PUBLIC SECTOR LAW
solutions to go forward

Memorandum **C O N F I D E N T I A L**

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Re	SPHN Project, Harmonisation of health data and biosamples in Swiss paediatric clinics Report on legal aspects
Version	final
Date	Zurich, 7 October 2019

Harmonisation of health data and biosamples in Swiss paediatric clinics Report on legal aspects

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A. Summary and Recommendations

1 The Project 'Harmonisation of health data and biosamples in Swiss paediatric clinics' will establish a harmonized set of data and biomaterials collected in paediatric clinics throughout Switzerland for the benefit of research in minors.

2 The Federal Human Research Act sets forth key provisions as to *further use of patient data and biomaterials*. General rules provide for the following:

a) *Consent* by the minor and his or her legal representative must be obtained *at the time of the collection of such data*, i.e. at the beginning of any clinical treatment;

b) The requirements of *informed consent* must be met, in particular an appropriate information on the possible scope of further data use;

c) General consent for further use of *biological material and genetic data in coded form* is possible. The same applies to research purposes involving further use of non-genetic health-related personal data in uncoded form;

d) General consent to further use of *biological material and genetic data in uncoded form* is not an option.

3 With regard to minors (children under 14 years, adolescents under 18 years) additional aspects need to be taken into consideration:

a) Swiss law considers minors as *particularly vulnerable persons*;

b) Subsidiarity: 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;

c) *The scope of the harmonized data set should not go beyond underage patient data and samples that have to be collected during clinical treatment anyway*. This requirement appears to be met to the extent that the data only enters the SPHN environment if it is available within a treatment context;

d) Children and adolescents must be *involved as far as possible* in the consent procedure, and *increasing weight* must be accorded to the views of children the older and more mature they are;

e) The focus must be on a *guarantee of data coding* (further use of data only in coded i.e. pseudonymised form) which would allow one *standard general consent* of the minor and/or legal representative for most types of data or further use involved.

4 The different consent requirements are shown in tables 1 and 2 in this report. In our opinion, it would be too far-reaching to introduce specific requirements for different categories of data and samples collected for the purposes of the harmonised data set. The question is to be discussed among the participating institutions and clinics from the point of view of *practicable and uniform handling*.

5 The HRA is currently being evaluated. SAMW and SPHN are encouraged to emphasize the need for revision as regards personalized medicine. Technology solutions for *electronic consent compliant with legal standards* need to be pushed forward.

6 With regard to general *data protection*, attention needs to be drawn to the fact that most clinics will fall into the scope of application of *cantonal rules*. These may vary slightly from the Federal Data Protection Act. Reference is made to the core principles such as proportionality and data security. However, if the Human Research Act provides for more specific regulation it precedes the data protection acts. Swiss data protection regulation is compatible with EU GDPR standards and currently undergoing revision.

7 Further public health acts such as the Cancer Registry Act need to be taken into consideration. The provisions imply *an obligation to collect and register cancer patient information*, as opposed to principles set forth in the HRA.

8 As regards *linking of existing data files and registries*, such as STATPOP with a minors' *electronic health record*, the Federal Act on the Electronic Health Records appears to set restrictions. The options with regard to linking of existing data files need further legal assessment.

B. Part One

1. Introduction

9 As children grow, their bodies undergo changes. Children of different ages may therefore differ in their susceptibility to harmful exposures: in the presentation of disease, in the appropriateness of diagnostic tests, and in response to treatments. Many diseases in children are rare and have long term effects leading to chronic disease later in life. Treatments tested in adults are often given to children without adequate testing. As a result, health-related data from children are heterogeneous. Clinical research in minors is hampered also by fragmented data and small numbers of samples.

10 Progress in medical genetics and in the digital world, on the other hand, is creating new opportunities for personalization and stratification of therapies in human medicine. Large amounts of medical data allow technology-supported research based on correlations that were previously impossible to establish.[1]

11 All this calls for a harmonization of all health-related data collected in minors and a commitment to collect information consistently over time as children grow older. In addition, important information on environmental, behavioural, social and family-related factors is not available from patient records, but can be obtained from parents. The harmonisation of the data collected in Swiss children's hospitals will allow to continuously improve diagnostics and treatment in children, and to understand long term effects of early life events.

12 At the center of the SPHN Project 'Harmonisation of health data and biosamples in Swiss paediatric clinics' is the establishment of a harmonized set of data and biomaterials collected in paediatric clinics throughout Switzerland. The project

a) creates an *inventory* of all health related data collected from minors;

b) develops a *consensus* among all major paediatric hospitals on which data and biosamples should be collected; and

c) examines whether *parents* are willing to provide health-related information via paper questionnaires, web-based or mobile phone apps.

13 Interest in scientific use of data is opposed to concerns regarding protection of patients' rights, especially children and minors who are not or not yet capable of judgement. Patient's interests and societal benefits must therefore be considered in a balanced way so that progress can be achieved at the highest possible level of safety.[2] At

[1] POMMERENING, 60; REY, 554; SPRECHER, Datenschutz und Big Data, 500. Detailed references see bibliography at the end of this report.

[2] POMMERENING, 64.

the same time, the different approaches and the interplay between collection of patient data for *clinical use* and in human medical research need to be addressed.

2. Mandate and scope of the legal report

14 On the basis of the consensus about the harmonised data set cited above, this legal report provides an analysis of the current legal framework in order to assure compliance within paediatric clinics that collect data for research. Data collection and exchange between clinicians and researchers must be in accordance with legal (and ethical) standards.

15 For this purpose, the Swiss federal legal bases in *human research* law, specific relevant health laws i.e. on medical registries as well as *data protection* law in a research context and need to be discussed. There are also numerous *cantonal laws* on patients' rights, hospitals and data protection, they may however not be discussed in detail within the scope of this project. Some substantial statutes relevant for major centers will nevertheless be mentioned in order to illustrate the topics covered therein.

