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Refresher Data Management mit Fokus auf Verschlüsselung

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Acquisition of data, permissions, and type of data under the Swiss HRA

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Disclaimer

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- All content based on **CTU-interpretation** of the act and its ordinances (based on Botschaft, Explanation documents and informal exchange with FOPH)
- Interpretation of the act and its ordinances still not harmonized across the different authorities
- Although all slides/content was checked carefully: Errors and omissions excepted (E&OE)
- Thanks to FOPH, CTU staff

English vs. German (incl. abbreviations)

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English

- Clinical Trials Ordinance (ClinO)
- 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)
- Bundesamt für Gesundheit (BAG)
- Humanforschungsgesetz (HFG)
- Humanforschungs-verordnung (HFV)
- Schweizerische Ethik-kommissionen für die Forschung am Menschen

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!)

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

Scope
(Art. 2 HRA)

Art. 2 Scope

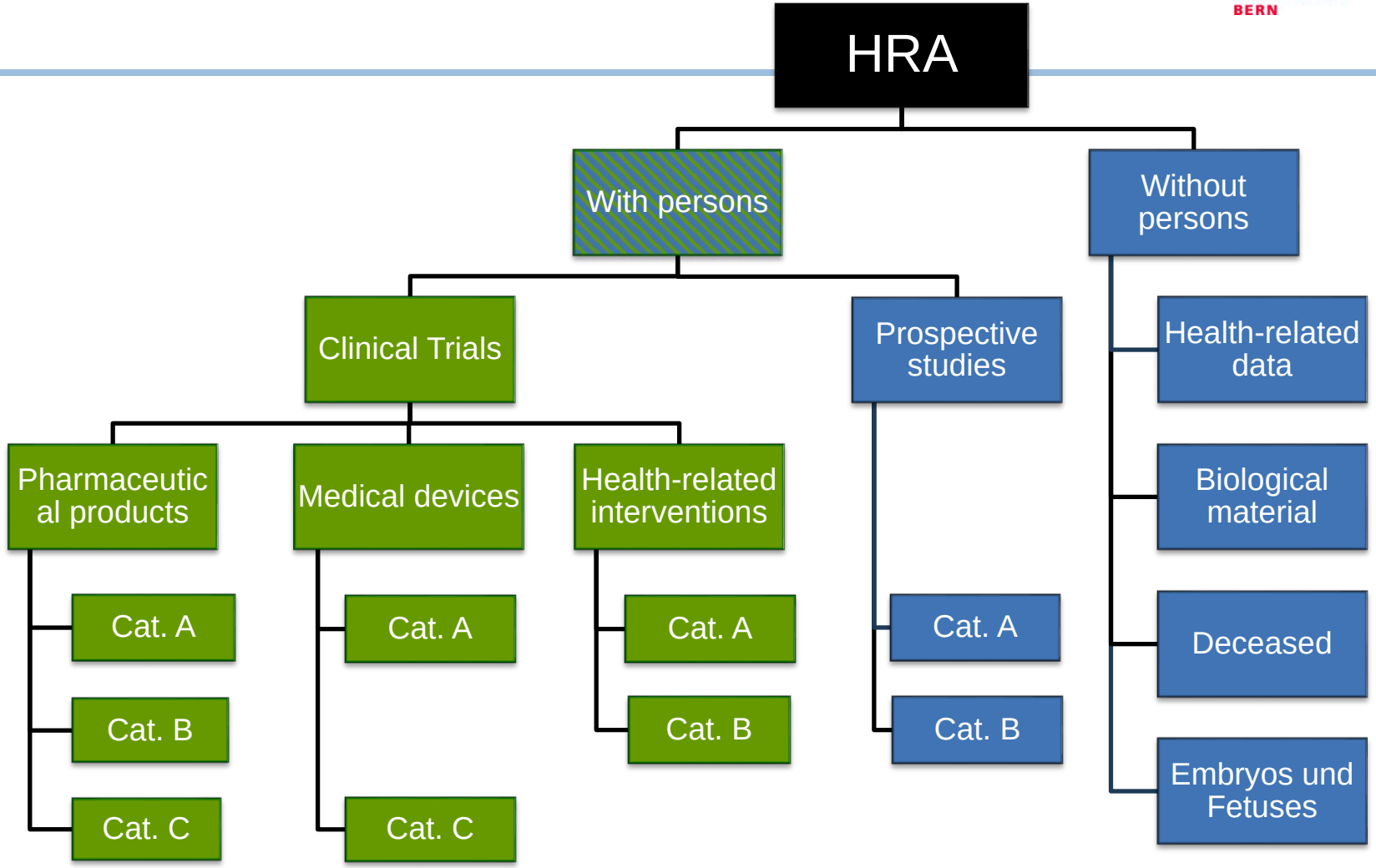
[1] This Act applies to research concerning human diseases and concerning the structure and function of the human body, which involves:

