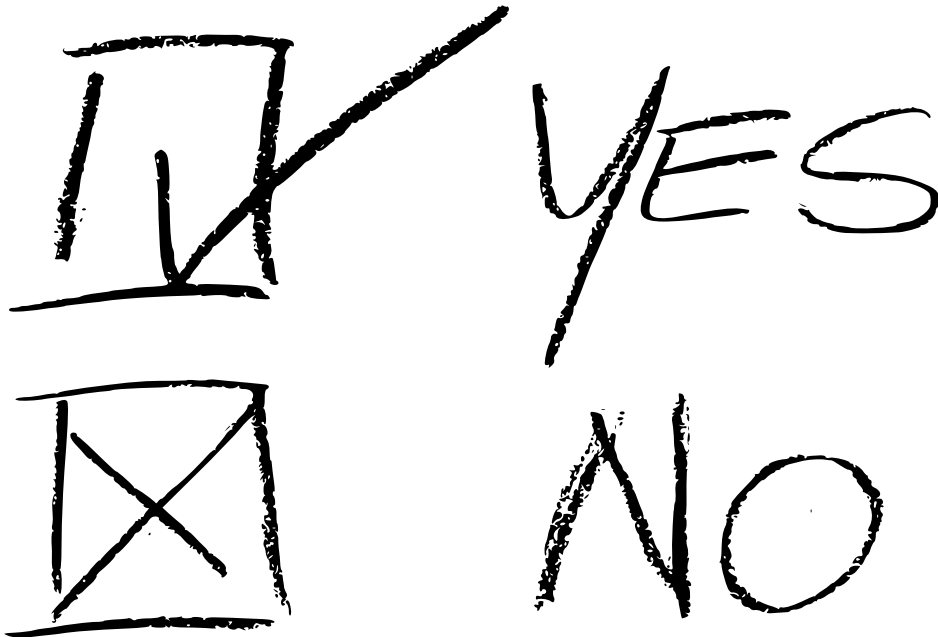


HRO Lunch – 02/10/2024

Consent for HRO3 projects

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(CRC – CHUV)



Plan of the presentation

1. Secondary-use of clinical data and biological samples in research - Ethical and legal framework
2. General Consent
3. Patients and investigators support



1. Secondary-use of clinical data and biological samples in research

Ethical and legal framework





Clinical research

- [Helsinki](#) declaration
- [Taipei](#) declaration
- GCP ICH [E6 \(R2\)](#)
- Regulation on clinical trials on medicinal products for human use ([2014/536](#))
- [HRA](#) – Federal Human Research Act
 - Ordinances: ClinO, ClinO-MD, HRO, OrgO-HRA

Data protection

- [GDPR](#) – General Data Protection Regulation (2016/679)
- [FDPA](#) – Federal Data Protection Act
 - Data protection ordinance [DPO](#)



DÉCLARATION DE L'AMM SUR LES CONSIDÉRATIONS ÉTHIQUES CONCERNANT LES BASES DE DONNÉES ET LES BIOBANQUES

*Adoptée par la 53^e Assemblée générale de l'AMM, Washington 2002
et révisée par la 67^e Assemblée Générale, Taipei, Taiwan, Octobre 2016*

PREAMBULE

1. La Déclaration d'Helsinki énonce les principes éthiques applicables à la recherche médicale sur des êtres humains y compris l'importance de protéger la dignité, l'autonomie, la vie privée et les droits des sujets de recherche, ainsi que d'obtenir leur consentement éclairé pour l'utilisation de données et de matériels biologiques humains identifiables.

2. Dans le cadre des soins de santé, des informations de santé sont collectées par les membres de l'équipe médicale afin d'enregistrer les événements de santé et d'aider les médecins en charge continue de leurs patients.

3. Cette Déclaration a pour objectif de traiter de la collecte, du stockage et de l'utilisation de données et de matériels biologiques identifiables, au-delà des soins individuels prodigués aux patients. En vertu de la Déclaration d'Helsinki, elle énonce des principes éthiques complémentaires relatifs aux bases de données de santé et les biobanques.

La Déclaration doit être lue dans son ensemble et chacun de ses paragraphes doit être lu en compte de tous les autres paragraphes pertinents.

4. Une base de données de santé est un système visant à collecter, organiser et analyser des données de santé. Une biobanque est une collection de matériel biologique avec des données biologiques fait référence à un échantillon prélevé sur un être humain, vivant ou décédé, et des informations biologiques, y compris génétiques, sur cet individu. Les bases de données de santé et les biobanques sont toutes deux des collections qui concernent des individus et une biobanque a des préoccupations similaires en termes de dignité, d'autonomie, de vie privée, de confidentialité et de sécurité.

