INSELGRUPPE

Chairman of the Executive Board
Legal & Compliance

DATA PROTECTION and PROFESSIONAL CONFIDENTIALITY

with particular application to research

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B. Data Protection

C. Professional Secrecy

D. Consent to Further Use for Research

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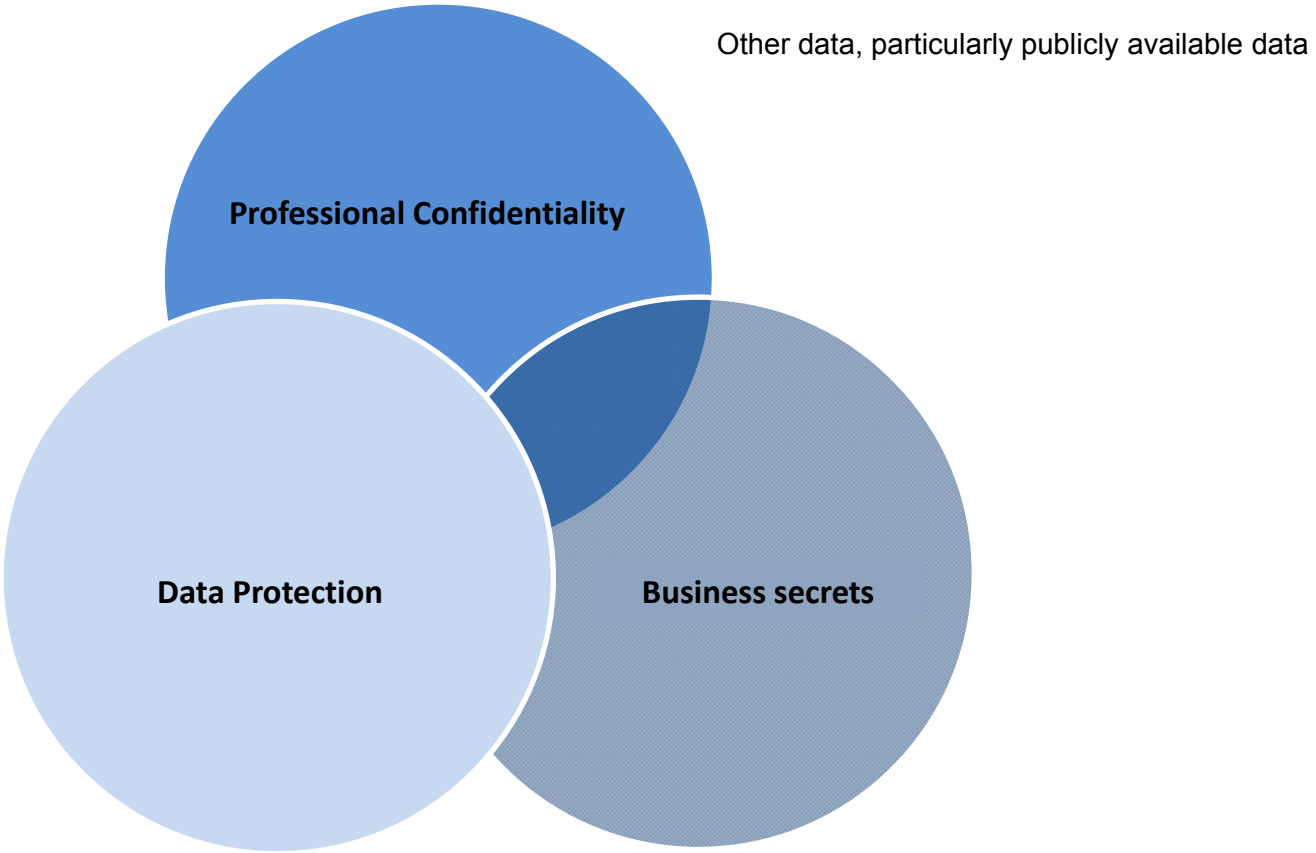
A. Categorization of Data



B. Data Protection

Data protection = Protection of personal information

«This law is designed to protect people from improper data processing by authorities.»
(Art. 1 of the Swiss Cantonal Data Protection Act (KDSG)

Personal Data

is all information about an identified or identifiable natural (or legal) person.