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

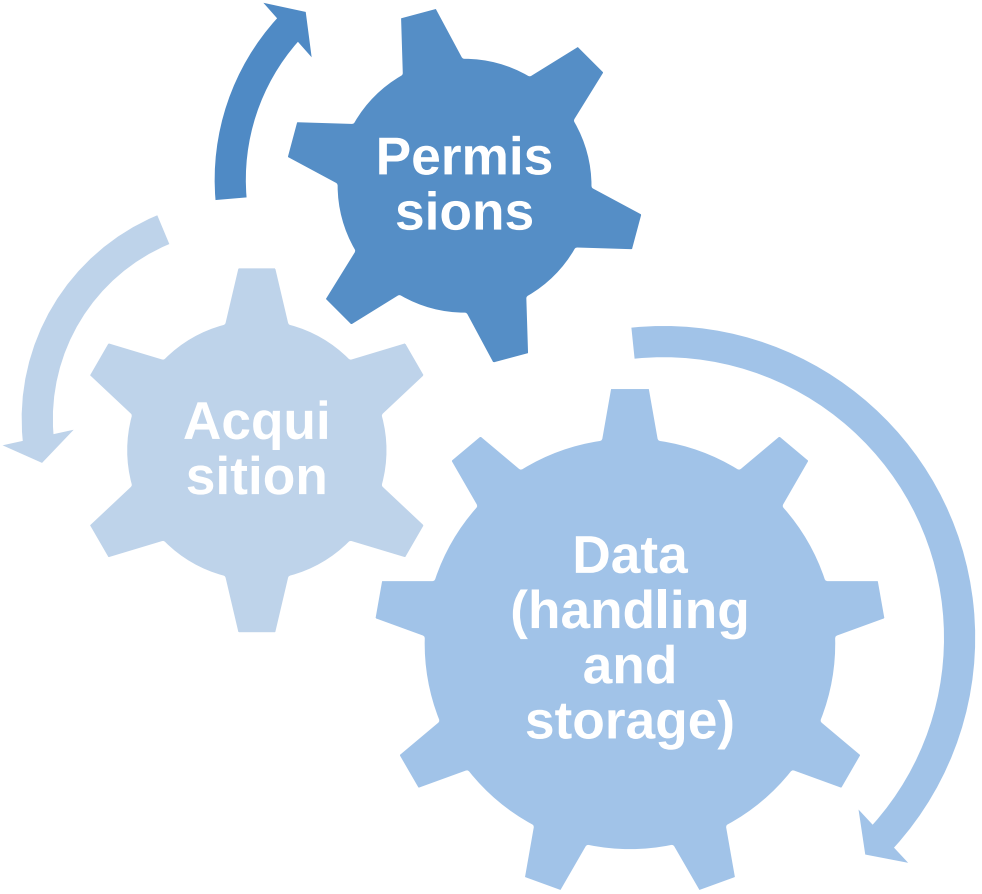
[2] It does not apply to research which involves:

a. IVF embryos in accordance with the Stem Cell Research Act of 19 December 2003[1];
b. anonymised biological material;
c. anonymously collected or anonymised health-related data.

Overview


HRA
With persons
Without persons
Clinical Trials
Prospective studies
Health-related data
Pharmaceutical products
Medical devices
Health-related interventions
Biological material
Cat. A
Cat. A
Cat. A
Cat. A
Deceased
Cat. B
Cat. B
Cat. B
Embryos und Fetuses
Cat. C
Cat. C
ClinO
HRO

Framework



FURTHER USE AS EXAMPLE

Further use
(Chapter 3, HRO)

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Art. 24 Further us

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.

