Legal framework for research & the Human Research Act (HRA)

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Plan

0. Questions of control
1. What do you know about the history of biomedical ethics?
2. Objectives and field of application of the HRA and it’s ordinances
3. Use and reuse of biological materials (HRA)
4. When do we need consent?
5. Evaluation of the research protocol
6. Research with vulnerable people

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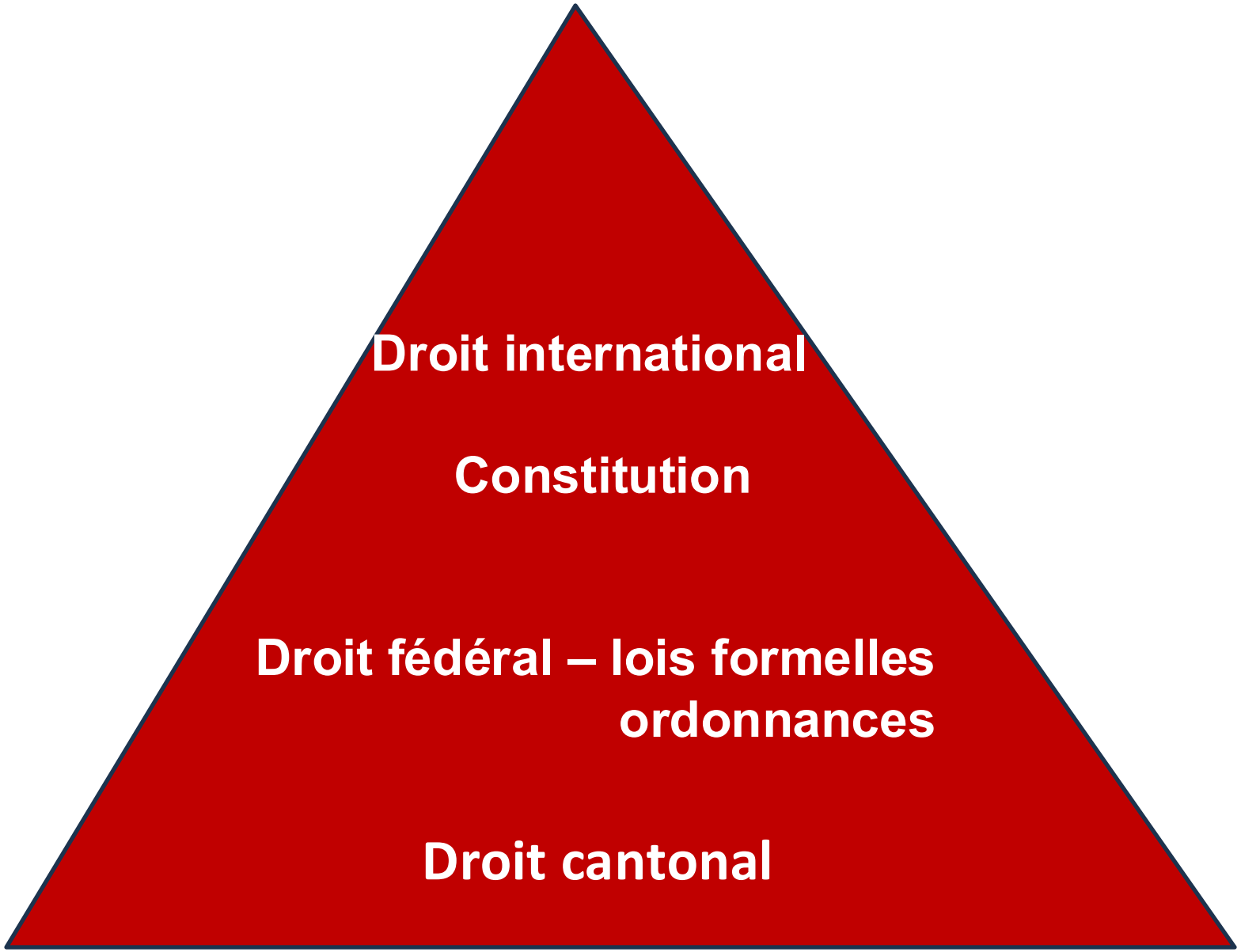

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0. Questions of control: Hard law or soft law?

- Directives de l'ASSM sur la Recherche humaine (2015)
- Décisions du Rectorat de l'EPFL sur les standards de la recherche
- International Ethical Guidelines for Health-related Research Involving Humans. Fourth Edition; Council for International Organisations of Medical Sciences (CIOMS); Geneva 2016
- Directives de l'ASSM «Procédures de tests génétiques préimplantatoires» (2020)
- Décisions de la Commission d'Ethique de la Recherche du Canton de Vaud
- Décisions du Tribunal Fédérale Lausanne
- La loi fédérale sur les cellules souches (2003)
- Convention européenne sur les droits de l'homme et la biomédecine (199 protocole relatif à la recherche biomédicale (2005)
- Déclaration of Helsinki; WMA (2024)

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Questions of control (2) Where to find your answers?

- You want to know whether the Federal Court has already ruled on the liability of a research project sponsor
- A researcher wonders whether the human body as such can be patented
- You wonder whether legislation on human research falls under federal or cantonal law
- Who issues authorisation for the mail order sale of medicines?
- The penalty applicable for breach of professional secrecy in human research?

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1. What do you know about the history of bioethics?

Interview with Tom L. Beauchamps on Autonomy in Research / Belmont Report 1978,

Principles of Bioethics, Oxford Press, 8ed 2019

https://www.youtube.com/watch?v=MLyR40fzwnY

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2. Scope & field of application of the HRA

Acceptable balance between innovation and medical progress and protection of research subjects

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Exemple no. 1

Mme Amion is attempting a new experiment.

For six months, she has been applying a mixture of almond milk and ointment to a bruise. She recently read about the benefits of almond milk on the body.

She first wants to test the milk on her own body before proposing it to a pharmaceutical company in her region.

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Human Research Act (2011)

Art. 1 Purpose

[1] The purpose of this Act is to protect the dignity, privacy and health of human beings involved in research.

[2] It is also designed to:

a. create favourable conditions for research involving human beings;
b. help to ensure the quality of research involving human beings;
c. ensure the transparency of research involving human beings.

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[3];
b. anonymised biological material;
c. anonymously collected or anonymised health-related data.

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What are the subquestions ?

a. What is the definition of research / is it scientific research?

b. Why is it necessary to regulate the domain of research?

c. How is research regulated within Switzerland?

d. Which types of research projects are subject to the Human Research Act (HRA)?

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a) How do we define scientific research?