WMA Taipei declaration

- Cover the collection, storage and use of identifiable data and biological material beyond the individual care of patients. In concordance with the Declaration of Helsinki, it provides additional ethical principles for their use in Health Databases and Biobanks (§3).
- Physicians must consider the ethical, legal and regulatory norms and standards for Health Database and Biobanks in their own countries as well as applicable international norms and standards (§6).
- Declaration available [here!](#)

Taipei declaration: ethical principles

Research and other Health Databases and Biobanks related activities should contribute to the benefit of society, in particular public health objectives (§ 8).

Participants RIGHTS

Privacy and confidentiality (§9)

Autonomy

- ✓ Control over the use of personal data and biological material (§9)
- ✓ Voluntary provision of personal data and biological material (§11)
- ✓ Consent modification/ revocation at any time (§15)
- ✓ Right to request for and be provided with information about their data and their use as well as to request corrections of mistakes or omissions (§14)

Protection

Investigators RESPONSIBILITIES

➤ Ensure participants privacy and confidentiality (§10)

➤ Inform participants (§12)

➤ Collect voluntary and informed consent (§11)

➤ Be transparent : any relevant information on Health Databases and Biobanks must be made available to the public (§20)

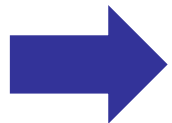
➤ Be inclusive: consult and engage with individuals and their communities (§20)

➤ Protect the interests and rights of the communities concerned, in particular when vulnerable (§17)

➤ An independent ethics committee must approve the establishment of Health Databases and Biobanks used for research (§19)

Governance arrangements must be clearly defined, in particular with regard to :

- Participants right to autonomy
- Participants privacy and confidentiality
- Procedure to share data and samples
- Procedure to get in touch with participants if necessary



Biobank/Register regulations



Règlement de la biobanque de recherche

N° de Dossier.....

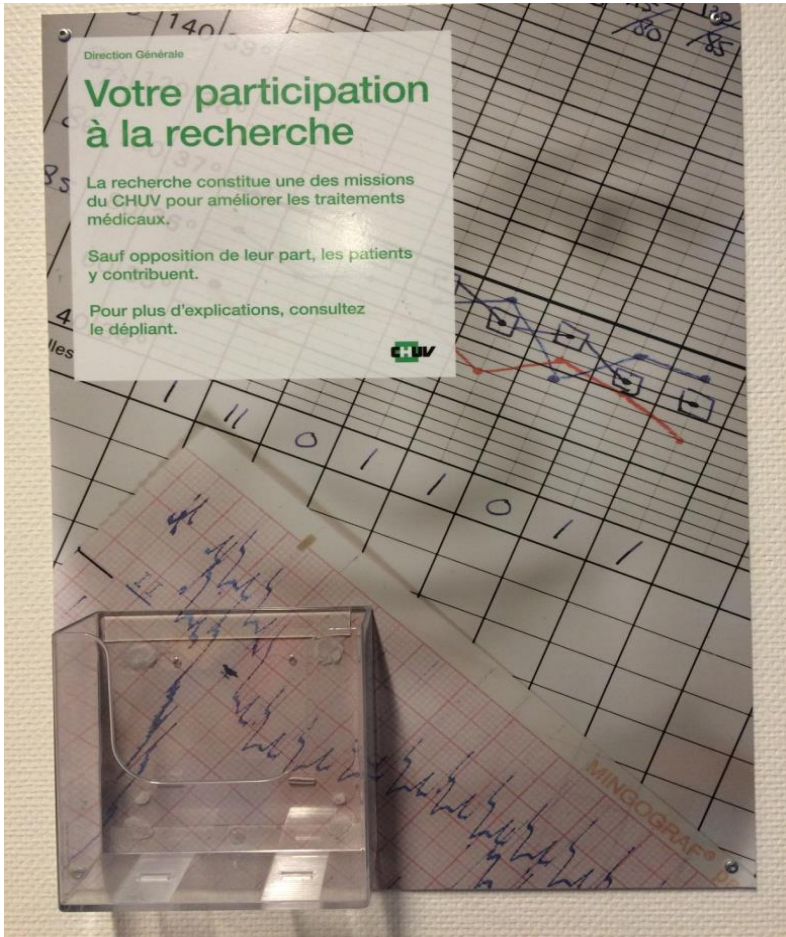
Ce règlement a été élaboré conformément à la Directive institutionnelle du CHUV « Biobanques de recherche et/ou biobanques cliniques : création, gestion et utilisation », dans le but d'harmoniser et de coordonner la gestion des biobanques existant au CHUV et à l'Université de Lausanne. Il est conforme à la législation suisse, et respecte les recommandations émises à ce sujet par l'Association Médicale Mondiale (AMM)¹.

