SCTO PLATFORMS

19 November 2025 | 12.00–13.00 | online seminar

Facts and pitfalls of observational studies

Research projects according to HRO Chapters 4 and 5: The rare cases

This seminar session consists of two parts. The first will examine the Ethics Committee's perspective on the requirements for such projects, while the second will outline the objectives and key features of concrete projects and provide practical guidance on preparing, conducting, and completing them.

Registration and more information:

sctoplatforms.ch/hro-chapters-4-5-rare-cases.ch

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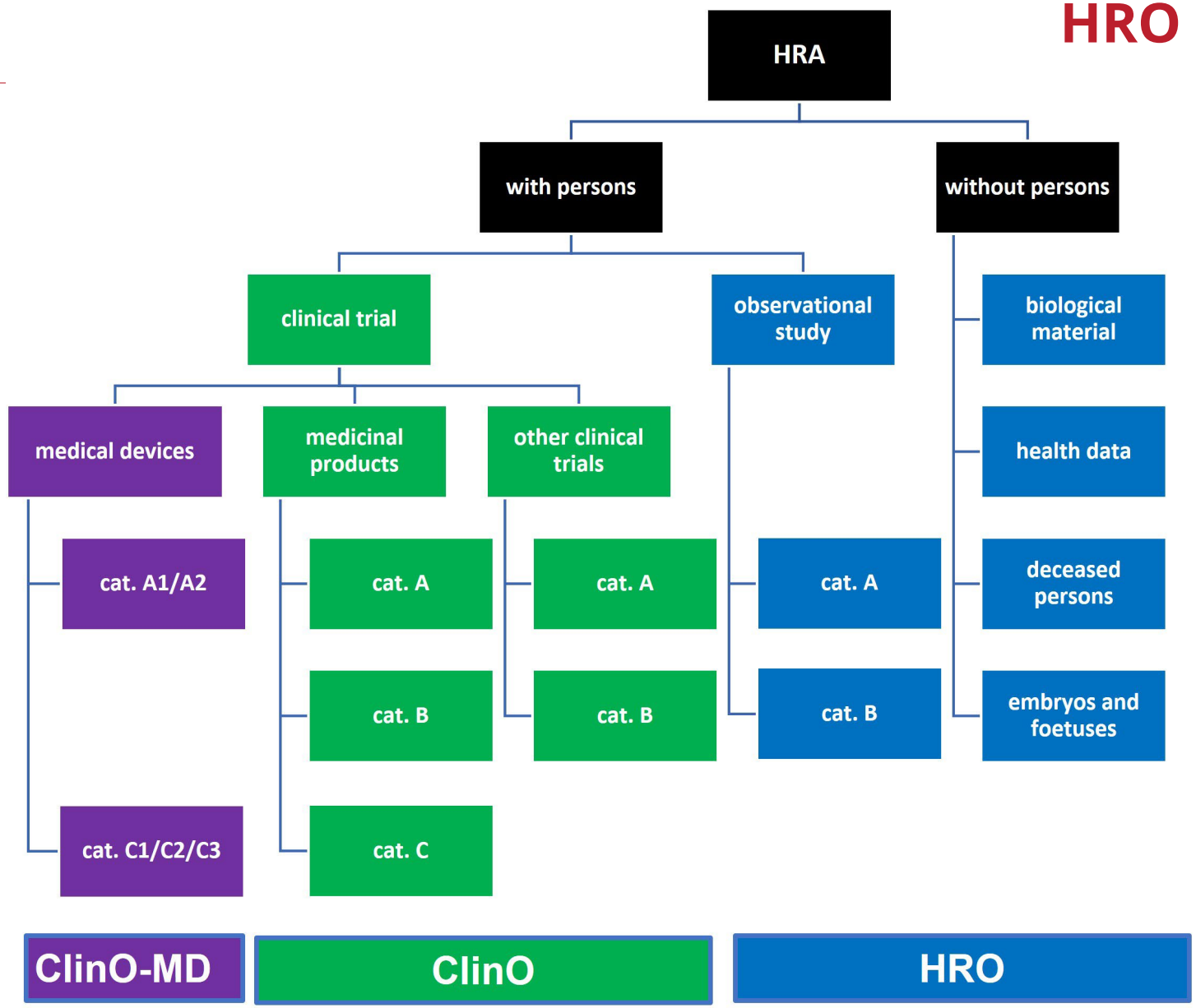
HRO - Where are we?



