological material and personal data used up to this point (lit. c); their right to receive information at any time in response to further questions relating to the research project (lit. d); their right to be informed of results concerning their health, and their right to forgo such information or to designate a person who is to take this decision for them (lit. e); measures to protect the biological material and the personal data (lit. f); the main sources of financing for the research project (lit. g); other points relevant to their decision (lit. h). Consent must be given in writing (Art. 28 Para. 3 HRO).

2) Informed consent for further use of biological material and genetic personal data in coded form *for research purposes* (Art. 29 HRO): The persons concerned must receive written or oral information on: the proposed further use of the code, biological material and coded genetic personal data for research purposes (lit. a); their right to withhold or to revoke their consent at any time without giving reasons (lit. b); measures to protect the biological material and personal data, and in particular management of the key (lit. c); the possibility of the biological material and the genetic personal data being passed on to third parties for research purposes (lit. d). Consent must be given in writing (Art. 29 Para. 3 HRO).

3) Information on the proposed anonymization of biological material and genetic personal data for research purposes (Art. 30 HRO): The persons concerned must receive written or oral information on: the proposed anonymization of the biological material and genetic personal data for research purposes (lit. a); their right to dissent (lit. b); the consequences of anonymization with regard to results concerning their health (lit. c); the possibility of the biological material and the data being passed on to third parties for research purposes (lit. d).

4) Informed consent for further use of non-genetic health-related personal data in non-coded form for research purposes (Art. 31 HRO). The persons concerned must receive written or oral information on: the proposed

further use of the non-genetic health-related personal data for research purposes (lit. a); their right to withhold or to revoke their consent at any time without giving reasons (lit. b); their right to be informed of results concerning their health, and their right to forgo such information (lit. c); measures to protect the personal data (lit d); the possibility of the personal data being passed on to third parties for research purposes (lit. e). Consent must be given in writing (Art. 31 Para. 3 HRO).

5) Information on the proposed further use of non-genetic health-related personal data in coded form for research purposes (Art. 32 HRO). The persons concerned must receive written or oral information on: the proposed further use of the non-genetic health-related personal data in coded form for research purposes (lit. a); their right to dissent (lit. b); measures to protect the personal data, and in particular management of the key (lit. c); the possibility of the personal data being passed on to third parties for research purposes (lit. d).

According to Art. 34 HRA in exceptional cases further use may be made without meeting the requirements of Art. 32 and Art. 33 HRA if it is impossible or disproportionately difficult to obtain consent or to provide information on the right to dissent, or this would impose an undue burden on the person concerned (lit. a); no documented refusal is available (lit. b); and the interests of research outweigh the interests of the person concerned in deciding on the further use of his or her biological material and data (lit. c). Art. 34 HRA should be applied very restrictively as its intent was not to provide legal grounds to evade the right to self-determination on a regular basis, but to regulate exceptional cases where the interference in the constitutional right to freedom of research would be disproportionate.[16] Concerning further use of data in terms of data sharing initiatives Art. 43 HRA (storage) must be considered as well.[17] The storage of biological material and health-related data or inclusion in biobanks or databases for yet undefined research projects is defined as further use (Art. 24 lit. c HRO), therefore the process of anonymization or coding of biological material and health-related data must take place before storing or including it in a data sharing platform (Art. 32 Para. 1 HRA).[18]

Federal Act on Data Protection (FADP)

As mentioned above depending on the person or organ processing data either the FADP or the cantonal data protection act is applicable. Data protection is concerned with processing personal data (Art. 1 FADP) that means all information relating to an identified or identifiable person (Art. 3 lit. a FADP).[19] If it is impossible to match the data to a specific person, data is therefore not considered personal data. Irreversibly anonymized data are not considered personal data and do not fall within the scope of the FADP.[20] Data can be qualified as

16 Cf. Dispatch of the Federal Council on the Human Research Act of 21st of October 2009, BBl 2009, 8045 *et seq*., 8123; Rudin Beat, Art. 32 - 35 HFG, in: Rütsche Bernhard (Hrsg.), Stämpflis Handkommentar zum Humanforschungsgesetz (HFG), Bern 2015, Art. 34 N 1 *et seq.*

17 Schläpfer Lea, Clinical Data Sharing: Nutzen, Risiken und regulatorische Herausforderungen, recht (2016), 136 *et seq.*, 140.

