



COMMISSION CANTONALE
D'ÉTHIQUE DE LA RECHERCHE
SUR L'ÊTRE HUMAIN

CER-VD

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Ethical aspects, legal questions and security of research participants

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Aim of the presentation

- Brief overview of the Swiss EC's
 - Duties and activities
- Research with human: applicable legislation

Aim of the presentation

- Discussion about :
 - Information and Consent
 - Study Protocol
 - Other key documents
- Terminological clarification:
 - investigator, sponsor, funding body,
 - open, coded, anonymised data
- Workshop on:
 - Research with children
 - Research with persons unable to consent
 - Research with incomplete information

TRREE program

<https://elearning.trree.org/>

TRREE stands for **T**rainning and **R**esources in **R**esearch **E**thics **E**valuation.

The program is built with different modules and aims provide basic training on the ethics of health research involving humans.

Aim of the presentation

- Brief overview of the Swiss EC's
 - Duties and activities

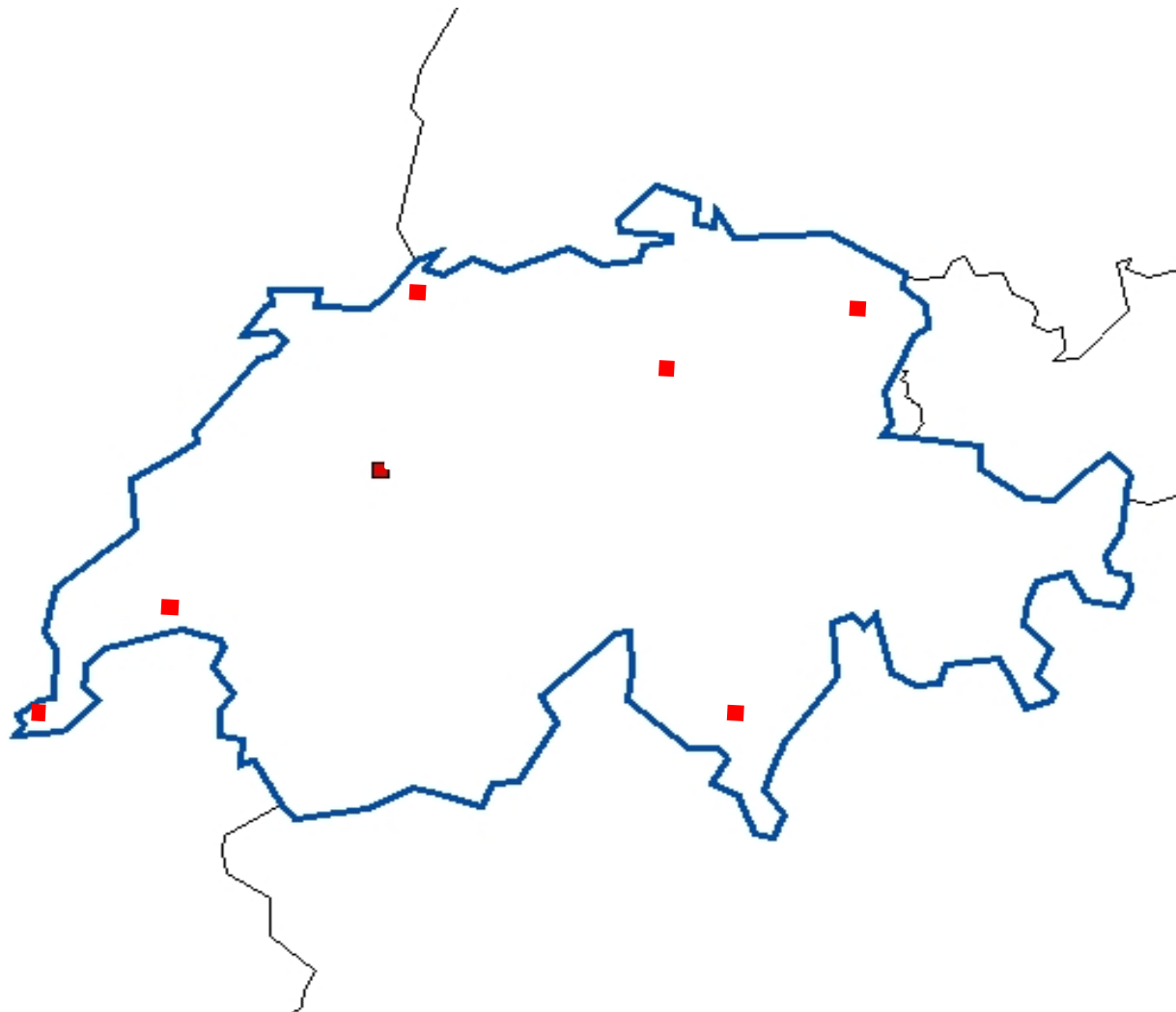
Swiss ECs: Duties

Art. 51 HRA : Duties

¹ Within the framework of their responsibilities under Chapter 8, **ethics committees shall assess whether research projects and the conduct thereof comply with the ethical, legal and scientific requirements of this Act. In particular, they shall assess whether the protection of the persons concerned is guaranteed.**

² They may **advise** researchers in particular **on ethical questions** and, if so requested by the researchers, **comment on research projects not subject to this Act**, and specifically projects carried out abroad.

Swiss EC's



Swiss Ecs: Scope of the HRA

Art. 2 HRA:

- 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.

Swiss EC's: Scope of the HRA:

Art. 2 HRA:

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.**



HRA: principles

Art. 4: Primacy of individual interests

Art. 5: Scientifically relevant topic

Art. 6: Non-discrimination of the research subjects

Art. 7: Consent of the subjects

Art. 11: Subsidiarity

Art. 12: Risks and burdens

Art. 13: Remuneration

Swiss ECs: Review area

[Art. 15 HRO](#) The responsible ethics committee shall review:

(...)

c. the research project with regard to:

- 1.scientific quality, in the case of a research project as specified in Article 6 letter a,
- 2.the ratio between the likely risks and burdens and the expected benefits (Art. 12 para. 2 HRA),
- 3.the measures taken to minimise risks and burdens, and for the protection and follow-up of participants (Art. 15 HRA), including precautionary measures in the handling of personal data,
- 4.the need to involve persons, and in particular persons who are particularly vulnerable (Art. 11 HRA),