according to Ch. Seiler, EC Bern

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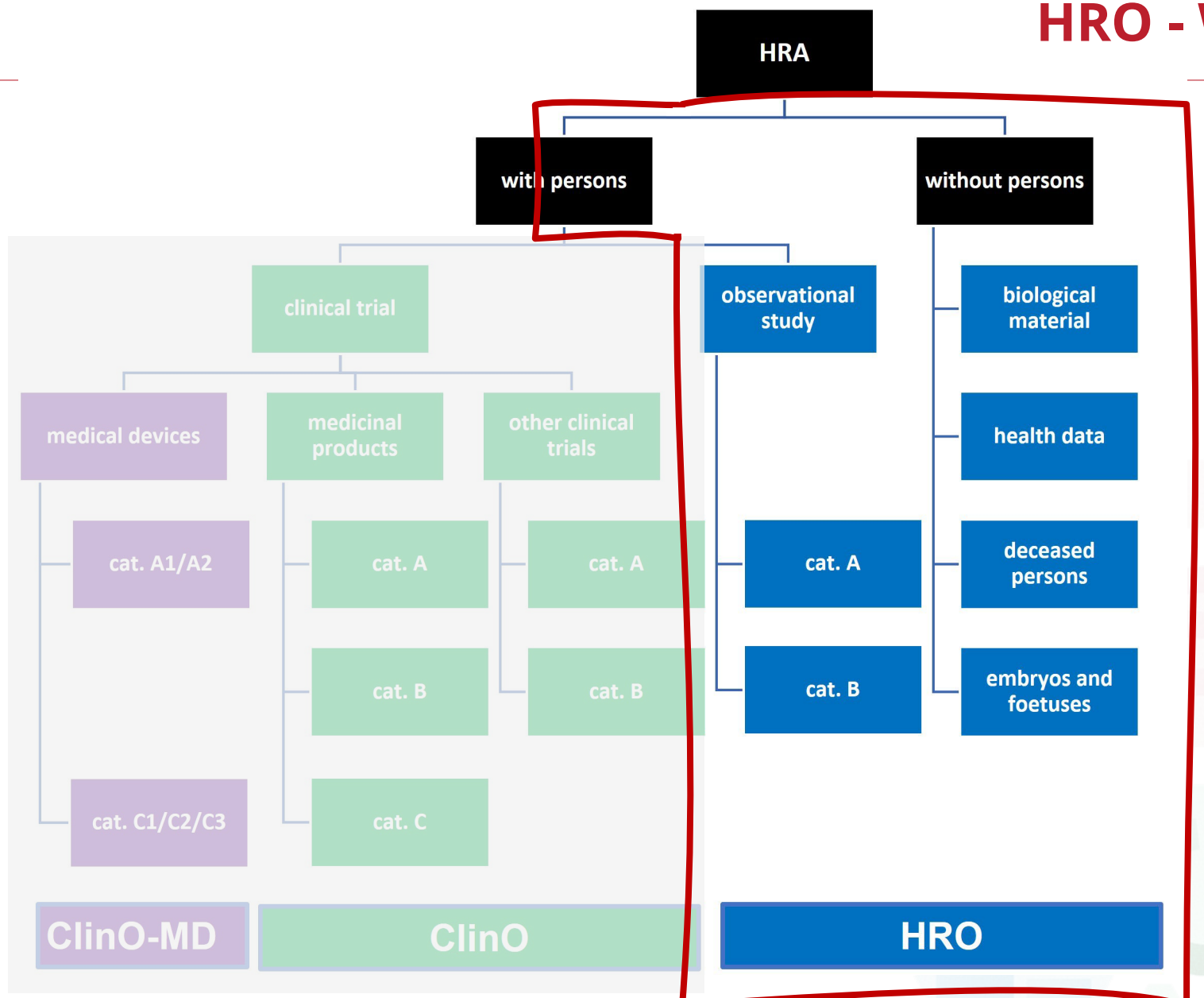
HRO - Where are we?



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General information

- **Questions**:
  - **during presentation**: in the chat mentioning the part (I or II) of the session that it refers to (→ for Q&A session at the end)

- Presentation recorded

- Video, slides and Q&A provided after the session

- Feedback poll at end → please fill in!

- HRO lunch project team:
  - Claudia Fila (CTC Zurich)
  - Antoine Poncet (HUG)
  - Verena Golz (DKF Basel)

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Presentation

Dr. sc. nat. Tobias Rosenberger

Head Scientific Office, Cantonal Ethics Committee Zurich

Tobias.Rosenberger@kek.zh.ch

Prof. Dr. Philipp Fürnstahl

ROCS) Head of Research in Orthopedic Computer Science (, University Hospital Balgrist Zurich, University of Zurich (UZH)

Philipp.Fuernstahl@balgrist.ch

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HRO Lunch Session - Part I

Requirements from the perspective of the Ethics Committee

Dr. sc. Nat. Tobias Rosenberger

Kanton Zürich

HRA Chapter 5: Research involving deceased persons

(+ HRA Chapter 6)

Dr. sc. nat. Tobias Rosenberger,
Scientific Secretariat EC Zürich

The numbers (since 2016)

HRO Chapter 4 (Deceased Persons):

CH: 260 (ZH: 131)

HRO Chapter 5 (Embryos and Fetuses):

CH: 5 (ZH: 0)