Processing

covers all the ways in which personal information can be handled, such as its procurement, storage, alteration, linking, circulation or destruction.

Disclosure

includes any means of enabling access to personal information, such as providing access, giving information, transmitting or publishing.

Further use for Research

Further use of biological materials and health-related personal information is defined as any use for research purposes of biological material which has already been sampled or data that has already been collected, including procuring and collecting, registering and cataloguing, storage and inclusion in biobanks or databases, or making accessible, making available or transferring such material or information (see Art. 24 of the Swiss Human Research Ordinance (HFV)

B. Data Protection

General Principles of Data Protection

Limitation of Purpose

Personal data may only be processed for the purpose specified in the procurement or which is evident from the circumstances.

Proportionality:

The processing of the data must be appropriate and necessary for the achievement of the intended purpose.

Data Access

Access to the data must be restricted to persons who need the data in order to fulfil their task.

Data Backup:

All data must be protected against loss and unauthorized processing through the application of appropriate technical and organizational measures.

B. Data Protection

Patient Data

Information that falls within the scope of confidential personal information, particularly where it concerns the emotional, mental or physical condition of a person, is regarded as **particularly sensitive personal data**.

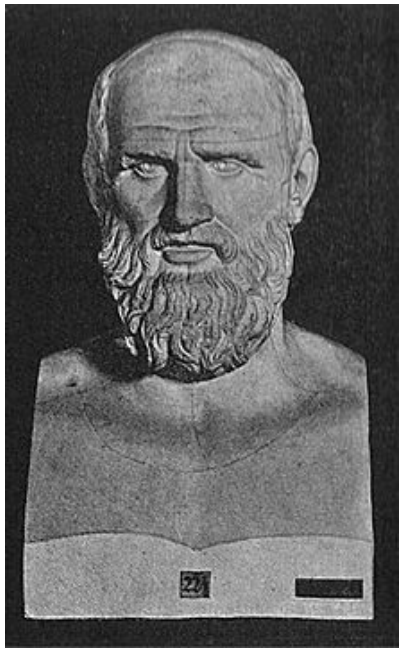
CAUTION:

The processing of personal data demands **more stringent requirements**.

Patient data are also subject to **professional secrecy**.

C. Professional Confidentiality

Professional Confidentiality = Protection of the relationship of trust



Source: Wikipedia

Art. 27 * Obligation to secrecy

[1] The specialist is obliged not to divulge to a third party any information confided to him or her by his or her patients or which the specialist comes to know during his or her treatment of the patient.

[2] The obligation to secrecy is waived if the patient or the competent department of the Gesundheits- und Fürsorgedirektion [Department of Health and Social Affairs] has authorized the disclosure of information or if there is a legal obligation to disclose or permit access to such information.

Canton of Bern Public Health Act (GesG; BSG 811.01)

Specialists, as defined by the GesG
Doctors, pharmacists, midwives and doulas, qualified nurses, paramedics, nutritionists, etc.

C. Professional Secrecy

Breach of professional confidentiality is punishable by law

Basic provision in Art. 321 of the Swiss Criminal Code (StGB; SR 311.0)

Art. 321

Breach of professional confidentiality

1.Clergy, lawyers, defence lawyers, notaries, patent agents, auditors subject to an obligation to secrecy under the Law of Obligations[322], doctors, dentists, chiropractors, pharmacists, midwives, psychologists, and their assistants who disclose confidential information confided to them in their professional capacity or which they have learned in the exercise thereof may, on complaint, be liable to a fine or a term of imprisonment of up to three years.[323]

Students, who disclose confidential information that they have learned during their studies, are also subject to criminal penalties.

A breach of professional secrecy is punishable by law even after the termination of studies or the exercise of a profession.