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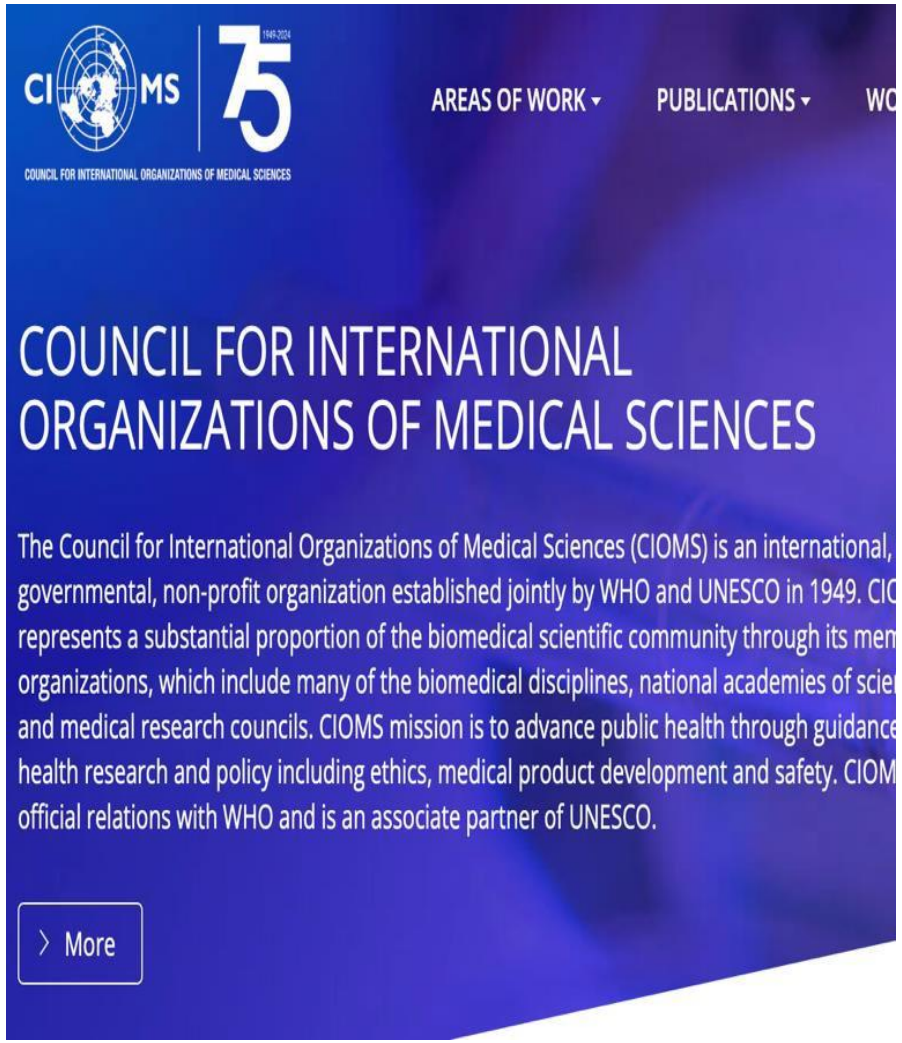
a) Scientific research ?

« La recherche méthodologique visant à obtenir des connaissances généralisables »

Loi fédérale relative à la recherche sur l'être humain, 30.09.2011



« Le terme «recherche» désigne une catégorie d'activités visant à **constituer un savoir généralisable, ou à l'enrichir.** Par savoir généralisable, on entend les **théories, principes ou corrélations, ou l'accumulation d'informations sur lesquels ceux-ci se fondent, vérifiables par des méthodes scientifiques éprouvées d'observation et de déduction.** Dans le présent contexte, ce vocable couvre les études tant médicales que comportementales relatives à la santé humaine. Généralement, on accole au mot «recherche» l'épithète «biomédicale» pour indiquer qu'il s'agit d'études en rapport avec la santé. »

(CIOMS, 2002, 2016)

Scientific research (2)

Recherche scientifique **v.** **Medical practice**

- Scientific expertise
- Protocol
- In the interest of research
- Without going against the interests of patients.

- Patient interests
- Adaptation/submission to patients interests

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Scientific research (3)

Art. 3 Définitions

a. Research means method-driven search for generalisable knowledge;

b. *Research concerning diseases* means research on the causes, prevention, diagnosis, treatment and epidemiology of impairments of physical and mental health in human beings;

c. *Research concerning the structure and function of the human body* means basic research, in particular on human anatomy, physiology and genetics, and non-disease-related research concerning interventions and impacts on the human body;

d. *Research project with an expected direct benefit* means a research project whose results can be expected to improve the health of the participants;

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Scientific research (4)

Finlande, *Medical Research Act No. 488/1999*
Watch a video: Ethical review in the human sciences in Finland (on YouTube)

France, *Law No. 2012-300 of 5 March 2012 on Research Involving Human Persons*

Islande, *Act on Scientific Research in the Health Sector No. 44/2014*

Lituanie, *Law on Ethics of Biomedical Research (2019*)

Norvège, *Act on Medical and health research* (2008)

Pays-Bas, *Medical Research Involving Human Subjects Act* (2012) **[…]**

Source: ***International Compilation of Human Research Standards*** **2021 Edition**
(U.S. Department of Health and Human)

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b) Why is it necessary to regulate the domain of research?

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Freedom of research v Personal Freedom, privacy

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Research with human beings in the field of their health