Research project (Chaper 3, HRO)

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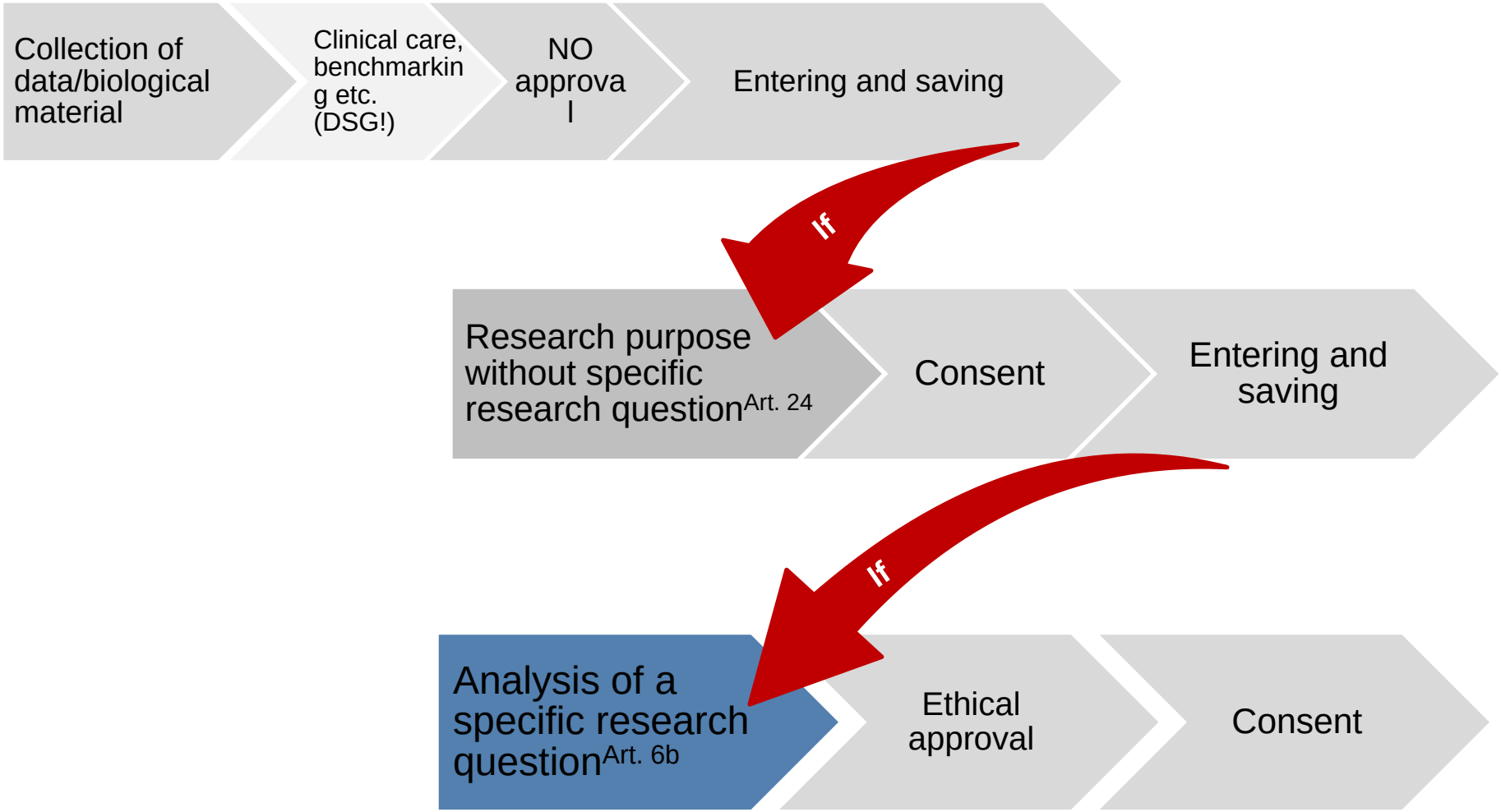
Art. 33 Research project
For the purposes of this Section, a research project is any project in which further use is made of biological material already sampled or health-related personal data already collected in order to answer a scientific question.