C. Professional Confidentiality

Legal penalties also apply to persons who divulge a professional secret, which they **have learned during a research activity as defined by the Swiss Human Research Act** (HFG): Art. 321 StGB

Professional secrecy in human research

Art. 321[to 324]

[1] Any person who discloses without authorisation a professional secret he has learned through his activity in human research in accordance with the Human Research Act of 30 September 2011[325], shall be subject to criminal penalty under Article 321.

[2] Professional secrets are permitted to be disclosed for research concerning human diseases and concerning the structure and function of the human body, if the requirements of Article 34 of the Swiss Human Research Act of 30 September 2011 are met and the responsible ethics committee has approved the disclosure.

C. Professional Confidentiality

Disclosure of patient data is

PERMITTED **WITHIN the treatment/administration team**	This includes all personnel involved in the treatment and administration process.
NOT PERMITTED to any **THIRD PARTY**	This includes all persons who are NOT involved in the treatment or administration process. Particularly **researchers**

The disclosure of patient data **to third parties is permissible** if there are **justifiable grounds.**

Primary justification: **Consent of the person concerned**

D. Consent to Research

RESEARCH INVOLVING HUMAN BEINGS:

Art. 118b of the Swiss Federal Constitution (protection of dignity and privacy)

Swiss Federal Act on Research involving Human Beings (Swiss Human Research Act; HFG SR 810.30)

[1] This law applies to research concerning human diseases and concerning the structure and function of the human body, which involves:

a. persons;
b. deceased persons;
c. embryos and foetuses;
d. biological material
e. health-related personal data.

[2] It does not apply to research that involves

a. IVF embryos in accordance with the Swiss Cell Research Act of 19 December 2003 (1);
b. anonymised biological material;
c. anonymously collected and anonymised health-related data.

Research with **anonymously collected** or **anonymised** health-related data is not subject to the HFG

BUT: **Anonymisation** of biological material and genetic data for a research project is subject to Art. 32 HFG (right of dissent)

D. Consent to Research

Uncoded data: The patient is identifiable. The data set used for the research is neither encrypted nor anonymised.

Coding ("pseudonymisation"): All data which can be traced to an actual person are replaced by neutral information (pseudonym). A correspondence table is used to determine which pseudonym corresponds to which identifiable data. The correspondence table ("key") is in the custody of a person who is not involved in the research project. The key is kept in a different location than the pseudonymised data.

Anonymisation: The identifiable data itself and all possibilities to recover the original data are made unrecognizable or deleted, particularly names, addresses, dates of birth and unique identification numbers. The person can no longer be identified, or can only be identified with extraordinary effort, and the process is irreversible.

Anonymisation and coding/decoding within the framework of the HFG:
Legal provisions of the Swiss Federal Council in Art. 25 - 27 HFV

D. Consent to Research

Guiding principle

Processing of data only with the **consent of the patient** or if justified on legal grounds

Art. 7 HFG:

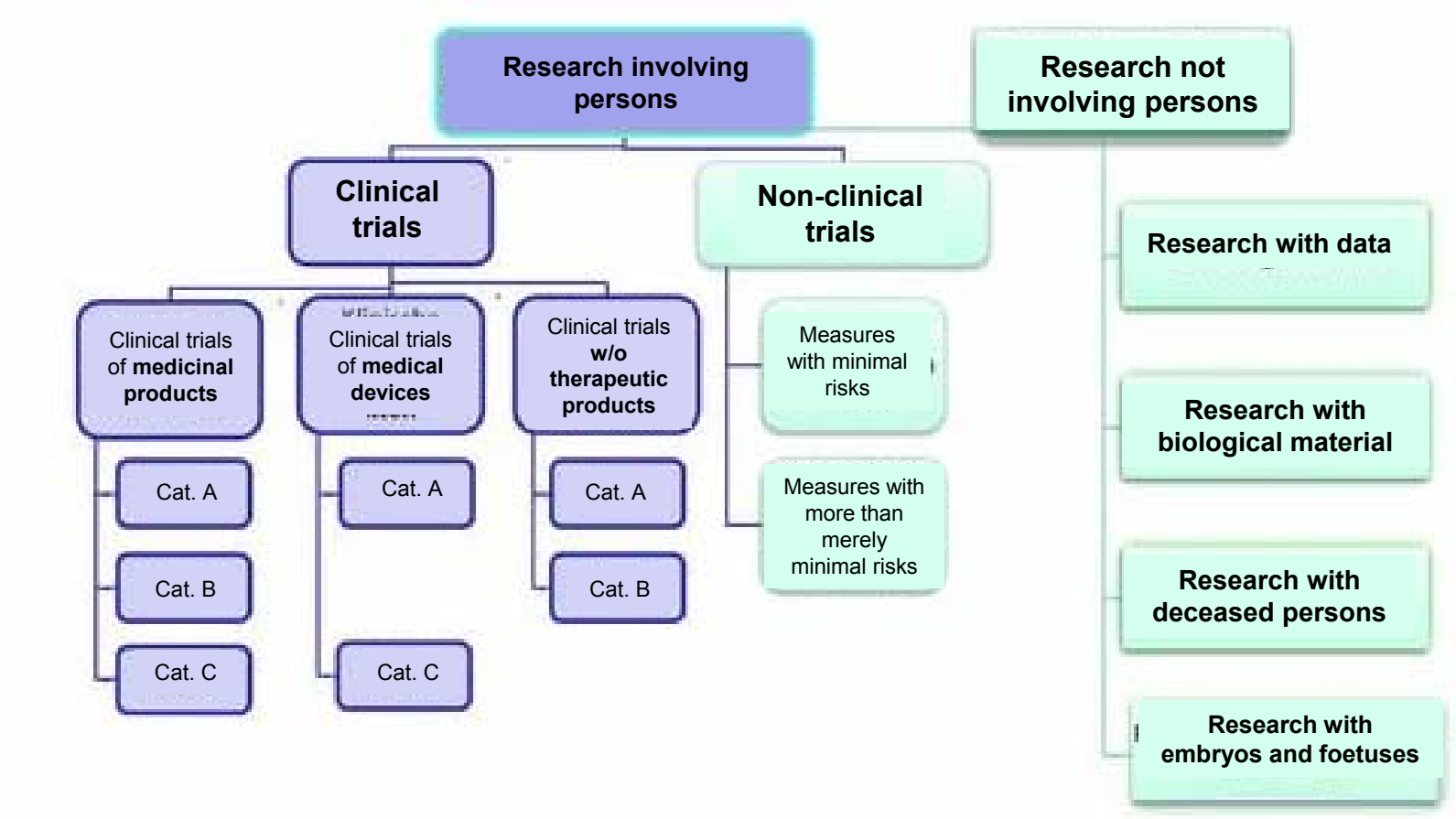
Art 7 Consent

[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.

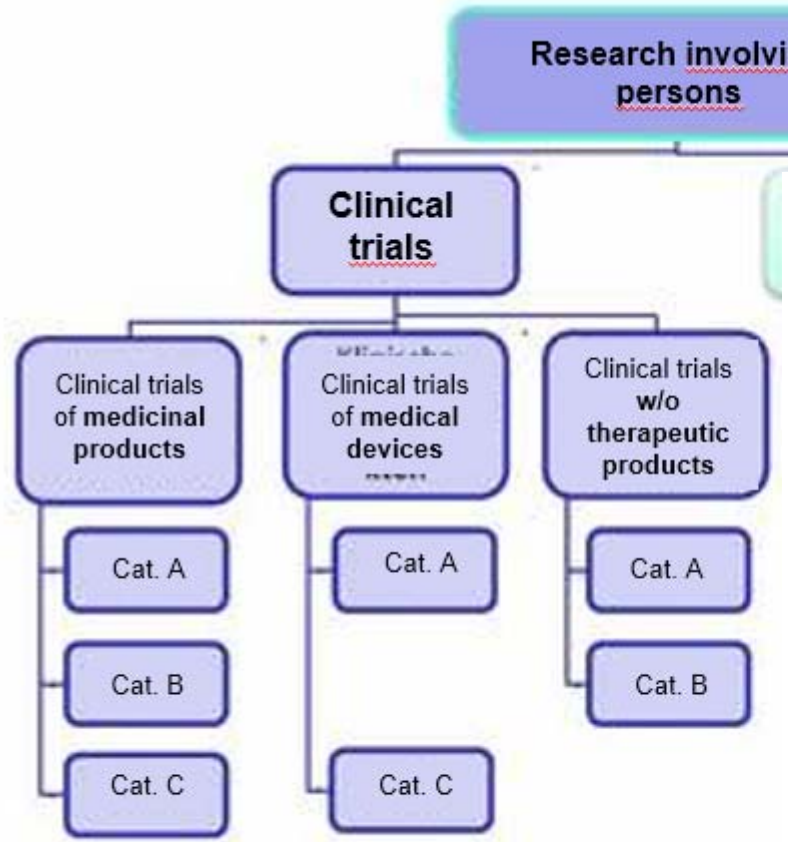
The Act specifies different stringent requirements for consent, **depending on the individual research projects and the nature of the data**

