

Data protection, rights, and health-related research

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Disclaimer

- > All content based on **my (strict) interpretation** of relevant regulations
 - > Although all slides/content was checked carefully: Errors and omissions expected (E&OE)
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English vs. German (incl. abbreviations)

English

- > Clinical Trials Ordinance (ClinO)
- > Federal Act on Data Protection (FADP)
- > Federal Office of Public Health (FOPH)
- > Human Research Act (HRA)
- > Human Research Ordinance (HRO)
- > Swiss Ethics Committees on research involving humans (Swissethics)

German

- > Verordnung über klinische Versuche (KlinV)
 - > Datenschutzgesetz (DSG)
 - > Bundesamt für Gesundheit (BAG)
 - > Humanforschungsgesetz (HFG)
 - > Humanforschungs-verordnung (HFV)
 - > Schweizerische Ethikkommissionen für die Forschung am Menschen
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Approval and consent («Bewilligung» and «Einwilligung»)

- > (Independent) ethics committee
 - Assesses research project/question and **appropriateness** of study-related procedures (incl. qualification)
 - > Study participants
 - Approve (consent to) the usage of **their** data
 - No specific research question, no approval needed
 - BUT: Consent by study participants always needed (data sovereignty; it is their data!)
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Terminology

- > Trial == experimental study
 - Controlled conditions
 - Often randomized but necessarily (dose-finding studies, single-arm studies)
 - > Study == research project
 - Prospective or retrospective
 - General term including trials
 - Specific (research) question to be answered
 - > Research project
 - Described in a protocol
 - Approved by ethics committee (and regulatory authority)
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Relevant (useful) regulations

- > Human Research Act
 - Clinical Trials Ordinance
 - Human Research Ordinance
- > International Council on Harmonization Good Clinical Practice (E6)
- > Kantonales Datenschutzgesetz (KDSGG/CDPA)
 - Datenschutzverordnung (DSV)
- > Council of Europe Convention 108
- > Strafgesetzbuch (Art. 321^{bis})
- > Leitfaden – Schweigepflicht von Gesundheitsfachpersonen (GEF Bern)
- > European Union General Data Protection Regulation (GDPR)
- > United States Health Insurance Portability and Accountability Act (HIPAA)

Important definitions

> Personal data

— Any information relating to an identified or identifiable individual („data subject“)

> Data processing

— All operations on personal (!) data e.g. collection, storage, preservation, alteration, retrieval, disclosure, making available, erasure, or destruction of, or the carrying out of logical and/or arithmetical operations

> Controller

— decision-making power with respect to data processing

> Processor

— processes personal data on behalf of the controller

Principles (e.g. DSG/FADP Art. 4; CDPA Art. 5)

1. Personal data may only be processed lawfully
2. Processing must be proportionate
3. Processing for the purpose indicated at the time of collection
4. Collection and purpose (of processing) must be evident to data subject
5. Informed, voluntary consent

Sensitive data

> Definition e.g., CDPA Art. 3

— ... *a person's intimate sphere, and in particular his or her psychological, mental or physical condition ...*

> Permissibility (CDPA Art. 6)

— ... *Personal data may be processed only if the law expressly authorises it ...* (→ Human Research Act)

Scope (Art. 2 HRA)