- 5.the criteria for the selection of participants,
- 6.the proposed procedure for providing information and obtaining consent, including the appropriateness of the period for reflection,
- 7.the appropriateness of the remuneration for participants and compliance with the prohibition of commercialisation (Art. 9 HRA),
- 8.compliance with scientific integrity requirements;

d. the completeness of the documentation for recruitment, information and consent, and its comprehensibility, especially with regard to the possible involvement of particularly vulnerable persons;

(...)

h. compliance with the requirements concerning the storage of biological material or health-related personal data specified in Article 5;

i. the suitability of the infrastructure at the research site;

j. the financing of the research project and the agreements between the sponsor, third parties and the project leader concerning the allocation of tasks, remuneration and publication;

Swiss ECs: Rewiew area - clarification

- For non-clinical trial, the HRA tackles a risk based approach.
- Risks are mainly considered in terms of body integrity.
- Art. 7 al. 3 HRO states that:

«A research project comes under Category A if the planned measures for sampling biological material or collecting personal data entail only minimal risks and burdens.

(...)

In particular, minimal risks and burdens may be in association with:

a) survey and observations

(...)

Swiss ECs: Rewiew area - clarification

Is the following equation correct?

«survey / observations = minimal risks»

If not, why, and for whom?

Swiss EC's: Scope of the HRA:

Having briefly reviewed the scope of the HRA, and the main principles we can see that:

- The application law focuses on biomedical research, resp. research on human disease and the functioning of the human body.
- The application law (HRA) and ordinances focus on the potential risks for research participants.
- There is no specific regulation for research projects involving human beings that do not fall under the scope of the HRA.

Swiss EC's: Scope of the HRA:

If your project does not fall under the scope of the HRA, are you good to go?

Scope of the HRA:

- [Art. 118b](#) of the Swiss Constitution does not specify the type of research involving human beings it concerns.
- The legal basis for other application laws regulating research with human beings is existing.
- Even for the time being, there is no legal no man's land.

Projects out of the scope of the HRA: Applicable legislation.

Federal Constitution of the Swiss Confederation

- [Art. 7](#): Human dignity

Human dignity must be respected and protected

- [Art. 10](#) : Right to life and personal freedom

(...)