D. Consent to Research



Source: Swiss Federal Office of Public Health (BAG)

D. Consent to Research



Research involving persons
⇨ **Informed consent**

Art. 16 Informed consent

[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.

[2] The person concerned must receive comprehensible oral and written information on:

a. the nature, purpose and duration of, and procedure for, the research project;
b. the foreseeable risks and burdens;
c. the expected benefits of the research project, in particular for themselves or for other people;
d. the measures for protecting the personal data that has been collected;
e. their rights

3 Before the person concerned decides to consent, they must be given a reasonable period of time for consideration.

plus **required prior information in accordance with Art. 7 of the Swiss Ordinance on Clinical Trials (KlinV) !**

D. Consent to Research

Research **not involving persons**

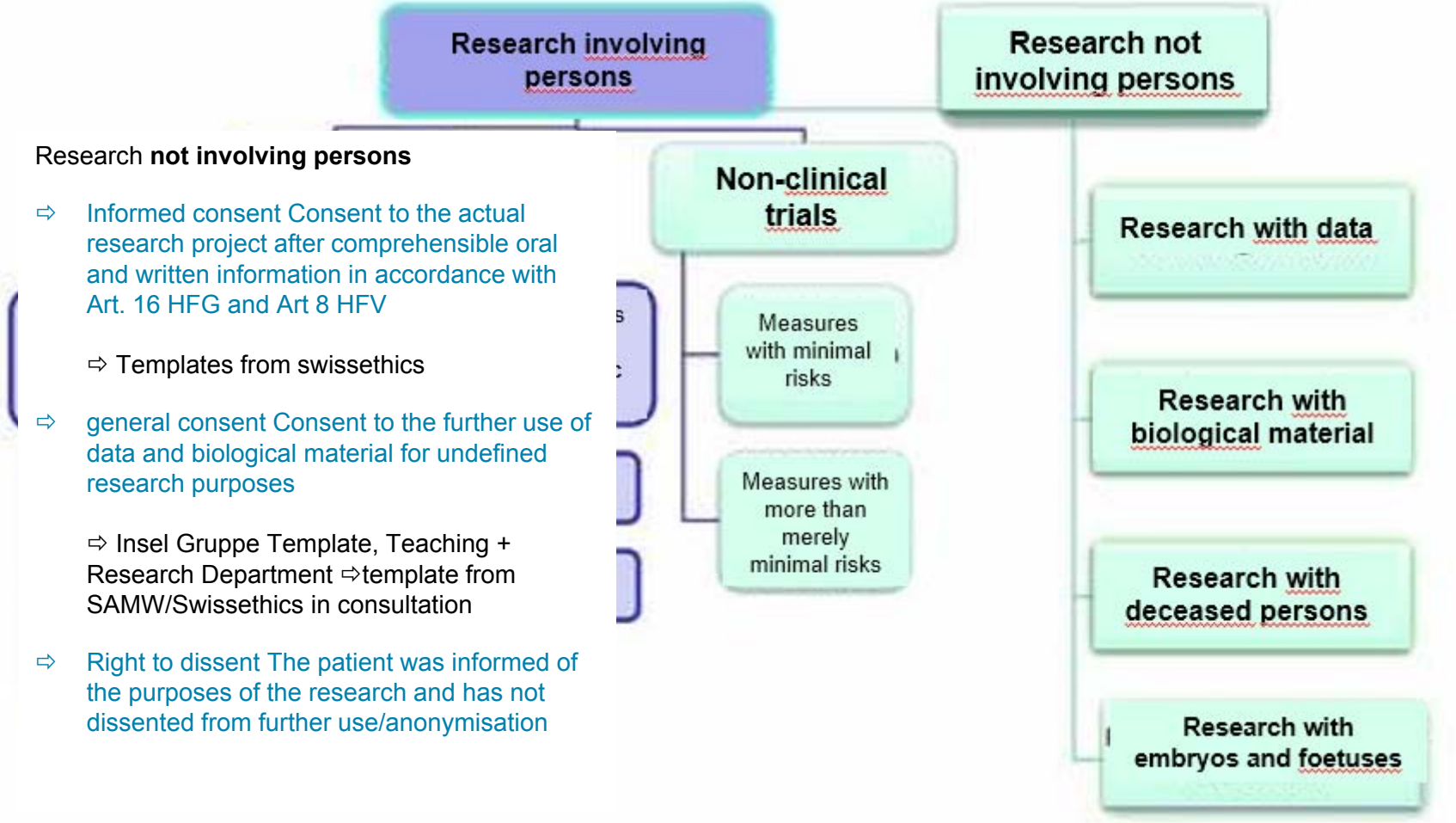
- ⇨ Informed consent Consent to the actual research project after comprehensible oral and written information in accordance with Art. 16 HFG and Art 8 HFV

