University of Basel
Department of Clinical Research
University Hospital Basel

Introduction to sensitive (patient) data
data under constraints

David Büchel, Claudia Saupper 2nd June 2023

Welcome to data under constraints – Who we are

Faculty of Medicine

Biomedical Engineering, DBE

Biomedicine, DBM

Department of **Clinical Research, DKF**

Department of **Public Health, DPH**

Department of **Sports, Physical Activity and Health, DSBG**

David Büchel
Data Manager at DKF
NCCR AntiResist Medical Data Officer
- Data manager
- Electronic data capture
- Clinical studies
- Overall coordination clinical data related aspects

Claudia Saupper
Senior IT PM at DKF
NCCR AntiResist Medical Data Office Member
- Clinical data pipeline
- Clinical data processing
- Clinical data storage

Agenda

1	Introduction
2	Regulatory & ethical aspects
3	Working with sensitive (patient) data
4	Approach towards sensitive (patient) data in NCCR AntiResist
5	Small group discussions
6	Summary of discussions

Introduction – where does data under constraints apply?

Does your research question include sensitive (patient) data?

Include any actions with regards to sensitive (patient) data in your proposal and Data Management Plan (DMP)

How to collect and store sensitive (patient) data? Who has access to that data?

Who is allowed to evaluate and select sensitive (patient) data?

How to safely remove and delete sensitive (patient) data?

Who is allowed to process, analyse and interpret sensitive (patient) data?

How to publish results including sensitive (patient) data?

How to preserve sensitive (patient) data?

How to share and who is allowed to re-use sensitive (patient) data?

Source: *The Data Life Cycle, courtesy of the ETH Zurich library*

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Regulatory & ethical aspects

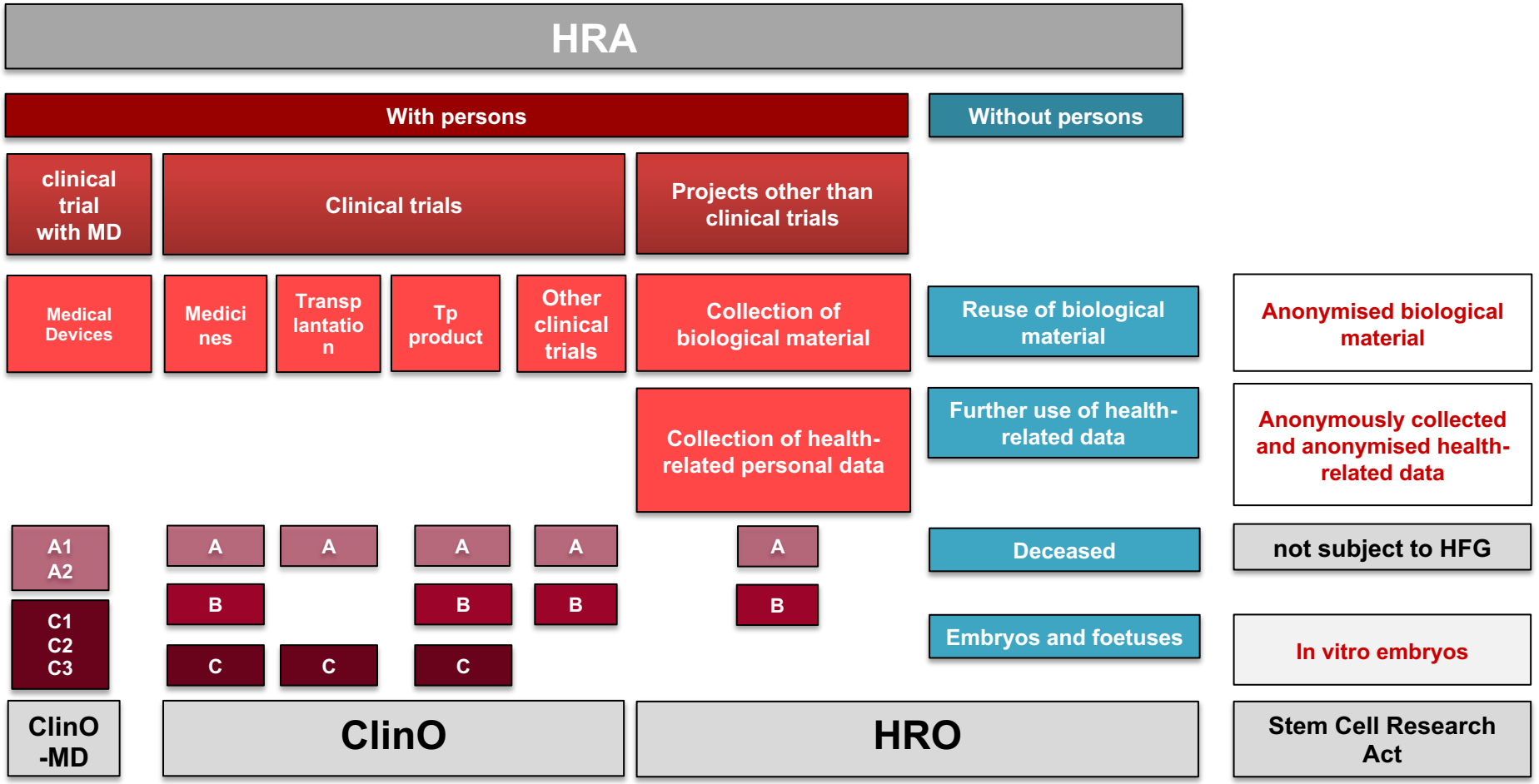
Learning content

1. Origin of Data under the Human Research Act (HRA)
2. Excursion to Data Protection
3. Human Research Act (HRA) in detail
4. Processes of Ethics Approval in a nutshell

Regulatory & ethical aspects

Origin of sensitive data

HRA Human Research Act
KlinV-Mep Ordinance on Clinical Trials with Medical Devices
ClinO Ordinance on Clinical Trials with the Exception of Clinical Trials of Medical Devices
HRO Human Research Ordinance



Regulatory & ethical aspects

Origin of sensitive data

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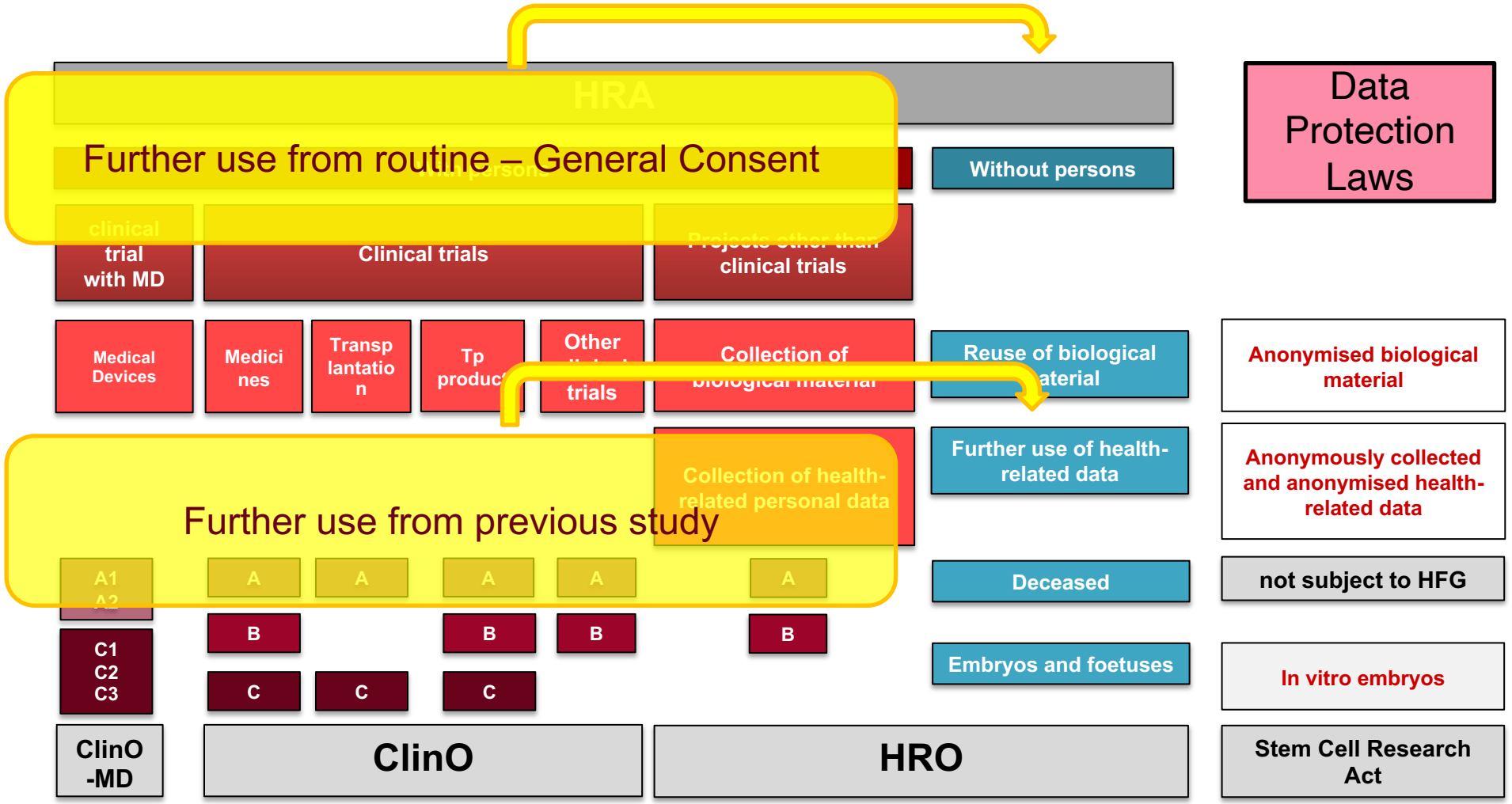


