'Big data analytics' and processing of health data for scientific research purposes : the Swiss legal framework

Research Protocol by Damian George, Prof. Florent Thouvenin, Chair for Information and Communication Law, University of Zurich

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1. Overview of the legal framework

a. Which laws regulate the processing of health data for research purposes?

What are the relevant applicable provisions governing the processing of health data in your country?

In Switzerland, the right to informational self-determination and the right to respect of private life are fundamental rights guaranteed by article 13 of the Swiss Federal Constitution (FC) and article 8 ECHR respectively. Research using health data may also affect the right to human dignity (article 7 FC) or personal freedom (article 10 FC). At the same time, the freedom of scientific research is also guaranteed by the Federal Constitution (article 20 FC). The Swiss Federal Data Protection Act[1] (DPA) and the accompanying Federal Ordinance to the Federal Act on Data Protection (DPO) apply to health data processed by federal bodies and private parties alike. Switzerland has signed the revised Council of Europe Convention 108 on data protection, but this Convention has no direct effect on individuals. At the point of writing the Convention 108 is undergoing revision and the Swiss Federal Council has expressed its wish to ratify Convention 108 as soon as possible[2]. It is further very important to note that Switzerland is neither a member of the European Union (EU) nor the European Economic Area (EEA) and hence **the GDPR is not part of the Swiss legal framework**. But the GDPR could apply directly if the behaviour of data subjects who reside in the EU is monitored or goods and services are offered to data subjects residing in the EU, regardless whether the processing takes place in the EU or not[3]. Nevertheless, the GDPR and the Convention 108, which was influenced by the GDPR, are key drivers behind a revision of the DPA and the DPO. These regulations are currently awaiting parliamentary discussion. Already Switzerland's current legal framework was heavily influenced by European developments: When the DPA was adopted in 1992 its concept with regard to scope, individual rights and enforcement showed many similarities to the EU framework set forth by the Directive 95/46/EC. E.g., the data protection law's scope is limited to personal data[4] and health data are considered to be sensitive data[5] in both Switzerland and the EU.

It is important to mention that most universities and hospitals in Switzerland are public institutions governed by cantonal law. Whenever these universities or hospitals are involved in research projects, they have to comply with the provisions of their cantonal data protection law. The cantonal data protection laws follow the same regulatory approach as the federal DPA. E.g., Zurich's Information and Data Protection Act differentiates between information and personal data and considers health data to be a special category of personal data[6], subject to specific safeguards[7].

With regards to health data there are several specific provisions that must be observed. In 2010 the Swiss people accepted a constitutional amendment creating article 118b FC, the **constitutional basis** for regulating research on the human being. Article 118b FC states

[1] Please note that while some laws are translated into English by the Federal Chancellery, English is not an official language in Switzerland. Hence merely the German, French or Italian version of the laws and ordinances are legally binding.
[2] Bundesrat, Botschaft zum Bundesgesetz über die Totalrevision des Bundesgesetzes über den Datenschutz und die Änderung weiterer Erlasse zum Datenschutz vom 15. September 2017, BBl 6941, 6943.
[3] Article 3 GDPR.
[4] Article 3 lit. a DPA; article 4 lit. a draftDPA; article 4(1) GDPR.
[5] Article 3 lit. c Ziff. 2 DPA; article 4 lit. c Ziff. 2 draftDPA ; article 4(15) GDPR.
[6] § 3 Zurich Information and Data Protection Act.
[7] Cf. § 17 Zurich Information and Data Protection Act.

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"*Para. 1: 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. Para. 2: The Confederation shall adhere to the following principles in relation to biological and medical research involving human beings: a) It is a requirement for any research project that the participants or their legal representatives have given their informed consent. The law may provide for exceptions. A refusal is binding in every case. b) The risks and stress for the participants must not be disproportionate to the benefits of the research project. c) A research project involving persons lacking the capacity to consent may be conducted only if findings of equal value cannot be obtained from research involving persons who have the capacity to consent. If the research project is not expected to bring any immediate benefit to the persons lacking the capacity to consent, the risks and stress must be minimal. d) An independent assessment of the research project must have determined that the safety of the participants is guaranteed*."

This constitutional basis allowed the Federal government to enact the Human Research Act (HRA), which entered into force in 2014 and is designated at protecting the dignity, privacy and health of human beings involved in research[8]. The provisions of the HRA are specified by the Human Research Ordinance (HRO) and the Ordinance on Clinical Trials (OCT). Furthermore, specific research areas are governed by specific laws. The Federal Act on Research involving Embryonic Stem Cells, the Federal Act on the Transplantation of Organs, Tissues and Cells, (Transplantation Act), the Federal Act on Medically Assisted Reproduction as well as the Federal Act on Medicinal Products and Medical Devices (TPA) must be observed whenever research is carried out in the respective area.

The handling of health data falls under the scope of certain **criminal provisions**. Information obtained in the capacity as a doctor, dentist, chiropractor, pharmacist, midwife, psychologist, or as an auxiliary to any of the foregoing persons is subject to professional secrecy pursuant to article 321 of the Swiss Criminal Code (SCC). If health data is obtained in a capacity of a member of a public authority, a public official or while executing official duties, it is protected by official secrecy also (article 320 SCC). Finally, a secret that has come to a person's knowledge in the course of his or her research activities involving human beings in accordance with the HRA is protected by article 321bis SCC. Violation of each of these provisions is sanctioned with a maximum penalty of three years imprisonment or a monetary penalty. Additionally, since health data qualify as sensitive data, their unauthorized disclosure is penalized with a fine for anybody who obtained the data in the course of his or her professional activities (article 35 DPA). Article 35 DPA is likely to apply to any professional researcher handling personal health data, but applies subsidiary to the provisions of the SCC.

Shared electronic health records are indirectly relevant in this context because they can potentially be an important source for health-related research. Do shared electronic health records exist in your country? How is the sharing of electronic patient records regulated? Can data stored in these records be used for research purposes?

In 2017 the Federal Act on Electronic Health Records (EHRA) and the Federal Ordinance on Electronic Health Records (EHRO) entered into force. The electronic health record is designed as a virtual dossier enabling health professionals to view a patient's health history. Once a patient has given free and informed consent[9] to the creation of an electronic health record, the data will be stored in a decentralized manner: The accessible health record consists merely of links that enable accessing, i.e. viewing, the respective health-related documents. The documents remain stored with the health professional or institution that created said document, i.e. there is no centralized storage system. Only health data relevant for treatment or other data uploaded by the person concerned can be accessed.

[8] Article 1 para. 1 HRA.
[9] Article 3 EHRA.

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The documents in the electronic health record are categorized into "normal access", "restricted access" and "secret" whereas "normal access" is the default setting[10]. With corresponding access-rights granted by the patient health professionals may then use the data as far as they are necessary for a specific treatment[11]. These access rights are valid until revoked by the patient[12]. However, the EHRA's scope is limited to treatments and **electronic health records may not be used for scientific research**. Nevertheless the Swiss Federal Council stated that the use of electronic health records for scientific research could be a project to pursue in the future[13].

b. Revision of the current legal framework under the GDPR

How are the necessary changes to the national data protection framework introduced by the GDPR addressed in your country? What is the adopted legislative approach? Is the GDPR implemented in your country by an entirely new legislative text or via amendments to the current data protection law? Please explain.

As mentioned before, Switzerland is not a member of the EU and hence has no duty to implement the GDPR. However, once the Council of Europe Convention 108 has been ratified this will necessitate changes to the current framework. Also, considering Switzerland's flourishing trade as well as the academic and cultural exchange with EU member states, the Federal Council intends to bring the current DPA more in line with the GDPR and hence has proposed a comprehensive revision to the DPA[14]. The draft DPA (draftDPA) would repeal the current DPA entirely. Note that the draftDPA has not been discussed and approved by the Swiss parliament yet and hence might be subject to alterations.

Notably, cantonal and municipal officials and health care professionals are subject to cantonal data protection rules. Whether the revision of the DPA would prompt respective amendments to the cantonal framework cannot be said with certainty at the current state, with the revision of the DPA being far from concluded. However, the revision of the cantonal framework is to be expected.

- What are the main characteristics of the legislative implementation of the GDPR in your country?