16 Furthermore it is important to note that, whereas a harmonised data set involves numerous institutions, labs and individual care takers, a *patient-centred approach* has to be adopted. This is because compliance with legal standards is essentially assessed on the basis of whether the rights of underage patients are adequately protected.

17 Regarding protection and handling of patient data, various legal studies have already been published. In particular, Swissethics provides guidelines for researchers, for example with regard to consent.[3] Whereas the approval of the responsible ethics committee is an essential formal requirement for concrete human research project, the harmonized paediatric data set must be placed in a broader clinical context where various federal and cantonal statutory regulations may have an influence on governance and compliance standards.

18 In this context, the focus obviously has to be on the aspect of the *underage status of patients*. This aspect gives rise to a number of specific legal questions, in particular regarding informed consent of minors, which are dealt with in greater detail here (*infra*, section 3.3).

19 As a last preface, it is not appropriate to examine existing gaps in regulation in the field of *big data* or *data mining*. The National Science Foundation's *Research Programme NRP 75* makes big data a core topic of research and covers ELSI aspects as well.[4] As a consequence, no further details on big data are elaborated in this report at this stage. The findings of NRP will be subsequently monitored.

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[3] See swissethics.ch, under Templates/Documents subpage.

[4] See www.nfp75.ch.

C. Part Two – Legal framework

20 As mentioned in previous working papers[5], the project faces a *fragmented regulatory environment*. Hereinafter we provide an overview on relevant regulations, focussing on human research (*infra*, 3.) and data protection (4.), before we mention further fields of interest such as the electronic health record or research in stem cells (5.).

3. Human research law

21 As a starting point, current legal standards laid down in the Federal Human Research Act (HRA)[6] and the corresponding Ordinances[7] will be examined.

3.1 Scope of application of the Human Research Act

22 As a *preliminary question* it must be clarified to what extent the collection of data itself is subject to research law. With regard to the harmonised data set, no concrete research project is planned at the time the data are collected in a *clinical or therapeutical context* (e.g. diagnostics). Rather, the data are collected with a view only to future paediatric research projects. The problem to be discussed is therefore whether the HRA is already applicable at the time of collection of data and biomaterials or only once a concrete research study is about to be established.

23 On one side, the HRA (only) applies to *research* concerning human diseases and concerning the structure and function of the human body, which involves, i.a. persons, biological material or health-related personal data (Article 2 HRA).

24 On the other side, the HRA contains specific provisions regarding *further use* of biological material and health-related personal data *for the purpose of research*.[8] In order to protect personality, the HRA provides for appropriate general consent and objection solutions in connection with the further use of biological material already retrieved and health-related personal data already collected.[9]

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[5] PUBLIC SECTOR LAW Working Paper of 3 September/30 November 2018.

[6] Federal Act of 30 September 2011on Research involving Human Beings (Human Research Act, HRA), SR 810.30.

[7] Ordinance of 20 September 2013 on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO), SR 810.301; Ordinance of 20 September 2013 on Clinical Trials in Human Research (Clinical Trials Ordinance, ClinO), SR 810.305.

[8] Art. 32 et sqq. HRA and art. 24 et sqq. Human Research Ordinance.

[9] Dispatch of the Federal Council on the Human Research Act, 21 October 2009, BBl 2009 *8045* 8098; specific provisions will be discussed in more detail in the following section.

25 The key provision reads as follows[10]:

> ***Article 17 HRA Consent to further use for research***
> If the intention exists to make further use for research of biological material sampled or health-related personal data collected, the consent of the persons concerned must be obtained *at the time of such sampling or collection*, or they must be informed of their right to dissent.

26 Since Article 17 HRA requires the consent of the data subject at the time of collection, it becomes obvious that the harmonised data set entails a reference to research law. Therefore the HRA and its Ordinances must be taken into account from the outset. General considerations of due diligence also support this conclusion.

3.2 Concept of consent in human research

27 Before going into the details of the special rules concerning minors, the concept of informed and general consent and objection of the HRA has to be presented.[11]

3.2.1 Written informed consent as a general principle

28 The general principle of *informed consent* is laid down in article 118b para 2 ltr. a of the Swiss Constitution[12] and specified in the following articles of the HRA:

> ***Article 7 HRA Consent***
> [1] Research involving human beings may only be carried out if, in accordance with the provisions of this Act, the persons concerned have given their informed consent or, after being duly informed, have not exercised their right to dissent.
>
> [2] The persons concerned may withhold or revoke their consent at any time, without stating their reasons.
>
> ***Article 16 para 1 HRA Informed Consent***

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[10] Note: English is not an official federal language; find official text in German, French or Italian at www.admin.ch, classified compiliation subpage (Systematische Sammlung des Bundesrechts).

[11] Further general principles of research law which lie outside the present thematic context are not dealt with here. Reference is made to Articles 4 et seq. of the HRA, which set out these principles.

[12] GÄCHTER/SCHÜTZE, Gesundheitsrecht, n. 165, 310 et. seq, also make reference to article 13 Constitution regarding the right to privacy. The principle of informed consent is also laid down in the Convention of the Council of Europe for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of 1997 ('Biomedizin-Konvention', adopted in Switzerland in 2008, SR 0.810.2'). Equivalent principles are set out in the Declaration of Helsinki by the World Medical Association.

[1] Persons may only be involved in a research project if they have given their informed consent. Consent must be given in writing; the Federal Council may specify exemptions.