Regulatory & ethical aspects

Data Protection

Federal law on data protection (Data Protection Act, DSG)

This compilation was prepared on the currently published version as of September 2023:
https://www.bj.admin.ch/bj/de/home/staat/gesetzgebung/datenschutzstaerkung.html

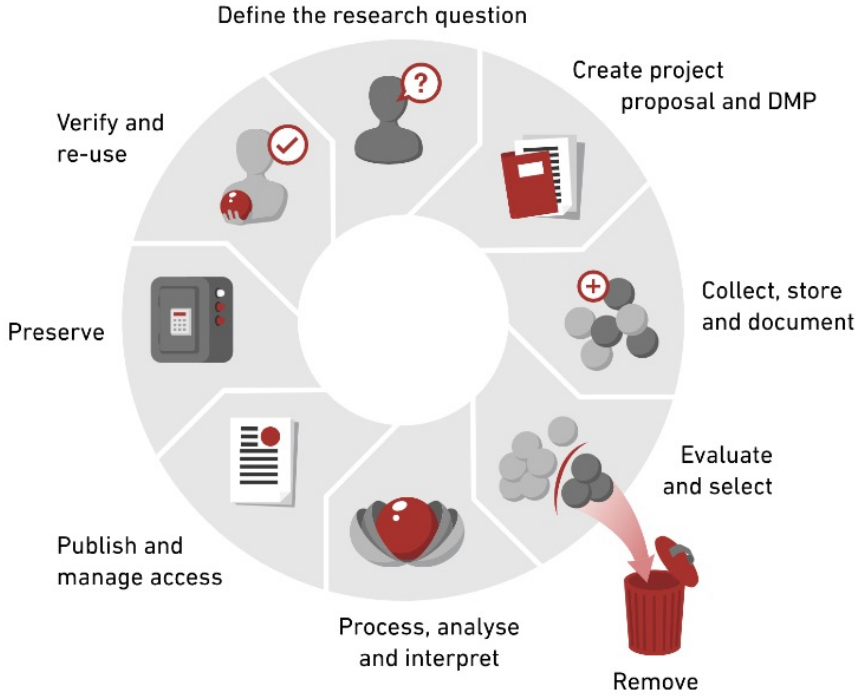
Since there is no English version of it, a non-certified deepL translation is used.

Art. 1 Purpose

The purpose of this Act is to protect the personality and fundamental rights of natural persons about whom data is processed.

Regulatory & ethical aspects

Data Protection



Art. 3 Terms (abbreviated)

a. **Personal data:** all information relating to an identified or identifiable person;

c. personal data requiring special protection:

1. data concerning religious, ideological, political or trade union views or activities,
2. data relating to health, privacy or racial or ethnic origin,
3. genetic data,
4. biometric data that uniquely identifies a natural person,
5. data on administrative or criminal prosecutions and sanctions,
6. data on social assistance measures;

Sensitive (patient) data

d. Processing:

any handling of personal data, regardless of the means and procedures used, in particular the acquisition, storage, retention, use, reprocessing, disclosure, archiving, deletion or destruction of data;

Source: https://www.bj.admin.ch/bj/de/home/staat/gesetzgebung/datenschutzstaerkung.html

Regulatory & ethical aspects

Data Protection

Art. 4 Principles (abbreviated)

[3] Personal data may only be obtained for a specific purpose that is clearly recognizable to the data subject; it may only be processed in a way that is compatible with the purpose.

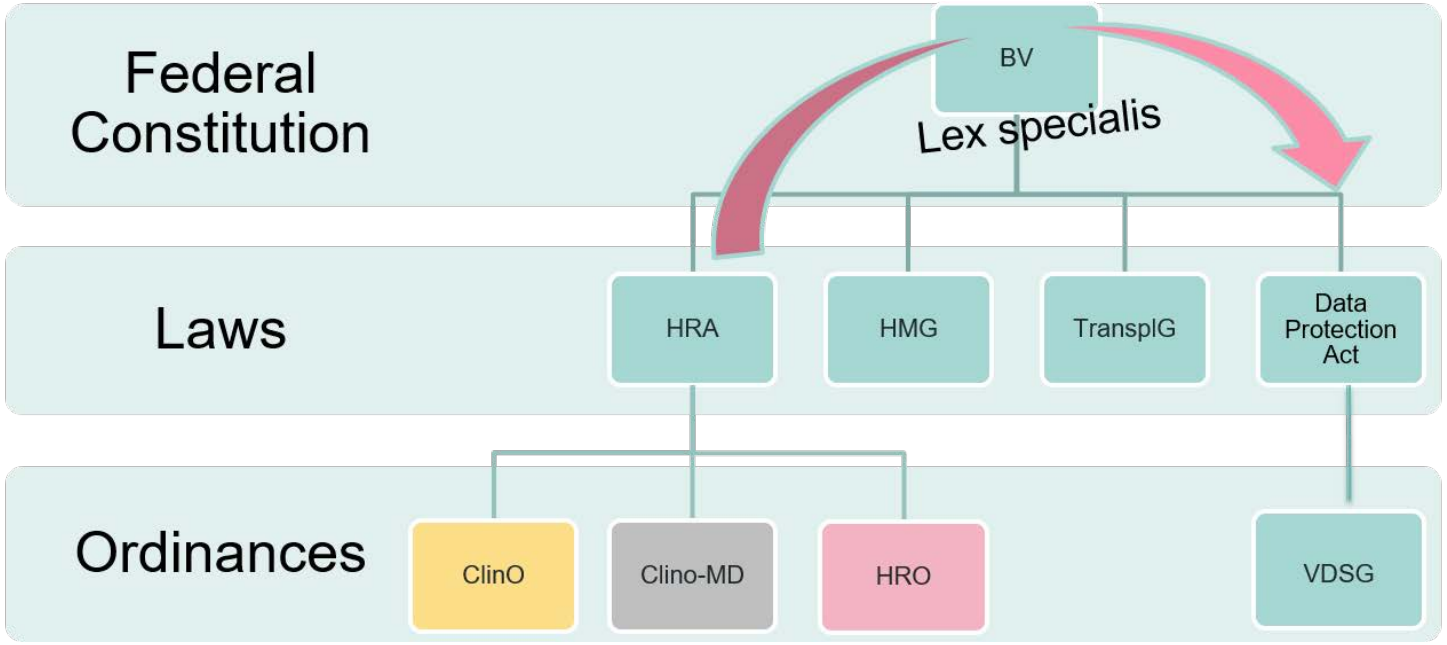
[4] Personal data may only be stored in a form that enables the data subject to be identified for as long as it is necessary for the purpose of the processing.