One of the DPA's as well as the draftDPA's main characteristics is that, unlike in the GDPR, the processing of data is allowed as long as it does not infringe the personality of the data subject. Hence, in general, personal data can be processed without the need of a legal basis (cf. article 6 GDPR). Within the DPA's framework, non-adherence to the principles relating to the processing of personal data, i.e. the principle of lawfulness, fairness, good faith, transparency, purpose limitation, informed consent, correctness of data and data security, will be infringing the data subject's personality[15]. Likewise, processing personal data against a person's express wish as well as the disclosure of personality profiles or sensitive data will be considered as such an infringement of personality[16]. However, an

[10] Article 1 EHRO.
[11] Article 2 lit. a EHRA; article 9 EHRA.
[12] Article 3 para. 1 EHRO.
[13] Bundesrat, Botschaft zum Bundesgesetz über das elektronische Patientendossier (EPDG) vom 29. Mai 2013, BBl 5321, 5372.
[14] Bundesrat, Botschaft zum Bundesgesetz über die Totalrevision des Bundesgesetzes über den Datenschutz und die Änderung weiterer Erlasse zum Datenschutz vom 15. September 2017, BBl 6941, 6970.
[15] Article 4 DPA, article 5 para. 1 DPA and article 7 para. 1 DPA ; article 5 draftDPA; article 7 draftDPA.
[16] Article 12 DPA; article 26 draftDPA.

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infringement of the data subject's personality can be justified if the data subject has consented to the processing, public interests or private interests are overweighing or the law allows such processing[17].

The draftDPA is set to introduce new rights for the data subject such as the right to explanation in connection with automated decision making, the heirs' right to access data of a deceased person, and introduces a set of new obligations to controllers, like data protection impact assessments or data breach notifications. A right to data portability, like it is established by article 20 GDPR, is not part of the amendments. However, the Federal Council recently commissioned a study on the possibility of introducing a right to data portability in Switzerland and, based on the respective findings, the Federal Department of Economic Affairs, Research and Education will examine possibilities for making data available for researchers[18].

- What is your own assessment of the legislative approach adopted in your country for implementing the GDPR?

Switzerland does not have to implement GDPR, but voluntarily plans on bringing its DPA more in line with it. In doing so, Switzerland applies a wait-and-see approach. Since Swiss research as well as the Swiss economy is highly interlinked with the EU, it is of outmost importance that Switzerland – being a third country from an EU controller's perspective – obtains an adequacy decision from the EU Commission pursuant to article 45 GDPR. With an adequacy decision the EU commission affirms that a country provides for a GDPR adequate level of data protection and hence transfers of data from the EU to this country may take place without further ado. For the time being, the adequacy decision based on Directive 95/46/EG remains in force[19] and hence data may flow from the EU to Switzerland. Whether a revision of the Swiss framework is actually necessary for obtaining an adequacy decision is disputed amongst politicians and legal scholars alike. However, ensuring adequacy is one of the main driving factors of the current revisions of the DPA.

The approach of entirely replacing the existing DPA makes sense, since this will lead to a clear legal framework. On one hand, getting the DPA in line with the GDPR is very important, since researchers and businesses operate cross-border on a daily basis and almost cannot comply with differing frameworks simultaneously. On the other hand, since the scope of the GDPR's obligations and rights may be restricted by each member state[20], a verbatim implementation seems unnecessary. Matter of fact, if the revision does not make use of the leeway given by the GDPR, Switzerland's data protection framework could end up being stricter than the framework of certain EU member states.

c. The national data processing authority

Can you provide a short description of the role of the data protection supervisory authority in your country in the domain of processing health data for research purposes under the current

[17] Article 13 DPA; article 27 draftDPA.
[18] Bundesamt für Kommunikation, Datenpolitik, 9 May 2018, https://www.bakom.admin.ch/bakom/de/home/digital-und-internet/big-data.html, last visited 23 May 2018.
[19] Cf. Article 45 para. 4 GDPR.
[20] Article 23 GDPR.

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legal framework? ***Can you describe the adopted or proposed changes to this role of the national data protection authority to ensure compliance with the GDPR?***

The Federal Data Protection and Information Commissioner (Commissioner) supervises federal bodies' compliance with the DPA[21]. He also advises private parties on data protection matters. The Commissioner may conduct investigations concerning the processing of personal data carried out by private parties when this possesses a risk to the personality of many individuals, collections of data need to be registered pursuant to article 11a DPA or cross-border disclosure is based on contractual safe-guards or binding corporate rules[22]. Under the draftDPA the Commissioner may investigate any violations of the DPA ex officio regardless whether a federal body or the private sector is concerned[23]. While under the current DPA the investigation is concluded with a recommendation[24], under the draftDPA the Commissioner may order that processing activities shall be altered or even halted[25]. The Commissioner may also take other measures inter alia he can order the federal body or private party to consult with the Commissioner against payment of a fee[26]. Note that the Commissioner's orders are subject to appeal with the Federal Administrative Court.

Cantonal bodies, such as most universities and hospitals or other research facilities governed by cantonal law, are supervised by the respective cantonal data protection commissioner. In Zurich the Data Protection and Information Commissioner supervises adherence to the cantonal data protection framework. He also gives advice to private parties with regard to their rights and also provides mediation in case of conflicts concerning data protection[27].

The Commissioner used to advise the Expert Commission on Professional Secrecy in health research pursuant to article 32 oldDPA, until the HRA entered into force[28]. The HRA assumed the Expert Commission on Professional Secrecy to the cantonal Ethics Boards. Since these boards are bodies governed by cantonal law, the cantonal data protection commissioners have assumed the advisory function (see for example the leaflet on personal data in health research published by Zurich's Data Protection Commissioner). However, the Federal Data Protection Commissioner also provides an overview on the legal provisions governing health research.

2. Transposition of Article 8.4 of Directive 95/46

Did your national legislator insert any additional exemptions for the processing of health data for research purposes? How is it/are they formulated? Please explain. Are there additional exemptions issued by the DPA?

[21] Article 27 DPA; article 43 draftDPA; compliance of cantonal bodies with cantonal data protection law is supervised by respective cantonal data protection commissioners.
[22] Article 28 DPA; article 29 DPA.
[23] Article 43 draftDPA.
[24] Article 27 para. 5 DPA; Article 29 para. 3 DPA.
[25] Cf. article 45 draftDPA.
[26] Article 45 para.3 lit. e draftDPA ; article 53 para. 1 lit. d draftDPA.
[27] § 34 Zurich Information and Data Protection Act.
[28] Annex I, No. 1 HRA.

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a. Transposition of Article 8.4 of Directive 95/46

Article 8 of Directive 95/46 prohibits, in principle, the processing of special categories of personal data concerning health. Article 8.2 lists a series of exceptions to this general prohibition. Article 8.4 states "*Subject to the provision of suitable safeguards, Member States may, for reasons of substantial public interest, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority*".

When transposing Directive 95/46 did your national legislator or supervisory authority make use of the power granted to Member States in Article 8.4 of the Directive? Did the legislator use this provision to insert any additional (i.e. additional to the exceptions listed in the Directive) exemption (to the prohibition to process health data) for the processing of health data for research purposes? If yes, how is such an exemption formulated? Please explain.

Not being an EU member state, Switzerland was and is under no obligation to implement the Directive 95/46. While the creation of the DPA was influenced by the Directive 95/46 the DPA does not prohibit the processing of health data. Nevertheless, the Swiss framework does provide for specific safeguards with regard to health data.

b. The regime applying to the processing of personal data for health research purposes

Is there a specific regime applying to data processing for research in the field of health purposes? What is the scope? Which are the steps, and who are the key actors?

There is a specific regime applying to data processing for research in the field of health purposes. The HRA contains a detailed set of rules that have to be observed when processing data for health research. Whenever an aspect of data driven research is regulated by the HRA it is safe to assume it supersedes the principle-based and more general DPA[29]. The HRA governs research concerning

- human beings,
- deceased human beings,
- embryos and foetuses,
- biological material
- and health related personal data[30].

[29] Eidgenössischer Datenschutz und Öffentlichkeitsbeauftragter (EDÖB), Medizinische Forschung, https://www.edoeb.admin.ch/edoeb/de/home/datenschutz/statistik--register-und-forschung/forschung/medizinische-forschung.html, last visited 16 April, 2018.
[30] Article 2 para. 1 HRA.