Consent and ethical approval



What are we doing when we perform a study?

- Definition of the data to be collected
- Collect data (questions, assessments, examinations, …)
- Record data from source data in a research database
- Save data
- (Data preparation)
- (Save data)
- Analyse data

What are we doing when we perform a study?

- Definition of the data to be collected
- Collect data (questions, assessments, examin… …)
- Record data from source data i… …ase
- Save data
- …
- …ave data)
- Analyse data

Research with persons
→ Ethical approval & informed consent

What are we doing when we perform a study?

- Definition of the data to be collected
- Collect data (questions, assessments …)
- Record data from sou…
- Save …
- …
- Analyse data

Further use
→ Ethical approval & informed consent (for further use; often general consent; Art. 34 i.e. exemption possible!)

What are we doing when we perform a study?

- Definition of the data to be collected
- Collect data (questions, assessments, exa… …)
- Record data from source d…
- Save data…
- …data)
- Analyse data

Further use
→ Informed consent (for storage (& potential research questions)) (no ethical approval)

What are we doing when we perform a study?

- Definition of the data to be collected
- Collect data (questions, assessments …)
- Record data from sou
- Save
- Analyse data

Further use
→ Ethical approval & informed consent (for research question if not already done before; Art. 34 i.e. exemption possible!)

What are we doing when we perform a study?

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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
  — 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
  — Informed consent (for storage (& potential research questions)) (no ethical approval)
> Start at 5: Further use
  — 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
  - Explicit consent
- Coded
  - No objection
- Anonymous
  - Outside the scope of the Human Research Act (HRA)

BUT!

Persons involved

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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

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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

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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

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

- Data sharing 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

PROSPECTIVE STUDIES OTHER THAN CLINICAL TRIALS

Research with persons (Chapter 2, HRO)

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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.

Initial questions

1. What is my data?
   - Biological material
   - Genetic data
   - Health-related data
2. What are my aims?
   - Answering a specific question (research project) i.e. outcome defined
     - Prospective study (most often observational study)
   - Collecting/storing already available data/samples for future studies
     - Register, observational study without study-specific procedures, linkage studies, …
3. What type is my data?
   - Uncoded
   - Coded
   - Anonymized

Study-related assessments/procedures

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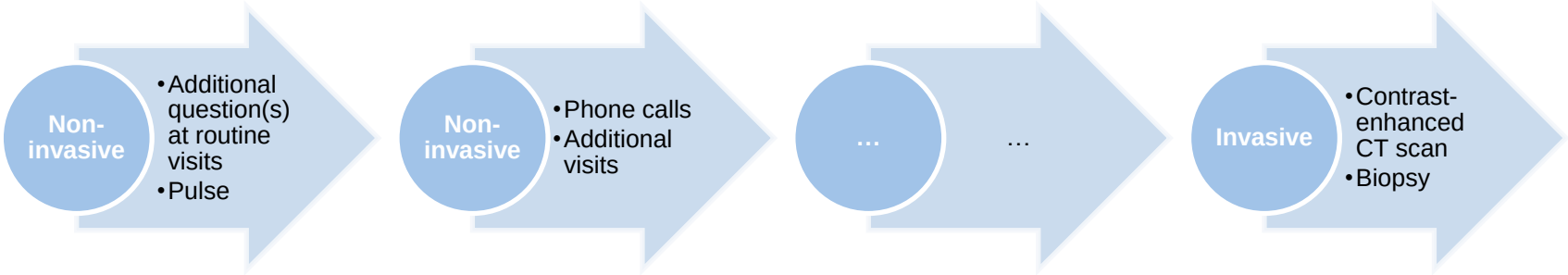
- **Anything** outside usual practice



Good practice (Federal Act on Data Protection, FADP/DSG)

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- Art. 4 Principles
  1. Personal data may only be processed lawfully.
  2. Its processing must be carried out in good faith and must be proportionate.
  3. Personal data may only be processed for the purpose indicated at the time of collection, that is evident from the circumstances, or that is provided for by law.

- For example, identifying information only accesible to restricted group of persons involved in trial