As of 26.09.2025

all projects: 20’753

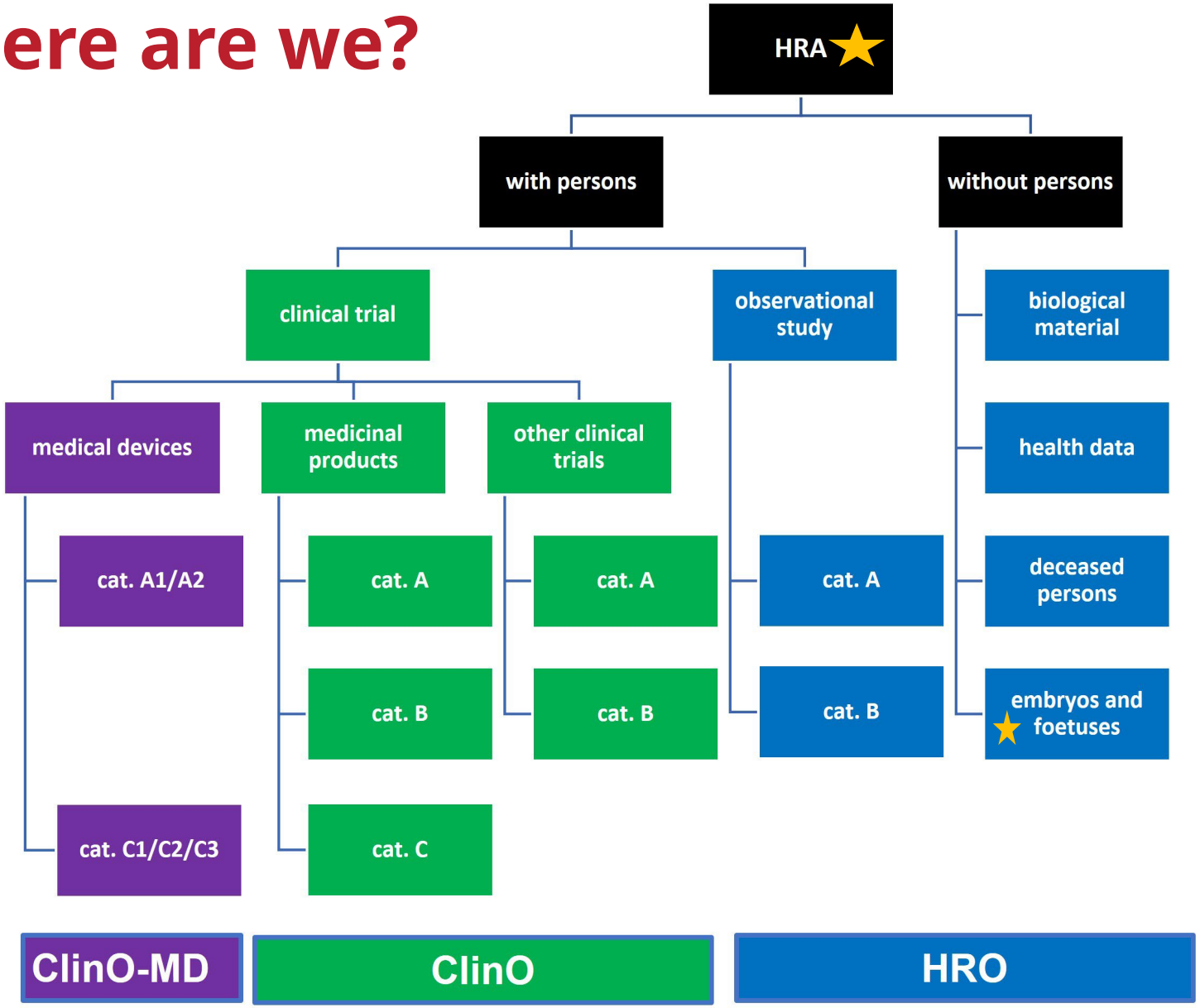
Overview

The Law

The EC

The law

HRO - Where are we?



according to Ch. Seiler, EC Bern

Legal base

Research Involving Deceased Persons

In the law: Chapter 5 HRA (articles 36-38)

in the ordinances: Chapter 4 HRO (articles 41-43)

Research involving Embryos and Fetuses from Induced Abortions and from Spontaneous Abortions including Stillbirths

In the law: Chapter 6 HRA (articles 39-40)

in the ordinances: Chapter 5 HRO (articles 44-46)

HRO chapters and differences

	Chapter 2 – collection/ sampling	Chapter 3 – further use of data/ material	Chapter 4 - deceased persons	Chapter 5 – embryos and foetuses
Direct person involvement	Yes	No	No	
Health risks possible	Yes	No	No	
Occurrence	prospective	retrospective	retrospective*	

HRO chapters and differences

	Chapter 2 – collection/ sampling	Chapter 3 – further use of data/ material	Chapter 4 - deceased persons	Chapter 5 – embryos and foetuses
Consent	Specific only	Specific or general (GC) or surrogate (article 34 HRA)	specific only; by proxy possible	specific and by proxy (pregnant woman or the couple)
numbers	High enough to generate generalisable knowledge		N≤1	
EC procedure	Simplified or ordinary	Presidential or simplified	simplified	

body parts vs. biological material

- Corpses and body parts are **not** “biological material”!

  Therefore, they don't fall under a general consent
- An anonymisation doesn’t exempt research from an EC approval! On the contrary: It makes it harder to prove that a consent was given!

Biological material means “bodily substances derived from living persons” (Art. 3 lit. e. HRA)

Combined projects with further use of data and biological material are possible. They are foremost chapter 4 submissions.

The articles of the law…

Article 36 HRA Consent

Deceased Persons

[1] Research may be carried out in deceased persons if, before their death, the persons concerned consented to the use of their body for research purposes.

[2] If no documented consent or refusal of the deceased person is available, the body or parts thereof may be used for research purposes if consent is given by the next of kin or by a trusted person designated during the lifetime of the deceased person.

[3] The consent of the next of kin or the trusted person is governed by Article 8 of the Transplantation Act of 8 October 2004.

[4] In the case of deceased persons whose death occurred more than 70 years previously, research may be carried out without consent being given as specified in paragraph 2. If such research is opposed by the next of kin, it may not be carried out.

Article 37 HRA

Deceased Persons

[1] A research project may be carried out in deceased persons when their death has been determined.

[2] A research project may be carried out in deceased persons undergoing artificial respiration if, in addition to the requirement specified in paragraph 1, equivalent findings cannot be obtained with deceased persons not undergoing artificial respiration. The Federal Council may specify further conditions.

[3] Anyone who carries out a research project in accordance with paragraph 2 must not have been involved in the determination of death or be authorised to issue instructions to the persons involved in this procedure.

Article 38 HRA

Deceased Persons

Small quantities of bodily substances removed in the course of an autopsy or transplantation may be anonymised for research purposes without consent, in the absence of a documented refusal of the deceased person.

Important!

- "small quantities" means *a few g or ml* without destroying the corps
- The sample must be anonymized immediately after sampling

Article 39 HRA

Embryo or Foetus

[1] A pregnant woman may only be asked whether she wishes to make her embryo or foetus available for research purposes after she has decided to undergo an abortion. For consent, Articles 16 and 22–24 apply *mutatis mutandis*.

[2] The time and method of induced abortion must be chosen without regard to the research project.