18 Cf. Opinion of the Swiss National Advisery Commission on Biomedical Ethics (NEK-CNE), Biobanks for research No. 24, Bern 2015, No. 159 with further suggestions to change the law so that coding or anonymization of patient data should only be required before giving access to it for research.

19 *Processing personal data*: Practically all cantons use the same or similar terms, Waldmann Bernhard, Oeschger Magnus, Datenbearbeitung durch kantonale Organe, in: Belser Eva Maria, Epiney Astrid, Waldmann Bernhard (Hrsg.) Datenschutzrecht: Grundlagen und öffentliches Recht, Bern 2011, 765 *et seq*., No. 14.

20 Cf. Blechta Gabor P., Art. 3 und 11 DSG, Vor Art. 1 und Art. 1 BGÖ, in: Maurer, Labmrou, Blechta (Hrsg.), Basler Kommentar zum DSG und BGÖ, 3. Aufl., 2014, Art. 3 FADP N 13.

anonymized when a disproportional effort is needed to assign the data to a specific person.[21] *Pseudonymized* data is not considered personal data if it is impossible to obtain the key for re-identification; people in charge of the key should treat pseudonymized data as personal data.[22] According to Art. 3 lit. c Nr. 2 FADP health-related data is considered as sensitive personal data; various provisions require a better protection of sensitive personal data.[23] If consent for the processing of sensitive data is required the person concerned must give their consent *explicitly* (Art. 4 Para. 5 FADP).

While processing personal data, the processor must comply with general principles regulated in Arts. 4 - 7 FADP.[24] Data security is considered as a core-element of every data processing:[25] Personal data must be protected against unauthorised processing through adequate technical and organisational measures (Art. 7 Para. 1 FADP); not meeting the requirements of data security might have legal consequences.[26] The processing of personal data must be carried out in good faith and must be proportionate (Art. 4 Para. 2 FADP). Personal data *may only be processed for the purpose indicated at the time of collection*, that is evident from the circumstances, or that is provided for by law (Art. 4 Para. 3 FADP). The collection of personal data and in particular the purpose of its processing *must be evident to the data subject* (Art. 4 Para. 4 FADP). If the consent of the data subject is required for the processing of personal data, such consent is *valid only if given voluntarily on the provision of adequate information* (Art. 4 Para. 5 FADP).

Anyone who, without authorisation, wilfully discloses confidential, sensitive personal data that have come to their knowledge in the course of their professional activities where such activities require the knowledge of such data is, on complaint, liable to a fine (Art. 35 Par. 1 FADP).

Swiss Criminal Code (CC)

In the doctor-patient relationship, medical confidentiality – that derives from the personality rights – is protected in *Swiss Criminal Code of 21st of December 1937* (CC)[27] in Art. 321.[28] In particular, Confidential information that has come to the knowledge of a person in the course of his or her research activities is protected by Art. 321*bis* of the Swiss Criminal Code (CC). No offence is committed if the person disclosing the information does so with the consent of the person to whom the information pertains (Art. 321 Nr. 2 CC). The disclosure of confidential information for re-

21 Waldmann Bernhard, Oeschger Magnus, Datenbearbeitung durch kantonale Organe, in: Belser Eva Maria, Epiney Astrid, Waldmann Bernhard (Hrsg.) Datenschutzrecht: Grundlagen und öffentliches Recht, Bern 2011, 765 *et seq*., No. 19.

22 Rudin Beat, Art. 3 DSG, in: Baeriswyl Bruno, Parli Kurt (Hrsg.), Stämpflis Handkommentar DSG, Bern 2015, Art. 3 N 14.

23 Cf. Blechta Gabor P., Art. 3 und 11 DSG, Vor Art. 1 und Art. 1 BGÖ, in: Maurer, Labmrou, Blechta (Hrsg.), Basler Kommentar zum DSG und BGÖ, 3. Aufl., 2014, Art. 3 N 27; because of the particular potential of the breach of personality through data processing all cantons offer a qualified protection of sensitive data, Waldmann Bernhard, Oeschger Magnus, Datenbearbeitung durch kantonale Organe, in: Belser Eva Maria, Epiney Astrid, Waldmann Bernhard (Hrsg.) Datenschutzrecht: Grundlagen und öffentliches Recht, Bern 2011, 765 *et seq*., No. 21.