[5] Anyone who processes personal data must check whether the data is correct and, if necessary, update it. Incorrect or incomplete personal data required for processing must be corrected or supplemented. Otherwise, the data must be destroyed.

Source: https://www.bj.admin.ch/bj/de/home/staat/gesetzgebung/datenschutzstaerkung.html

Regulatory & ethical aspects

Hierarchy of legal regulation & Overview of Regulations



General Data Protection laws:

Information & Data Protection Act (IDG BS)

Federal law on data protection (DSG CH)

European General Data Protection Regulation (EU-GDPR)

Special Laws:

Federal Health Insurance Act (KVG)

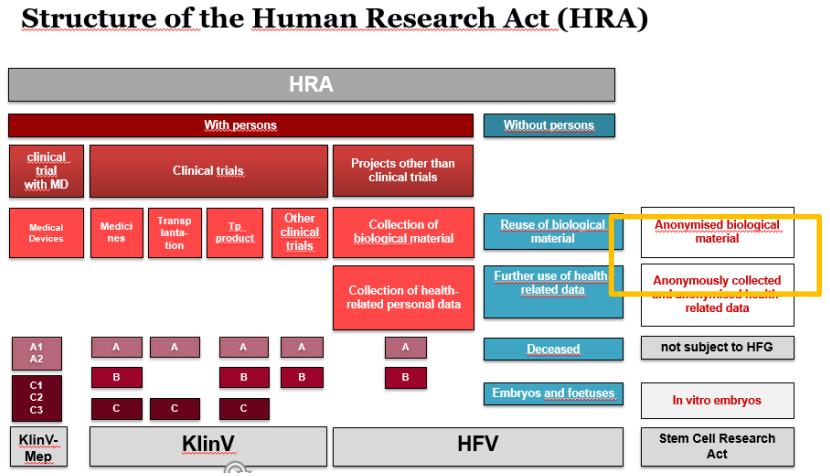
Federal Act on Controlling Communicable Human Diseases (EpidA)

Human Research Act (HRA) & Ordinances

Source: 810.30 Bundesgesetz über die Forschung am Menschen (Humanforschungsgesetz, HFG) vom 30. September 2011 (Stand am 1. Dezember 2022)
Source: https://www.fedlex.admin.ch/eli/cc/2015/297/en

Regulatory & ethical aspects

Scope of the HRA



HRA Art.2

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

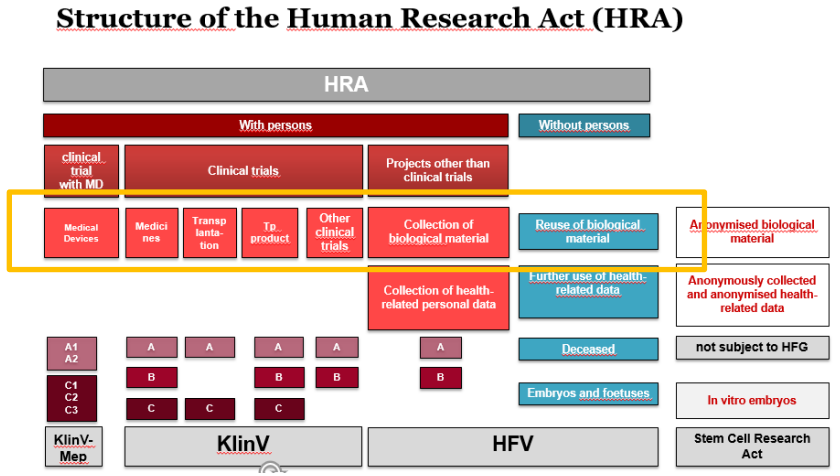
a. persons;
b. deceased persons;
c. embryos and foetuses;
d. biological material;
e. health-related personal data

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

a. IVF embryos in acc. with the Stem Cell Research Act of 19 December 2003[3];
b. ***anonymised biological material;***
c. anonymously collected or anonymised health-related data*.*

Regulatory & ethical aspects

Scope of the HRA



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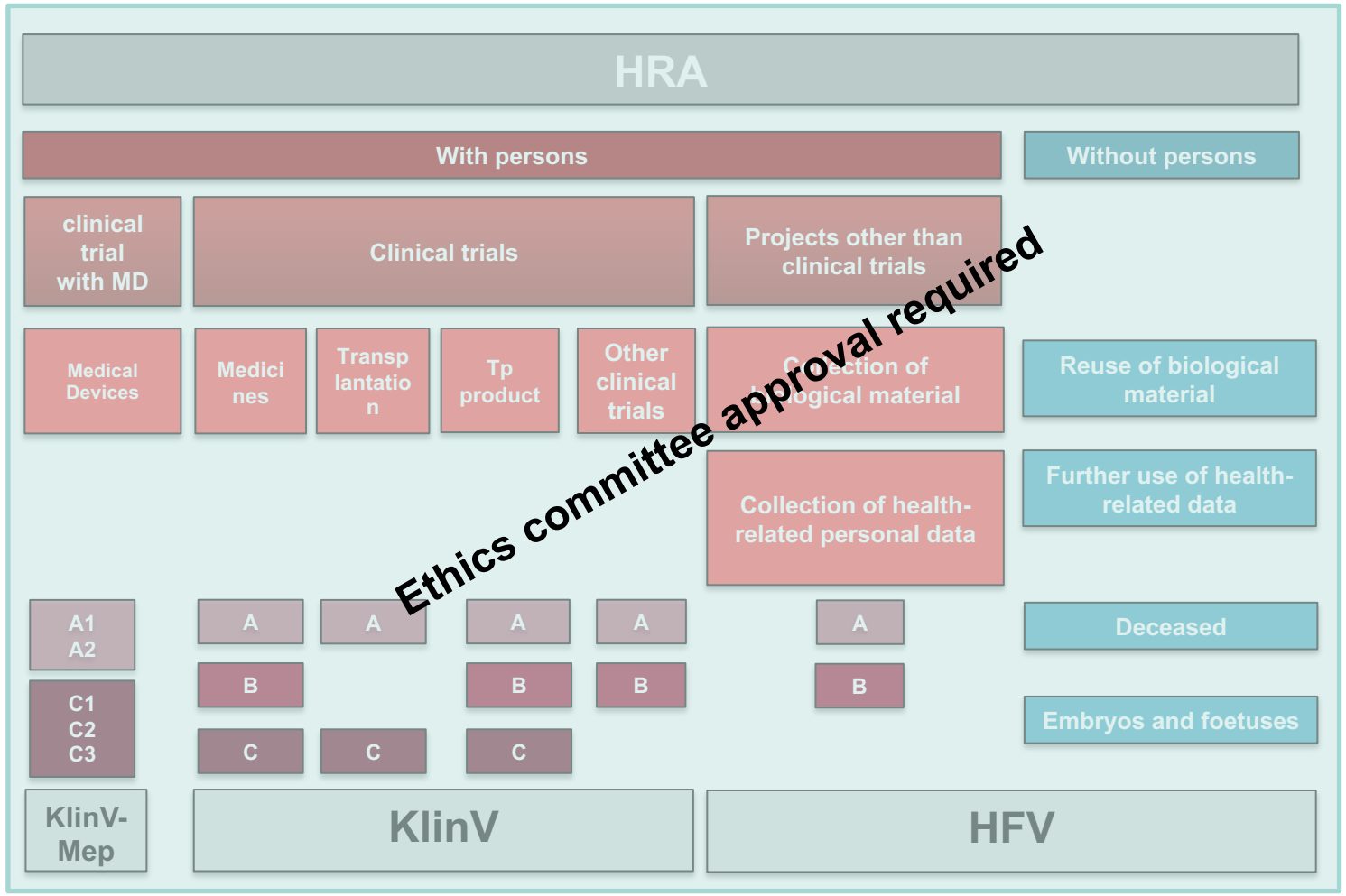
a. IVF embryos in acc. with the Stem Cell Research Act of 19 December 20033;
b. anonymised biological material;
c. anonymously collected or anonymised health-related data.