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Research in connection with IVF embryos is not governed by the HRA, but by the Federal Act on Research involving Embryonic Stem Cells[31]. When biological material is anonymized or health related data is gathered anonymously or anonymized the provisions of the HRA shall not apply either. However, the conditions for carrying out research without the individual's information and consent (article 34 HRA) must be observed regardless, whenever the data is subject to professional secrecy[32] (cf. IV.A).

The conduct of research falling within the HRA's scope needs to be authorized beforehand by the **Cantonal Ethics Board**[33]. The competent Ethics Board is determined by the canton where the research is conducted. In case of several research institutes in multiple cantons being involved in research carried out according to a standard protocol (multicentre research project), the Ethics Board where the project lead is seated is responsible for granting authorization[34]. A list of Cantonal Ethics Boards in Switzerland is provided by swissethics, a joint working group of the Cantonal Ethics Boards[35]. Swissethics is responsible for the coordination and standardisation of working processes as well as education and training of the members of the ethics committees. Note, that depending on the research's scope **further approvals** might be necessary. Research involving certain types of medicinal products[36], involving therapeutic products or medical devices not applied in accordance with approved conditions of use[37] and clinical trials involving genetically modified organisms[38] will need authorization from the Swiss Agency for Therapeutic products. Clinical trials involving the transplantation of human organs, tissues or cells[39], clinical trials involving radiopharmaceuticals or other radioactive sources with an effective dose of more than 5 mSv per person per year[40] need to be authorized by the Federal Office of Public Health.

Since 1 January 2016 submissions with all Cantonal Ethics Boards have to be done electronically using the Business Administration System for Ethics Committees (BASEC). The Ethics Board confirms receipt and formal completeness of the application within seven days and shall reach a decision within two months[41]. Also the researchers have to classify their project with regard to the associated risk beforehand. Research measures that are associated with only minimal risks and burdens fall within category A, while other measures fall within category B. For example, minimal risks and burdens may be associated with surveys and observations, removing or collecting bodily substances without invasive interventions, taking swabs, or examinations using medical devices bearing conformity markings without a contrast medium. Hence latter collection methods fall within category A[42].

Even if authorization has been granted, significant changes to the research protocol require a separate authorization[43]. Furthermore, serious events, discontinuation of the research project, exceeding the permitted dose guidance value for radiation sources and any immediate safety measures taken will trigger reporting duties[44]. Whenever the competent Ethics Board deems the safety and security of the persons concerned to be endangered, it may revoke or suspend an authorization. It also can tie the authorization to further conditions[45].

[31] Article 2 para. 2 lit. a HRA.
[32] Bundesrat, Botschaft zum Bundesgesetz über die Forschung am Menschen vom 21. Oktober 2009, BBl 8045, 8092.
[33] Article 45 para. 1 lit. a HRA.
[34] Article 47 para. 2 HRA.
[35] http://www.swissethics.ch.
[36] Article 30 et seqq OTC; cf. article 19 and 20 OTC regarding a categorization of medicinal products.
[37] Article 54 TPA.
[38] Article 22 para. 4 OTC and article 32 OTC.
[39] Article 36 Transplantation Act.
[40] Article 28 para. 2 OTC; article 19 HRO.
[41] Article 16 para. 1 HRO; article 45 para. 2 HRA.
[42] Article 7 HRO.
[43] Article 18 para. 1 HRO.
[44] Article 20 et seq. HRO.
[45] Article 48 HRA.

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Authorization will be granted to proposals that comply with the ethical, legal and scientific standards set forth by the HRA[46]. While these standards cannot be easily summarized, it should be noted that the HRA follows certain guiding principles: The primacy of individual interests[47], the scientific relevance and requirements of research[48], the principle of non-discrimination[49], the principle of informed consent and the right to receive information[50] as well as the prohibition of commercialization of the human body[51].

From which generally applicable data protection provisions are researchers exempted and under what conditions? For what reasons? From which provisions? What are the consequences?

The HRA does not grant researchers any specific exceptions from the DPA rather it sets forth a different framework (see hereinafter) and is seen as *lex specialis* to the DPA.

Whenever the HRA or another more specific law does not apply, the DPA will apply. Federal and most cantonal public bodies conducting research for purposes not related to specific persons are under certain conditions exempted from (i) the purpose limitation principle[52] and (ii) the limitations for disclosing personal data[53]. Furthermore, federal bodies conducting research are under certain conditions also exempted from the requirement to process sensitive data and personality profiles only with a legal basis[54]. While there are no specific exceptions for private researchers, whenever researchers need a justification for processing personal data the processing for research not relating to a specific person shall be considered a justifying legitimate interest under certain conditions[55]. One of the common conditions for all these exceptions to apply is that the research results are published in a manner that does not allow for re-identification of the persons concerned[56].

c. Are there additional specific conditions governing the processing of data for scientific research purposes?

While the principle of informed consent is enshrined in the general data protection framework, the HRA specifies the principle of informed consent in articles 16 et seq. HRA and the HRO. Note that a distinction must be made between consent to medical treatment and consent given for medical research. Only the latter is governed by the HRA. Following article 16 HRA in connection with article 8 HRO consent is deemed “informed” if information on the following aspects is provided to the persons affected:

- nature, purpose and duration of, and procedure for, the research project;
- main sources of financing for the research project;

[46] Article 45 para. 2 HRA.
[47] Article 4 HRA.
[48] Article 5 HRA; article 10 HRA.
[49] Article 6 HRA.
[50] Article 7 HRA; article 8 HRA.
[51] Article 9 HRA.
[52] Article 22 para. 2 lit. a DPA ; § 9 para. 2 Zurich Information and Data Protection Act; § 10 Basel Stadt Information and Data Protection Act.
[53] Article 22 para. 2 lit. c DPA ; § 18 Zurich Information and Data Protection Act; § 10 Basel Stadt Information and Data Protection Act.
[54] Article 22 para. 2 lit. b DPA.
[55] Article 13 para. 2 lit. e DPA.
[56] Article 13 para. 2 lit. e DPA; article 22 para. 1 DPA; § 10 Basel Stadt Information and Data Protection Act; § 9 para. 2 2 Zurich Information and Data Protection Act.

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- efforts and commitments resulting from participation;
- the expected benefits of the research project, in particular for themselves or for other people;
- foreseeable risks and burdens;
- measures taken to protect the personal data collected;
- measures envisaged to cover any damage arising from the research project, including the procedure in the event of a claim;
- the participant's rights, in particular the right to refuse or withdraw consent without need to justify doing so, the right to obtain further information at any given point in time, and the right to information on results relating to their health respectively the right to refuse such information or designating somebody who may decide whether they shall be informed;
- the consequences a withdrawal of consent has on the previously collected biological material and personal data;
- other points relevant to their decision[57].

In exceptional cases information can be provided merely partially. Such an exception can be present when (i) the research's methodology necessitates partial information and (ii) the research project entails no more than minimal risks and burdens. However, full information must be provided as soon as this is possible and only after the participant's fully informed consent has been given may the biological material or the health-related personal data be used in the research project[58].

Following the guiding principle of informational self-determination, consent may be revoked anytime without justification[59].

What are the suitable safeguards applied to the exemption foreseen by Article 8.4 of the Directive in your country?

As mentioned earlier, Swiss data protection law does not know the principle of prohibition with regard to sensitive data. Hence there is no need for exemptions from such a principle. Nevertheless, Switzerland has implemented safeguards to ensure the safety of research participants, especially with regard to vulnerable groups.

Are there any specific provisions concerning (i) professional secrecy?

Pursuant to article 321bis para. 2 SCC professional secrets may be disclosed for the purpose of research into human health, provided that the conditions of article 34 HRA are met. According to article 321bis SCC in conjunction with article 34 HRA biological material or health-related data may be subjected to **further use without consent** of the person concerned in exceptional cases: (i) 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; (ii) no documented refusal is available; (iii) 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; and (iv) an authorization for disclosure has

[57] Article 16 HRA in connection with article 8 HRO.
[58] Article 18 HRA.
[59] Article 7 HRA.

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been obtained from the responsible ethics committee. Notably, informed consent of the person concerned will also justify disclosure of professional secrets protecting solely said person. If the intention to make further use of biological material or health related data exists at the time of collection or sampling, however, the consent of the person must be obtained at said time or he or she must be informed on her right to dissent[60].