29 In addition to providing appropriate information about a specific research project, attention must also be drawn to the requirement that consent must be given in *written form*. Whereas the Federal Council lists few exceptions to the requirement of written consent in Article 9 of the Human Research Ordinance (HRO),[13] the Council does not address the question if written consent can only be given on paper or, in today's world, also by electronic means, comparable to options under the electronic health record.[14] Reference is made here to the various infrastructure development projects that are concerned with electronic consent, data governance and citizen centered consent.[15]

3.2.2 General consent for further research use of data

30 The principle that a *general consent* must be obtained at the time data or material is collected with the intention to make further scientific use was cited above (cf. Article 17 HRA, no. 25). Reaching routine status, and high levels of consent with in- and outpatients at the time of data retrieval would indeed be very beneficial for research with minor patients.

31 The individual provisions concerning further use of data are now examined in more detail. Article 32 para 1 HRA requires an *informed consent* by the person concerned, or by the legal representative or next of kin for any *research project* that involves a further use of biological material and genetic data in *uncoded form*. Given the sensitivity of data involved, general consent is not permitted at this stage.[16]

32 General consent for research purposes is however possible for further use of biological material and genetic data in *coded form* (Article 32 para 2 HRA). The same applies to research purposes involving further use of non-genetic health-related personal data in uncoded form (Article 33 para 1 HRA).

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[13] Exceptions to written form of consent are only permitted in specific projects concerning adults capable of judgement (cf. art. 9 para 1 ltr. a HRO).

[14] Regarding electronic health record act cf, *infra* 5.2.1. It should be mentioned here that cantonal hospitals are usually required by cantonal law to maintain an electronic hospital information system. These cantonal provisions contradict the traditional understanding of handwritten consent under contract law and should lead to the valid granting of electronic consent instead of handwritten consent (cf. Art. 6 Civil Code). The growing importance of technology in clinics also suggests digital solutions for consent.

[15] Visit www.sphn.ch, Projects subsite for further reference.

[16] ROTHWELL, ERIN / BOTKIN JEFFREY R., Ethical issues in genetic research with infants: Biospecimen use and genome sequencing, in: KODISH/NELSON (ed.), Ethics and Research with Children, 155 et sqq.; Dispatch of the Federal Council (fn. 9), 8122.

33 The term '*research purpose*' is used when no concrete research project is planned at the time of data retrieval, but biological material and data are to be stored for research projects to be realized in the future (yet unknown).[17] Different requirements apply to the use of other data like non-genetic information.[18]

34 In practice it is difficult to obtain retroactive consent for research projects concerning existing data or bio-samples of 100+ patients, and the *escape clause* of Article 34 HRA is often applied by ethical committees.[19] Considering the growing importance of data protection in the health sector, it will however become more difficult to invoke this exception, in particular for research projects involving data obtained after the introduction of the HRA.

35 This illustrates the importance of introducing a practicable general consent and the need for appropriate technological solutions to achieve a high level of patient approval at the same time with the best possible data security.[20]

36 In the cases referred to in articles 31 para 3 and 32 para 2 HRA, the patient is to be informed about the right of opposition (*opt-out*). In this way, any reconnection and request of the participating person at a later stage can be avoided, which may be beneficial both for the researchers and for the persons participating in a research project.

37 The table below provides a condensed and simplified overview of the different consent requirements depending on type of data or material involved and future research project:[21]

	Type of material or data	Biological material and genetic data	Non-genetic data
Degree of identification	Uncoded (personal data)	Project specific informed consent	General consent
	Coded	General consent	Right to dissent (opt-out)
	Anonymized	Right to dissent (opt-out)	Out of scope of HRA

[17] Dispatch of the Federal Council (fn. 9), 8121.

[18] Cf. JUNOD/ELGER, (fn. 19), n. 18.

[19] VALÉRIE JUNOD / BERNICE ELGER, Données codées, non-codées ou anonymes: des choix compliqués dans la recherche médicale rétrospective, Jusletter, 10 December 2018, n. 9.

[20] Further information on the technology used for data storage and transfer (BiomedIT): SIB Swiss Institute of Bioinformatics, dcc.sib.swiss.

[21] Sources: SAMW-Bulletin 3/2016, 3; SPRECHER FRANZISKA, General consent and Human research act, Presentation at SPHN public event, Berne 28. August 2017; JUNOD/ELGER, (fn. 19), n. 8.

Table 1: HRA-regulations on informed consent, general consent and opt-out clauses.

38 On this background, the additional criteria for underage patients are discussed hereafter.

3.3 Children and adolescents under the Human Research Act

3.3.1 Definitions of child and adolescent

39 The HRA contains special provisions for research with children and adolescents that start with *definitions*:

a) A *'child'* means a legal minor *under 14 years* of age (Article 3 letter j HRA);

b) an *'adolescent'* means a legal minor aged *14 years or more* (Article 3 letter k HRA);

c) A person is of age (*majority*) if he or she has reached the age of 18 years, According to Article 14 of the Swiss Civil Code.

40 In this legal report persons under 18 are accordingly designated as "*minors*" or "*underage patients*".

3.3.2 Subsidiarity of research with children: a constitutional principle

41 Swiss law considers minors as *particularly vulnerable persons*.[22] As a consequence the principle of subsidiarity takes a key role, which is laid down in Article 118b letter c of the Federal Constitution:

42 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.

43 This requirement is applicable for all persons who are particularly in need of protection and it is especially significant with regard to research involving children: in view of children's lack of decision-making capacity, the fact that research interventions in children may only be undertaken for scientifically compelling reasons represents the most important protective condition.[23]

44 The conclusion to be drawn for the present project is that *the harmonized data set should not go beyond underage patient data and samples that have to be collected*

[22] Cf. title of HRA, chapter 3; Swiss National Advisory Commission on Biomedical Ethics NEK-CNE, Opinion No. 16/2009, Research with Children, Berne 2009, p. 6, 17.