Art. 2 Scope

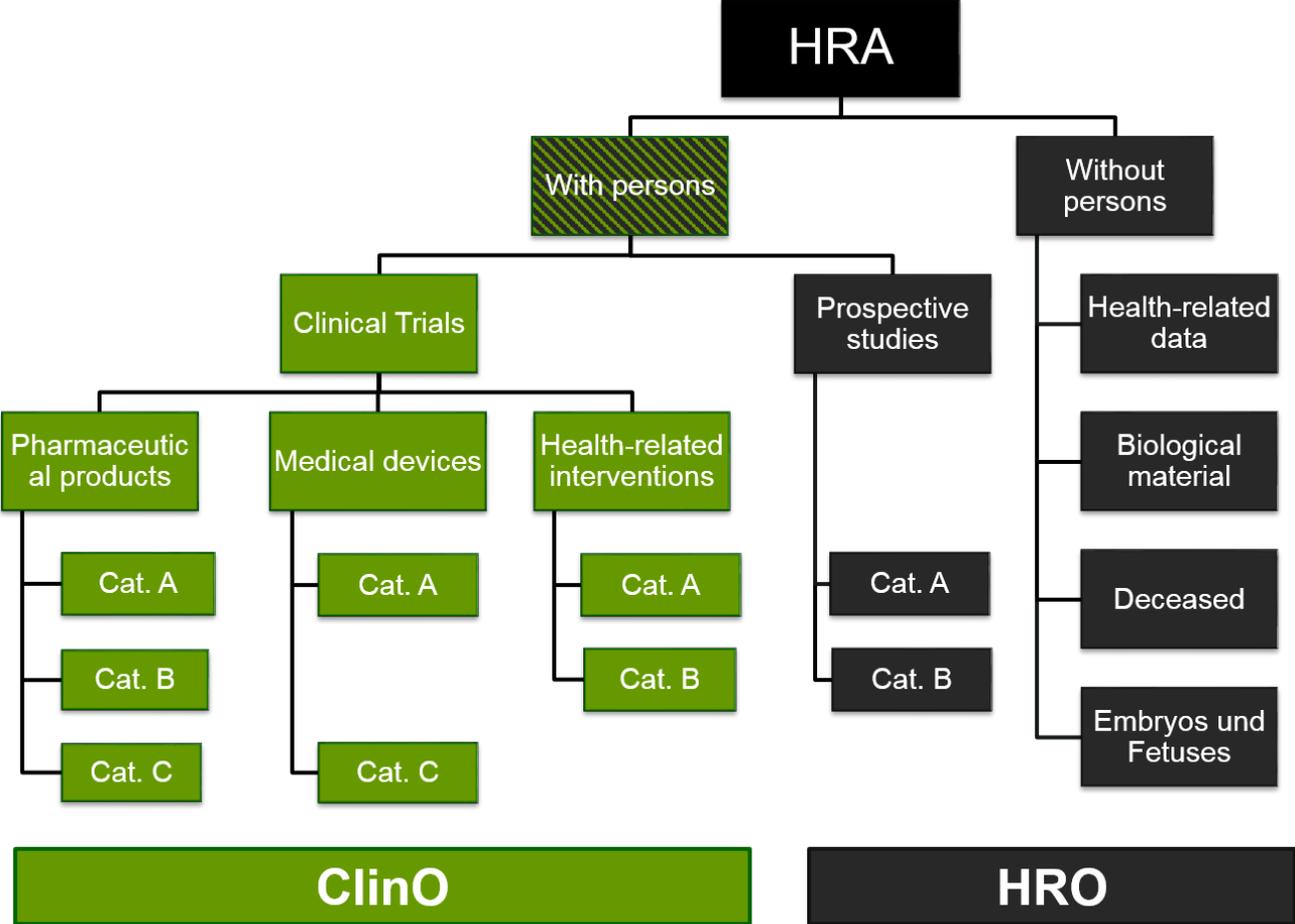
¹ This Act **applies** to research concerning human diseases and concerning the structure and function of the human body, which involves:

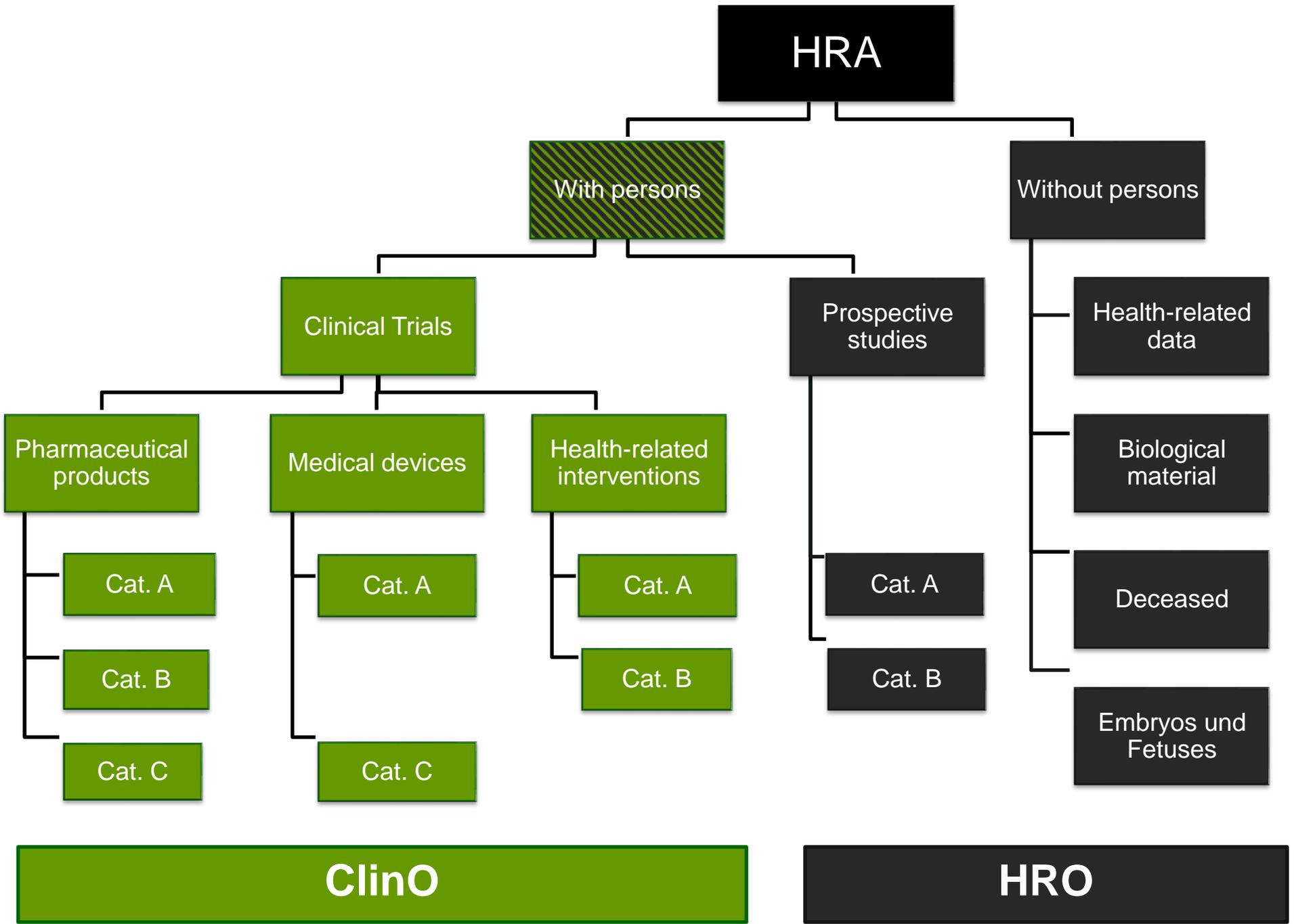
- a. persons;
- b. deceased persons;
- c. embryos and foetuses;
- d. biological material;
- e. health-related personal data.

² It **does not apply** to research which involves:

- a. IVF embryos in accordance with the Stem Cell Research Act of 19 December 2003¹;
 - b. **anonymised** biological material;
 - c. **anonymously collected** or **anonymised** health-related data.
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Overview





Regulations

- > Research with persons

 - ClinO

 - HRO, chapter 2

 - Personal data

- > Further use

 - HRO, chapter 3

 - Personal or coded data (anonymization of data)

Potential reason for confusion/problems?

- > "I am not malicious"
 - Laziness
 - Adhering to the law (Human Research Act) is optional
- > Not strictly defining their research project
- > Confusing some articles in the HRA (e.g. Art. 57 Confidentiality)

- > No careful planning
- > Not applying risk-based approaches

CLINICAL TRIALS

Good Clinical Practice guidelines

- > Data (protection) covered in several places ...
- > 1.16 Confidentiality
 - *Prevention of disclosure, to other than authorized individuals, of a **sponsor's proprietary information** or of a **subject's identity**.*
- > 2.11 (Principles)
 - *The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules ...*
- > 1.58 & 5.5.5 & 8.3.21
 - *Identification of subjects via an unambiguous identification code*
 - All reporting of data from investigator by ID instead of identifying information (*name*)

ICH GCP on data handling (5.5)

- > 5.5.1 ... appropriately qualified individuals ... to handle data, to verify the data, ...
 - Education and (trial-specific) training (CV, certificates, documented training of protocol, standard operating procedures etc.)
- > 5.5.3 (c) audit trail and no deletion of data
 - (d) unauthorized access to data
 - (e) list of individuals authorized to make changes
 - (f) data back-up
- > See principles at beginning and data protection regulations ...