24 Many of the principles of data processing are found in cantonal data protection acts; some cantonal acts contain additional principles, some substantiate constitutional provisions mentioned above, cf. Waldmann Bernhard, Oeschger Magnus, Datenbearbeitung durch kantonale Organe, in: Belser Eva Maria, Epiney Astrid, Waldmann Bernhard (Hrsg.) Datenschutzrecht: Grundlagen und öffentliches Recht, Bern 2011, 765 *et seq*., 51 *et seq.*

25 "Kernelement jeder Datenbearbeitung", Baeriswyl Bruno, Art. 7 DSG, in: Baeriswyl Bruno, Parli Kurt (Hrsg.), Stämpflis Handkommentar DSG, Bern 2015, Art. 7 N 1.

26 Cf. Aebi-Müller Regina E., Fellmann Walter, Gächter Thomas, Rütsche Bernhard, Tag Brigitte, Arztrecht, Bern 2016, § 9 No. 100.

27 Schweizerisches Strafgesetzbuch, Code pénal Suisse, Codice penale Svizzero, SR 311.

28 Büchler Andrea, Gächter Thomas, Medical Law in Switzerland, 2nd ed., Alphen aan den Rijn 2016, No. 369 *et seq.*

search activities is not punishable if the requirements of Art. 34 HRA are met (Art. 321*bis* Para. 2 CC). Anonymized data is not confidential and does not fall within the scope of Art. 321*bis* CC.[29]

Federal Act on Human Genetic Testing (HGTA)

The *Federal Act on Human Genetic Testing of 8th of October 2004 (HGTA*) prescribes that genetic tests can only be performed with the informed consent of the concerned person (Art. 5 Para. 1).

Further use of biological material for the purpose of genetic testing in the medical context is solely feasible with the informed consent of the person concerned (Art. 20 Para. 1 HGTA).

The HGTA is currently under revision: The pre-draft of the HGTA (PD-HGTA)[30] explicitly states that before a genetic test the person concerned must *inter alia* be informed about the handling of the biological material and genetic data after the performance has been completed (Art. 6 lit. d PD-HGTA); this includes the information about further use.[31] Art. 10 PD-HGTA is basically following the concept of Art. 32 Para. 2 and 3 HRA with reference to the provisions restricting prenatal genetic tests (Art. 15 PD-HGTA) and genetic tests with persons lacking the capacity to consent (Art. 14 PD-HGTA); the purpose is to ensure that results of tests that are forbidden by the law (e.g. genetic tests with no health-related purpose in people lacking the capacity to consent) will get back to the person concerned through further use.[32] Concerning the further use for research purposes Arts. 32 - 34 HRA are applicable; Art. 10 HGTA therefore will only regulate further use for other purposes than research.[33]

Federal Act on the Electronic Patient Record (EPRA)

The *Federal Act on the Electronic Patient Record of 19th of June 2015*[34] (enacted on April 15, 2017) does not regulate the research use of medical data that will be contained in an electronic patient record[35]. The scope of this law is limited to the requirements for data processing in the electronic patient record (Art. 2 Para. 1) to ensure the quality of medical treatments, improve treatment processes, patient security and the efficiency of the health care system (Art. 1 Para. 3). Moreover, it is important to notice that this act includes a provision that states that patients cannot be obliged to make data from the electronic patient record accessible (Art. 3 Para. 4).

3.3.2 Summary of the Legal Analyses

Legal texts relevant to data access can be identified on different levels of the multi-layered Swiss regulation of medical law and data protection: The fundamental right to self-determination (Art. 10 Para. 2 of the Swiss Federal

29 Oberholzer Niklaus, Art. 320*bis* 321*ter* StGB, in: Niggli Marcel A., Wiprächtiger H. (Hrsg.), Basler Kommentar. Strafrecht II. Art. 111-392 StGB, 3. Aufl., Basel 2013, Art. 321*bis* N 8: "Soweit eine anonymisierte Verwendung der Informationen möglich ist und daraus keine Rückschlüsse auf die Identität des Patienten gezogen werden können, liegt schon gar kein Eingriff in das Patientengeheimnis vor, so dass die Tatbestandsmässigkeit von vornherein entfällt."

30 https://www.admin.ch, ch, d, gg, pc, documents, 2374, GUMG_Entwurf_de.pdf of 18th of February 2015.

31 Explanatory Notes concerning the complete revision of the Federal Act on Human Genetic Testing of 18th of February 2015, 54.