[23] Swiss National Advisory Commission on Biomedical Ethics NEK-CNE, (fn. 22), 11.

during clinical treatment anyway. In view of the current consensus, this requirement appears to have been met to the extent that the data only enters the SPHN environment if it is available out of a treatment context. There is no intention (nor funding) to collect samples and data that are not required therapeutically and only for future research projects. In this respect, the subsidiarity principle certainly represents a *caveat* to be observed at any stage of the project.

3.3.3 General requirement: best possible involvement

45 Corresponding with the rule of separate treatment of children and adolescents[24] and their increasing ability of judgement the following two general principles laid down in Article 21 HRA need to be taken into account:

a) First, that children and adolescents must be *involved as far as possible* in the consent procedure, and

b) Second, that *increasing weight* must be accorded to the views of children the older and more mature they are.

46 *Judgement* is generally presumed except in the case of infants, the severely mentally ill or the severely mentally handicapped. A person is therefore usually to be treated as capable of judgement unless the specific circumstances indicate otherwise. The result is that children's ability to judge is a *flexible criterion* that must be examined on a case-by-case basis and in relation to the specific research project.[25] It must be examined whether the minor in question is in a position

- to perceive the situation (cognitive faculty);
- to perceive the significance and scope of an action (ability to judge in the proper sense);
- to form his or her own judgement (decision-making faculty); and
- to act in accordance with this judgement (ability to act).[26]

47 The question was raised if a minor needs to confirm his consent once he reaches majority. The answer may be found in Article 7 para 2 HRA cited above. According to the rule a consent may be revoked at any time. When a patient capable of judgement reaches the age of majority, she or he is thus free to legally accept or revoke a consent given at earlier age by her or his legal representative.

48 Articles 22 and 23 HRA lay down the consent rules for *specific research projects* with minors. The severity of the rules differs depending on whether it is a research project with children or adolescents, whether the minor is capable of judgement or not, and

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[24] SPRECHER, FRANZISKA, Medizinische Forschung mit Kindern und Jugendlichen, 311.

[25] BGE 98 Ia 396, 102 II 367 und 117 II 231; GÄCHTER/RÜTSCHE, Gesundheitsrecht, 312.

[26] Dispatch of the Federal Council (fn. 9), 8112. Swiss National Advisory Commission on Biomedical Ethics NEK-CNE, (fn. 22), 11.

whether it's a research project with or without an expected direct benefit for the minor participants[27]. Table 2 below provides a condensed overview of the consent requirements depending on the characteristics of the project in question:

Research project	Without expected direct benefit	With expected direct benefit
Child **Capable of judgement**	Child: informed consent; and Legal representative: informed consent in writing, and Project with only minimal risks and burdens; and Expected substantial findings beneficial for persons with same problem	Child: informed consent; and Legal representative: informed consent in writing.
Adolescent **Capable of judgement**	Adolescent: informed consent in writing; and Legal representative: informed consent in writing if more than minimal risks and burdens.	Adolescent: informed consent in writing; and Legal representative: informed consent in writing if more than minimal risks and burdens.
Child **Lacking capacity**	Legal representative: informed consent in writing; and Child: no visible opposition either verbally or by behaviour, and Project with only minimal risks and burdens; and Expected substantial findings beneficial for persons with same problem	Legal representative: informed consent in writing; and Child: no visible opposition either verbally or by behaviour.
Adolescent **Lacking capacity**	Legal representative: informed consent in writing; and Adolescent: no visible opposition either verbally or by behaviour; and Project with only minimal risks and burdens; and Expected substantial findings beneficial for persons with same problem	Legal representative: informed consent in writing; and Adolescent: no visible opposition either verbally or by behaviour.

Table 2: Consent scheme in children and adolescent

[27] A research project with an expected direct benefit means a research project whose results can be expected to improve the health of the participants (art. 3 ltr. 3 HRA);

3.4 Discussion

55 The consent requirements set out above are now to be assessed against the background of the harmonised data set.

56 As explained above, the rules of the HRA presuppose an *existing research project* which should either yield a direct or at least indirect benefit. The data set, on the other hand, is about the coordinated safeguarding of data for further scientific use. Reference is therefore made to the remarks on the further use of patient data (3.1, above).

57 On the other hand, the question arises to what extent the specific HRA requirements concerning minors must be taken into account in every individual case once the harmonized data set is introduced in the clinics.

58 Since no concrete projects are concerned, no statement can yet be made about any direct or indirect benefit. Nor can we say anything about expected substantial findings beneficial to minors with same health conditions. The corresponding requirements for projects with no direct benefit (Table 2 left column, above) are therefore in my opinion not applicable to the collection of data as such. Rather, they but must be examined by the responsible ethics committee with regard to the concrete research project. But what can be said is that further risks and burdens for the minor can be ruled out, since data and samples are only to be re-used.

59 Furthermore, it has been stated that research with unconded biological material and genetic data always requires a project specific informed consent. Since research with genetic data in minors may be involved at a later stage, a mere right to opt-out by dissent is therefore not an option.

60 This leads to the *conclusion* that the focus must be on a *guarantee of data coding* so that the data set may be covered by one standard general consent of the minor and/or legal representative.

61 In this context, it is important to point out problems associated with coding (pseudonymization) and anonymization of health data: experts indicate that data such as blood samples can be traced back to a specific person without major technical difficulties (re-identification).[28] According to practitioners only a few individual levels of a person's blood sample may point to a specific person out of 10^5 samples. These obstacles must however be met with adequate safety measures set forth by SAMW and BiomedIT.

62 In addition, the consent requirements of the rules cited above are to be adopted, i.e. *written consent of the legal representative* and, whenever possible, *written consent*

[28] ECKHARDT, 163; SPRECHER, Datenschutz und Big Data, 516.

of the adolescent and informed consent of the child or at least no recognisable rejection when concerning minors lacking mental capacity.[29]

63 It has already been stated that the modalities of the written general consent with regard to use of technology and to practicability are not to be clarified in a paediatric context, but on a general level.[30]

3.5 Evaluation and revision of the Human Research Act

64 The HRA is currently being evaluated by the University of Zurich on behalf of the Federal Office of Public Health. The report is expected by the end of 2019 and will indicate the need for revision of the HRA.