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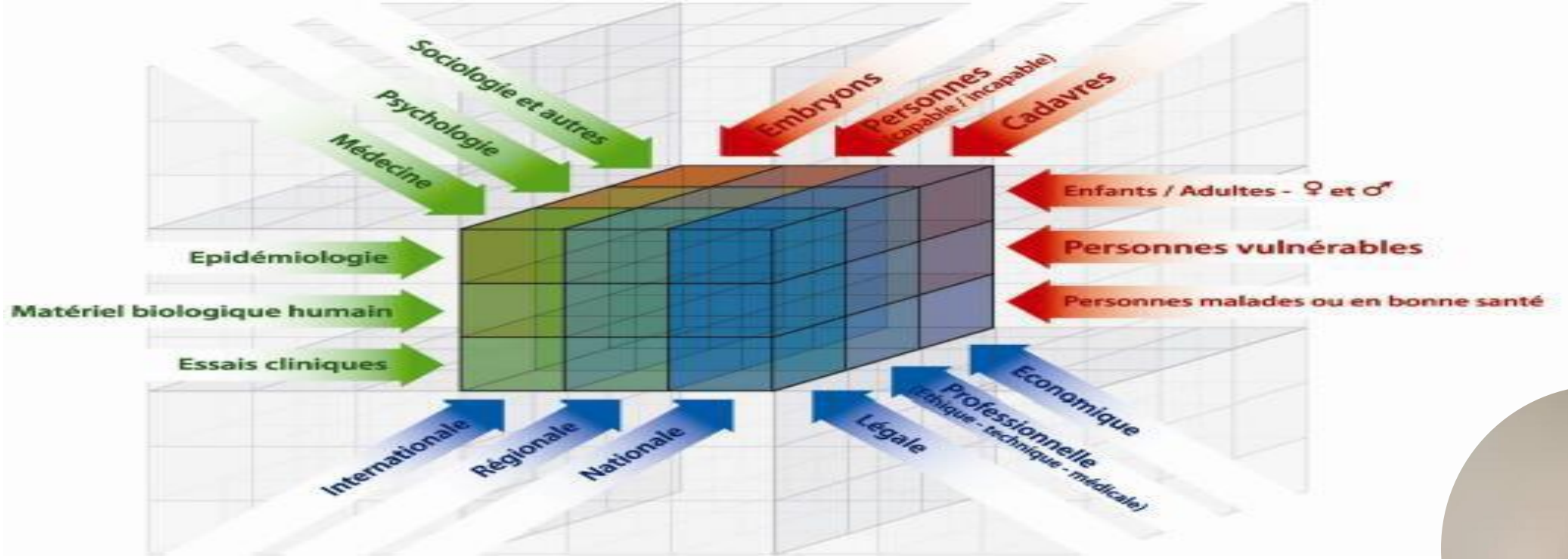
Research with human beings in the field of health from different perspectives



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Legal & ethical framework (non-exhaustive)

Code de Nuremberg (10 août 1947)
Conventions de Genève (12 août 1949)
Déclaration d'Helsinki de l'AMM (dernière révision 2013)
Déclaration de Taipei de l'AMM sur les considérations éthiques concernant les bases de données de santé et les biobanques (2016)
Pacte International sur les droits civils et politiques (16 décembre 1966)
Directives éthiques internationales pour la recherche biomédicale impliquant des sujets humains préparées par le CIOMS en collaboration avec l'OMS (1982, 1993, 2002)
Bonnes Pratiques Cliniques de la Conférence Internationale d'Harmonisation (ICH-GCP) (1996) Règlement européen sur les essais cliniques de médicaments (2014)
Convention européenne sur les droits de l'homme et la biomédecine (1997) et son protocole relatif à la recherche biomédicale (2005)
Législations nationales

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c) How is it regulated?

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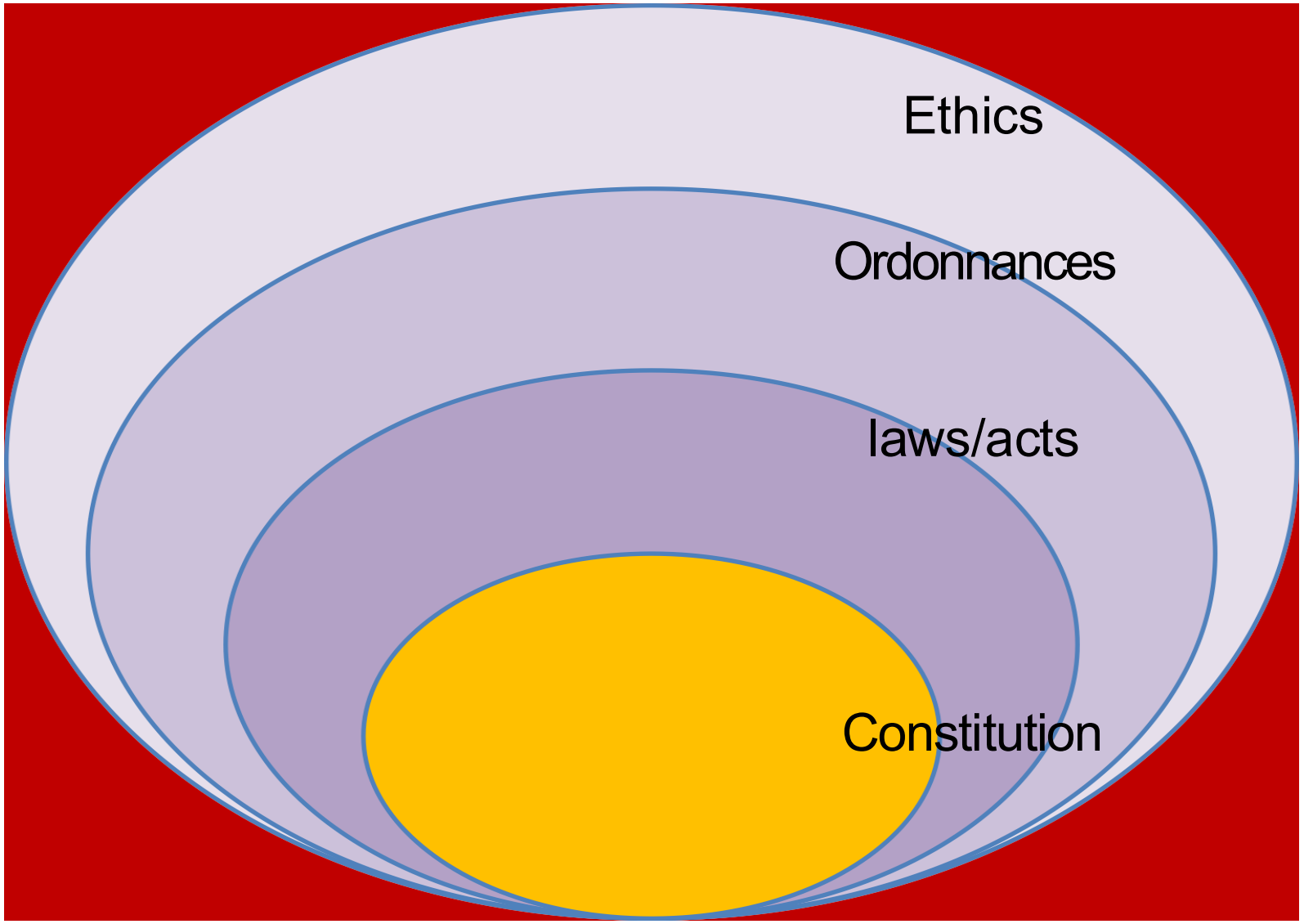
Suisse legal framework - recap



Source: TRREE

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Constitutional level

Art. 118*b*[81] Research on human beings

[1] The Confederation shall legislate on research on human beings where this is required to protect their dignity and privacy. In doing so, it shall preserve the freedom to conduct research and shall take account of the importance of research to health and society.