  ⇨ Templates from swissethics

- ⇨ general consent Consent to the further use of data and biological material for undefined research purposes

  ⇨ Insel Gruppe Template, Teaching + Research Department ⇨template from SAMW/Swissethics in consultation

- ⇨ Right to dissent The patient was informed of the purposes of the research and has not dissented from further use/anonymisation



D. Consent to Research

Overview of consents under the HFG

"Subject" The form of further use	biological material and genetic data (Art. 32 HFG)	non-genetic health-related personal data (Art. 33 HFG)
uncoded (identified)	for a (specific) research project with informed consent	(generally) for research purposes with informed consent
uncoded (pseudonymised)	(generally) for research purposes with informed consent	(generally) for research purposes without dissent
anonymised	(generally) for research purposes without objection to anonymisation	permissible without further consideration

Beat Rudian, Introductory Remarks Art. 32-35 HFG; in: Rütsche (publisher), Stämpflis Handkommentar Humanforschungsgesetz [Handbook, Swiss Human Research Act]

D. Consent to Research

Exception:

Research **without** the consent of the person concerned

(HFG)

Art. 34 Absence of informed consent and information (HFG)

If the requirements for informed consent and information specified in Articles 32 and 33 are not met, further use may be made of biological material or health-related personal data for research purposes in exceptional cases if:

a. 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; (and)
b. there is no documented refusal; and
c. the interests of the research outweigh the interests of the person concerned in deciding on the further use of his or her biological material and data.

D. Consent to Research

Overview of Further Use

Further use of biological material and health-related personal data for research		a) not informed about research **OR** b) dissent (patient was informed in advance and has made use of this right)	No dissent (patient was informed in advance and has **NOT** made use of this right and has not signed any further consent)	General Consent (informed consent)	Informed Consent (study-specific consent)
Non-genetic health-related personal data (Art. 33 HFG)	anonymised	√	√	√	√*
	coded	X	√	√	√*
	uncoded	X	X	√	√*
Genetic data (Art. 32 HFG)	anonymised	X	√	√	√*
	coded	X	X	√	√*
	uncoded	X	X	X	√*
Biological material/residual material (Art. 32 HFG)	anonymised	X	√	√	√*
	coded	X	X	√	√*
	uncoded	X	X	X	√*
Deceased persons: residual material in connection with an autopsy or transplantation (Art. 38 HFG)	anonymised	X		√	√*
	coded	X	X	√	√*
	uncoded	X	X	X	√*

*The kind of use has to be defined in Informed Consent; it may vary from study to study.