Regulatory & ethical aspects

Structure of the Human Research Act (HRA) & Ethics Committee



Anonymised biological material

Anonymously collected and anonymised health-related data

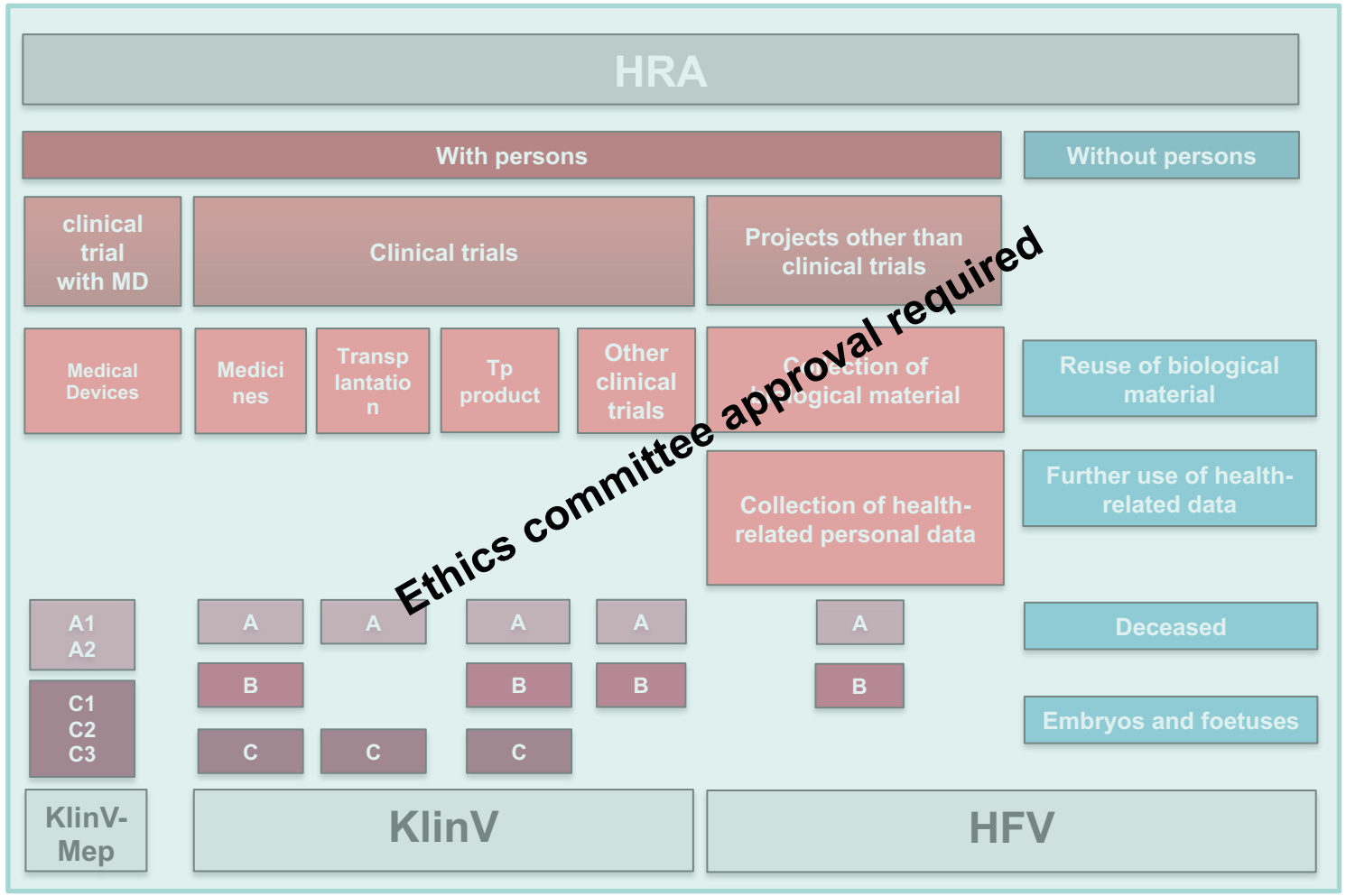
not subject to HFG

In vitro embryos

Stem Cell Research Act

Regulatory & ethical aspects

Structure of the Human Research Act (HRA) & Ethics Committee



The Ethics Committee reviews:

- ➢ Allocation to the regulation (KlinV / KlinV-Mep/ HFV) and risk categorization are the responsibility of the ethics committee

- scientific quality & integrity
- Risks, burdens and anticipated benefits
- necessity of involving persons
- procedure for obtaining informed consent
- funding, agreements between the parties
- Data protection requirements

Regulatory & ethical aspects

Required documents for the Ethics Committee (EC)

Study protocol

- Synopsis

Study information

- (Informed Consent Form, patient/participant info, ...) from this project or the original project

Further documents given to participants:

- diaries, questionnaires, …
- recruitment documents such as flyers, advertisements, …

Data Collection Form ((e)CRF)