[3] Embryos and foetuses from induced abortions may be used for a research project when death has been determined.

[4] Anyone who carries out a research project in accordance with paragraph 3 must not be involved in the abortion or be authorised to issue instructions to the persons involved in this procedure.

Article 40 HRA

Embryo or Foetus

1 Embryos and foetuses from spontaneous abortions including stillbirths may only be used for research purposes with the consent of the couple concerned. For consent, Article 16 applies mutatis mutandis.

2 Embryos and foetuses from spontaneous abortions may be used for a research project when death has been determined.

Soft law

Empfehlung der SAMW: Verwendung von Leichen und Leichenteilen in der medizinischen Forschung sowie Aus- und Weiter- und Fortbildung (2008, angepasst 2014)

Recommandations: Utilisation de cadavres et de parties de cadavres dans la recherche médicale et la formation prégraduée, postgraduée et continue (2008, adaptées 2014)

SAWM-Guidelines and Handbooks

related to death and dying

The EC

Chapter 4 HRO: What we check

- Completeness of the documentation

- Correct informed consent (art. 36 HRA)
- *Special requirements if the deceased person undergoes artificial respiration*

- Compliance with the prohibition of commercialisation (Art. 9 HRA);

- Scientific quality (is there a research question? hypothesis?)

- Qualifications of the projectleader and compliance with the requirements for the storage

Chapter 5 HRO: What we (would) check

- Completeness of the documentation

- Correct informed consent (art. 44 HRO)

compliance with the requirements specified in Article 39

- Compliance with the prohibition of commercialisation (Art. 9 HRA);

- Scientific quality (is there a research question?; hypothesis?)

- Qualifications of project leader and compliance with the requirements for the storage

What are the ethical questions?

- Disturbing the dead («Störung der Totenruhe»); reverence, **respect**, piety
- Damage prevention -> Benefits for the living
- Good reserach (**respect the will of the donor** and prevent waste)
- prohibition of commercialisation

typical applications

- **Orthopaedic** research on functions, operation techniques and medical devices
  - University Hospital Balgrist
  - AO Research Institute Davos
  - Medical devices manufacturers

The more uncommen cases

- Evaluation of an automated intravitreal injection system in human donor eyes
- Mechanical, biochemical and histological properties of ear cartilage [*Cartilago meatus acustici]*
- Layer-to-layer white matter dissection atlas of the human brain in a novel 3D immersive photogrammetry environment
- Expression changes of prion modifying genes in brains of patients suffering from prion disease

Kanton Zürich

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HRO Lunch Session - Part II

Practical guidance for the project management

Prof. Dr. Philipp Fürnstahl

HRO Lunch Cases: Research Involving Deceased Persons

Prof. Philipp Fürnstahl
Research in Orthopedic Computer Science
University Hospital Balgrist, University of Zurich

Balgrist
University Hospital

Universität Zürich[UZH]

Table of Contents

Translational Research for Medical Device Development

… the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public

TRL 1-3 — **Early-stage concepts** and proof-of-concepts validated in **lab experiments**

TRL 4-5 — **Integrated Prototype** validated in **pre-clinical experiments**

TRL 6 — **"First-in-human" study** demonstrates safety and performance during **first use in humans**

TRL 7-8 — **Randomized controlled trials** confirm safety and efficacy in larger patient populations

TRL 9 — **Postmarket-surveillance** after market entry

Surgical Treatment

Research & Development: Data collection, incremental development, validation

Devices: Treatment planning, implants, robots, guidance systems, new surgical techniques

Ex-vivo experiments: Full surgical procedure replicated on (real) ex-vivo anatomy, instruments, and devices

Regulatory Pathway: Essential pre-requisite before entering in-vivo trials

Translational Research for Medical Device Development

Balgrist University Hospital

University of Zurich[UZH]

Highly specialized hospital **treating patients with musculoskeletal disorders**

Chair of orthopedics at the **University of Zurich**

balgristcampus

Hub for musculoskeletal research with 20+ professorships and research groups

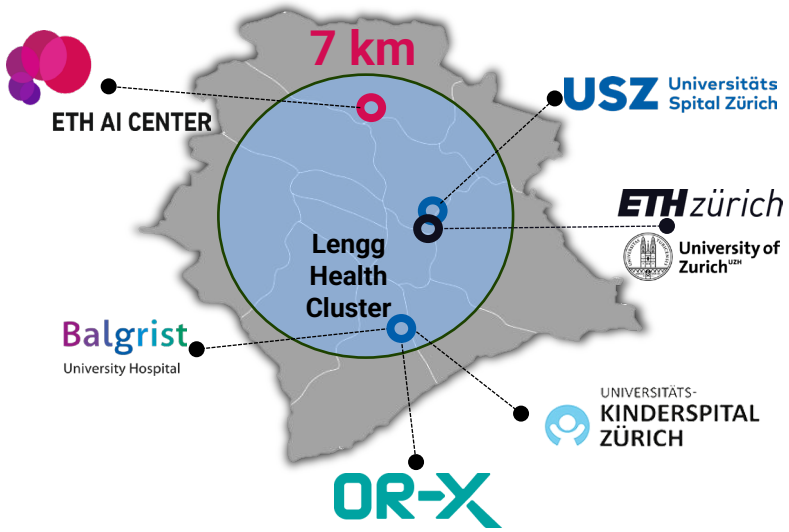
National research infrastructure with 3 centers: diagnostic imaging, biobank, movement analysis

OR-X Translational center for surgery

Translational Center for Surgery

Universität Zürich[UZH]