65 Adoption of new approaches in the revised HRA, like dynamic consent, i.e. a digital communication interface that enables two-way communication between participants and researchers, would raise transparency levels in research and be beneficial for both sides.

4. Data protection

4.1 Preliminary remarks

66 This section now examines possible implications of general data protection law for the harmonised data set. Data protection refers to different types of personal data, of which patient or health data are only a part. Although data laws state only few rules on medical research, general governance standards can nevertheless be derived from it, which should be observed in everyday clinical practice (*infra*, 4.1).

67 On the other hand, it should be noted that Switzerland is lagging behind in regulating technological development. For example, the Swiss Act on Data protection (FADP) does not yet contain binding principles on data cloud applications or the collection of big data for no primary purpose ("data mining").[31] Therefore these aspects are not further detailed in this report. Clinics are called upon to work with the SAMS - and ultimately with the regulator - to develop best practices in the use of big data adapted to international standards.

68 Moreover, specific standards regarding health data use for medical research in the EU under new General Data Protection Regulation (GDPR) need to be taken into account (infra, 4.3).

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[29] Regarding assessment of mental capacity cf. Swiss National Advisory Commission on Biomedical Ethics NEK-CNE, (fn. 22), 17.

[30] *Supra*, n. 29, and footnote. 14.

[31] JUNOD, 72 ff., on transparency requirements and the case law of the European Court of Human Rights (ECHR), SPRECHER, Datenschutz und Big Data, 482.

4.2 Federal Act on Data Protection and revised Act

69 The Federal Act on Data Protection (FADP)[32] applies to data processing by *private persons*, e.g. a private lab or practitioner as well as *federal authorities* (Article 2 para. 1 FADP).

70 Data processing by cantonal bodies such as a cantonal university hospital is subject to the relevant *cantonal data protection law*, the provisions will thus vary slightly from one cantonal data protection act to another.

71 The FADP is currently undergoing a closely followed revision, with one of the aims being to adapt the Act to EU law. The bill has already been through both chambers of Parliament, although differences remain between them. Entry into force of a new act is not imminent and appears highly unlikely to happen before the end of 2020 at the earliest.

4.2.1 Partial Precedence of Human Research Act on Data Protection Act

72 The FADP or a relevant cantonal data protection act will thus, as a general principle, apply to data processing for scientific purposes such as considered in this report. Both the federal and most cantonal acts contain provisions facilitating data processing for research purposes (see *infra,* 4.2.3).

73 However, given the more specific ambit of the HRA or other specific regulation, where the latter contains a provision on the same issue as the FADP or applicable cantonal data protection act, such as e.g. consent, the provisions of the specific legislation will generally prevail over more general requirements of the relevant data protection legislation. In the dispatch on the HRA, the Federal Council expressly states that the provisions of HRA governing the further use of data for research purposes take precedence over the Data Protection Act (cf. Articles 13 and 22 of the Data Protection Act).[33] Other regulations in FDAP keep their relevance for medical research.

4.2.2 General principles

a) Federal Act on Data Protection (FADP)

74 Pursuant to the FADP, every instance of data processing, be it the collection, storage, disclosure, deletion or any other type of processing, must comply with a set of basic principles in order to be lawful (Articles 4, 5 and 7 FADP). Furthermore, data subjects, *i.e.* the individuals whose personal data is being processed, have a right to in-

[32] Federal Act of 19 June 1992 on Data Protection (FADP), SR

[33] Dispatch of the Federal Council (fn. 9), 8121. Former Article 32 FADP governing the federal secrecy committee has been repealed upon enactment of the HRA, see ROSENTHAL/JÖHRI, Handkommentar DSG 1st. ed. (2008), Art. 32 N 1 et sq.

formation regarding, *inter alia*, the data content relating to themselves, the origins of the data and the purposes of data processing (Article 8 FADP).

75 The basic principles are the following:

a) *Proportionality* (Article 4 para. 2 FADP); in particular, this includes the requirement that only the types of data strictly required for the purposes at hand be processed (data minimisation);

b) *Purpose restriction* (Article 4 para. 3 FADP): Personal data may only be processed for the initial purposes – such as indicated at the moment of collection, evident from the circumstances or provided for by law;

c) *Transparency* (Article 4 para. 4 FADP): The processing of personal data and in particular its purpose must be evident to the data subject;

d) *Correctness* of data (Article 5 FADP); persons processing personal data must take all reasonable steps to ensure that the data in question is correct or ensure correction or deletion of incorrect data; and

e) *Data security* (Article 7 FADP): protection of personal data against inadequate processing through adequate technical and organisational measures.

76 These principles are largely reflected in the HRA as far as they are not further specified for research purposes (*supra*, 3.2).

b) Cantonal Law

77 Most cantonal data protection laws contain largely similar principles. In the case of the Canton of Berne, cf. Article 5 of the Cantonal Data Protection Act (KDSG)[34].

4.2.3 Human research

a) Federal Act on Data Protection (FADP)

78 Under the FADP, data relating to the "health or intimate sphere" of an individual is considered *sensitive personal data* (Article 3 lit. c 2 FADP). As such, the following requirements apply to collection by *public federal bodies* of such data, its disclosure to third parties and processing for scientific purposes:

79 The *collection* of sensitive personal data by public federal bodies must be justified by one of the following means (Article 17 FADP):

a) Formal legal basis for the type of processing in question;

[34] Datenschutzgesetz vom 19.2.1986, Canton of Berne.

b) Processing must be indispensable in order to fulfil a task clearly set out by formal law; this could possibly be the case for hospitals with a legal mandate to conduct research in the field in question; or

c) Explicit consent on an *ad hoc*-basis.