² Every person has the right to personal liberty and in particular to physical and mental integrity and to freedom of movement.

(....)

- [Art. 13](#) : Right to privacy

(...)

² Every person has the right to be protected against the misuse of their personal data.

Projects out of the scope of the HRA: Applicable legislation.

Swiss Civil Code

Art. 28 B: Protection of legal personality

1. Principle

¹ Any person whose personality rights are unlawfully infringed may petition the court for protection against all those causing the infringement.

² **An infringement is unlawful unless it is justified by the consent of the person whose rights are infringed or by an overriding private or public interest or by law.**

Projects out of the scope of the HRA: Applicable legislation.

The Code of Obligations

- [Art. 1 A](#). Conclusion of the contract

¹ The conclusion of a **contract requires a mutual expression of intent by the parties.**

² The expression of intent may be express or implied

- [Art. 20 E](#): Terms of the contract/ II. Nullity

II. Nullity

¹ A contract is void if its terms are impossible, unlawful or immoral.

² However, **where the defect pertains only to certain terms of a contract, those terms alone are void unless there is cause to assume that the contract would not have been concluded without them.**

Projects out of the scope of the HRA: Applicable legislation.

Federal Act on Data Protection

[Art. 3: Definition](#)

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;
- d. *personality profile*: a collection of data that permits an assessment of essential characteristics of the personality of a natural person;
- e. *processing*: any operation with personal data, irrespective of the means applied and the procedure, and in particular the collection, storage, use, revision, disclosure, archiving or destruction of data;
- f. *disclosure*: making personal data accessible, for example by permitting access, transmission or publication;
- g. *data file*: any set of personal data that is structured in such a way that the data is accessible by data subject;
- (...)

Projects out of the scope of the HRA: Applicable legislation.

Federal Act on Data Protection

Art 4 Principles

¹ Personal data may only be processed lawfully.¹

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.

⁴ The collection of personal data and in particular the purpose of its processing must be evident to the data subject.²

⁵ If the consent of the data subject is required for the processing of personal data, such consent is valid only if given voluntarily on the provision of adequate information. Additionally, consent must be given expressly in the case of processing of sensitive personal data or personality profiles.³

Projects out of the scope of the HRA: Applicable legislation.

Federal Act on Data Protection

[Art. 7 Data Security](#)

- ¹ Personal data must be protected against unauthorised processing through adequate technical and organisational measures.
- ² The Federal Council issues detailed provisions on the minimum standards for data security.

Projects out of the scope of the HRA: Applicable legislation.

Swiss Criminal Code

[Art. 321](#) Breach of professional confidentiality

Breach of professional confidentiality

1. Any person who in his capacity as a member of the clergy, lawyer, defence lawyer, notary, patent attorney, auditor subject to a duty of confidentiality under the Code of Obligations¹, doctor, dentist, chiropractor, pharmacist, midwife, psychologist or as an auxiliary to any of the foregoing persons discloses confidential information that has been confided to him in his professional capacity or which has come to his knowledge in the practice of his profession is liable on complaint to a custodial sentence not exceeding three years or to a monetary penalty.²

A student who discloses confidential information that has come to his knowledge in the course of his studies is also liable to the foregoing penalties.

A breach of professional confidentiality remains an offence following the termination of professional employment or of the studies.

2. The person disclosing the information is not liable to any penalty if he does so with the consent of the person to whom the information pertains or on the basis of written authorisation issued in response to his application by a superior authority or supervisory authority.

3. The federal and cantonal provisions on the duty to testify and on the obligation to provide information to an authority are reserved

Projects out of the scope of the HRA: Applicable legislation.

- Institutional requirements (IRB's, Sponsor's office, institutional directives)
- Third parties requirements (Funding body, publishing companies, research partners etc.)

Projects out of the scope of the HRA

Requirements to use data for research:

- Consent
- Data Security

Informed Consent

“(...) a freely-taken decision whether or not to participate in a research project, based on careful consideration of the advantages and disadvantages of such participation for the person involved”.

TRREE program, module 3.1

Informed Consent

What conditions are required for an informed consent?

Informed Consent: key elements

- Competence (understanding)
- Capacity (to consent)
- Information
- Voluntariness

Information

A researcher wants to recruit you for a research project.

What would you like to know about it before deciding whether or not to participate?