[2] The Confederation shall adhere to the following principles in relation to biological and medical research involving human beings:

a. It is a requirement for any research project that the participants or their legal representatives have given their informed consent. The law may provide for exceptions. A refusal is binding in every case.

b. The risks and stress for the participants must not be disproportionate to the benefits of the research project.

c. A research project involving persons lacking the capacity to consent may be conducted only if findings of equal value cannot be obtained from research involving persons who have the capacity to consent. If the research project is not expected to bring any immediate benefit to the persons lacking the ca
consent, the risks and stress must be minimal.

d. An independent assessment of the research project must have determined that the saf
participants is guaranteed.

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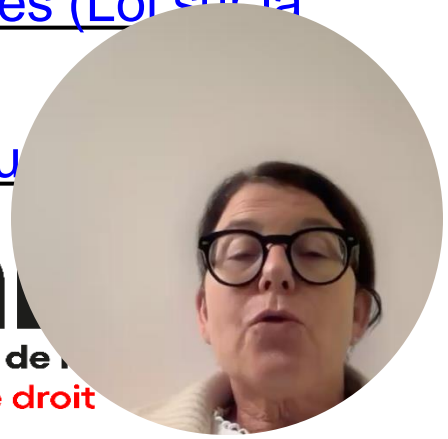
Federal laws/acts

Loi fédérale du 30 septembre 2011 relative à la recherche sur l'être humain (Loi relative à la recherche sur l'être humain, LRH)
Loi fédérale du 19 décembre 2003 relative à la recherche sur les cellules souches embryonnaires (Loi relative à la recherche sur les cellules souches, LRCS)
Loi fédérale du 25 juin 1954 sur les brevets d'invention (Loi sur les brevets, LBI)
Loi fédérale du 15 décembre 2000 sur les médicaments et les dispositifs médicaux (Loi sur les produits thérapeutiques, LPTh)
Loi fédérale du 30 mars 1911 complétant le code civil suisse (Livre cinquième: Droit des obligations)
Loi fédérale du 28 septembre 2012 sur la lutte contre les maladies transmissibles de l'homme (Loi sur les épidémies, LEp)
Loi fédérale du 25 septembre 2020 sur la protection des données (LPD)
Loi fédérale du 8 octobre 2004 sur la transplantation d'organes, de tissus et de cellules (Loi sur la transplantation)
Loi du 22 mars 1991 sur la radioprotection (LRaP)
Loi fédérale du 21 mars 2003 sur l'application du génie génétique au domaine non hu
le génie génétique, LGG)
Loi fédérale du 16 décembre 2005 sur la protection des animaux (LPA)
Loi fédérale du 15 juin 2018 sur l'analyse génétique humaine (LAGH)



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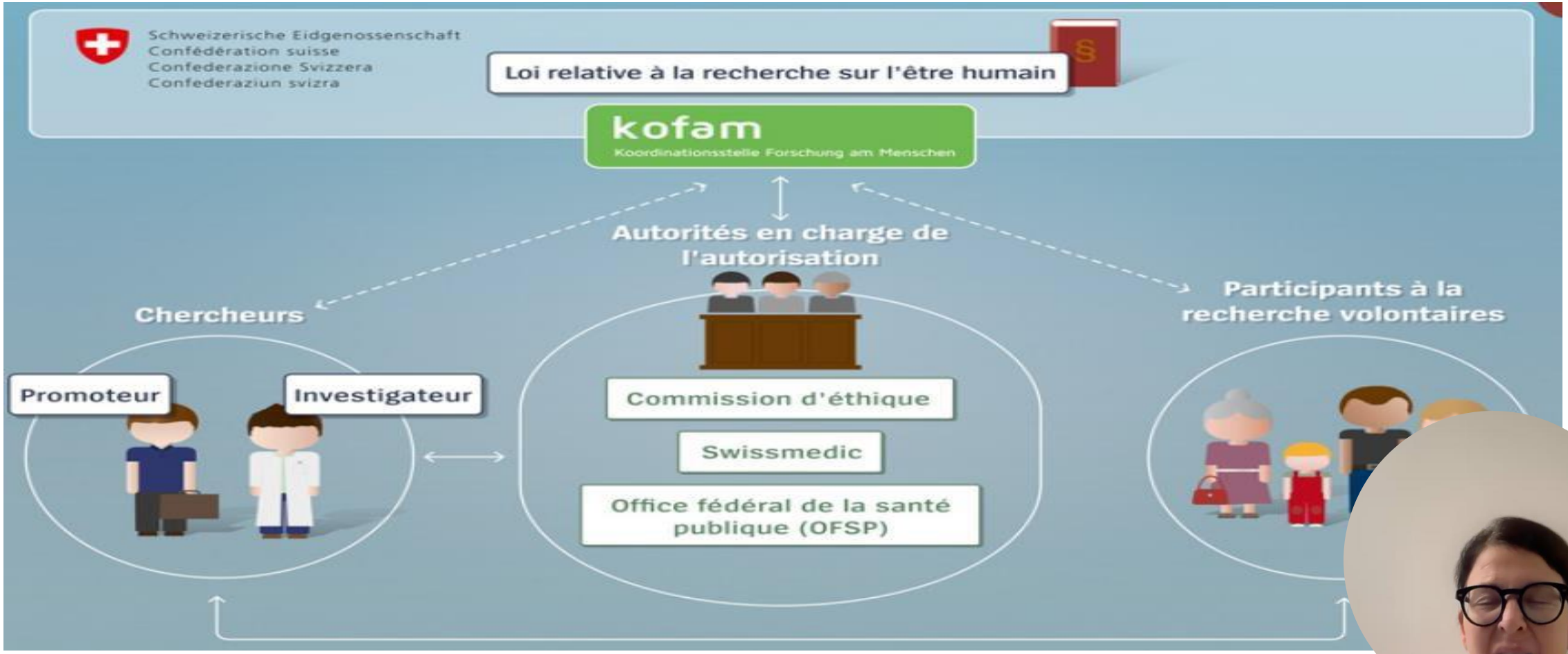
Stakeholders in the authorisation process



Source: KOFAM. Les acteurs des projets de recherche sur l'être humain.

Human Research Act (2011)

Art. 2 Scope

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Art. 2 Scope of the HRA

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→ Autorisation necessary

→ Autorisation HRA not necessary; but other laws are applicable; research ethics remains applicable

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Art. 4-10 General principles of the HRA

- Primacy of human interests
- **Relevant scientific issues (art. 5) :** human health & diseases, body structures, public health issues
- Non-discrimination
- Consent
- Right to information
- Prohibition of commercialisation
- **Scientific requirements (art. 10)**
  - it complies with recognised standards of scientific integrity;
  - It meets scientific quality criteria;
  - it complies with internationally recognised rules of good practice in human research;
  - Those responsible have sufficient professional qualifications.