CV of the project leader

Cover Letter

Contracts with sponsors/financier/other centres

Regulatory framework

- DTUA, MTA, Biobank Regulations, …

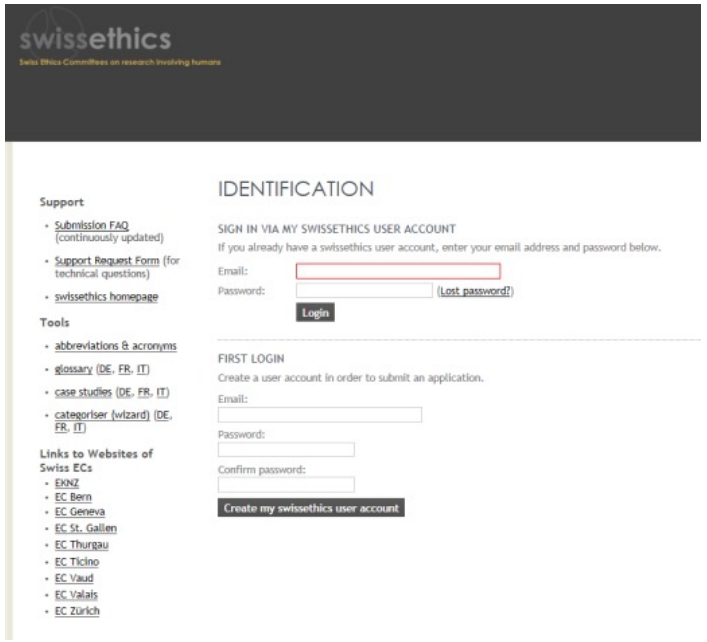
More information: http://swissethics.ch

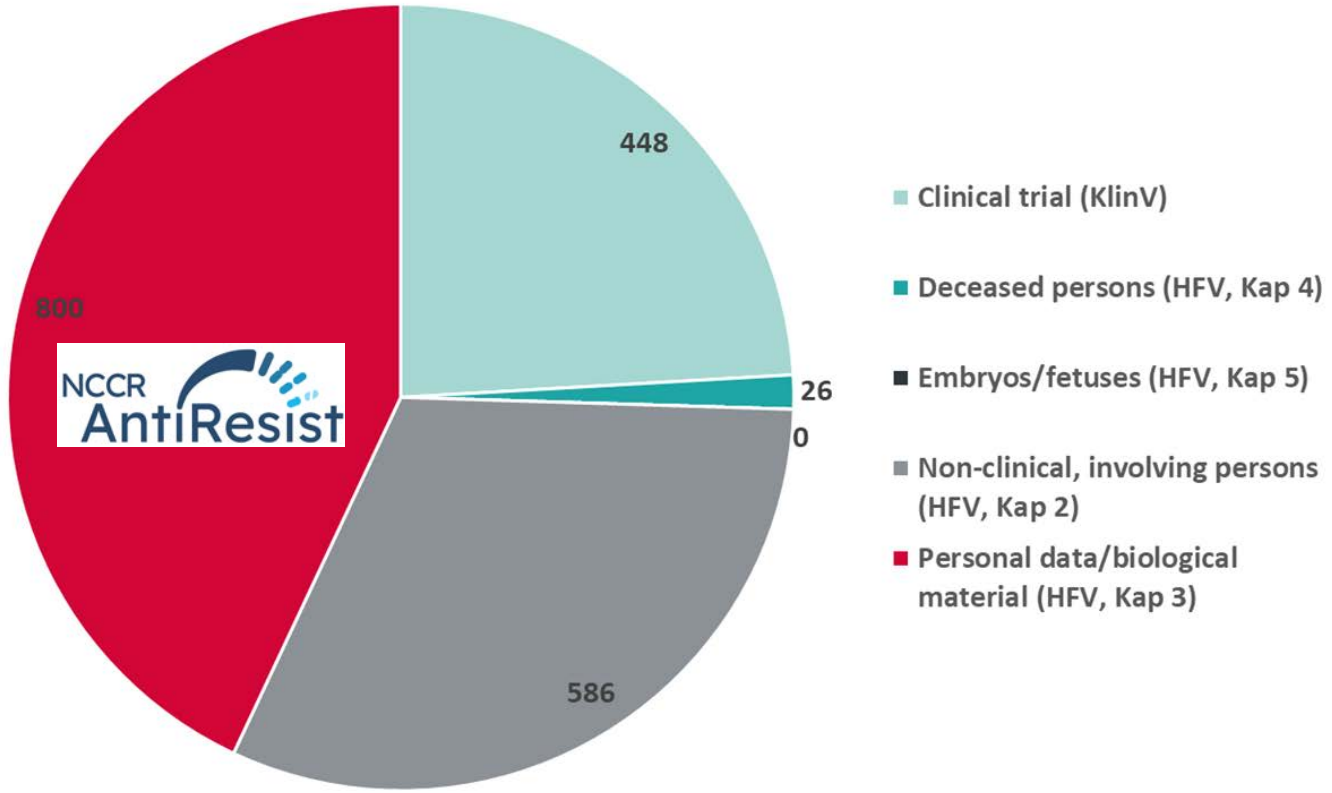
Regulatory & ethical aspects

EC Submission & Situation in Switzerland

BASEC (Business Administration System for Ethics Committiees)

= interactive web application with area for the researchers and area for the Ethics Committees





Meeting dates EKNZ: http://eknz.ch/sitzungsdaten

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Working with sensitive (patient) data

Selected topics

Sensitive (patient) data

- Do I have sensitive (patient) data or what is sensitive (patient) data?

Data de-identification (Anonymisation / Pseudonymisation)

- What do I need for my project and what is the difference?

Secure Data Storage for sensitive (patient) data

- Where can I store sensitive (patient) data and what do I have to consider?

Data Processing / Handling of sensitive (patient) data

- What do I have to consider regarding data processing/handling of sensitive (patient) data?

Publishing of results based on sensitive (patient) data

- What do I need to consider when publishing sensitive (patient) data?

Sharing of sensitive (patient) data

- Is it possible to share sensitive (patient) data and if yes, what to consider?

Sensitive (patient) data

Do I have sensitive (patient) data or what is sensitive (patient) data?

Definition **Federal Act on Data Protection …**

Art. 3 Definitions

The following definitions apply:

a. *personal data (data):* all information relating to an identified or identifiable person;

b. *data subjects:* natural or legal persons whose data is processed;

c. *sensitive personal data:* data on:

1. religious, ideological, political or trade union-related views or activities,
2. health, the intimate sphere or the racial origin,
3. social security measures,
4. administrative or criminal proceedings and sanctions;

… but what does this mean for me and my research?

Sensitive (patient) data

Do I have sensitive (patient) data or what is sensitive (patient) data?