Rights of participants (narrow)

- > Informed consent (principle 3-5)
 - Further use → consent at trial enrollment (data sharing policies!)
- > Withdrawal of consent
- > Restricted access to personal data (see also KDSG Art. 15)
- > Data is deleted or rendered anonymous as soon as the purpose of the processing permits (see also KDSG Art. 15)
- > Access to data (KDSG Art. 21; see also GDPR)
 - *in a generally understandable form and in writing if so requested*
 - *unless significant and overriding public interests or third party interests particularly worthy of protection preclude this*
- > Correction (KDSG Art. 23)
 - *Every person has the right to have incorrect or unnecessary personal data about them corrected or destroyed.*

Withdrawal of consent

- > Data stays in database
 - No deletion of data (but see next slide)
- > Anonymization after completion of data analysis (as defined in an approved trial protocol; see project definition)
 - Unless allowed by participant (documentation!)
 - Unless anonymization not possible and initial consent

Deletion of data

> Partial information (HRA Art. 18)

- Clinical trials with specific methodology that does not 'allow' fully informed consent and minimal risks
- Fully informed consent as soon as possible
- Participant does not provide fully informed consent (post hoc)

> Emergency situations (HRA Art. 31 & ClinO 15-17)

- Initial consent by proxy e.g. independent physician
- No analysis of data before post hoc consent
- Participant does not provide post hoc consent
 - But: ClinO Art 17 Para 4 (validity compromised if described in protocol)
- Participant dies and no proof of consent in advance directive, otherwise, or by proxy

RESEARCH WITH PERSONS (OBSERVATIONAL STUDIES)

Research with persons (Chapter 2, HRO)

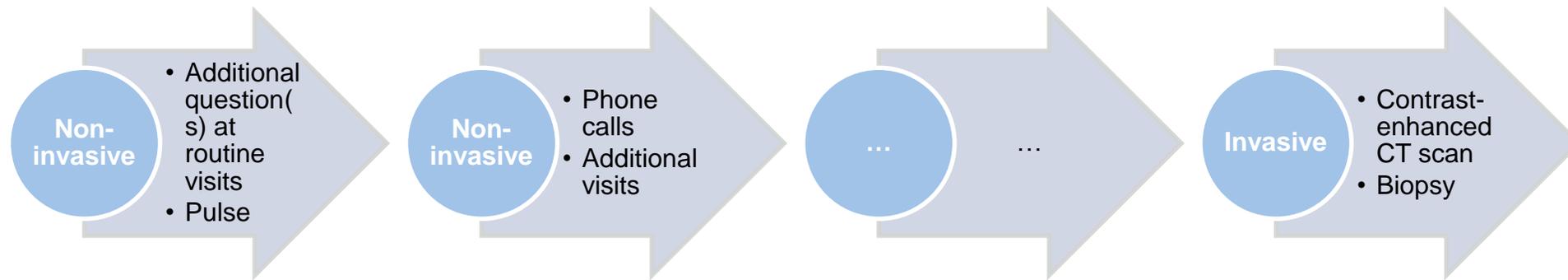
Art. 6 Research project

For the purposes of this Chapter, a research project is any project in which biological material **is sampled** or health-related personal data **is collected** from a person in order to:

- a. answer a scientific question; or
 - b. make further use for research purposes of the biological material or the health-related personal data.
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Study-related assessments/procedures

> **Anything** outside usual practice (needed for care)



FURTHER USE

Further use (Chapter 3, HRO)

Art. 24 Further use

Further use of biological material and health-related personal data is defined as any handling, for research purposes, of biological material **already sampled** or data **already collected**, and in particular:

- a. procuring, bringing together or collecting biological material or health-related personal data;
 - b. registration or cataloguing of biological material or health-related personal data;
 - c. storage or inclusion in biobanks or databases;
 - d. making accessible or available or transferring biological material or health-related personal data.
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Research project (Chaper 3, HRO)

Art. 33 Research project

For the purposes of this Section, a research project is any project in which further use is made of biological material already sampled or health-related personal data already collected in order to answer a scientific question.

What are we doing when we perform a study?

1. Definition of the data to be collected
 2. Collect data (questions, assessments, examinations, ...)
 3. Record data from source data in a research database
 4. Save data
 5. (Data preparation)
 6. (Save data)
 7. Analyse data
-
- > Start at 2: Research with persons
 - Ethical approval & informed consent
 - > Start at 3: Further use (project according to Art. 33)
 - Ethical approval & informed consent (for further use; often general consent; Art. 34 i.e. exemption possible!)
 - > Start at 3 and end at 6: Further use (Art. 24)
 - Informed consent (for storage (& potential research questions)) (no ethical approval)
 - > Start at 5: Further use (project according to Art. 33)
 - Ethical approval & informed consent (for research question if not already done before; Art. 34 i.e. exemption possible!)
-

How do we get the already collected data?