80 Furthermore, when collecting personal data, public federal bodies must *inform* the individuals affected of at least the following (Article 18a FADP):

a) The identity of the controller of the data file (i.e. the entity with the power to decide on the purposes and means of processing);

b) The purpose of the processing (in this instance, both the provision of medical treatment and research);

c) The categories of data recipients if a disclosure of data is planned (in this instance, e.g. participants in the research network etc.);

d) The individual's right to information about the processing of personal data relating to the individual in question (Article 8 FADP);

e) The consequences of a refusal to provide the personal data in question.

81 *Disclosure* of sensitive personal data to third parties, e.g. a central research infrastructure platform managed jointly with third parties or by a third party only, must be justified by one of two means (Article 19 FADP):

a) Formal legal basis or indispensable nature of the data *in the case at hand* for the fulfillment of a task clearly set out by formal law; or

b) Explicit consent *ad hoc* of the individual concerned.

82 *Consent* relating to the processing of sensitive personal data must be given explicitly, tacit consent may not be presumed. In order for it to be valid, such explicit consent must be voluntary and given based on the provision of adequate information (Article 4 para. 5 FADP). However, in the light of the more specific regulation in human research law, the provisions of HRA take precedence over the FADP.

83 If the public federal authority intends to process the personal data for the *purposes of research,* planning or *statistics*, different rules apply. In a logical extension of the change of purpose, the purpose restriction (processing only for the purposes initially indicated, Article 4 para. 3 FADP – see *supra* para. 75) no longer applies.

84 Furthermore, the requirements relating to the justification of the *collection* of sensitive personal data or the *disclosure* of such data to third parties by one of the means set out above - legal basis, indispensable nature, explicit *ad hoc* consent (Articles 17 and 19 FADP) - no longer apply in such a case (Article 22 para. 2 FADP). This '*re-*

search privilege' is further specified in the conditions of Articles 31 et sq. HRA (supra, 3.2.2), which precede Article 22 FADP.[35]

b) Profiling under the Revised Act

85 Under the revised draft FADP as it currently stands, personal data relating to health, "genetic data" as well as "biometric data which unequivocally identify an individual" are all considered sensitive personal data.[36] The planned changes to the current situation regarding the research privilege may be described as negligible.

86 However, in accordance with EU law, the new draft introduces the term "profiling", defined as "the assessment of certain characteristics of a person on the basis of automatically processed personal data, in particular to analyse or predict (...) health (...)." In the project at hand, an instance of data processing would only be considered profiling if the prediction of health outcomes for future medical treatment on an individual were conducted in a fully automatic manner, using e.g. algorithms without human intervention.

87 Depending on future needs, research using children's health data may fall under the definition of "profiling". This fact, when compared with the research privilege as stated above, may lead to additional requirements regarding consent, legal basis or the need for preliminary approval from the Federal Data Protection Commissioner or, if applicable, an ethics committee. This would need to be clarified considering the facts of a particular instance of data processing.

c) Canton of Berne: Cantonal Act on Data Protection (KDSG)

88 In the following, the situation in the Canton of Berne is described in place of all other cantonal data protection regulations. It is therefore binding for the University Hospital of Berne (Insel) and other cantonal institutions.

89 The KDSG states that personal data relating to the "physical condition" of an individual is considered sensitive personal data (Article 3 para. 1 lit. b KDSG).

90 As a general rule, any kind of *processing* of sensitive personal data by public cantonal bodies is lawful under the following conditions (Article 6 KDSG):

a) It is provided by an explicit legal basis;

b) It is strictly necessary for the fulfilment of a statutory task of the authority in question; or

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[35] The conditions pursuant Article 22 para. 1 FADP are: a) the data is rendered anonymous as soon as the purpose of the processing permits; b) the recipient only discloses the data with the consent of the federal authority; and c) the results are published in such a manner that the data subjects may not be identified.

[36] See Article 4 letter c, no. 2, 3 and 4 of the Draft FDAP.

c) The data subject has provided explicit consent.

91 Provided this requirement is met, the *collection* of personal data is then subject to less additional requirements than at federal level; the data subjects are to be informed of the legal basis and the purpose of data processing only upon the latter's request or if personal data is collected systematically, namely with questionnaires (Article 9 para. 4 KDSG). Where the provision of personal data by the data subject is not mandatory, this must be indicated at the time of collection (Article 9 para. 3 KDSG).

92 The *disclosure* of personal data to other public authorities must be justified by one of the following means (Article 10 para. 1 KDSG):

a) The public cantonal authority responsible for the disclosure is obliged or authorised by law to disclose the data in order to fulfil its statutory tasks;

b) The authority requesting personal data proves that it is legally entitled to process the data and that it is not subject to any obligation of confidentiality; or

c) Despite the incompatibility of the purposes, the data subject has expressly consented or the disclosure is in his/her interest.

93 The processing of personal data for *research purposes* is authorised by cantonal law provided that the public authority (Article 15 para. 1 KDSG):

a) Uses the personal data anonymously or at least without direct personal identification as soon as the processing purpose permits; and

b) Discloses the results of the processing in such a way that the persons concerned cannot be identified.

94 In the same way, the relevant cantonal law allows disclosure to third parties for research purposes, subject to adequate assurance that the recipient of the data fulfils the above requirements relating to the use and disclosure of data, that personal data are not disclosed to further third parties and that the recipient ensures that relevant safety measures are undertaken (Article 15 para. 2 KDSG).

95 With regard to these requirements, it must again be assumed that the provisions in the HRA, as a federal, specific regulation, take *precedence over the cantonal rules*.