5) Proteomics Results

8) Bacterial Strain Name

1) Patient Date of Birth

6) Number of Patients in Study

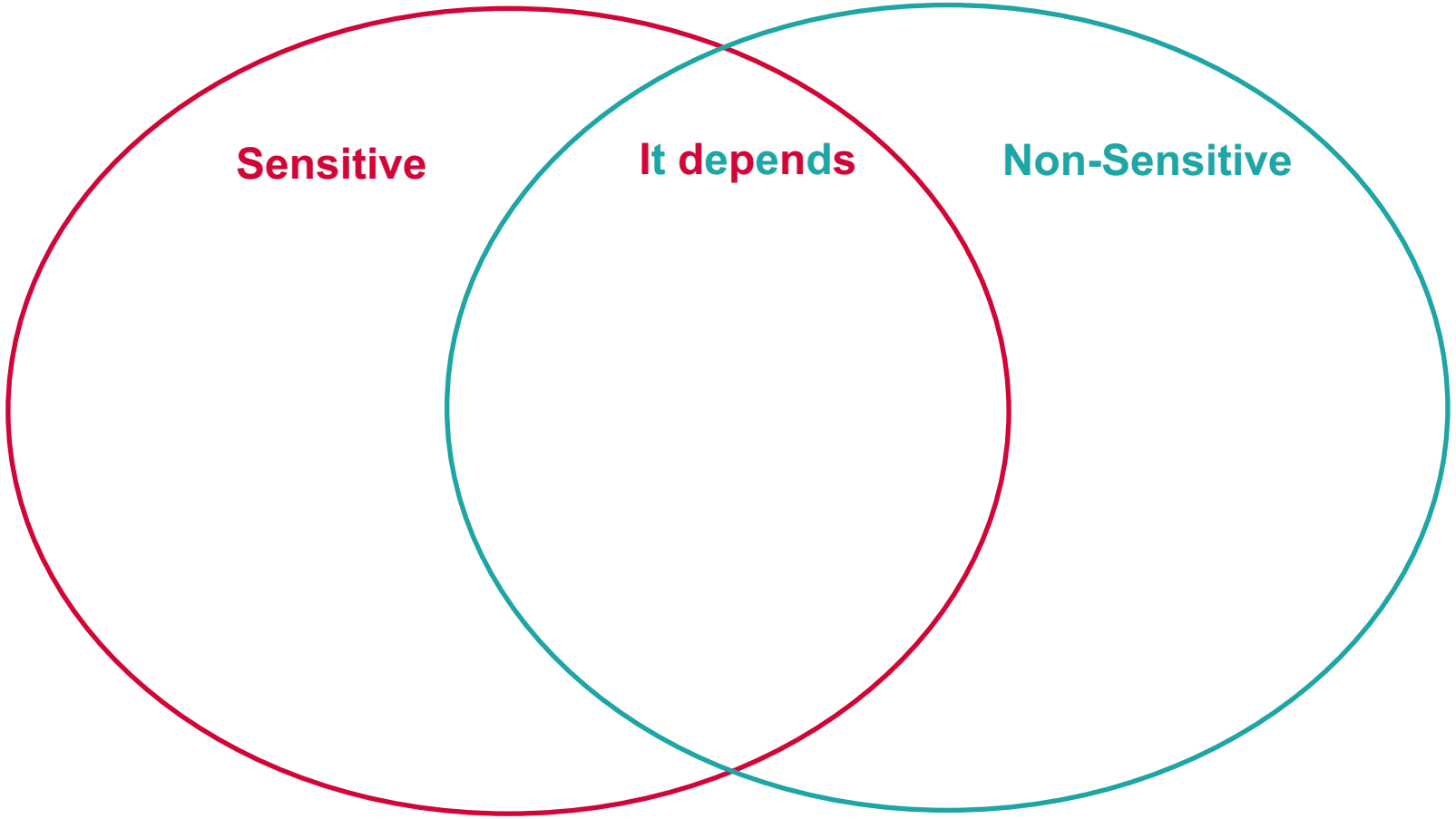
2) Patient Year of Birth

7) Whole Human Genome

4) Human Brain Scan

9) Bacterial Genomic Results

3) Bacterial Cell Image

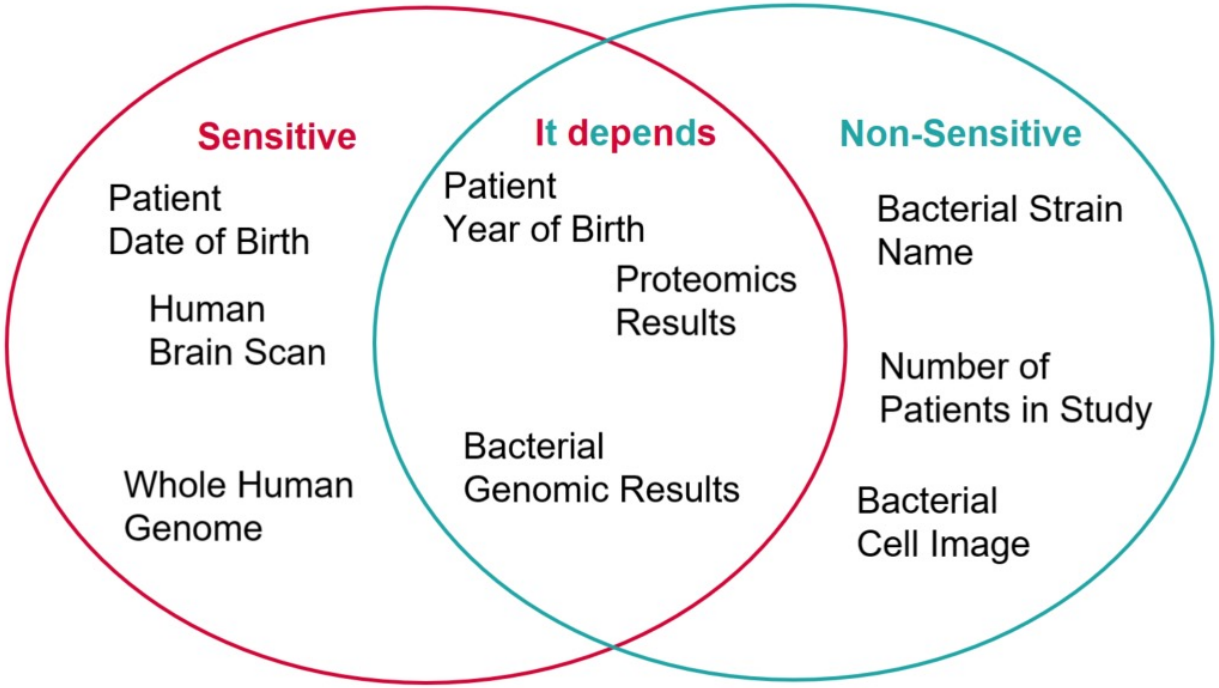


Sensitive (patient) data

Do I have sensitive (patient) data or what is sensitive (patient) data?

Please remember

- The sensitivity of data needs to be assessed for each dataset
- Depending on the type, the complexity and amount of data it might be sensitive or not
- If in doubt ask your data management responsible, your PI or a legal/regulatory person responsible for your project



Data de-identification (Anonymisation / Pseudonymisation)

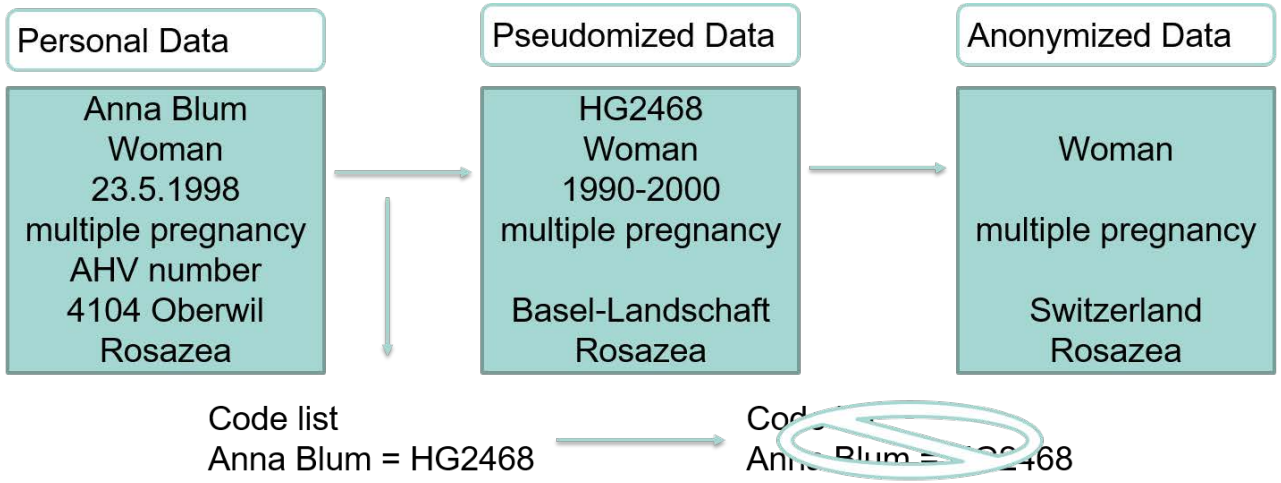
What do I need for my project and what is the difference?

Pseudonymisation

- Removal of the personal reference, while retaining a certain key (e.g. key mapping table).
- Key is stored separately
- In scope of Human Research Act (HRA) & Federal Act on Data Protection

Anonymisation

- **Re-identification** of a person only possible with **disproportionate effort**
- Out of scope from Human Research Act (HRA) & Federal Act on Data Protection



There is no fixed definition of anonymisation, it is rather a concept to reduce the risk.

Anonymisation and Pseudonymisation are not the same!

Data de-identification (Anonymisation / Pseudonymisation)

What do I need for my project and what is the difference?

- **Replicability**
  - How consistently is a variable related to a specific person?
    - laboratory values (low, except outliers!)
    - demographics (high)
- **Data source availability**
  - Which external data sources could be used for linkage attacks
- **Distinguishability**
  - How many persons share a specific combination of variables?
    - Year of birth & Canton (low)
    - Date of birth & ZIP code (high)
    - Rare Genomic Variation & Fürstentum Lichtentein (high)
    - Common disease and country (low)

Data de-identification (Anonymisation / Pseudonymisation)

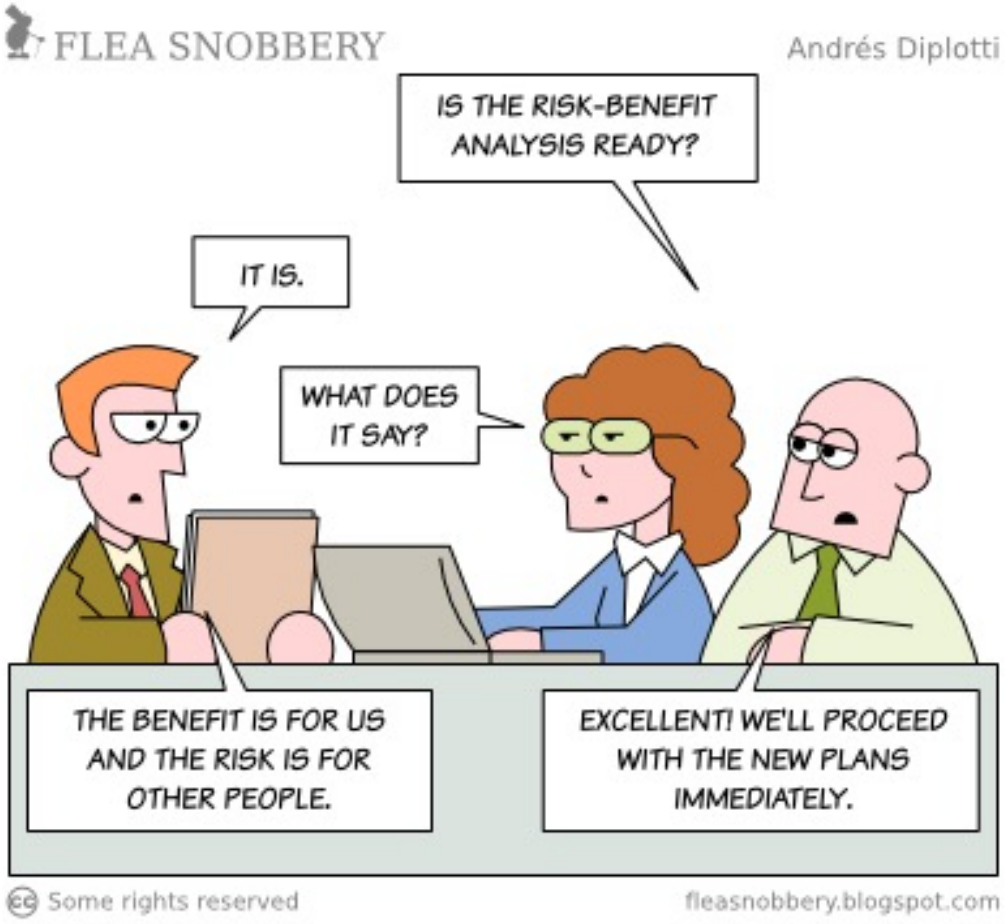
What do I need for my project and what is the difference?

