

# Facts and pitfalls of observational studies

Research with health-related data

Legal implications and challenges

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- Research with data and biological material is becoming more and more relevant.
- Focus: **Retrospective** research with **existing data (HRO, Chapter 3)**
- First take home message: There are lots of legal Clauses, guidelines etc. who **regulate** this topic

## **Who owns the Data?**

- The **patient** (hence his right to refuse, withdraw etc.)
- Not the hospital, research institution, project leader, physician etc.
- However: It's Hospital's and Institution's (not patient's) **obligation to take care of data security**, e.g. (Clause 5 (1) HRO):
  - Restriction of the handling to those persons who require the data to fulfil their duties;
  - Prevention of unauthorised disclosure, alteration, deletion and copying of the data;
  - Documentation of all processing operations which are essential to ensure traceability.
  - PM: Breach of medical professional confidentiality (punishable by law) applies also within the research context.


## Responsibilities of hospital, institution etc.

- IIT:
  - (generally) Hospital, institution etc. = Controller
  - Consultant (e.g. external IT company) = Processor
- Pharma sponsored RP: Joint Controllership
- Contract in question (often required by EC): Data Transfer and Use Agreement (**DTUA**)
- <https://sphn.ch/services/dtua/>

## **Two categories of data** (depending on “sensibility”)

- Non-genetic health-related data (as to be found e.g. in medical records)
- Genetic data (and biological material) > higher requirements in terms of IC etc.

## **Three ways to process the data**

- Uncoded form (identifying *per se*, “Klardaten”)
  - Pseudonymized form
  - Anonymized form
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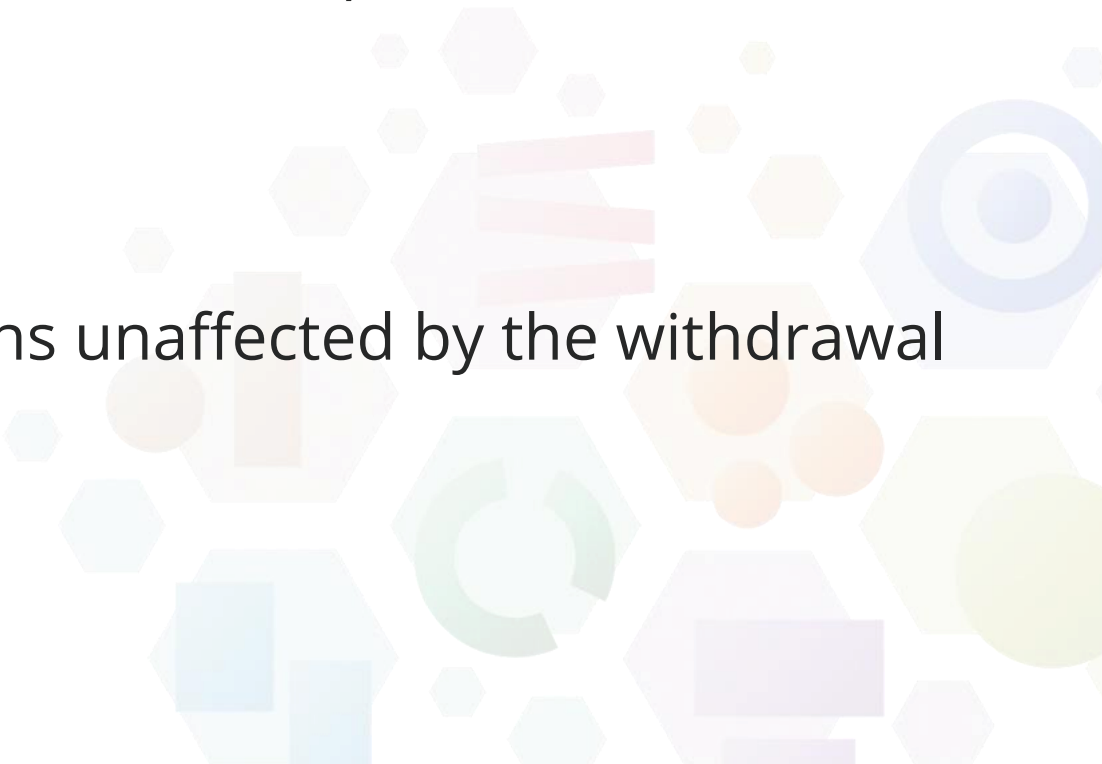
## Two x Three = 6 options of data handling

	Genetic Data & Biological Material	Non-genetic health-related Data
Uncoded (identifying <i>per se</i> )	One specific RP, IC	«for research purposes», GC
Coded (Pseudonymized)	«For research purposes» (= various, ev. not yet defined RPs in the future), GC	«For research purposes», Right to oppose
Anonymized	«For research purposes», Right to oppose against A.	Permissible without further ado

## Talking about «For research purposes» [I]

- Road to paradise: General Consent (“GC”) or “Research Consent” (“Forschungskonsent”)
- <https://dkf.unibas.ch/en/competencies/patient-data-samples/research-consent/>
- Patient is asked whether he/she is willing to provide data & biological material ...
- ... generated within the **treatment** and **diagnostic** context ...
- ... for (several, future) research purposes.
- No “extra” data, no extra material (> specific IC; HRO Chapter 2)

## Talking about «For research purposes» [II]

- Pro: health risk in terms of research actions = 0%
  - Con: The marriage paradoxon (“For ever and ever”)
  - However: Withdrawal at any time
  - But: Data used in the meantime remains unaffected by the withdrawal
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- The background of the slide is decorated with a collection of semi-transparent, colorful geometric shapes. These include various sizes of hexagons, circles, and squares in shades of light blue, green, orange, and purple, scattered across the right side of the slide.

## Definition of “Anonymization”

- Re-identification of the individual **impossible**; or
- Re-Identification **theoretically possible**, but only **with disproportionate effort**
- (Approach of a “relative” A.)
- A. becoming more and more a challenge...

## Definition of “Pseudonymization”

- Re-Identification possible via key
- Key to be stored separately from data collection by a person not involved in the RP.
- Conditions for breaking the code: Clause 27 HRO

## Relation between the (federal and cantonal) Data Protection Laws and the HRA – which applies when?

- Data Protection Laws stipulate **general** data protection rules.
- They apply unless there is a **specific law** regulating a **specific subject**.
- HRA (plus its ordinances, such as HRO) regulate Research on Human Beings and stipulate various regulations which **overrule** the Data Protection laws.
- E.g. the right to delete a person's data does not apply concerning a raw data set which has been analyzed within a research project in the past.
- Correctly and irreversibly anonymized data: Neither HRA nor DP laws apply anymore – **but keep in mind the A-problem (!)**.

Thank you very much.