OR-X – Translational Center for Surgery



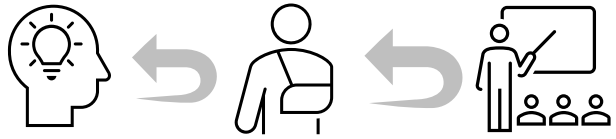
- Dedicated to advancing **research and education** in the **surgery of the future**
- National infrastructure of the "**Swiss Roadmap for Research Infrastructures 2023**"
- **Open-access** for the national and international community

3 Pillars for Improving Patient Treatment

Surgical Training

Research & Development

Clinical Translation



OR-X users and use cases

- surgical training
- surgical innovations

- basic and translational research (university research groups)

- Product development and validation
- Industry training

OR-X – A Place to Perfect Surgical Interventions

Operating Room OR-X

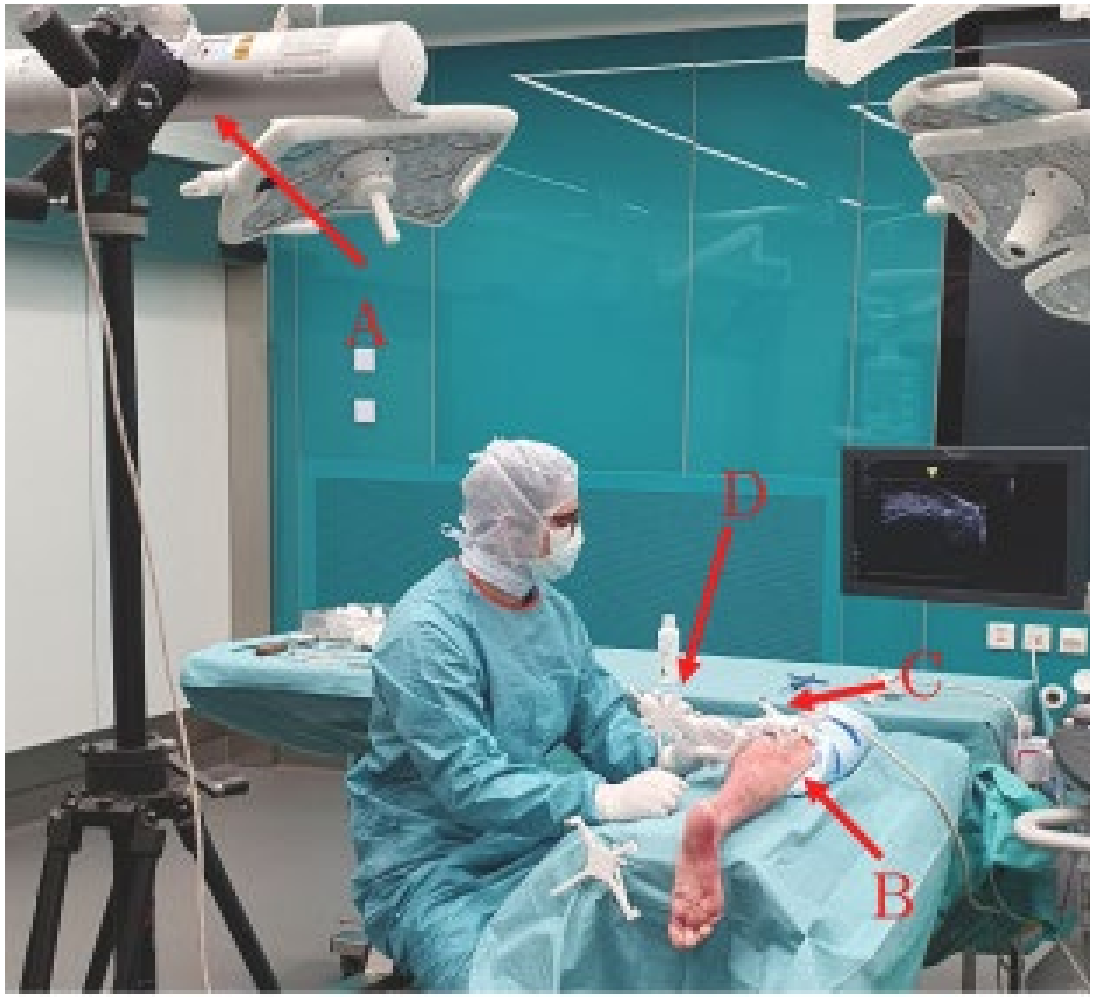
- Highly realistic surgical infrastructure
- Cutting-edge technology (Robotics, AR, high-performance network)
- Ex-vivo human, in-vivo animal

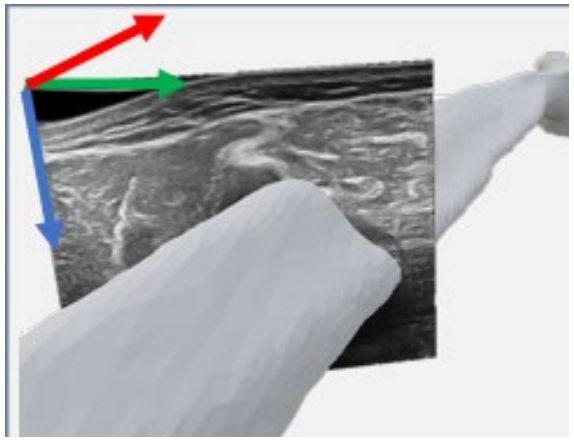
Skills Lab OR-X

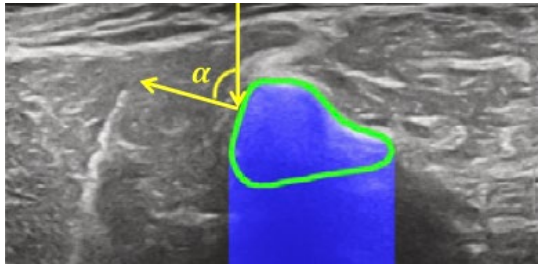
- Surgical courses in real OR environment
- 6 surgical workstations
- Train is a safe environment without time pressure