Are there any specific provisions concerning (ii) express consent for specific data?

The HRA deals with privacy in connection with health data, i.e. specific data[61]. Article 7 HRA states that consent to research must be informed and can be revoked anytime, without need to justify the reasons for doing so. While neither the HRA nor the HRO state that consent must be express, article 9 HRO requires consent to be documented in writing and written consent will have to be express. Exceptions from the requirement of written form can be made on a case-by-case basis if the person concerned is unfit to read or write, and the project lead can document the consent by other means[62]. Furthermore, category A research projects (cf. above II.B) involving adults with power of judgment do not need written consent, if this would be disproportionate and the exception from the written consent has been disclosed in the application for authorization from the Ethics Board[63].

Are there any specific provisions concerning (iii) deceased data subjects?

Research with deceased persons may be conducted whenever they consented to making their corpse available to research while still being alive[64]. Whenever a persons' dissent to being subjected to research is documented, in general, no research may be carried out with his or her corpse[65]. If neither consent nor dissent to post-mortal research is documented, the next of kin or a trusted person designated during the lifetime of the deceased have to be consulted[66]. These persons are asked whether they are aware of any declaration of the concerned person's intention to permit post mortal research; if they are not aware of such a declaration and they give their informed consent, research may be conducted. In cases where contacting the next of kin or the trusted person is impossible, no research may be conducted[67]. However, if the person concerned died more than 70 years ago, the next of kin or the trusted person may only object to research being carried out[68].

Are there any specific provisions concerning (iv) minors or persons subject to guardianship?

In the HRA a person under 14 years of age is considered a child[69]; a person older than 14 years of age but still a minor, i.e. less than 18 years of age, is considered an adolescent[70]. Power of judgment (sometimes referred to as "capacity") is assumed in a legal sense, whenever a person does not lack the capacity to act rationally by virtue of being under age or because of a mental disability, mental disorder, intoxication or similar circumstances[71]. As a general rule, children, adolescents and adults lacking power of judgment must be involved in the consent procedure as far as possible[72]. The weight of children's and adolescents' views increases with their maturity[73]. Again, a

[60] Article 17 HRA.
[61] Article 2 para. 1 lit. e HRA.
[62] Article 7 para. 2 HRO.
[63] Article 9 para. 1 HRO.
[64] Article 36 para. 1 HRA.
[65] Article 36 para. 2 HRA.
[66] Article 36 para. 2 HRA.
[67] Article 36 para. 3 HRA in connection with article 8 para. 2-4 Transplantation Act.
[68] Article 36 para. 4 HRA.
[69] Article 3 lit. j HRA.
[70] Article 3 lit. k HRA; article 14 para. 1 Civil Code.
[71] Article 16 Civil Code.
[72] Article 21 para. 1 HRA.
[73] Article 21 para. 2 HRA.

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distinction must be made between consent to medical treatment and consent given for medical research. With regard to consent to medical research, a further distinction between research projects with and without expected direct benefits for the person involved is made by the HRA.

If the research project has an **expected direct benefit**, meaning that it is expected that the results will improve the health of the participants[74], it may involve children or adolescents provided that (i) they possess the *power of judgement*, (ii) give informed consent, and (iii) the child's legal representative respectively the adolescent's legal representative in cases where the research project entails more than minor risks and burdens gives informed consent in writing[75]. Research with an expected direct benefit involving children or adolescents *lacking power of judgment* may be carried out if (i) the legal representative has given informed consent and (ii) the child or adolescent does not visibly, either verbally or through its behaviour, express its opposition to the research project[76]. Adults lacking power of judgement may be involved if (i) they consented to such research while still being able to exercise such judgment and this fact is documented, or their legal representative, a trusted person or the next of kin give their informed consent in writing and (ii) the person concerned does not visibly, either verbally or through its behaviour, express its opposition to the research project[77].

If the research project **does not entail an expected direct benefit** there are **additional requirements** to be met: The project may only involve children (with or lacking power of judgment) or adolescents without power of judgment if the research project (i) entails no more than minimal risks and burdens and (ii) is expected to yield substantial findings and could benefit persons with the same disease or disorder or in a similar situation in the long term[78].

Are there specific requirements about the data subject's information or about the person from whom the data was collected?

Pursuant to article 8 HRA the person concerned must be informed on results relating to their health. Such information must be communicated in an appropriate manner and the person concerned might choose to forgo such information. However, the scope of article 8 is limited to the results of the research and does not provide any information on the data collection. So while the HRA does not contain any specific provisions on the right to information on the data source, the DPA as well as the cantonal data protection laws do. If personal health-data are gathered in a data file, i.e. a set of personal data that is structured in such a way that the data subject can be singled-out easily, the controller must inform the person concerned on this collection and its purpose. This duty set forth by the DPA and applies to private researchers and federal bodies[79]. However, cantonal bodies are often subject to a similar information duty whenever sensitive data are gathered by third parties, see e.g. the laws of Zurich and Basel Stadt[80]. These information duties are not absolute. They often provide for a balancing of interests test, allowing forgoing information in case of legitimate and overweighing interests[81].

Are there specific penalties if the conditions for processing for scientific research in the field of health purposes are not respected? What do those penalties entail?

[74] Article 3 lit. d HRA.
[75] Article 22 para. 1 HRA; article 23 para. 1 HRA.
[76] Article 22 para. 3 HRA; article 23 para. 2 HRA.
[77] Article 24 para. 1 HRA.
[78] Article 22 para. 2 and 4 HRA; article 23 para. 3 HRA; article 24 para. 2 HRA.
[79] Article 14 para. 1 DPA; article 18a para. 1 DPA.
[80] § 12 para. 2 Zurich Information and Data Protection Act; § 15 para. 3 Basel Stadt Information and Data Protection Act.
[81] Cf. article 14 para. 5 DPA in connection with article 9 para. 1 and 4 DPA; article 18b para. 1 DPA in connection with article 9 para. 1 and 4 DPA; § 23 Zurich Information and Data Protection Act; § 15 para. 3 Basel Stadt Information and Data Protection Act.

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Whoever conducts health research without obtaining proper, informed consent in accordance to the HRA is subject to a custodial sentence not exceeding three years or to a monetary penalty[82].

d. Formalities prior to processing: the general regime under the current framework

Is there a regime requiring the fulfilment of certain conditions prior to any processing activities different from that applicable to research in the field of health? If yes, what does that regime entail? Where in the applicable legislation can it be found? What are this regime's main steps and conditions?

The DPA requires controllers to notify the Commissioner of certain processing activities. The Commissioner does not authorize these activities, but rather just needs to be informed. However, if the Commissioner deems the activities to be non-compliant with the DPA, he may take further action.

Cross-border transfer of personal data might trigger duties to inform the Commissioner, if the foreign country does not provide for an appropriate level of data protection, like this is currently the case with the U.S.A. As a rule of thumb, Switzerland considers the same countries to have an adequate level of data protection as the EU Commission[83]. In the absence of legislation that guarantees adequate protection the disclosure of personal data to such a country is only allowed in limited circumstances[84]. Inter alia if sufficient safeguards, in particular contractual clauses, ensure an adequate level of protection abroad[85] or disclosure is made within the same legal person or company or between legal persons or companies that are under the same management, provided those involved are subject to data protection rules that ensure an adequate level of protection[86], disclosure is allowed. But if these exceptions are invoked, the Commissioner needs to be informed beforehand on said safeguards or data protection rules[87].

Furthermore, private parties need to register data files, i.e. any set of personal data that is structured in such a way that the data subject can be singled-out easily[88], with the Commissioner under certain conditions. Such conditions are that they own a data file from which they (i) regularly process sensitive data[89] or personality profiles[90] or (ii) disclose personal data to third parties on a regular basis[91]. While, as a general rule, federal bodies need to register all data files with the Commissioner[92], data files exclusively used for research not related to a specific person are exempted[93].