96 The Berne cantonal law does not specify whether this specific provision means that the data subject's consent to the use of its sensitive personal data for research purposes is no longer necessary, given the existence of a specific legal basis concerning research. Although Article 15 KDSG certainly constitutes a formal legal basis for the processing of personal data for research purposes and thus can provide the necessary justification, it is nevertheless advisable to include research purposes in the data subject's consent as stated in the discussion on HRA (*supra*, 3.4).

4.3 European data protection regulation with regard to research

4.3.1 Relevance for Switzerland

97 Upon enactment of the EU General Data Protection Regulation (GDPR)[37] in May 2018 data protection has become paramount in businesses throughout Europe. Because the GDPR is not binding for Switzerland, federal or cantonal data protection commissioners or courts may not apply it. However it is questionable whether EU authorities may enforce the rules against Swiss enterprises and here in particular hospitals if the rights of European citizens are infringed. In theory GDPR has such extraterritorial effect on data processors and controllers in Switzerland.[38]

98 An important aspect is that the data protection regulation in Switzerland has been deemed as conform to GDPR by the European Data Protection Board, which facilitates cross border exchange of personal data. At the same time Swiss clinicians and researchers need to have guarantees that data transferred into foreign countries is treated by the same standards as applied in Switzerland.

99 It would go beyond the scope of this investigation to examine GDPR in its high degree of detail. As a consequence, an outline on GDPR regulations regarding research and minors is provided thereinafter.

4.3.2 Core principles

100 The General Data Protection Regulation (GDPR) seeks to ensure the free movement of data throughout the European Union (EU) and give expression to the right to personal data protection within and beyond the EU, as long as an EU data subject's data or data collected in the EU are being processed. It details the lawful basis of the processing of data and delineates prohibitions for processing special categories of data, such as health and genetic data, sets out the conditions for consent, outlines the individual rights of data subjects, and provides data subjects with a mechanism to enforce their rights.

101 Article 4 GPDR defines the notions of 'genetic data' (13) and 'data concerning health' (15) and treats them as *sensitive data* thus in the way it is qualified Swiss data protection.[39] The principles of processing are comparable or identical to those of the FDAP listed above (Articles 5 et seq. GDPR).[40]

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[37] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), L119, 4 May 2016, p. 1-88.

[38] See examples in the Guidelines 3/2018 of the European Data Protection Board.

[39] Recital 10 of GDPR.

[40] KAZEMI, 83.

4.3.3 GDPR research exemption

102 With regard to human research and biobanks, Article 89 GDPR contains key provisions.

103 Article 89 GDPR provides for processing of data for scientific research purposes, if there are appropriate *safeguards* for the rights of the person involved. While the GDPR does not exhaustively specify what those safeguards are, it indicates their purpose is to 'ensure that technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation.' These measures may include pseudonymisation provided it enables meeting the intended research purposes.[41]

104 With regard to human research, the European Data Protection Board has recently issued an opinion on the *interplay between the EU Clinical Trials Regulation (CTR) and the GDPR* in 2019.[42] The opinion addresses specifically the issue of *secondary use* of data with a specific focus on consent:

> "Article 5(1)(b) GDPR provides that where data is further processed for archiving purposes in the public interest, scientific, historical research or statistical purposes, these shall a priori not be considered as incompatible with the initial purpose, provided that it occurs in accordance with the provisions of Article 89 GDPR, which foresees specific adequate safeguards and derogations in these cases. Where that is the case, the controller could be able, under certain conditions, to further process the data without the need for a new legal basis. These conditions, due to their horizontal and complex nature, will require specific attention and guidance from the EDPB in the future. For the time being, the *presumption of compatibility*, subject to the conditions set forth in Article 89, should not be excluded, in all circumstances, for the secondary use of clinical trial data outside the clinical trial protocol for other scientific purposes."[43]

105 The interplay between the CTR and GDPR will therefore undergo further assessment by the EDPB, for the time being further use of health data for scientific research appears to be deemed compatible with the initial purpose.

106 Furthermore, the WP 29 Guidelines on Consent contain provisions with regard to Article 8 GDPR regulating consent of children. However the Guidelines do not refer directly to research, rather to so-called "information society services", i.e. commercial

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[41] STAUNTON, CIARA / SLOKENBERGA, SANTA / MASCALZONI, DEBORAH, 1164.

[42] European Data Protection Board, Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR) (art. 70.1.b)), 23 January 2019, Brussels 2019.

[43] European Data Protection Board, Opinion 3/2019 (fn. 42), 8.

digital services.[44] Guidelines involve the appropriate consent by either the child or the legal representative.

5. Other laws with relevance for the harmonized data set

5.1 Cancer Registration Act and other statutory registries

107 In research law, the focus is on the question of the admissibility of projects and individual consent requirements. A different perspective is taken by registration laws. According to the Federal Cancer Registration Act (CRA)[45] and the respective ordinance, which come into force on 1 January 2020, physicians and hospitals are obliged to collect data for each diagnosis of cancer. Pursuant to Article 14 para 2 ltr. d CRA, the national cancer registration agency collects the data and prepares them for further use in research.

108 Patient rights will not extend to informed consent, but to a mere opt-out clause according to which the persons concerned or their legal representatives can object to the use of the data after having been sufficiently informed (Article 6 CRA).

109 Without going into the CRA and other registration laws in more detail, it must be pointed out here that, in addition to the Research Act, there are *other laws of importance for data collection in clinics*. As mentioned above, the regulations in the field of oncology in particular partly derogate the approval requirements from research law.

110 In the opinion held here, it would be too far-reaching to introduce specific requirements for different categories of data and samples collected for the purposes of the harmonised data set. The question is to be discussed among the clinics from the point of view of practicability and compliance. *Uniform handling* among the participating institutions is, however, strongly recommended.