32 Cf. Explanatory Notes concerning the complete revision of the Federal Act on Human Genetic Testing of 18th of February 2015, 57; cf. also Art. 10 Para. 2 and Art. 11 HGTA.

33 Cf. Explanatory Notes concerning the complete revision of the Federal Act on Human Genetic Testing of 18th of February 2015, 58.

34 Bundesgesetz über das elektronische Patientendossier, Loi fédérale sur le dossier électronique du patient, Legge federale sulla cartella informatizzata del paziente [SR 816.11].

35 Dispatch of the Federal Council on the Federal Act on Electronic Patient Record of 29th of May 2013, BBl 2013, 5321 *et seq*., 5323.

Constitution [FC] and Art. 28 of the Swiss Civil Code) embraces legal relationships both in private and public law and is of central importance. Depending on the person or organ processing data, either the FADP or the cantonal data protection act is applicable. The Human Research Act (HRA) and the Human Research Ordinance (HRO) are regulating the further use of biological material and health related data specifically (Arts. 32 - 34 HRA, Arts. 28 - 31 HRO). If existing biological material or personal health-related data collected in clinical care are to be used for research, Arts. 32 *et seq.* HRA apply. According to the law, a general consent (understood as giving consent to yet undefined research projects for an infinite period of time) is possible for further use of coded biological material and genetic data (Art. 32 Para. 2 HRA, Art. 29 HRO) and personally identifying non-genetic health-related personal data (Art. 33 Para. 1 HRA, Art. 31 HRO). The HRO explicitly repeats important rights deriving from personality rights, such as the right to revoke consent, or the right to know and the right not to know.

A criminal provision is set to ensure the enforcement of the provisions: Anyone who is wilfully or negligently violating Arts. 32 - 34 HRA shall be liable to a fine (Art. 63 lit. c HRA).

While processing personal data, the processor must also comply with general principles regulated in Arts. 4 - 7 FADP or cantonal law: Data security is considered as a core-element of every data processing. Personal data may only be processed for the purpose indicated at the time of collection, that is evident from the circumstances, or that is provided for by law. The collection of personal data and in particular the purpose of its processing must be evident to the data subject. If the consent of the data subject is required for the processing of personal data, such consent is valid only if given voluntarily on the provision of adequate information. According to the Federal Act on Human Genetic Testing (HGTA) the person concerned must *inter alia* be informed about the handling of the biological material and genetic data after the performance has been completed. For further use of biological material and health-related data for research purposes, the more specific provisions of the HRA apply. The provisions regulating medical confidentiality Art. 321 *et seq.* of the Swiss Criminal Code (CC) have to be taken into account as well. This does not regulate the use of medical data for research purposes. Moreover, it prescribes that patients cannot be obliged to make data from the electronic patient record accessible (Art. 3 Para. 4).

The requirements for obtaining general consent for research purposes are not regulated precisely in the HRA. It is argued that general consent might undermine personality rights and the protection of sensitive personal data. For a data access initiative, it would be important to establish a framework showing its specific compliance with data protection that could be handed to the person concerned to promote information and transparency. The principle of informed consent stipulates that the person concerned should be adequately informed in order to be able to make a decision. Consent must be freely given. The SAMS and swissethics have compiled a template for obtaining general consent in hospitals for further use of health-related data and biological material which is open to consultation. A national discussion about the concretisation of general consent that compensates for the insufficient legal regulation is highly appreciated. For reasons of legal certainty, in this regard it is recommended to specify and adapt the provisions of the HRA.

04

The Ethical Framework

Ethical Framework for Responsible Data Processing in the SPHN

Based on the findings of this study, the ELSIag has proposed an **Ethical Framework for Responsible Data Processing in the Swiss Personalized Health Network**. Following the indications of the SPHN's Data Coordination Center (as per communications with the ELSIag Chairwoman), the framework covers also the use of data generated outside the conventional ambit of basic research, medical research and clinical care. These data may include data obtained also from a variety of devices not originally intended, nor necessarily licensed for medical use, such as smartphones, sensor-equipped wearables and the like. Such data may include both measurements generated through those devices and textual data generated by users through them – as, for instance, by posting content on social networking websites and applications. The version of the framework presented in this section corresponds to the published version available at https://www.sphn.ch/en/about/publications.html (version 1 followed by a version 2).

This work was further expanded and resulted in a publication (DOI: 10.1377/hlthaff.2017.1558).