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d) Which types of research projects are subject to the Human Research Act (HRA)?

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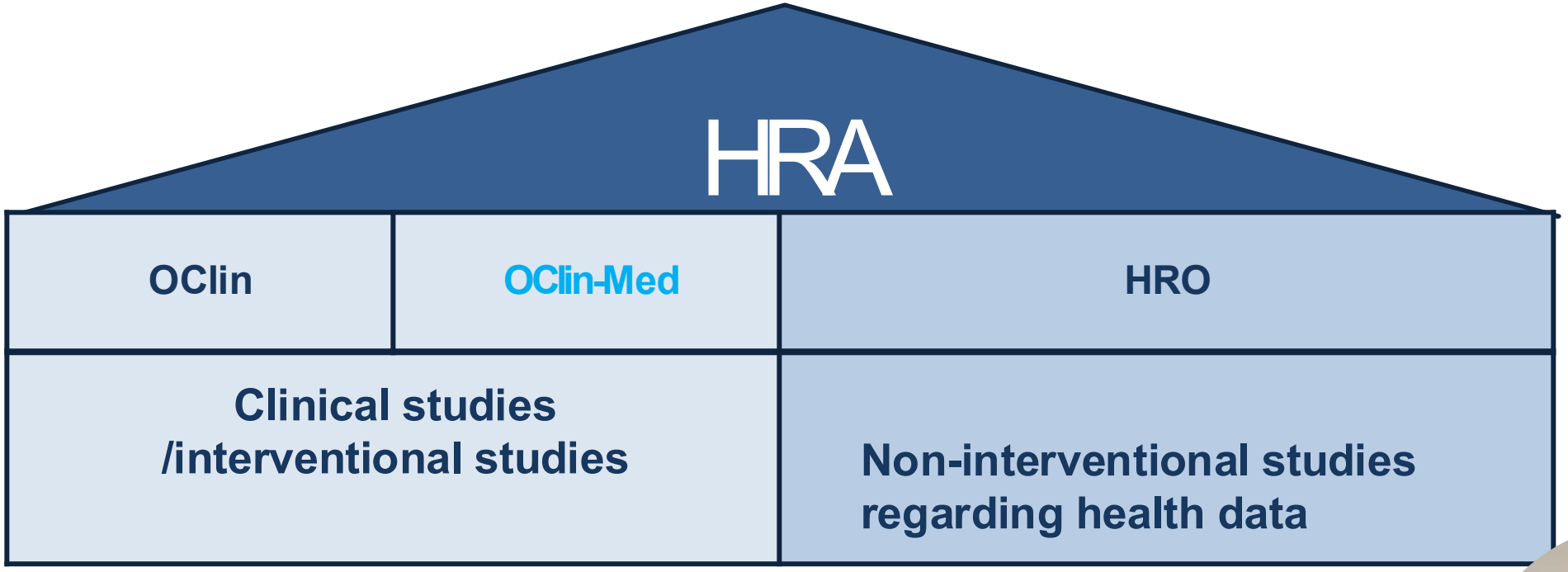
Legal types of research projects (HRA)



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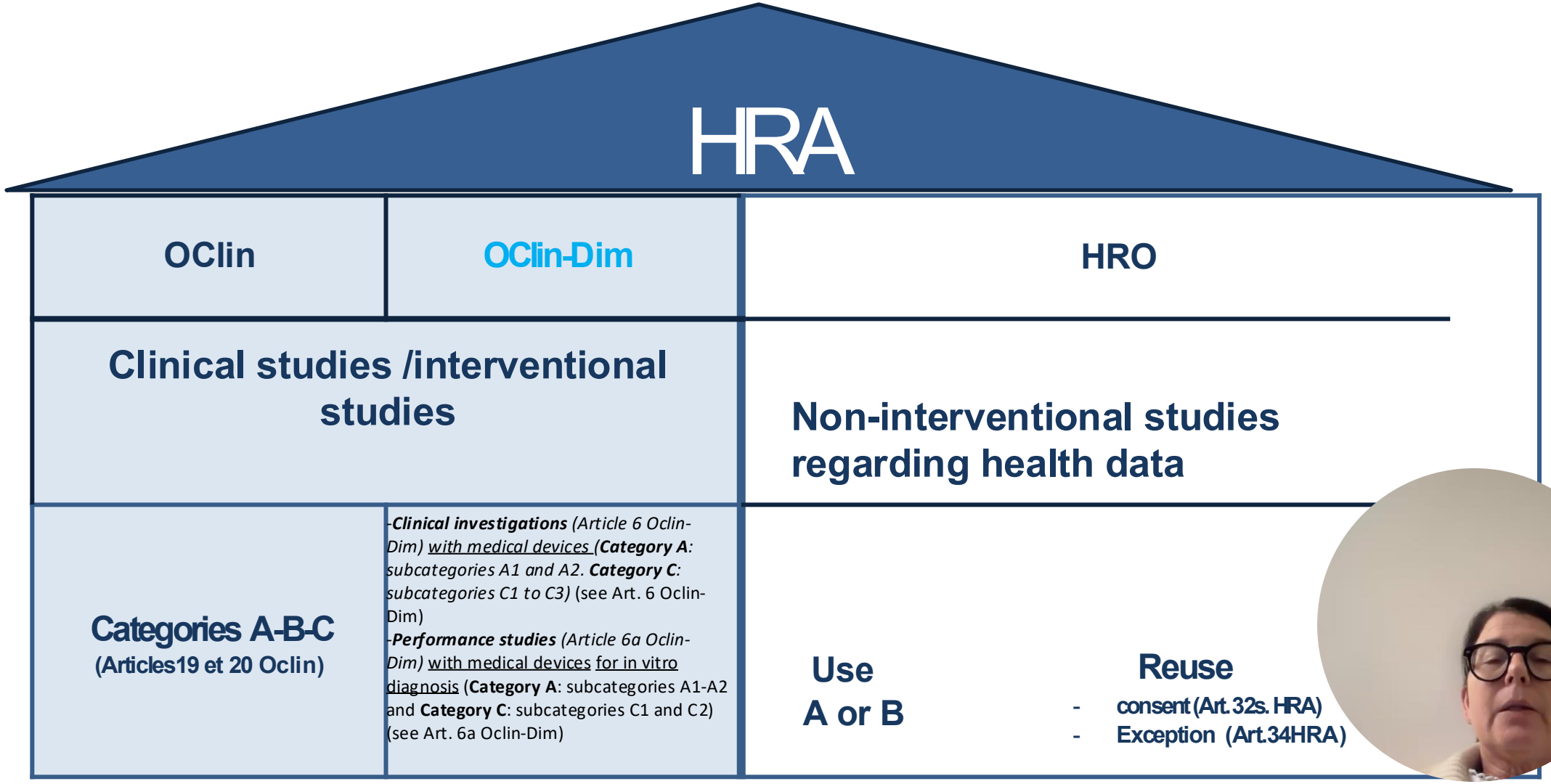
Types of research projects according to rsiks



Autorisations by whom?