- > Look-up electronic health records, archive etc. and extraction
 - Patients primarily consented to the storage and use of their data **only** for health-care purposes **not** for any research purposes!
- Requires explicit consent or general consent (earlier years: Generalbewilligung!)

How do we store and use (non-genetic) data?

- > With identifying information (HRO Art. 31)
 - Explicit written consent (exceptions for written form → HRO Art. 9)
- > Coded (HRO Art. 32)
 - No objection
- > Anonymous
 - Outside the scope of the Human Research Act (HRA)

BUT!

Persons involved

Usually

- > Roles
 - Investigator
 - Study Nurse, Sub-Investigator
 - Statistiker
 - Zentrallabor
 - DSMB
 - Adjudication Committee
 - ...

According to HRA

- > Persons involved in the research project
- > All others

Anonymous data

Anonymous in the usual sense

- > Identification of person impossible (or only with disproportionate efforts)
- > For the person who uses the data

Anonymous according to the HRA

- > Identification of person impossible (or only with disproportionate efforts)
- > For the whole study team
 - Investigator
 - Study Nurse/Coordinator
 - Statistiker
 - ...

Coded data

Coding in the usual sense

- > Data without identifying information («anonymous») but with ID e.g. consecutive number
- > Key to decode ID (separate from the user at the time of data handling) e.g. patient-log

Coding according to the HRA

- > Data without identifying information («anonymous») but with ID e.g. consecutive number
- > Key to decode ID **not** controlled by **study team**
 - Trustee
 - Person not subjected to directions by members of study team
- > Breaking the code only to avert immediate risk to health

Conditions for breaking the code (HRO)

Art. 27 Conditions for breaking the code

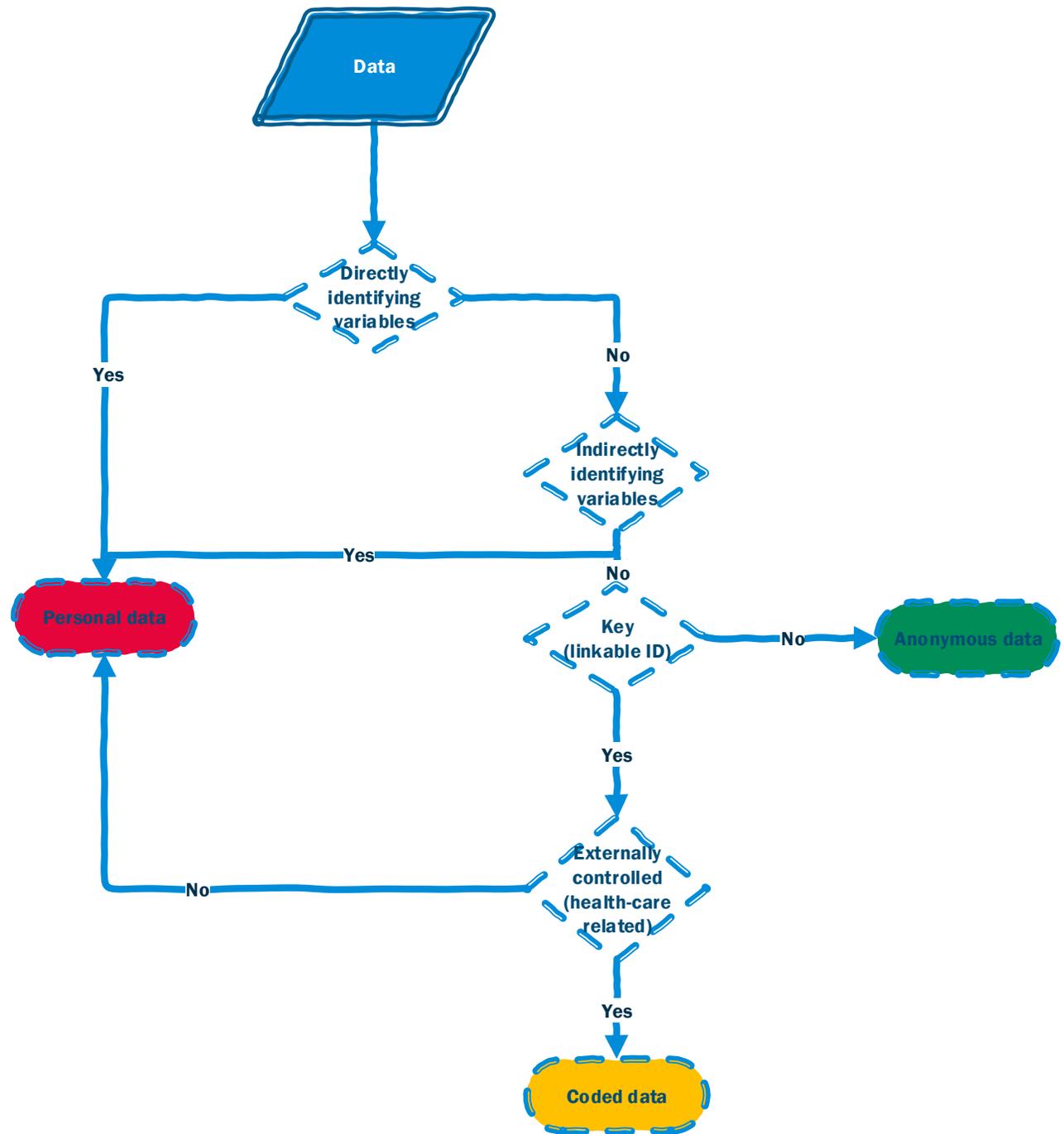
For coded biological material and coded health-related personal data, the code **may only** be broken if:

- a. breaking the code is necessary to **avert an immediate risk** to the health of the person concerned;
- b. a **legal basis** exists for breaking the code; or
- c. breaking the code is necessary to **guarantee the rights** of the person concerned, and in particular the right to revoke consent.

→ Breaking the code is related to the medical care of a participant not, for example, data quality

Reality

- > Prospective studies always use identifying data (follow-up!), retrospective data very often
- > Coded
 - extremely rare if at all
 - Only useful in situations where one can expect clinically relevant discoveries by study-related examinations for individual participants e.g. genotyping, (re-)assessment of images, pathological (re-)assessments
- > Maybe anonymous



Data sharing (HRO Art. 24)

- > Sharing data requires
 - Anonymization or
 - Explicit consent to share data in uncoded form (personal data)
- > Distinguish non-genetic health-related data ↔ genetic data/biological material
 - Anonymization of genetic data/biological material requires explicit consent (Art. 30 HRO)
 - Non-genetic health-related data **NOT**
- > Scope (Art. 2 HRA)!
 - ... does **not** apply ... **anonymised** health-related data

Sharing clinical trial data

- > Inform trial participant about further use and get consent (HRA Art. 17)
 - Data sharing policies (SNF, EU, ...)
 - Although probably not absolutely mandatory (anonymization)
- > Anonymization in health-related research
 - Disproportionate effort to identify person(s)
 - Separating the link (link ID-person) is not sufficient
 - Explicitly identifying information
 - Name(s), date of birth, address, phone numbers, E-Mail, AHV-ID, PID, study IDs, ...
 - Potentially identifying information
 - Study site, dates, freetext, ...
 - Orphan diseases, small populations
 - Combination of data points/variables (study database with usually 100s of variables) ...

GENERAL DATA PROTECTION REGULATION (GDPR)

GDPR

- > In effect since May 25th, 2018
- > Not directly applicable to Switzerland
 - But application might be agreed upon in a contract with EU partner (but see next slides)
- > No national regulation (but see revision of DSG)
- > EU comission accepted Swiss data protection regulation as appropriate (200/518/EG; Abl. L 215/I vom 25.8.2000)
 - This will most likely not change

GDPR in a nutshell I

- > Definitions (pseudonymization, anonymization, further use ...)
 - See Human Research Act
- > Data only to be used for purpose of project
 - See Human Research Act (Further Use concept)
 - "Eigenforschung" requires consent → Swiss Further Use
- > Current trials with EU participants
 - Completed → do nothing
 - Still collecting data → information to EU participants
 - New → written confirmation about information

GDPR in a nutshell II

- > Information for participants
 - Data Protection Officer
 - Complaints (data protection agency)
 - Rights: information, correction, deletion
- > Registration with data protection agency

GDPR main issues

- > Data Protection Officer
- > Right to be forgotten (Deletion of data on request)
 - Not for trials with pharmaceutical products or medical devices
BUT
 - For Other Clinical Trials (ClinO chapter 4) and
 - Other prospective studies (observational)
 - Right to be forgotten in contradiction to ClinO Art. 9

Not applicable to researchers

> Human Research Act

- Art. 57 Confidentiality (ethics committee and authorities)
- Art. 58 Processing of personal data (ethics committee)
- Art. 59 Disclosure (ethics committee and authorities)
- Art. 60 Transmission (authorities)