E. Storage of Research Data

Art. 18 KlinV; Art. 5 HFV

1 Any person who stores health-related data for research must ensure its protection through the adoption of appropriate operational and organizational measures, in particular by:

a. restricting the handling of the health-related personal data to those persons who require this data to fulfil their duties;
b. preventing the unauthorized or accidental disclosure, alteration, deletion and copying of health-related personal data;
c. recording all processing operations that are essential for ensuring traceability.

2 Any person who stores biological material must, in particular:

a. comply with the principles set out in paragraph 1, with any necessary alterations
b. ensure that the technical requirements are met for appropriate storage of biological material;
c. make available the resources required for storage.

E. Storage of Research Data

Protecting research data using the example of the database in the Insel Gruppe

1. Directive Standards for data bases with health-related personal data in research

4. Specific requirements for the databases
Databases used in research must meet the following requirements:

a. Access and user control: Only those individuals who are participating in the research project, have access to the relevant databases.
b. Personal login authentication: the person who has access to the database must be clearly identifiable.
c. Access control/Traceability: All processes that are relevant for ensuring traceability must be documented. To this end, all accesses, entries, alterations and deletions must be logged in the database in a consistent manner. The database in which the data is stored must be technically suitable for this purpose (Please Note: Excel tables usually DO NOT meet these requirements).
d. Storing access logs: All accesses must be able to be retrieved and traced at a later date. Consequently, the corresponding access logs must be kept in accordance with the retention period of the research project (see also section 5.11 below).

⇨**Login**

⇨**defined user rights/roles**

⇨**Audit trial**

2. Obligation to report

The Teaching + Research Department maintains a database (IRDIS) which holds all of the Insel Gruppe's research databases. There is an obligation to report: Every research database must be registered in IRDIS.

3. IT Solutions

The Teaching + Research Department, together with CTU Bern, provides various solutions for storing data in databases, which meet the legal requirements.

E. Storage of Research Data

Protecting research data using the example of the biobank

BIOBANK BERN

Liquid Biobank Bern LBB

BIOBANK BERN
LIQUID

Weitere Informationen

Tissue Bank Bern TBB

BIOBANK BERN
TISSUE

Weitere Informationen

E. Storage of Research Data

Example: Biobank Regulation relating to research projects involving human beings/**Liquid Biobank (LBB)** in the Inselspital [University Hospital] Bern

Requirements, particularly for

- **separate storage** of health-related data (including identifying information) and the samples: Storage of the key is separated from the samples and data by a person who is not involved in the research projects;
- Data are stored identifiably; **Decoding** (re-identification) only after a decision by the advisory committee of the LBB;
- Sharing of data and samples, in principle in **encrypted (pseudonymised) form**, (for research projects or other biobanks)
- Sharing of identifiable data and samples only with «**informed consent**»
- Sharing of samples only if there is a **Material Transfer Agreement** (MTA)

F. Important Information Sources

- **Swiss Federal Act** on Research involving Human Beings (HFG: SR 810.30)
  Swiss Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HFV; SR 810.301)
  Swiss Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance, KlinV; SR 810.305)

  available at https://www.admin.ch/gov/de/start/bundesrecht/systematische-sammlung.html
- **SAMW Handbook** «Research with Human Subjects» is available at http://www.samw.ch/en/Publications/Handbooks.html
- **Swiss Ethics Commissions on research involving humans** (swissethics, available at http://www.swissethics.ch/index_e.html)
- **CTU Bern** (Clinical Trial Unit, University of Bern; available at www.ctu.unibe.ch)
- **Unitectra** (available at www.unitectra.ch/en)

F. Questions and Suggestions