5.2 Medical secrecy

111 Another essential aspect in the context of the harmonized data set is medical professional secrecy, laid down in Article 321 para. 2 Swiss Criminal Code. Large sections of the data set concern information protected by medical secrecy such as diagnoses or laboratory values.[46]

112 As a consequence, further data use in research is in most cases accompanied by a disclosure of professional secrecy. In this case it is advisable to request at the same time

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[44] See also KAZEMI, 110.

[45] Bundesgesetz vom 18. März 2016 über die Registrierung von Krebserkrankungen (Krebsregistrierungsgesetz, KRG), SR 818.33.

[46] GÄCHTER/SCHÜTZE, Gesundheitsrecht, n. 370.

that the person or clinic concerned *be released from professional secrecy* when making the request regarding the extraction of the material or the collection of the data.[47]

5.2.1 Electronic health record

113 The Federal Act on the Electronic Patient Record (EHRA)[48] regulates the framework conditions for the introduction and dissemination of electronic patient files. The aim of the electronic patient file is to strengthen the quality of medical treatment, improve treatment processes, increase patient safety and the efficiency of the healthcare system and promote patients' health competence. The file is used within a context of therapy – even "a concrete case of treatment"[49] – and the act does not make any reference to scientific research.

114 It should be mentioned here that Article 3 para 1 EHRA stipulates that consent to the creation of an electronic patient file must be given in writing. If consent is given electronically, the written form is deemed to have been complied with if the consent is signed with an electronic signature that meets the requirements of the Swiss Code of Obligations.[50]

115 With regard to questions raised as to *linking a minors electronic health record* to those of family members or third party registries, such as STATPOP, the law does not contain specific provisions. In view of the fact that the EHRA is confined to a treatment context, it cannot be ruled out that certain restrictions apply as to the linking of existing data sources. This aspect should be further examined.

5.3 Cantonal patient and hospital laws

116 Furthermore, on the cantonal level, health, patient and specific hospital acts must be taken into consideration. By comparison, these laws appear very heterogeneous, reaching from mere institutional decree[51] to comprehensive regulation[52]. Insofar as they treat patients' rights, the focus is on self-determination, i.e. right to information, informed consent and access to documents.[53]

117 It may also be mentioned in this context that cantonal hospital and patient laws require electronic hospital information systems that meet (at least) the local data protection standards. The institutions participating in the harmonised data set must therefore ensure that the adopted procedure complies with the cantonal regulations

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[47] Dispatch of the Federal Council (fn. 9), 8107.

[48] Bundesgesetz vom 19. Juni 2015 über das elektronische Patientendossier (EPDG) SR 816.1.

[49] Cf. wording of art. 2 ltr. a EHRA.

[50] Dispatch of the Federal Council, BBl 2013 5321, 5376.

[51] I.e. Spitalgesetz Kanton Basel-Landschaft, SR BL 930.

[52] I.e. Patientinnen- und Patientengesetz Kanton Zürich, SR ZH 813.13.

[53] I.e. § 32 Spitalgesetz Kanton Luzern, SR LU 800a; §§ 20 et seq. Patientengesetz ZH (n. 52).

applicable to them. These individual cantonal aspects can be further elaborated if necessary.

5.4 Federal laws without a direct project reference

118 A certain number of other federal acts contain provisions on research or on the use of sensitive personal data in health care. However, insofar as they have no direct reference to the present project, they are not further assessed in this context. For the sake of clarity, a few laws of general relevance are mentioned below.

5.4.1 Human Genetic Testing

119 The Federal Act on Human Genetic Testing (HGTA)[54] stipulates the conditions under which human genetic testing may be performed, .i.a., in the medical context. The Act does however not apply any longer to genetic testing performed for research purposes (Article 1 para 3 HGTA). For this reason, the HGTA does not play a crucial role in the context of the present project aimed at a harmonised data set for research, even if genetic information is collected from minors in individual cases. The HGTA will therefore not be discussed in more detail here.

5.4.2 Embryonic stem cells

120 The Federal Stem Cell Research Act, (StRA)[55] sets out conditions for the use of surplus human embryonic stem cells in research. Thus, the law concerns a different field of research than paediatrics, which is why it is not appropriate to address it here.

5.4.3 Health insurance (data protection provisions)

121 Health insurance law[56] contains numerous provisions on the exchange and processing of data. These relate to specific areas of responsibility within the scope of health insurance and do not refer to data collection for research purposes. The provisions on file inspection may be of relevance. These are dealt with in the chapter on data protection.

6. ELSI aspects

122 The Ethical, Legal and Social Implications advisory group (ELSIag) as advisory body to the SPHN has addressed the respective challenges and set forth an Ethical Frame-

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[54] Federal Act of 8 October 2004 on Human Genetic Testing (HGTA), SR 810.12.

[55] Federal Act of 19 December 2003 on Research Involving Embryonic Stem Cells (Stem Cell Research Act, StRA), SR 810.31.

[56] In particular art. 84 et sqq. Swiss Federal Act of 18 March 1994 on Health Insurance (Bundesgesetz vom 18. März 1994 über die Krankenversicherung (KVG)), SR 832.10; art. 47 Federal Act of 6 October 2000 on the General Part of the Social Insurance (Bundesgesetz vom 6. Oktober 23000 über den Allgemeinen Teil des Sozialversicherungsrechts (ATSG)), SR. 830.1.

work for Responsible Data Processing in Personalized Health Research.[57] The Framework provides ethical guidance to the partners of SPHN as to the collection, storage, analysis and sharing of personal data for research purposes.

Summary on findings and recommendations: see *supra*, Section A-

[57] Swiss Personalized Health Network, ELSI Advisory Group, Ethical Framework for Responsible Data Processing in Personalized Health Research, Version 2, Bern 2018.

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