It might look like a good idea to just take the road down anonymization alley, but …

- It might be more time consuming to do a proper anonymization then writing up the legal documents needed in case of pseudonymization

- It might lead to data that is not useful anymore for a particular research question as to many variables needed to be omitted or changed

And even if you anonymize your data you might be on the safer side to still have a DTUA in place.



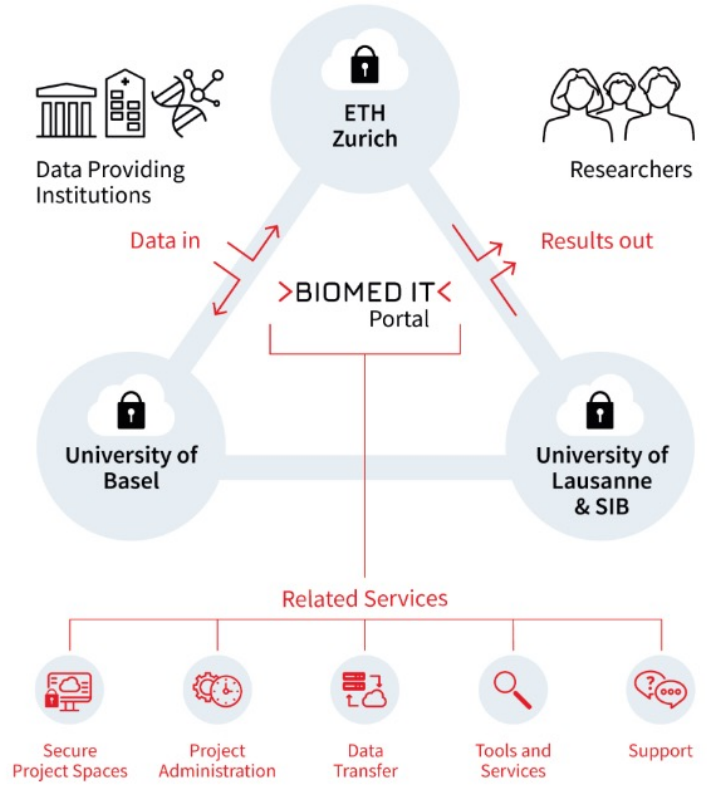
Secure Data Storage for sensitive (patient) data

Where can I store sensitive (patient) data and what do I have to consider?

Sensitive data imposes higher requirements on data storage:

- IT Governance (e.g. Risk Management)
- Asset Management (e.g. Media Handling)
- Access Control (e.g. Users, Data Providers)
- Operations Management (e.g. Backup)
- …

A solution for sensitive (patient) data is the BioMedIT infrastructure from Swiss Personalized Health Network (SPHN)



Recommendation: Check with your institute on options on how to get access to BioMedIT or what other solutions they can provide you for your sensitive (patient) data

Data Processing / Handling of sensitive (patient) data

What do I have to consider regarding data processing/handling of sensitive (patient) data?

The legal/regulatory documents needed for the processing / handling of sensitive (patient) data

- Ethics
- Informed Consent
- Data Transfer and Use Agreement
- Data Transfer and Processing Agreement
- …

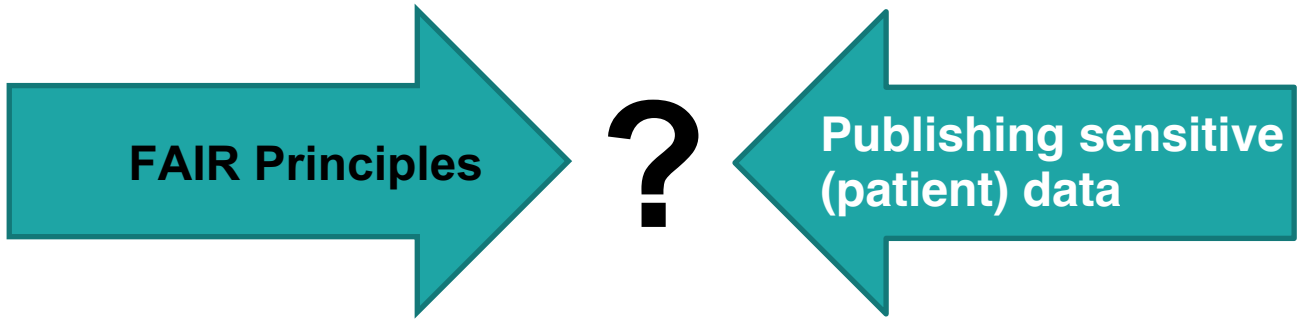
Everybody needs to be aware/trained how to deal with sensitive (patient) data

- Overall training on processing/handling of sensitive (patient) data
- Guideline on internal data sharing (e.g. within a consortium)
- Project relevant instructions or training
- …

Come up with a solution that keeps your sensitive (patient) data save …
… but does not stifle research

Publishing of results based on sensitive (patient) data

What do I need to consider when publishing sensitive (patient) data?



Recommendations:

If possible publish metadata only with information on how to request access to the data

- Make sure the data is stored in an secure place in your institution or BioMedIT

If data needs to be published make sure it is an acceptable platform that allows the data to be protected according to your requirements

- This depends on the kind of data you have

Check with your institution for the Data Access Committee / Data Governance Board

- They might be able to help you with further questions on Data Sharing and in case a sharing requests comes your way

Sharing of sensitive (patient) data

Is it possible to share sensitive (patient) data and if yes, what to consider?

Quick Answer -> YES!

Long(er) Answer -> …

- You need the legal documents and agreements like the DTUA in place
- Check if you ethical approval allows for further use of the data and sharing
- Check with your Legal Department
- Check with your Data Access Committee / Data Governance Board

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Approach towards sensitive (patient) data in NCCR AntiResist

Setup NCCR AntiResist:
- 3 Hospitals
- 5 Universities
- ~20 Research Groups

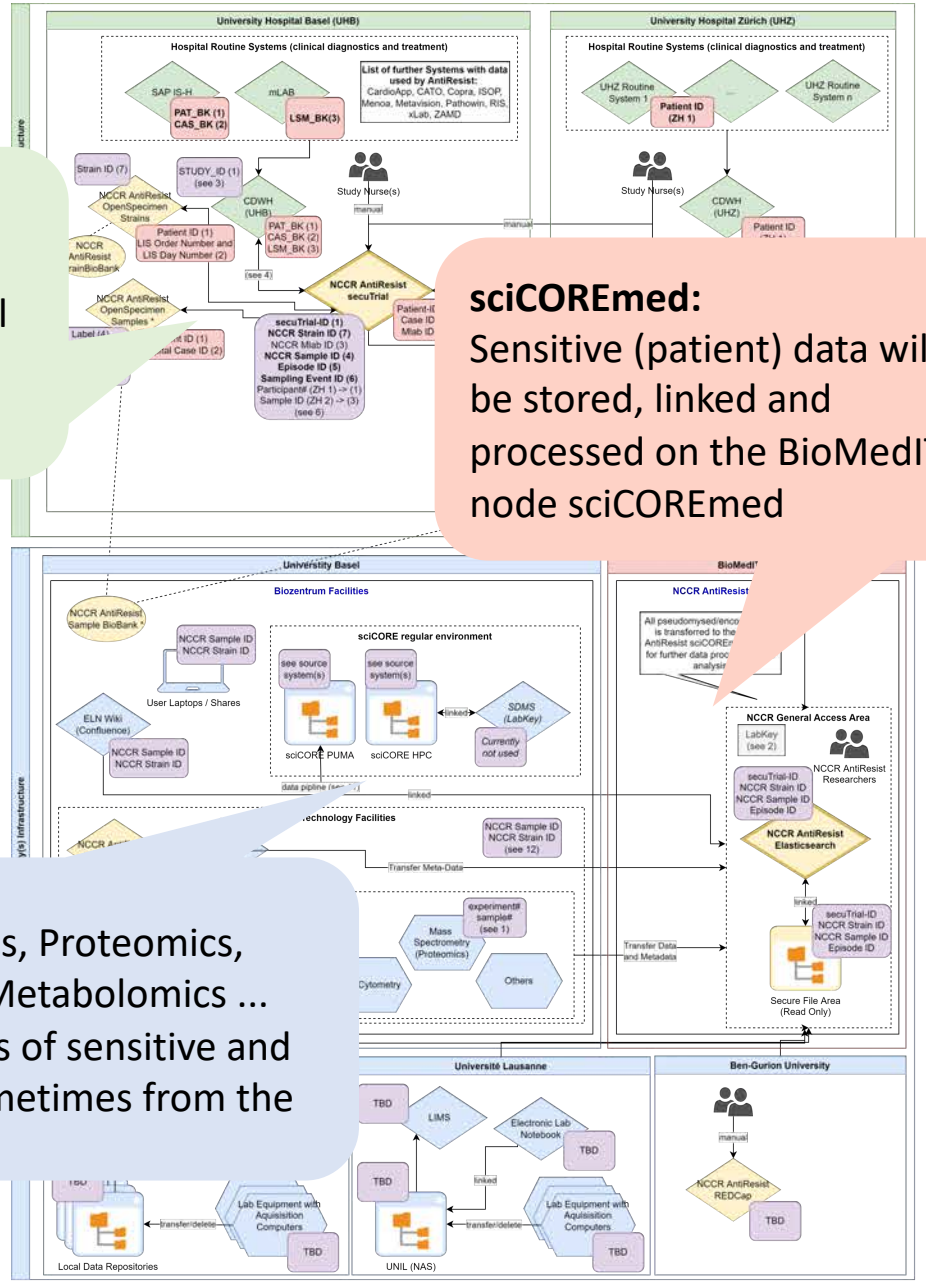
- Un-encoded **patient data** always stays with the corresponding hospital