120+ days of ex-vivo experiments and courses per year with 50% R&D and 50% education

Use Case 1: Ex-Vivo Data Collection

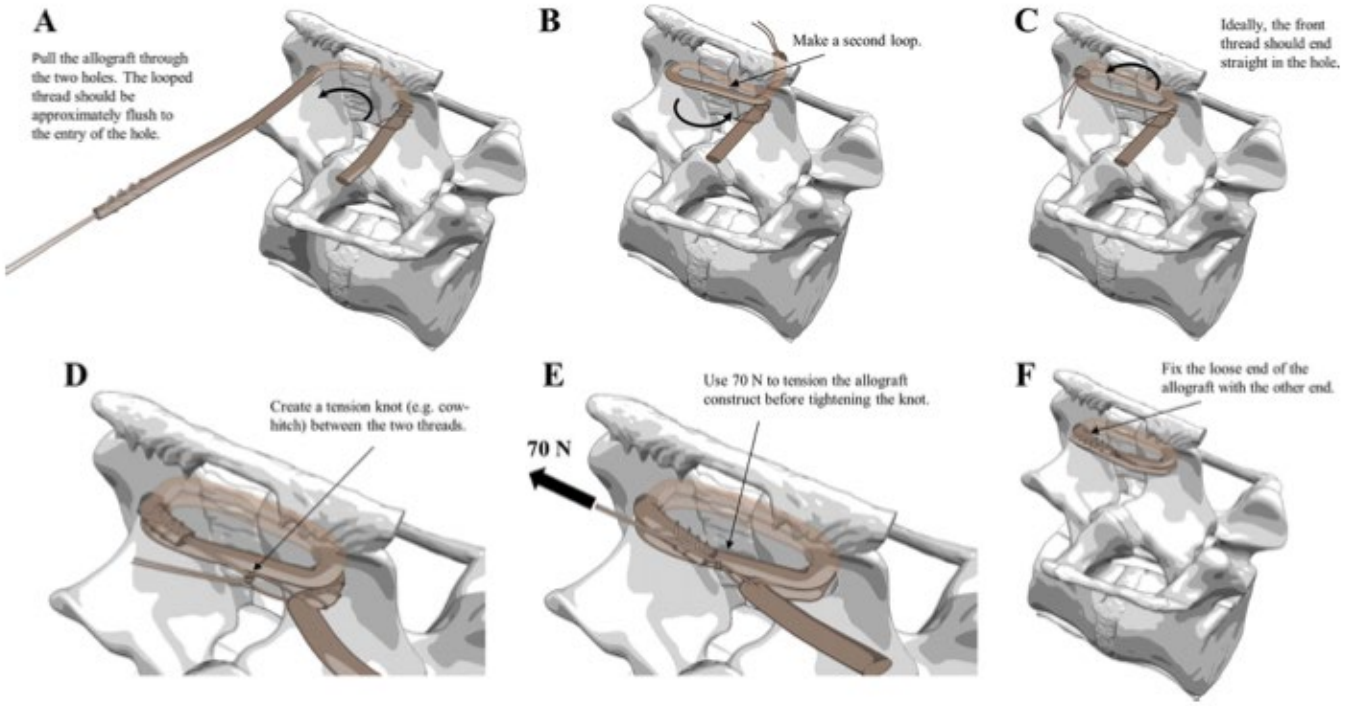


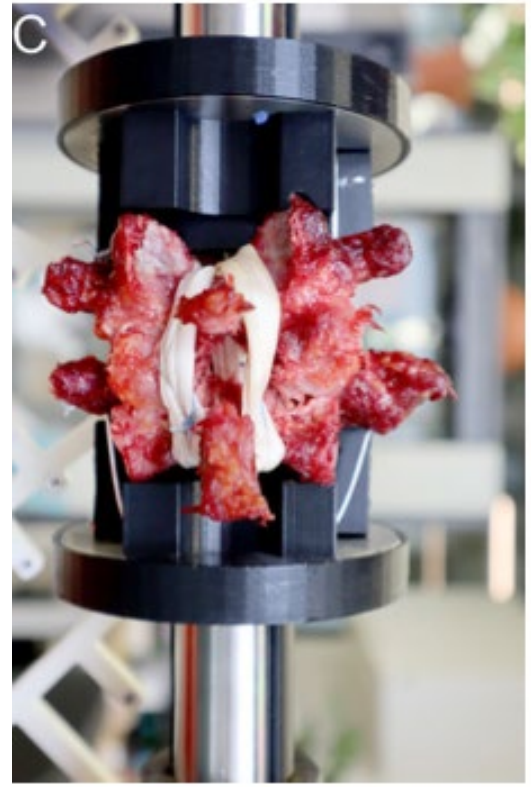




Wu, Luohong, et al. "UltraBones100k: A reliable automated labeling method and large-scale dataset for ultrasound-based bone surface extraction." Computers in Biology and Medicine, 2025.