AUTORISATION

Risks levels (Oclin/Oclin Dim clinical trial & non-interventional research)

- A
- B
- C

EC VD

Particular nature of the research (Oclin/Oclin Dim clinical trial). The research involves administering a new drug to patients with a specific disease.

- Standardised medicines, medical devices and transplants, and GMOs → **Swissmedic (not Cat. A)**
- Transplantation, stem cells, ionisation, gene therapy, research with GMOs and pathogens → **OFSP en**

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Clinical trials of medicinal products not classified as medical devices (Art. 19 OClin)

A	B	C
-Medicinal product already on the market and used in accordance with the summary of product characteristics or for a condition of the same classification (ICD), or for a self-limiting condition and at a lower dosage than that specified in the package leaflet.	-Medicinal product already on the market but - not used according to the package leaflet - not used as for category A	Medicinal product not admitted in Switzerland
⇩ **EC**	⇩ **EC** communicates results to **Swissmedic** + ev. **FOPH**	⇩ **EC** communicates results to **Swissmedi** ev. **FOPH**

Clinical trials of medical devices
- Clinical investigations - (Art. 6 Oclin-Dim)

Category A (conditions)

a. It The item bears a conformity marking as defined by Art. 13 ODim;
b. it is utilised in accordance with the instructions for use;
c. and its availability on the market, as well as its deployment or use, are not prohibited Switzerland.

Sub-catergory A1

The person concerned are not subject to any add. Invasive or burdensome procedures (compared to the procedures under normal conditions of the use of the device to be analysed)

Sub-category A2

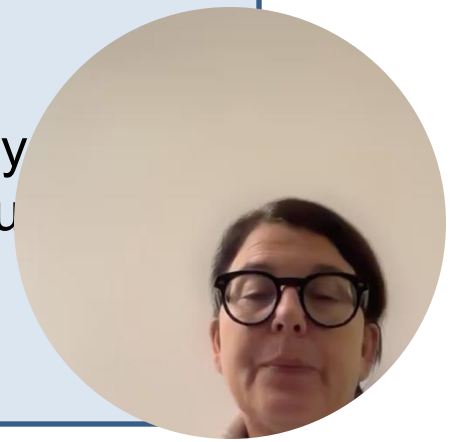
The person concerned is subject to supplementary invasive or burdensome procedures (compared to the procedures under normal conditions of the use of the device to be analysed)

Category C

a. The device to be analysed bears a conformity marking within the meaning of Art. 13 ODim but is not used in accordance with the instructions for use (subcategory C1);

b. The device to be analysed does not bear a conformity marking within the meaning of Art. 13 ODim (subcategory C2);

c. The device to be analysed may made available on the market, pu service or used in Switzerland (subcategory C3).



(Art.6a Oclin-Dim)

Classification des études des performances avec des dispositifs médicaux de diagnostic in vitro
(selon l'article 6*a* OClin-Dim)

Études des performances avec des dispositifs médicaux de diagnostic in vitro

Catégorie A

Étude interventionnelle avec :
- Dispositif avec marquage de conformité
- Dispositif utilisé conformément au mode d'emploi
- Dispositif qui n'est pas interdit en Suisse
- Avec ou sans procédure au sens de l'art. 6*a*, al. 1, let. b, ch. 2

Étude non-interventionnelle

Sous-catégorie A1

Étude interventionnelle
Dispositif avec marquage de conformité, utilisé conformément au mode d'emploi et sans interdiction en Suisse.

Sous-catégorie A2

Étude non-interventionnelle
au sens de l'art. 6*a*, al. 1, let. a, ch. 1 à 3
- avec application supplémentaire de procédures chirurgicales invasives pour prélever du matériel biologique ***ou***
- avec des procédures invasives ou lourdes supplémentaires pour les personnes concernées[1].

Étude non-interventionnelle,
qui n'est pas régie par l'art. 2*a*, al. 1 à 3 OClin-Dim.

Catégorie C

Étude interventionnelle avec :
- Dispositif sans marquage de conformité ***ou***
- Dispositif utilisé de manière non conforme au mode d'emploi ***ou***
- Dispositif interdit en Suisse

Sous-catégorie C1

Dispositif avec marquage de conformité, mais qui n'est pas utilisé conformément au mode d'emploi.

Sous-catégorie C2

Dispositif sans marquage de conformité

Sous-catégorie C3

Dispositif interdit en Suisse
(mise à disposition sur le marché, mise en service, administration).

1. selon l'art. 6*a*, al. 1, let. b, ch. 2

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Prélèvement et utilisation de matériel biologique – classification (Art 7 ORH)

Non-interventional biomedical research project

→ Category A → The risks and constraints inherent in the planned measures for the collection of biological material or personal data are minimal. §1 → **Minimal and temporary impact on the health of the individual, considering their vulnerability and the specific circumstances.**

→ Category B → The risks and constraints inherent in the planned measures are more than minimal.§2

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3. The legal issues surrounding the re-use of biological material for research purposes

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Data associated with biological material

Organs, tissues, cells and body fluids (blood and urine, etc.)

and the related data

- Data not related to health
- Data related to health
- Data related to genetics

Bio bancs

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How can we mitigate the individual protection and liberty of science when it comes to reuse of biological material in research?

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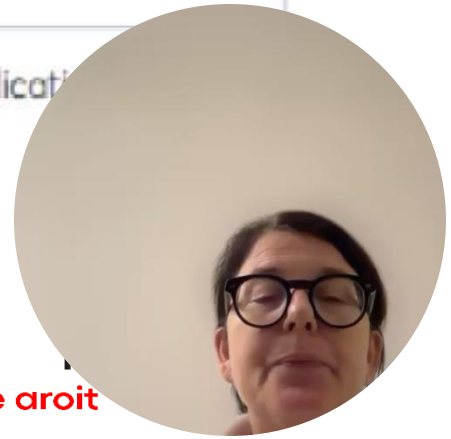
4. When do we need to consent?