[82] Article 62 para. 1 HRA.
[83] A list of countries as well as further information on cross-border transfers may be found on the Commissioner's webpage.
[84] Cf. Article 6 DPA.
[85] Article 6 para. 2 lit. a DPA.
[86] Article 6 para. 2 lit. g DPA.
[87] Article 6 para. 3 DPA; article 6 DPO.
[88] Article 3 lit. g DPA.
[89] Cf. article 3 lit. c DPA.
[90] Cf. article 3 lit. d DPA.
[91] Article 11a para. 3 DPA.
[92] Article 11a para. 2 DPA.
[93] Article 18 para. 2 DPO.

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3. Further processing of health data (for research purposes): the current regime

How is the notion of further processing regulated in your national framework?

Further processing of data is potentially in conflict with the purpose limitation principle. The DPA does only allow the processing for a purpose "indicated at the time of collection"[94]. Unlike the GDPR, the DPA does not allow for the processing of personal data in a manner that is merely compatible with the initial purposes[95]. Hence, if the further use encompasses purposes not specified at the time of collection, the purpose limitation principle will be violated. This non-adherence to the purpose limitation principle will be infringing the data subject's personality[96]. As mentioned earlier, an infringement of the data subject's personality can be justified if the data subject has consented to the processing, the controller has overweighing private or public interests, or by law. Obtaining informed consent for further use is, however, very difficult, because the information provided at the time of collection would already have to specify the purpose of the further use. This is next to impossible, since it is a distinctive feature of Big Data analytics that further use of the data is made for purposes unforeseen at time of its collection. Nevertheless, processing personal data for scientific research can be a legitimate interest under the DPA. For private parties the interest in processing personal data for (i) purposes not relating to a specific person, in particular for the purposes of research, planning and statistics, and (ii) publishing the results in such a manner that the data subjects may not be identified can be considered legitimate and overweighing[97]. Similarly, public bodies may process personal data for (i) research purposes not relating to a specific person as far as (ii) the data is anonymized as soon as possible and (iii) the results are published in a manner that does not allow re-identification[98]. But any researcher receiving data from a public body, may only disclose said data with the federal bodies' prior consent[99]. Furthermore, it must be noted that the activities of public bodies are always limited by the principle of legality. Hence federal bodies need a legal basis for processing personal data, in particular sensitive personal data, for research purposes regardless[100].

Are there specific conditions to the further processing for scientific research in the field of health purposes?

The articles 32 et seqq. HRA govern the notion of processing health data for further use in research. "Further use" is defined as any handling, for research purposes, of biological material already sampled or data already collected. In particular, procuring, bringing together or collecting biological material or health-related personal data, registration or cataloguing of biological material or health-related personal data, storage or inclusion in biobanks or databases, making accessible or available or transferring biological material or health-related personal data are deemed to be "further use"[101].

[94] Article 4 para. 4 DPA.
[95] Article 5 para. 1 lit. a GDPR.
[96] Article 12 para. 1 lit. a DPA.
[97] Article 13 para. 2 lit. e DPA.
[98] Article 22 DPA; cf. § 9 para. 2 Zurich Information and Data Protection Act; § 10 para. 1 Basel Stadt Information and Data Protection Act.
[99] Article 22 lit. b DPA.
[100] Article 5 para. 1 FC.
[101] Article 24 HRO.

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Notably, if the intention to make further use of biological material or health related data exists at the time of collection or sampling, the **consent** of the person must be obtained at said time or he or she must be informed on her right to dissent[102].

Further use of **biological material** and **genetic data** may be made if the person concerned has given her informed consent. Consent must be limited to a *specific research project*; it is not possible to give a "general consent", i.e. the data subject cannot consent to data being used for any research possible[103]. Article 28 HRO lists various aspects of the research project that written and oral information has to be provided on, in order for consent to be informed[104]. If sufficient consent has been given, the data may be used in an identifying or pseudonymous way. Whenever data is anonymized, it does not fall within the HRA's scope of application[105] and the respective safeguards do not apply anymore. Hence anonymization of said data is only possible, after the person concerned has been informed on the right to object anonymization and did not exercise such a right. The conditions for consent as well as the safeguards with regard to children, adolescents and adults lacking power of judgment apply by analogy[106].

Further use of **non-genetic health-related data** may be made if the person concerned has given her informed consent. In the case of non-genetic health-related data consent may be given to health research in general and must not be limited to a specific research project[107]. If sufficient consent has been given, the data may be used for further research in an identifying way. Non-genetic health related data may be used in a coded, i.e. pseudonymized, manner as long as the person concerned has been informed on their right to dissent and did not exercise this right[108]. Again, the conditions for consent as well as the safeguards with regard to children, adolescents and adults lacking power of judgment apply by analogy[109].

Like all research projects involving humans, further use of biological material or health related personal data **needs to be authorized** by the competent Cantonal Ethics Board[110]. Additionally, if **neither consent** has been obtained **nor information on the right to dissent** has been provided, the further use of biological material or health-related personal data needs to be approved by the Cantonal Ethics Board[111]. Here the Ethics Board's authorization serves as a "consent-substitute"[112]. The authorization has to be obtained for a specific research project; there is no possibility to obtain an authorization for generic purposes such as "internal research".

What are the rights of the data subject when it comes to further processing?

There are no specific rights with regard to further processing in the DPA. While in the EU there is a general right to object to processing that is merely based on legitimate interests[113], there is no such right enshrined in Switzerland's DPA. However, consent to processing of personal data may be revoked at any time. If consent is revoked at an inopportune juncture and the data in question does not pertain to the "core of the data subject's personality", the data subject can be held liable for damages[114].

[102] Article 17 HRA.
[103] Bundesrat, Botschaft zum Bundesgesetz über die Forschung am Menschen vom 21. Oktober 2009, BBl 8045, 8122.
[104] Cf. article 28 HRO.
[105] Article 2 para. 2 lit. b and c HRA.
[106] Article 32 para. 1, 2 and 3 HRA; cf. II.C.
[107] Bundesrat, Botschaft zum Bundesgesetz über die Forschung am Menschen vom 21. Oktober 2009, BBl 8045, 8122.
[108] Article 33 para. 2 HRA.
[109] Article 33 para. 1 and 2 HRA; cf. II.C.
[110] Cf. article 33 et seq. HRO.
[111] Article 45 para. 1 lit. b HRA.
[112] Bundesrat, Botschaft zum Bundesgesetz über die Forschung am Menschen vom 21. Oktober 2009, BBl 8045, 8124.
[113] Article 14 Directive 95/46/EG; article 21 GDPR.
[114] Swiss Federal Court, BGE 136 III 401, consid. 5.4.

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What about the data subject's rights and further processing for scientific research purposes?

As mentioned already, pursuant to the HRA consent may be revoked at any time without justification[115]. Whenever children, adolescents and adults lacking power of judgment are involved the rules with regard to consent and objection to further processing as describe previously[116] do apply. If genetic data or biological material shall be anonymized for research purposes, the person concerned, its legal representative, or the next of kin must be informed on this step in order to exercise their right to object such anonymization[117].

4. The GDPR's impact on the current regulatory framework for the processing of health data for research purposes

a. The impact of the GDPR on the rules applying to processing for research in the field of health

Please provide a summary of the main relevant characteristics of the new law/Bill (as far as it is relevant for processing health data for research purposes).

The GDPR has triggered a revision of the DPA. However, the draft of the draftDPA has not been discussed by the Swiss parliament yet. Unlike the DPA, the GDPR has not significantly impacted the HRA yet[118]. To our knowledge, no amendments to HRA are planned in the near future. Since the HRA applies as *lex specialis* in the area of health research, the regime will remain mostly unchanged. The draftDPA will affect research only in areas not governed by the provisions of the HRA.

For data intense research the changes concerning information duties and the introduction of processing for compatible purposes stand out. Furthermore, biometrical data that allow for identifying a person as well as genetic data will be considered sensitive data by law[119]. The draftDPA is also set to introduce some new concepts, such as privacy by design and privacy by default, rights with regards to automated decision making, including profiling, data protection impact assessments and data breach notifications. However, the latter aspects are covered by the HRA and will only be relevant for health research beyond the HRA's scope of application or any other *lex specialis* in this regard.

How is (or will be) Article 9(2)(j) implemented in your country?

Switzerland not being an EU member state, there is no need to implement article 9 para. 2 lit. f GDPR.

[115] Article 7 para. 2 HRA.
[116] Cf. II.C.
[117] Article 32 para. 3 HRA.
[118] The only alteration foreseen in the HRA is a reference to the draftDPA, which will bring the HRA up to date with the numbering of article of the draftDPA (Article 62 draftDPA (Anhang) Nr. 51).
[119] Article 4 lit. c (3) and (4) draftDPA.