- **Research data** (sensitive/non sensitive) will be produced and (temporarily) stored on the given infrastructure from each institution

- BioMedIT (**sciCOREmed**) for the aggregation and joint analysis of sensitive (patient) data and non-sensitive research data

Clinical Data:
~ 500 variables of sensitive patient related data from clinical routine systems to specially entered clinical study data

sciCOREmed:
Sensitive (patient) data will be stored, linked and processed on the BioMedIT node sciCOREmed



Research Data:
Imaging, Genomics, Proteomics, Transcriptomics, Metabolomics ...
... all combinations of sensitive and non-sensitive (sometimes from the same lab)

Approach towards sensitive (patient) data in NCCR AntiResist

Support Structure Setup

Support Structure with Medical Data Office and Research Data Officer

Medical Data: Medical Data Office

MDO | Data Architect | Regulatory

- Coordination on the medical side
- Setup of secuTrial Database for patient related data
- Data Flow and technical setup including data transfers to sciCOREmed
- Ethics and DTUA/DTPA
- …

Research Data: Research Data Officer

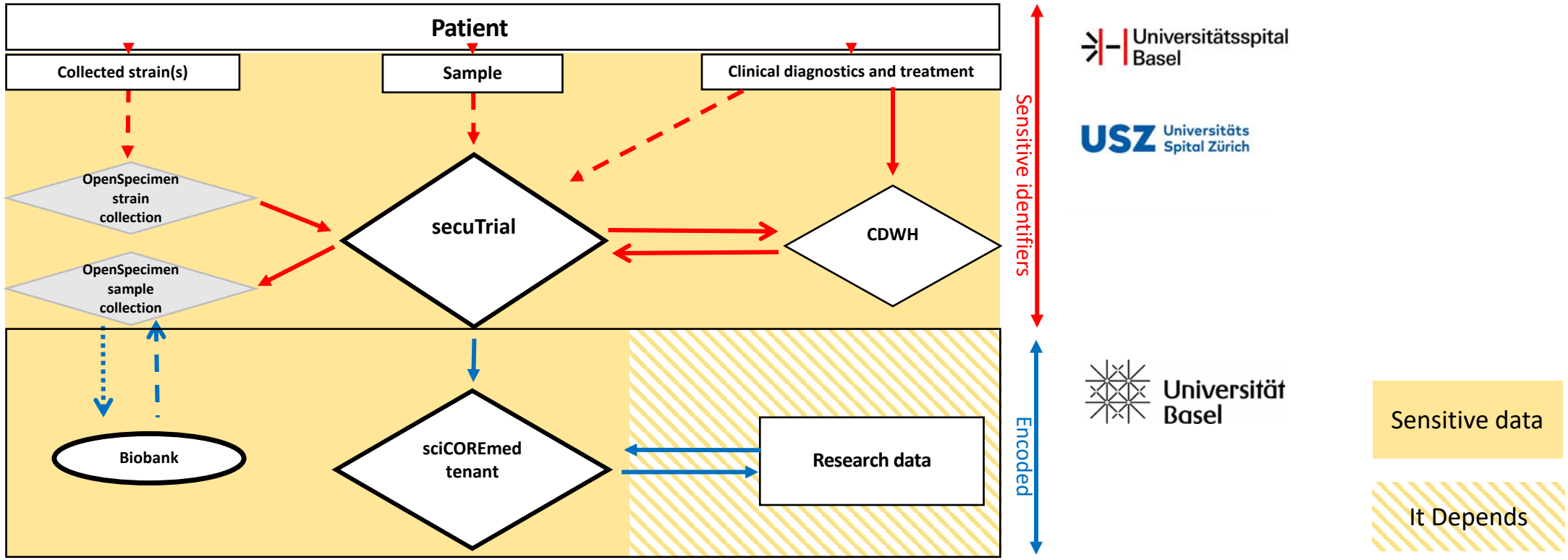
RDO

- Coordination on the research side
- Support with setup of sciCOREmed tools for data linking and analysis
- Consolidation of research data
- Metadata / Ontologies
- ...

- Approach and support for handling sensitive data and linking of sensitive and non-sensitive data
- NCCR AntiResist Data Sharing Policy - Including training on sensitive data
- …

Approach towards sensitive (patient) data in NCCR AntiResist

Infrastructure and Encoding



- All sensitive (patient) data including sample material is encoded (pseudonymised) and the un-encoded data does not leave the University Hospital Infrastructure (E.g. Case Number, Patient ID, Lab Testing ID, …)
- Electronic Data Capture System (secuTrial) for additional patient related study data

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Small group discussions

- Please form groups of 3 to 4 people
- Nominate 1 person as the spokesperson for the group who will present the major discussion points later
- Discuss the topics you prepared or that came up for you during the session
- We will walk around and join the discussions here and there
- **You have 10 minutes!**

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Summary of discussions and further questions

- Each group to shortly present what their discussion topics where and what questions are still open.

- We will collect the questions and send out answers to the participants

Key Learning(s)

If you deal with sensitive data always keep this in mind

- **If in doubt …**
  - **… check within your project with a legal representative, a regulatory expert, a data manager, your PI**
- Think about data protection, too
- The merge of existing data sets as well the repeated evaluation of data sets (further use) also fall within the scope of HRA
- Anonymised data and samples are not within the scope of the HRA, but anonymization has its own drawbacks
- Ethics vote required for research questions answered with data and samples of human origin (Ethics vote required for publication)
- The will of the data and sample donor must always be respected (informed consent)
- Encoded data can still be sensitive data

People/Patients entrust us with THEIR data to make OUR research possible …
… value this and keep in mind that this could change in case of too many bad news
(e.g. data breaches, re-identification of public person)

University of Basel

Department of Clinical Research

University Hospital Basel

Thank you
for your attention.

Further Material

Humanforschungs-Gesetz (HFG): https://www.fedlex.admin.ch/eli/cc/2013/617/de
Humanforschungs-Verordnung (HRO): https://www.fedlex.admin.ch/eli/cc/2013/642/de
Datenschutzgesetzt (DSG): https://www.fedlex.admin.ch/eli/cc/1993/1945_1945_1945/de
Swiss Ethics: https://swissethics.ch/en

SPHN – Data Transfer and Use Agreement: https://sphn.ch/services/dtua/
SPHN – DMP: https://sphn.ch/2021/12/21/guidelines-for-the-creation-of-a-data-management-plan/
SPHN – De-Identification: https://sphn.ch/network/data-coordination-center/de-identification/

BioMedIT: https://www.biomedit.ch/
BioMedIT – Information Security Awareness Training: https://edu.sib.swiss/enrol/index.php?id=556
sciCOREmed: https://scicore.unibas.ch/

Departement for Clinical Research (DKF): https://dkf.unibas.ch/de/

NCCR AntiResist: https://www.nccr-antiresist.ch/en/