Lien avec l'individu	Matériel biologique et données génétiques (Art.32 LRH)	Données non génétiques (Art.33 LRH)
Données non codées (permettant l'identification)	Information + consentement pour chaque projet de recherche	Informations sur la réutilisation pour des projets de recherche futurs encore indéfinis + consentement général à des fins de recherche
Données codées	Informations sur la réutilisation pour des projets de recherche futurs encore indéfinis + consentement général à des fins de recherche	Informations sur la réutilisation pour des projets de recherche futurs encore indéfinis + possibilité de refuser la réutilisation > Droit d'opposition
Données anonymisées	**Données génétiques:** informations sur la réutilisation à des fins de recherche futures encore indéfinies + possibilité de refuser la réutilisation > Droit d'opposition	En dehors du champ d'applicat… LRH

Source: ACADÉMIE SUISSE DES SCIENCES MÉDICALES (ASSM), Bulletin 3/2016 : « Consentement général: un modèle uniforme pour faciliter la recherche sur tout le territoire suisse », Bâle, 2016. Page 3.



Exception to consent (art 34 LRH)

Obtaining consent must pose disproportionate difficulties or be impossible, and no document attesting to the person's refusal must exist, and the interest of the research must outweigh the right to self-determination of the person concerned.

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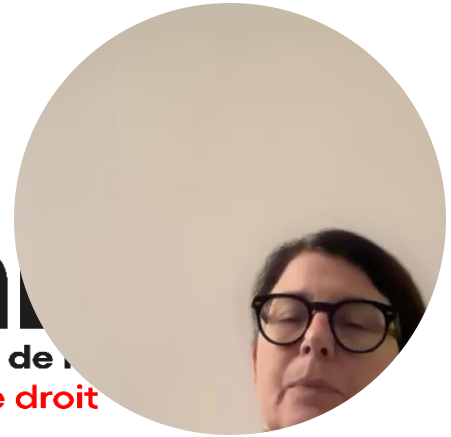
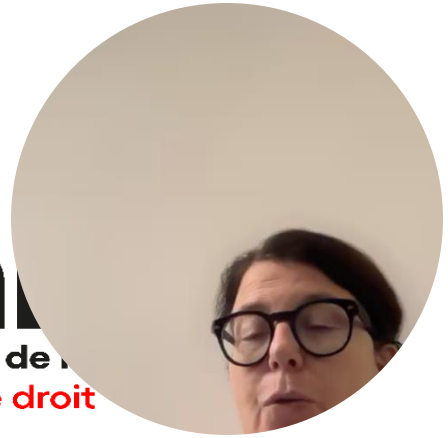


Autres projets de recherche

- Research projects on deceased persons, with consent given during their lifetime (Art. 36 LRH)
- Consent of the woman for any research project on an embryo or foetus resulting from an abortion (Art. 39 HRA)
- Consent of the couple concerned for any research project on an embryo or foetus resulting from a spontaneous abortion or stillbirth (Art. 40 HRA)



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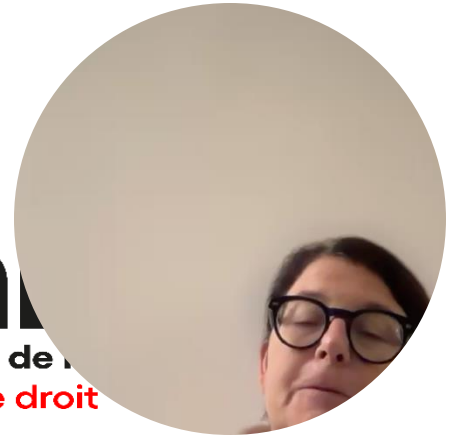
5. Evaluation of the research protocol

Assess the compliance of research projects with ethical, legal and scientific requirements (Art. 51(1) HRA)

→ **HRA**

Conselling researchers (art. 51 (2) HRA)

→ **EC is free to give advice**



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6. Research with vulnerable subjects

Subsidiarité

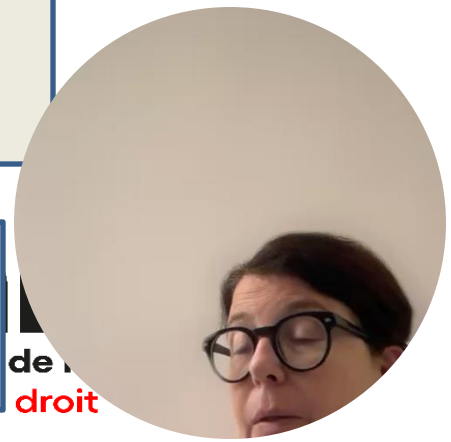
- Adultes incapables de discernement
- Enfants
- Adolescents
- Femmes enceintes
- Les personnes privées de liberté
- Recherche en urgence

→ **Sans bénéfice direct escompté**

- Risque minimal pour la PPV
- \+ Résultats essentiels pour les personnes du groupe du PPV, escomptés