Use Case 2: Surgical Techniques

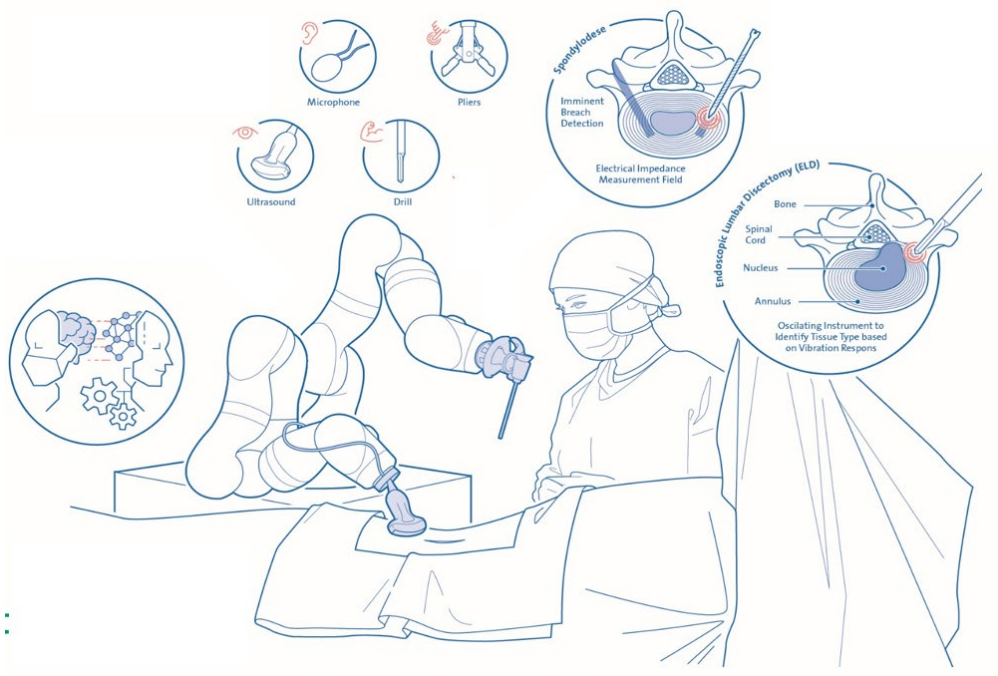




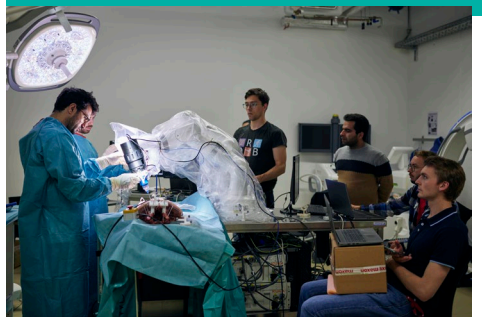
M Farshad et al., Vertebropexy as a semi-rigid ligamentous alternative to lumbar spinal fusion, Europ Spine Journal, 2023

Use Case 3: Surgical Technologies / Large R&D Project

Call: H2020-ICT-2020-2
Duration: **01/01/2021 – 30/06/2024**
Project ID: 101016985



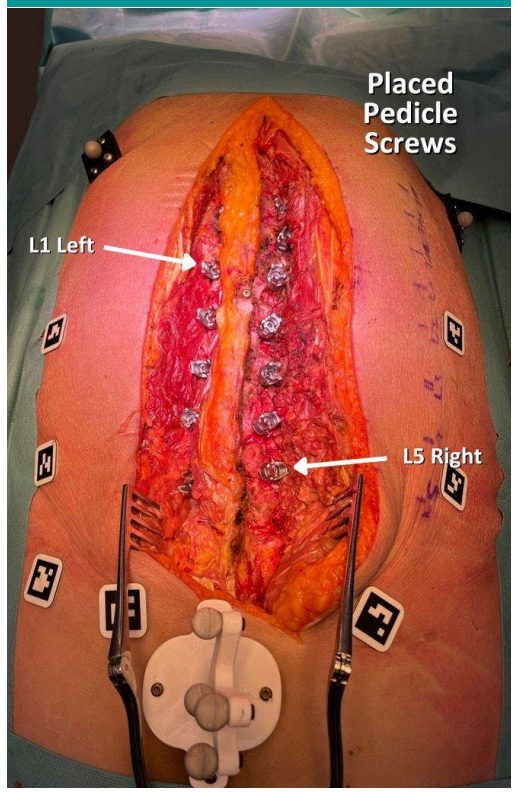
8 INTEGRATION WEEKS

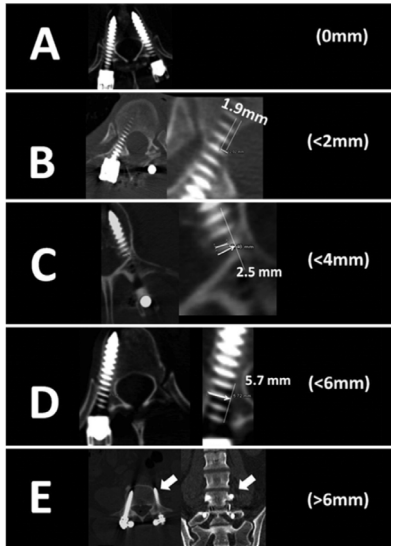


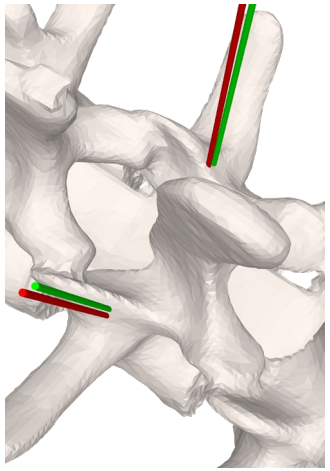
+35 EX-VIVO EXPERIMENTS

Use Case 3: Surgical Technologies / Large R&D Project

EX-VIVO HUMAN







77.78% screws placed with Gertzbein-Robbins (GR) grade A

Level	Side	Entry Point (mm)	Angle Offset (°)	GR grade
L1	L	1.75	3.62	A
L1	R	3.06	2.72	A
L2	L	2.12	4.66	A
L2	R	1.20	4.04	A
L3	L	3.23	1.87	C
L3	R	6.60	8.01	B
L4	L	7.80	8.08	A
L4	R	4.11	3.88	A
L5	R	5.08	1.21	A
L5	L	Excluded due to soft tissue proximity/ surgical approach issues		