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b. Modification to the processing authorisation procedure applying to research in the field of health

How will the processing authorisation procedure (if any exists) be affected by the implementation of the GDPR? Can you describe any such change? Is it a logical change? Is the supervisory authority involved? If yes, how?

Since the HRA is not amended, there will be no alterations to the authorization procedure.

What about the rights of the data subject and the obligations of the controller?

With the introduction of the draftDPA the data subject will have some additional rights with regard to information: As mentioned earlier, information duties are only partially covered by the HRA and hence the general regime, the federal draftDPA and the cantonal data protection laws apply. The draftDPA also introduces new information duties with regard to the data storage period and automated decision-making being in place as well as the logic involved in such decision-making[120]. Controversially, the draftDPA also introduces a right to access to data of deceased people for straight line relatives, widows and widowers, the registered or unmarried partners at the time of death, executors of will and anybody with an interest worthy of protection[121]. Under the envisaged framework, the controller will have to inform on automated decision making, including profiling, whenever such processing impairs the data subject or even has legal consequences[122]. The data subject, upon its request, has a right to present its point of view to the controller and can demand that the automated decision is checked by a natural person[123]. However, these rights with regard to automated-decision making can be waived[124].

Furthermore, the concept of processing for compatible purposes is introduced[125]. However, unlike in the EU, there is no specification that processing data for scientific or statistical purposes shall be deemed compatible with the original purpose.

5. Further processing for research purposes under the GDPR

The notion of further processing under the GDPR:

Further processing of personal data for scientific research purposes is regulated in the GDPR by Article 5(1)(b) ("*further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes*") and Article 89(1) ("*Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subject to appropriate safeguards, in accordance with this Regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that technical and organisational*

[120] Article 23 para. 2 lit. d and f draftDPA.
[121] Article 16 para. 1 draftDPA.
[122] Article 19 para. 1 draftDPA.
[123] Article 19 para. 2 draftDPA.
[124] Article 19 para. 3 draftDPA.
[125] Article 5 para. 3 draftDPA.

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measures are in place in particular in order to ensure respect for the principle of data minimisation. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner").

Given the regime applied to further processing in the GDPR, can you describe the consequences, if any, in your national legal framework?

Since the HRA is not amended, there will be no consequences with regard to further processing. As in the current framework (cf. III) under the draftDPA federal bodies will be exempted from the purpose limitation principle for research purposes[126]. Likewise private data processors still would be allowed to invoke an overweighing interest if data are processed for a research purpose not relating to a specific person and (i) the data is rendered anonymous as soon as the purpose of processing allows for it (ii) sensitive personal data is disclosed to third parties in such a manner that the data subjects may not be identified and (iii) the results are published in such a manner that the data subjects may not be identified[127].

6. Health data sources for research purposes

a. Sources of data and their regulation

Does your national framework contain specific provisions for anonymised or pseudonymised health data?

The HRA states that it does not apply, if health data is anonymized[128]. This is in fact misleading, since the HRA does contain specific provisions on anonymous health data that need to be observed. But research with **anonymized data** is privileged under the HRA. The DPA, however, does not apply at all, since its scope is limited to personal data.

Anonymized *non-genetic health data* may be used for further research regardless whether the person originally concerned consented or has had the possibility to object such use. Anonymized *biological material and genetic data* may be used for further research if the person concerned respectively the next of kin or its legal representative in cases of children, adolescents and adults lacking power of judgment (see II.C) were beforehand informed on the right to object anonymization and did not exercise said right[129]. If it is impossible or disproportionally difficult to obtain consent from the data subject, an authorization from the Cantonal Ethics Board needs to be obtained as a consent substitute for making further-use of anonymized data covered by professional secrecy[130]. Note that in order for biological material or health related data to be considered anonymous "all items which, when combined, would

[126] Article 35 para. 2 draftDPA.
[127] Article 27 para. 2 lit. e draftDPA.
[128] Article 2 para. 2 lit. b and c HRA; Bundesrat, Botschaft zum Bundesgesetz über die Forschung am Menschen vom 21. Oktober 2009, BBl 8045, 8092.
[129] Article 32 para. 3 HRA.
[130] Art. 322bis para. 2 SCC in connection with article 34 HRA; cf. II.B.

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enable the data subject to be identified without disproportionate effort, must be irreversibly masked or deleted"[131]. In particular, "name, address, date of birth and unique identification numbers must be masked or deleted"[132].

Pseudonymous data is also privileged under the HRA. *Biological material* and *genetic data* may be used for research in pseudonymous form, after the person concerned respectively the next of kin or its legal representative in cases of children, adolescents and adults lacking power judgment (see II.C) have given their informed consent to making data available to a specific research project or scientific research in general[133]. *Non-genetic health data* may be used if the respective person did not dissent pseudonymization after being informed[134]. Data will be considered pseudonymized if they are anonymous from an unauthorized person's point of view[135]. It is required that the key is stored separately from the data with a trusted person not involved in the research project[136]. The person concerned may, however, object the further use of data at any point in time. The consequences of this objection are set forth in article 10 HRO.

What are the different sources of health data that can be used for research purposes?

- **DIRECT COLLECTION FROM PATIENTS:**

Under the current legal framework: please explain the currently applying rules that a researcher, who intends to collect health data directly from individuals (e.g. via a survey, or by asking patients to wear a monitoring device, etc.), should follow.

Research involving human beings needs to be authorized beforehand. Hence the researcher will have to file an application for authorization pursuant to Annex 2 HRO with the competent Ethics Board. Inter alia he or she will have to file a summary of the research protocol in a national language, the full research protocol and reasons for the requested risk categorisation, the information sheet, consent form and recruitment documents distributed to participants. The researcher has to fulfil certain requirements (cf. II.C.) for the Ethics Board to approve the informed consent mechanism.

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

Since the HRA is not amended, there will be no changes.

- **COLLECTION FROM HEALTH PROFESSIONALS AND HEALTH INSTITUTIONS**

Under the current legal framework: please explain the rules currently applying that a researcher, who intends to obtain health data from medical staff, hospitals, etc., should follow.

Again, the research project needs to be authorized by the competent Ethics Board. The researcher is bound by the same rules as when collecting the data directly from the patients. If the research is carried out with pre-existing data-sets stemming from either a treatment or another research context, the rules for making further-use of health related data (article 32 et seq. HRA; cf. III) apply. The medical staff, hospitals etc. are bound by professional secrecy

[131] Article 25 para. 1 HRO.
[132] Article 25 para. 2 HRO.
[133] Article 32 para. 2 HRA.
[134] Article 33 para. 2 HRA.
[135] Article 26 para. 1 HRO.
[136] Article 26 para. 1 HRO.

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as well as by the rules applying to disclosure of sensitive data. Whenever a patient consents to disclosing his medical data this will be a waiver of respective professional secrecy; elsewise the Ethics Board can approve the use of data without consent under certain conditions (cf. II.C).

Furthermore, the medical staff or hospitals need to observe several rules on disclosure of sensitive data (see above). Private hospitals may disclose sensitive data if the person concerned has given his or her informed consent. Also disclosure is possible without the participants consent (provided the data stays within Switzerland[137]), if the data is processed for research purposes not relating to a specific person and the results are published in such a manner that the data subjects may not be identified[138]. Hospitals will most likely be cantonal bodies due to the federal organization of health care in Switzerland and need to comply with cantonal data protection laws. The freedom of academic research guaranteed in article 20 FC serves as legal basis for disclosure[139]. In Zurich, for example, a public hospital may disclose the data, if (i) the researcher needs the data for research purposes not relating to a specific person, (ii) the data is anonymized as soon as possible, (iii) the results do not allow drawing conclusions on the persons concerned, (iv) the original data is destroyed after the analyzation and (iv) there is no legal statute prohibiting such disclosure[140]. The researcher should file a request with the public hospital in which he introduces the research institution, briefly explains the research project and its purpose, states if there are any additional legal basis for the project, elaborates on the scope of personal data needed, the project design with regard to use of data and measures taken to protect the data as well as on how the aforementioned conditions for disclosure are met[141]. Disclosure is at the discretion of the public hospital[142].