Informed Consent: key elements

Art. 16 HRA

- 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 taken to protect the personal data collected;
- e. their rights.

Informed Consent: key elements

Art. 8 HRO

¹ In addition to the points specified in Article 16 paragraph 2 HRA, the persons concerned must receive information on:

- a. the effort involved and the obligations arising from participation;
- b. their right to withhold or to revoke their consent without giving reasons;
- c. the consequences of revoking consent to further use of the biological material and personal data collected up to this point;
- d. their right to receive information at any time in response to further questions;
- e. their right to be informed of results concerning their health, and their right to forgo such information or to designate a person who is to take this decision for them;
- f. the measures envisaged to cover any damage arising from the research project, including the procedure in the event of a claim;
- g. the main sources of financing for the research project;
- h. other points relevant to their decision on participation.

² If the intention exists to make further use for research of the biological material sampled or the health-related personal data collected, the persons concerned must also receive information on the points specified in Articles 28-32.

³ The information may be provided in stages. It may be additionally presented in a non-textual form.

⁴ Appropriate measures must be taken to ensure that the persons concerned have understood the essential elements of the information provided.



Key document: research plan / protocol

Is a research plan needed?

What is the use a research plan?

Key document: Research plan

- [Research plan template.](#)

Other key documents

- If you version it and store a TC version in addition to each new version, the research plan/protocol will be your best friend.
 - It gathers all information about your project and the way data is processed (also in the future)
 - You can change it/ you have to modify it.
 - It reflects the actual state of your research.
 - You can go back to a former state of your research.
 - You can have read or used by others.

Other key documents

- **Agreements and Contracts**
- **Data Management Plan**
- **Staff list / delegation log**
- **Authorizations (copyright protected questionnaires, Institutions, Schools etc.)**
- **(Insurance)**

Key concepts

- **Further use**
- **Project leader vs Sponsor vs Funding body**
- **Open vs anonymised vs coded data**

Key concepts

Further use

Plan ahead. If you don't know exactly what you will find, you know you might want to re-use (or let other reuse) you data. You can add this to the research plan and the information to the participants.

Key concepts

Project leader

¹ The project leader is responsible for the conduct of the research project in Switzerland and for protection of the participants at the research site.

Key concepts

Sponsor:

² The project leader is also responsible for organising the research project, and in particular for the initiation, management and financing of the project in Switzerland, provided that no other person or institution headquartered or represented in Switzerland takes responsibility for this (sponsor).

Key concepts

Funding body:

Most of the time, the funding body is not the sponsor of a given research project (except if the industry is involved).

The external funding body will (generally) not bear any responsibility for the project. But the funding body may have requirements. If you have any doubts, let these be checked by the legal department of your institution.

Key concepts

Anonymisation

Art. 25 Anonymisation

¹ For the anonymisation of biological material and health-related personal data, all items which, when combined, would enable the data subject to be identified without disproportionate effort, must be irreversibly masked or deleted.

² In particular, the name, address, date of birth and unique identification numbers must be masked or deleted

Key concepts

Coding:

Art. 26 Coding

¹ Biological material and health-related personal data are considered to be correctly coded in accordance with Article 32 paragraph 2 and Article 33 paragraph 2 HRA if, from the perspective of a person who lacks access to the key, they are to be characterised as anonymised.

² The key must be stored separately from the material or data collection and in accordance with the principles of Article 5 paragraph 1, by a person to be designated in the application who is not involved in the research project.

Data protection

Art. 5 Storage of health-related personal data and biological material

¹ Any person who stores health-related personal data for research must take appropriate operational and organisational measures to protect it, and in particular:

- a. restrict the handling of the health-related personal data to those persons who require this data to fulfil their duties;
- b. prevent unauthorised or accidental disclosure, alteration, deletion and copying of the health-related personal data;
- c. document all processing operations which are essential to ensure traceability.

Data protection

Can you fulfill these duties on
your own?

Data protection

It's the duty of the institution! Your job is to do research.

As the sponsor of research projects, the institution has to provide (easy to use) solutions in line with the applicable regulations, inform and train the in-house researchers and set up SOP's. In so doing, the conception work will be done once at the institutional level for each type of research projects, not at the project level. (And the evaluation work will be quicker.)

Instead of discussing the sensitivity of each data, adopt only standards high enough for the sensitive data.



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