Cavalcanti et al., Bridging innovation and practice: the journey of FAROS from technical design to in-vivo animal validation, CLINICAI (MICCAI), 2024

Responsibilities of the Research Facility

OR-X Responsibilities

Preparation: OR-X properly and accurately stores and prepares the specimen (thawing, mounting)

Ethics: The PI of the research group is responsible for obtaining ethical approval and ensuring compliance with ethical standards

OR-X Code-of-Conduct: Ensures dignity of donors (no pictures, respectful use), hygiene

Documentation: OR-X specimen tracker

Ethical resource utilization: Maximize specimen re-use (re-notification required)

Fresh-Frozen Human Specimen

Embalmed Human Specimen

Human Specimen Management

Acquisition from Tissue Provider

Provider: Tissue Bank US/EU/CH, Anatomical Institute ZH

Ordering: Order form, inclusion/exclusion, description of experiments, media transmission

Their responsibility: Donor information, informed consent, biological tests

Costs: admin, services, and delivery (no „purchase“ allowed)

Age	80	**Specimen ID Range**	
Height	63 in.	**From**	**To**
Weight	94 lbs.		
BMI	16.65		
Sex	Female		
Race	White		
Primary Cause of Death	COLON CANCER, MALIGNANT NEOPLASM OF LUNG AND BONE,		
Secondary Cause of Death	SJOGREN'S SYNDROME		

Serology Results

	Initial Results	Confirmatory Results
Hepatitis B	Non-Reactive	
Hepatitis C	Non-Reactive	
HIV-1/HIV-2	Non-Reactive	
Other	Not Detected	
Other		
Other		
Other		

Serology Notes OTH01: SARS-CoV-2 TR 051723

Human Specimen Management

Acquisition from Tissue Provider

Provider: Tissue Bank US/EU/CH, Anatomical Institute ZH

Ordering: Order form, inclusion/exclusion, description of experiments, media transmission

Their responsibility: Donor information, informed consent, biological tests

Costs: admin, services, and delivery (no „purchase“ allowed)

Donation authorization

I donate and authorize this gift of my body to Company for medical research, scientific use or educational purposes.

- This authorization to proceed with donation is not a contract for services with Company, but is an expression of my intention and informed consent for donation
- This gift is being made voluntarily without any obligation of any kind on the part of Company.
- Any recovered organs, tissues or parts of the body may be used indefinitely into the future for medical research, scientific use or student or physician education and surgical training, but not for public exhibition, though anonymized photos or video documents may be used for scientific publication or presentation.
- No compensation will be given to the donor, the donor’s estate, the donor’s next of kin or any third party as a result of donating this gift or the outcomes of its use.
- Extensive surgical preparation of the body may be performed including embalming, long term preservation and the surgical removal of the extremities, arms, legs, hands, feet, head, spine, and/or other organs, tissues or fluids from the body.
- ….

OR-X Translational Center of Surgery

Disposal by Tissue Provider / BVA

Before Disposal: Removal of implants, Ensure that donor‘s bodyparts remain together

Disposal: Bevölkerungsamt or Swiss tissue bank

Documentation: OR-X needs to provide documentation for correct crematation

Crematation authorization

I authorize the cremation of this gift of my body pursuant to whole body donation.

- I understand donation and cremation will be conducted under the laws applicable in the state in which that legal entity is organized.
- Cremation is a necessary outcome of whole body donation and cremated remains to be returned will likely not be from the whole body and will not include tissue that has been recovered for use in medical research, scientific use or education.
- Company, its assignee or end users of tissue may arrange for the final disposition of tissues recovered for medical research, scientific use or education in any manner subject to local, state or federal law and may include commingling and cremation or incineration as medical or pathological waste.
- Cremated remains not to be returned or resulting from medical research, scientific use or education may be scattered at land or sea or interred in a shared ossuary and will not be recoverable.
- …

Ethical Approval

Study Protocol

- Background (relevance)
- Goal of the study
- Provider, Anatomy, Number of Specimen
- Inclusion/Exclusion criteria
- Methodology
  - Hypothesis
  - Summary of experimental protocol
  - Sample size
  - Data evaluation
- Reporting obligation (project changes)
- Data storage (secure)
- Ethical consideridations (justification)

Ammendment required (w.r.t specimen)

- Change in number of specimen
- Change in tissue provider
- Re-use of specimen

Challenges & Conclusion

PI holds responsibility, but well-designed facility processes are essential to ensure compliance

Timing:
- Coordination between facility and staff availability, specimen delivery, and ethical approval
- A single delay can significantly impact the project timeline

Ethics:
- Right study size is critical: too small → high administrative overhead, too large → risk of merging multiple studies into one
- Tissue tracking involves parallel processes from ethics and tissue providers, each with different requirements.

No „GCP“ for ex-vivo experiments:
- No “GCP” for ex-vivo experiments: scientists need training in experimental design and execution
- Ethical standards and hygiene practices must be taught and consistently applied.

Human Specimen Acquisition / Handling:
- Strong dependency to US providers
- No collaboration or coordination among Swiss facilities
- No cantonal or national best practice guidelines for facilities like OR-X

THANK YOU!

Our research is only possible with an outstanding team, strong collaborators and an inspiring research environment.

Q&A session – questions?

Part1: Tobias Rosenberger

Part 2: Philipp Fürnstahl

Thank you for participating!

Further questions to:

Tobias.Rosenberger@kek.zh.ch

Philipp.Fuernstahl@balgrist.ch

Verena.Golz@usb.ch

HRO lunch series 2026

«2 spring and 2 autumn sessions again in planning»

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