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

Since the HRA is not amended, there will be no changes to the rules applying to direct collection of data from patients. The rules governing the disclosure of sensitive data by cantonal bodies are likely to be revised but, since no actual proposal has been put forward yet, it is unclear if and how they will change.

- **PRIVATE DATABASES**

Under the current legal framework: please explain the rules currently applying for the setting up of and the use of a private database with health data for research purposes.

As far as private databases contain anonymous data they are neither governed by the DPA[143], nor by the HRA[144]. However, making data available in a database could be a disclosure of a professional secrecy. To avoid a violation of article 320 or 321 SCC by entering personal health data into the health register, the latter must be authorized by the cantonal ethics board and the conditions set forth by article 34 HRA must be met[145]. Entering data into the health database will qualify as further use and hence the application must contain the respective information enlisted in Annex 2 HRO.

[137] Cf. article 42 HRA for the conditions of cross-border transfer.
[138] Article 13 para. 2 lit. e DPA.
[139] Data Protection Commissioner Zurich, leaflet on personal data in health research, November 2017, p. 1, last visited 2 May 2018.
[140] § 18 Zurich Information and Data Protection Act.
[141] Data Protection Commissioner Zurich, leaflet on personal data in health research, November 2017, p. 2, last visited 2 May 2018.
[142] § 18 para. 1 Zurich Information and Data Protection Act; Data Protection Commissioner Zurich, leaflet on personal data in health research, November 2017, p. 1, last visited 2 May 2018.
[143] Article 2 DPA in connection with article 3 lit. a DPA.
[144] Article 2 lit. b and c HRA; however, the standards of anonymization set forth by the HRA and the HRO will have to be met (see above).
[145] Article 321bis para. 2 SCC; article 45 para. 1 HRA.

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Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

Private databases processing non-anonymous data would fall within the draftDPA's scope of application. However, their setup and most aspects of the data usage are governed by the HRA, which will remain unchanged. Hence there will be no changes to the rules applying to disclosure of professional secrecy and registration of private databases. Novel rules set forth by the draftDPA, like the right to access data of deceased persons or the duty to inform on automated decision-making, might apply, depending on the setup of the database.

- **PUBLIC DATABASES**

Under the current legal framework: do public authorities make available health data for research purposes in your country and under what conditions?

Switzerland's federal organization with regard to the health sector has led to a patchwork of cantonal databases with different scopes, organization and funding. An overview of medical databases in Switzerland is provided by the Forum Medizinische Register. After all, in March 2016 the Swiss parliament adopted the Federal Act on the Registration of Cancer Diseases, which creates a legal framework for registration of data on cancerous diseases and is likely to enter into force January 1, 2019[146]. The national cancer registration will be carried-out by the National Institute for Cancer Epidemiology and Registration (NICER)[147]. Under the Federal Act on Cancerous Diseases public and private medical staff and hospitals alike are obliged to collect various basic data on cancer diseases[148]. The cantonal register, the child cancer register, the national cancer registration as well as the Federal Office on Statistics will support research[149]. Upon request they will provide anonymized data for research purposes[150]. For other processing activities the HRA applies[151].

The State Secretariat for Education, Research, and Innovation mandated the Swiss Academy of Medical Science (SAMS) with the development of a Swiss Personalized Health Network (SPHN) and has allocated respective funding[152]. Inter alia, the SPHN aims at developing a dynamic scalable network of interoperable data providers in Switzerland[153]. These are still ongoing undertakings, but they could impact the public disclosure of data for health research in Switzerland.

Under the revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

The draftDPA is not set to trigger a substantial review of the Federal Act on the Registration of Cancer Diseases[154]. The rules governing the disclosure of sensitive data by cantonal bodies are likely to be revised but, since no actual proposal has been put forward yet, it is still unclear if and how they will change.

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[146] Federal Office of Public Health, Information on Enforcing the Federal Act on Registration of Cancerous Diseases, https://www.bag.admin.ch/bag/de/home/themen/strategien-politik/nationale-gesundheitspolitik/gesetzgebungsprojekt-registrierung-von-krebserkrankungen/informationen-zum-vollzug.html, last visited 7 May, 2018.
[147] Explanatory Report on the Federal Act on the Registration of Cancer Diseases, p. 108.
[148] Cf. article 3 Federal Act on the Registration of Cancer Diseases.
[149] Article 23 para. 1 Federal Act on the Registration of Cancer Diseases.
[150] Article 23 para. 2 Federal Act on the Registration of Cancer Diseases.
[151] Article 23 para. 4 Federal Act on the Registration of Cancer Diseases.
[152] Swiss Academy of Medical Science (SAMS), Swiss Personalized Health Network, https://www.samw.ch/en/Projects/SPHN.html, last visited 7 May, 2018.
[153] Swiss Personalized Health Network, Projects, https://www.sphn.ch/en/projects.html, last visited 7 May, 2018.
[154] Bundesrat, Botschaft zum Bundesgesetz über die Totalrevision des Bundesgesetzes über den Datenschutz und die Änderung weiterer Erlasse zum Datenschutz vom 15. September 2017, BBl 6941, 7190, stating that in the Federal Act on the Registration of Cancer Diseases the term «owner» shall be replaced with «controller».

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b. Application of the national framework to the AEGLE cases

1. Type 2 diabetes

For research into non-malignant chronic diseases AEGLE offers a platform that consists of a large pool of semantically annotated healthcare data, big data analytics libraries and APIs for federating with public and private data sets. The AEGLE project uses existing databases with pseudonymized health data collected from patients who expressed their consent to their data being used for research purposes. Health care researchers then can perform different workflows with the data sets. The AEGLE platform enables users to use, develop and improve predictive and cohorting analytics for their patients.

Current legal framework: which procedural or other steps would the researcher have to follow to use this data for 'big data' analytics on the AEGLE platform? Is a new ethical or other approval required? From which body?

The further use of biological material or health-related personal data for research purposes carried-out in Switzerland needs an authorization by a cantonal Ethics Board[155]. A research project is deemed to be carried-out in Switzerland, whenever the conduct that could affect the dignity, personality or health of persons is performed on Swiss soil. It is likely that **analyzing** pre-existing data sets from non-Swiss residents falls within this qualification. However, research with anonymous data does not fall within the HRA's scope of application. Health data will be considered anonymous if all items that would enable the data subject to be identified without disproportionate effort, are irreversibly masked or deleted[156]. As far as the researcher could only identify the data subjects by using disproportionate efforts, such data is not governed by the HRA. Hence analyzing such data would not need any authorization. These distinctions are murky and difficult to make. Researchers are well advised to consult the competent cantonal Ethics Board on this matter beforehand[157].

In the general data protection framework pseudonymized data, i.e. data where the data subject's identity is disguised by using an artificial identifier, will be deemed personal data under two conditions: (i) The method used was a two-way encryption, meaning that decryption of this data is possible and it is likely that the researcher makes use of the decryption function or (ii) the researchers possess the key to the pseudonymized data sets. Neither condition is likely to be fulfilled in the case at hand. Hence the analysis of these data sets will most likely not fall within data protection law's scope. Accordingly, analysis of pre-uploaded data on the AEGLE platform is unlikely to trigger any duties arising from data protection law.

The legal situation is different if the **researcher uploads data** collected in Switzerland to the AEGLE platform. This will be deemed making further use in the meaning of article 24 HRO. This further use will need to be authorized by the cantonal Ethics Board. Non-genetic health data may be used if the person concerned has not objected to making the data available for research[158]. As far as the information given was sufficient[159] and the other requirements of the HRA have been met, the cantonal ethics board will approve such further use on the AEGLE platform.

[155] Cf. Part. III.
[156] Article 25 HRO.
[157] The cantonal Ethics Board can advise researchers on projects not governed by the HRA (cf. article 51 para. 2 HRA). The researchers may also file a "jurisdictional inquiry" via the BASEC platform and for a levy of CHF 200.- the Ethics Board will confirm that no authorization is needed (see https://kek.zh.ch/internet/gesundheitsdirektion/kek/de/fragen_antworten.html, last visited 9 May, 2017).
[158] Article 33 para. 2 HRA; cf. section III.
[159] Cf. section II.C.