→ **Avec bénéfice direct escompté**

- Risques plus élevés pour la PPV acceptable, mais proportionnels aux bénéfices

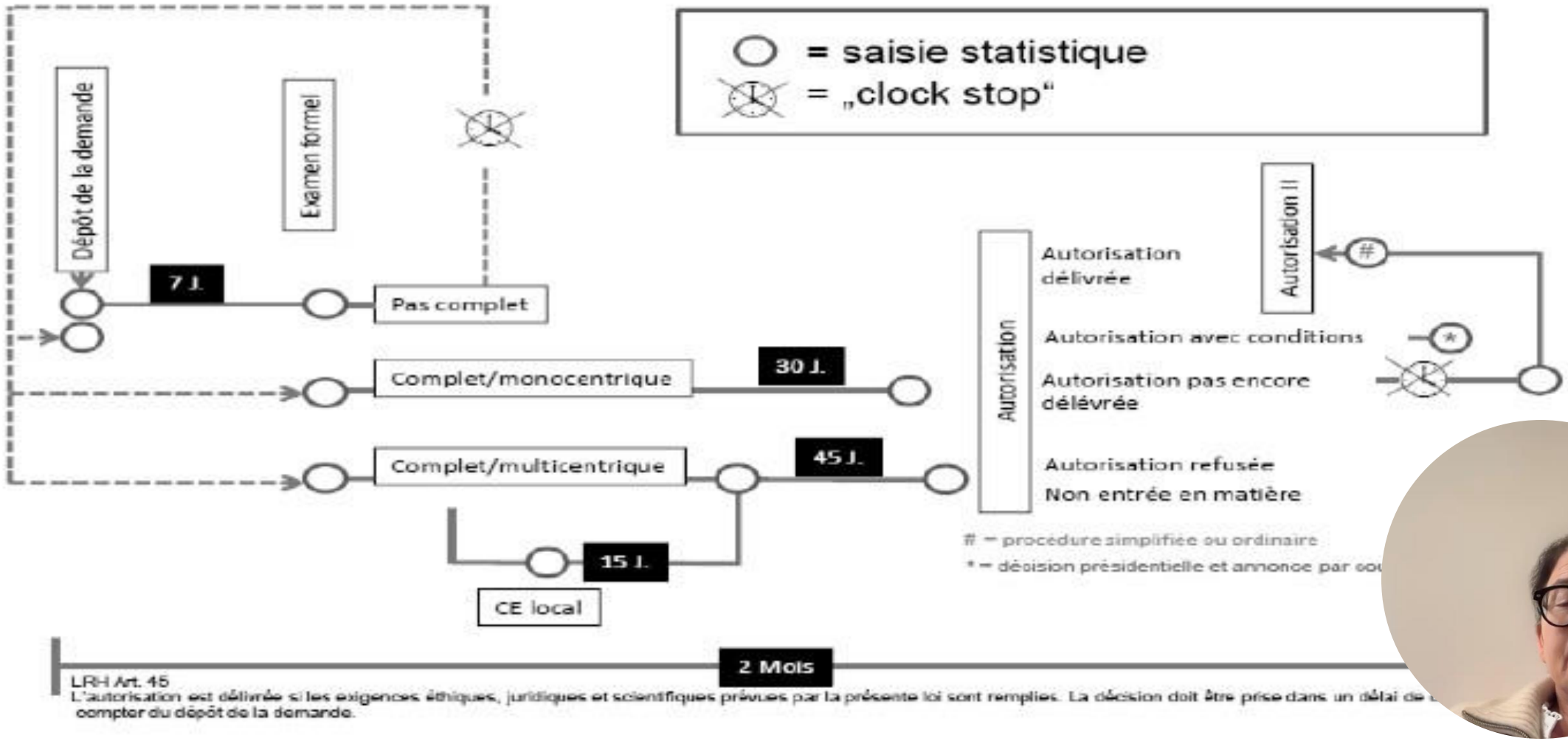


Criteria for the évaluation des protocoles (*see* TRREE- Module 2.1)

- Scientific value
- Social value
- Qualifications of the investigators
- Compensation for dammages forseen
- Selection of the participants
- Consent and Infromation
- Risks-benefit ratio
- Conflict of interests
- Protection of one's private life, privacy, personnality and health
- Care and follow-up of research subjects

Processus

Délais-Definitions (Projet, G. Schubiger 01.04.14)



Composition EC VD – Exemple

env. 40 **membres** (OrgHRA, Art. 52 HRA)

- Médecine : 40 %
- Ethics : 12,5%
- Law: 10 %
- Pharmacy: 12,5 %
- Psychology : 10%
- Nusing Science : 7,5 %
- Biology : 2,5%
- Biostatistics : 12,5 %
- Patients / patients représentation : 5%
- Othe domains: 5%

canton de vaud
LIBERTÉ ET PATRIE

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

CER-VD

Av. de Chailly 23
1012 Lausanne

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« *Let us not forget that progress is an optimal goal, not an unconditional commitment and that its tempo in particular, compulsive as it may become, has nothing sacred about it* »

Hans Jonas, 1969

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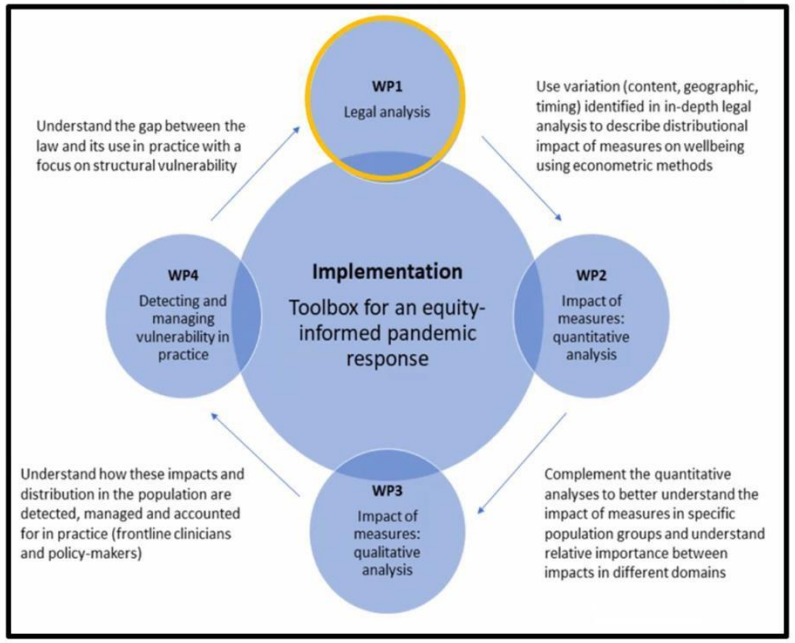
Ex. 1

A (comparative) legal mapping of the Covid-19 measures adopted throughout Switzerland



Overview of the NRP80 project "*Covid-19 policies and inequities in adult wellbeing: Building back fairer from the pandemic in Switzerland*" (2023-2026)

- **Longitudinal data collection** of a large selection of legal and regulatory measures adopted in Switzerland during the Covid-19 pandemic
- **Measures related to**:
  - **Social distancing and maintenance of the capacity of the healthcare system to function** (*dataset 1*)
  - **Compensation of the social and economic consequences of the social distancing measures** (*dataset 2*)
- **Location:** All cantons (incl. Federal measures)
- **Period covered :** 01 Jan. 2020- 17 Feb. 2022
- **Method:** A systematic collection and analysis of legal and regulatory provisions, or *Policy surveillance* (following the methodology used for the LawAltas developed by the Center for Public Health Law Research, University of Temple, USA)

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Ex. 2

Databases we used

Database	Scope	Targeted population	Characteristics	Well-being dimensions considered
LC65+	Local	65+	- 3 samples C1, C2, C3 recruited at 5-year intervals at the same age - Born before / during / at the end of World War II - Representative of the older population in the city of Lausanne	- Self-reported health - Frequency of going outdoor - Healthcare use (medical consultations)
Swiss Household Panel	National	18+	- Longitudinal survey - From 2018 to 2022 (including a specific COVID survey)	- Satisfaction with life in general - Satisfaction with personal relations - Change in financial situation
Survey of Health, Ageing and Retirement	International	50+	- Longitudinal survey - 2 COVID surveys and wave 8 (beginning of 2020)	- Depression - Sleeping troubles - Loneliness

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