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On the AEGLE platform the data will be made available to foreign research institutions and most likely will be stored in servers outside of Switzerland. Under the unlikely assumption that the data qualifies as personal data (see above) this will qualify as **cross-border transfer**. Pursuant to article 42 para. 2 HRA in connection with article 6 DPA, there is a legal presumption that data can be disclosed to a country whose legislation guarantees adequate protection. EU states are deemed to guarantee adequate protection[160]. If the legislation does not provide for an adequate level of protection or other reasons lead to the possibility of the data subject's privacy being endangered, disclosure will be only allowed if there are sufficient safeguards in place and the Commissioner has been informed on theses safeguards beforehand[161].

If cantonal bodies like hospitals or universities are involved in the research project and the data qualifies as personal data (see above) the cantonal data protection laws will apply. In Zurich, like in many other cantons, data may be uploaded and analyzed on the AEGLE platform if (i) the researcher needs them for research purposes not relating to a specific person, (ii) the data are anonymized as soon as possible, (iii) the results do not allow drawing conclusions on the persons concerned, (iv) the original data is destroyed after the analyzation[162]. For public bodies in Zurich cross-border transfer is possible to all signatory states to the Council of Europe Convention 108 or whenever other appropriate safeguards are in place[163].

Should the patient be informed about the new research project? Is a new patient consent, specifically focusing on the precise research project, required?

For pseudonymized non-genetic health data, non-objection to making data available to research in general is sufficient. There is no need to inform the patient about the specific project[164]. If the research into non-malignant chronic diseases uses pseudonymized genetic data then the person concerned needs to consent to making data available to research in general. Again, there is no need to inform the patient about the specific project[165].

Revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

Since the HRA is not amended, there will be no changes to the aforementioned procedures. The rules governing the disclosure of sensitive data by cantonal bodies are likely to be revised but, since no proposal has been put forward yet, it is unclear if and how they will change. With regard to cross-border transfer by private research institutions the most notable change is that the Commissioner's competence to assess whether a foreign country provides for an adequate level of protection is assumed by the Federal Council. Once the draftDPA has entered into force the Federal Council will not just publish a list but enact a legally binding ordinance specifying to which countries disclosure can take place[166].

[160] Cf. the respective list published by the Commissioner.
[161] Article 6 para. 1 lit. a in connection with para. 3 DPA.
[162] § 18 Zurich Information and Data Protection Act.
[163] Cf. § 19 IDG Zurich Information and Data Protection Act.
[164] Article 33 para. 2 HRA.
[165] Article 32 para. 2 HRA.
[166] Article 13 para. 1 draftDPA.

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2. Intensive Care Unit (ICU)

AEGLE uses data generated by ICU devices like data from ventilation and biosignal monitors (i.e. heart rate variability) without collecting the patient's consent (after pseudonymisation). The Clinical Decision Support Platform (CDS-UI) can offer real-time support, while the R&D-UI offers descriptive and predictive analytics and may be used for both research purposes but also for generating quality metrics.

Current legal framework: which procedural or other steps would the researcher have to follow to use this data for 'big data' analytics on the AEGLE platform? Is a new ethical or other approval required? From which body? Should the patient be informed about the new research project? Is a new patient consent, specifically focusing on the precise research project, required?

The data processed during the CDS-UI qualifies as processing for treatment purposes and hence is not governed by the HRA. As already mentioned in the Type 2 diabetes case study, as far as the researcher could only identify the data subjects by using disproportionate efforts, such anonymous data is not governed by the HRA. For similar reasons analysis of pre-uploaded data on the AEGLE platform is unlikely to trigger any duties arising from data protection law.

Entering the data into the R&D-UI can be deemed processing for further use of health data for research purposes. The data generated will qualify as non-genetic health-related data. Since no consent is obtained, article 34 HRA applies[167]: The researcher may make further-use of the data provided (i) 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; (ii) no documented refusal is available; (iii) the interests of research outweigh the interests of the person concerned in deciding on the further use of his or her data; and (iv) authorization for disclosure has been obtained by the responsible ethics committee. The first condition will likely be met, since ICU patients are suffering from severe or even life-threatening diseases and obtaining consent would definitely be an undue burden. Provided that no documented refusal is registered, as a third condition, the interests of the researcher have to be weighed against the patient's interests. For example, the interest in research might be overweighing if many people would benefit from the research or the research question is of special interest (e.g. relates to a severe disease)[168]. Following a risk-based approach, the interest in research involving pseudonymized data is also more likely to outweigh the patient's interests than when unencrypted data is used[169]. The latter considerations are likely to tip the balancing of interests in favour of research carried out on the R&D UI, since it uses pseudonomyized data; however, a case-by-case analysis is needed.

The researcher will need to obtain an authorization for the research project as well as the "consent-substitute" from the cantonal Ethics Board. The Ethics Board may authorize further use for a research purpose in general[170]. Due to article 34 HRA being an exemption clause and in order to carry out the balancing of interests the research purposes need to be specified. If the data qualify as personal data, regarding cross-border disclosure and disclosure by public bodies the rules explained in connection with the Type 2 diabetes AEGLE platform apply (cf. VI.B.1).

[167] Cf. II.C.
[168] Bundesrat, Botschaft zum Bundesgesetz über die Forschung am Menschen vom 21. Oktober 2009, BBl 8045, 8124.
[169] Bundesrat, Botschaft zum Bundesgesetz über die Forschung am Menschen vom 21. Oktober 2009, BBl 8045, 8124.
[170] Cf. the wording of article 34 HRA; see also article 39 lit. a HRO.

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Revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

Most aspects of the use of the Intensive Care Unit for research purposes are governed by the HRA. Since the latter will remain unchanged there will be no changes. Regarding cross-border disclosure the rules governing the disclosure of sensitive data by cantonal bodies are likely to be revised but, since no proposal has been put forward yet, it is unclear if and how they will change.

3. Chronic Lymphocytic Leukaemia (CLL)

The AEGLE project re-uses, after pseudonymisation, data coming from biobanks. In particular, AEGLE supports the analysis of next generation sequencing (NGS) and immunogenetics data. The patients have given their informed consent for the samples and for the processing of their data. But this consent was given in general terms and not specifically for AEGLE.

Current legal framework: which procedural or other steps would the researcher have to follow to use this data for 'big data' analytics on the AEGLE platform? Is a new ethical or other approval required? From which body? Should the patient be informed about the new research project? Is a new patient consent, specifically focusing on the precise research project, required?

As already mentioned in the Type 2 diabetes case study, as far as the researcher could only identify the data subjects by using disproportionate efforts, such anonymous data is not governed by the HRA. For similar reasons analysis of pre-uploaded data on the AEGLE platform is unlikely to trigger any duties arising from data protection law. (cf. VI.I.B). This should even be the case when genetic data is handled, since the efforts to actually identify a person are disproportionate and a researcher usually has no interest in actually going through this effort.

Any information on the genotype qualifies as genetic data under the HRA[171]. Uploading this data to the AEGLE platform can qualify as processing for further use of genetic data for research purposes. Further use of genetic data may be made in pseudonymized form when the person concerned has given his or her informed consent[172]. If informed consent has been given to research purposes in general, this is sufficient. There is no need to inform the patient on the precise research project.

Making further use of genetic data needs to be authorized by the competent cantonal Ethics Board. The Ethics Board will examine if consent has been obtained in compliance with the rules set forth by the HRA, in particular whether the information of the participants was sufficient[173].

If genetic data were to be qualified as personal data, the rules regarding cross-border disclosure and disclosure by public bodies would apply (cf. VI.B.1).

[171] Article 3 lit. g HRA.
[172] Article 32 para. 2 HRA; Cf. III.
[173] Article 16 HRA; article 8 HRO.

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Revised legal framework: will the currently existing procedures and rules change in view of the implementation of the GDPR in your country?

The revised DPA will clarify that genetic data qualifies as sensitive personal data[174]. But as far as the researcher has no possibility and no interest in connecting the data with a data subject, such data cannot qualify as personal data. If the researcher has access to the key used for pseudonymization the revised rules on cross-border transfer for private researchers would apply (see above). Regarding cross-border disclosure the rules governing the disclosure of sensitive data by cantonal bodies are likely to be revised but, since no proposal has been put forward yet, it is unclear if and how they will change.

[174] Article 4 lit. c para. 3 draftDPA.

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