Il est utilisé pour les biobanques de recherche. Il contient des dispositions générales et des dispositions spécifiques.

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¹ Déclaration de l'AMM sur les considérations éthiques concernant les bases de données de santé et les biobanques, dite Déclaration de Taipei, adoptée par la 53^e Assemblée générale de l'AMM, Washington 2002 et révisée par la 67^{ème} Assemblée Générale, Taipei, Taiwan, Octobre 2016, <https://www.wma.net/fr/policies-post/declaration-de-lamm-sur-les-considerations-ethiques-concernant-les-bases-de-donnees-de-sante-et-les-biobanques/>



Until 31/12/2013, general authorization to waive professional secrecy for research projects

National legal framework

Federal Act on Research involving Human Beings (Human Research Act, HRA)

of 30 September 2011 (Status as of 1 September 2023)

The Federal Assembly of the Swiss Confederation,
on the basis of Article 118b paragraph 1 of the Federal Constitution¹,
and having considered the Dispatch of the Federal Council dated 21 October 2009²,
decrees:

Chapter 1 General Provisions

Section 1 Purpose, Scope and Definitions

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.

01/01/2014, entry into force of the human research act (HRA) and its ordinances.

Swiss federal human research act

HRA <https://www.fedlex.admin.ch/eli/cc/2013/617/fr>

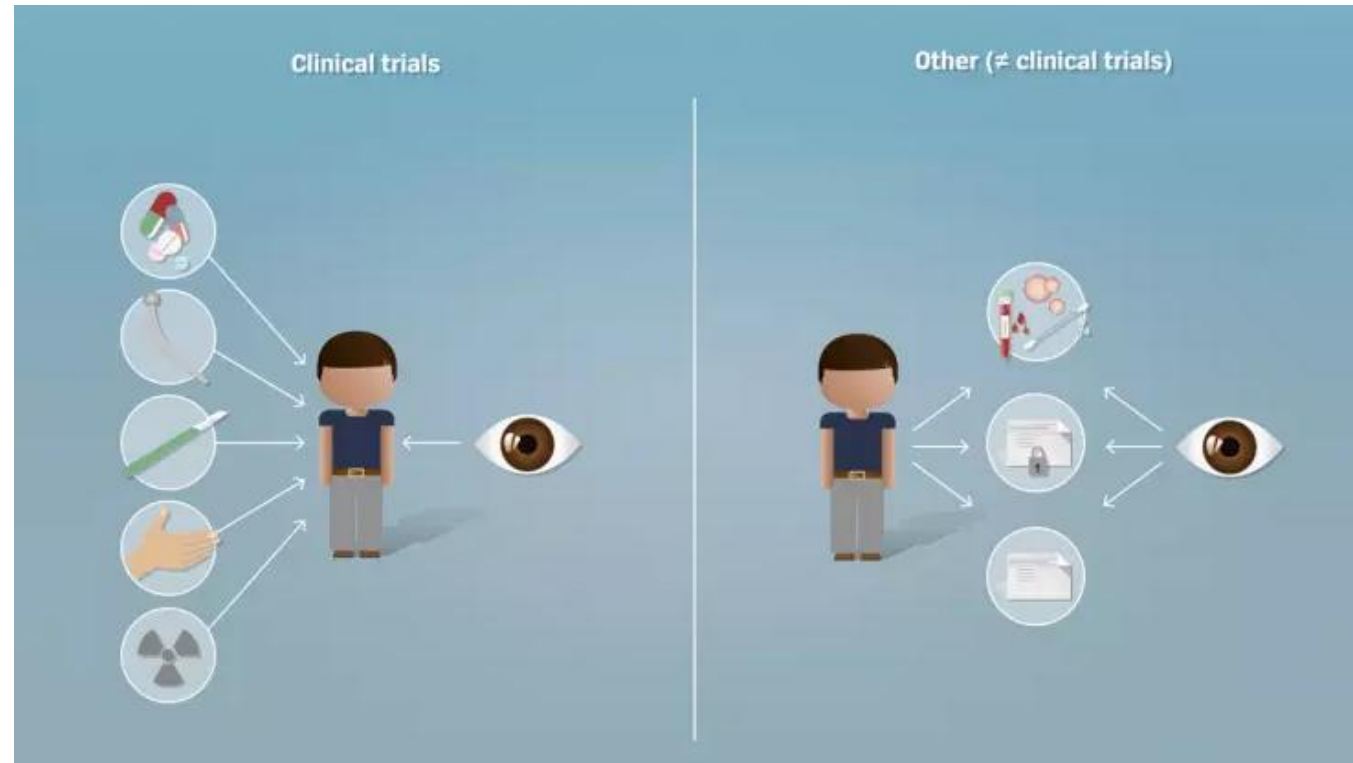
Implementing ordinances:

HRO **Human research ordinance**
<https://www.fedlex.admin.ch/eli/cc/2013/642/en>

ClinO **Ordinance on Clinical Trials with the exception of Clinical Trials of Medical Devices**
<https://www.fedlex.admin.ch/eli/cc/2013/643/en>

ClinO-MD **Ordinance on clinical trials with medical devices**
<https://www.fedlex.admin.ch/eli/cc/2020/553/en>

OrgO-HRA **HRA organisation ordinance**
<https://www.fedlex.admin.ch/eli/cc/2013/644/en>



ClinO (-MD)

HRO

HRO chapter 2: Research projects associated with data and samples collection

HRO chapter 3: Secondary use of samples and data

A tool to help you categorize your project: [Categoriser | Kofam](#)

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.

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 biological material or personal data 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.¹¹



Art. 7 Consent

¹ Research involving human beings may only be carried out if, in accordance with the provisions of this Act, the persons concerned have given their informed consent or, after being duly informed, have not exercised their right to dissent.

² The persons concerned may withhold or revoke their consent at any time, without stating their reasons.

Specific consent

- Clinical study (ClinO)
- Observational prospective study (HRO2)
- Secondary use of *identified* data/samples (HRO3)

General consent

- Secondary use of *coded* data/samples (HRO3)

Information and non-objection (opt-out)

- Anonymization of genetic data/samples and secondary use (HRO3)

Art. 34 Absence of informed consent

If the requirements for informed consent specified in Articles 32 and 33 are not met, further use may be made of biological material or health-related personal data for research purposes in exceptional cases if:

- a. it is impossible or disproportionately difficult to obtain consent or to provide information on the right to dissent, or this would impose an undue burden on the person concerned;
- b. no documented refusal is available; and
- c. the interests of research outweigh the interests of the person concerned in deciding on the further use of his or her biological material and data.

For HRO3 projects, exceptionally, if you are unable to obtain informed consent of the people you wish to include in your study, you may apply to the EC to obtain a waiver under article 34 HRA.

- Justify methodologically and statistically the size of your patients cohort
- Indicate the number of persons that have signed GC and deceased persons
- Argue why you want to obtain a waiver according to article 34 HRA

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.

² Any person who stores biological material for research must, in particular:

- a. comply with the principles set out in paragraph 1 *mutatis mutandis*;
- b. ensure that the technical requirements are met for appropriate storage of the biological material;
- c. make available the resources required for storage.

Data/samples collected for a research project should be stored in a secure manner to ensure patients confidentiality:

- Avoid uncoded files → use coded or anonymised data
- NO USB key/smartphone/external hard-disk → use a secure network
- Excel/Access files are not recommended → use a validated data capture tool (SecuTrial[®], REDCap[®], DiData, ...)

Human research ordinance (HRO)

To collect data for my research project, patients will be asked to fill in questionnaires.
What kind of consent should I use?

- General consent
- **A specific consent**
- Art 34 derogation
- No consent is needed



2. General consent

Participer à la recherche

Information sur l'utilisation des données de santé et des échantillons à des fins de recherche et le consentement général à la recherche



A consent

- Signed once
- Valid for an unlimited period of time
- Revocable at any time

That enables

- Secondary use of coded/anonymised
 - Clinical data
 - Biological samples

Data and samples could be used in research projects

- Authorised by an EC
- Unknown at the time of signature*
- Conducted in Switzerland or abroad
- In private or academic fields

** GC could also be used in prospective studies, as long as it's HRO3 (+ GC is accompanied by an information about the project)*

Participer à la recherche

Comment tes données médicales et échantillons peuvent-ils être utiles pour les chercheurs-euses ?
Ce qu'il faut savoir sur le consentement général à la conservation et à la réutilisation d'échantillons et de données à des fins de recherche



What if patients do not complete GC form?

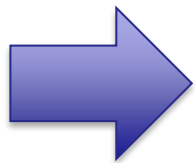
Your consent is voluntary.

It remains in effect for an indefinite period, or until you withdraw it. You may withdraw your consent at any time, without having to give a reason. To do so, you simply need to inform the Research Consent Unit at the address shown on the back of this document.

If you decide not to participate in research by ticking "NO" for statement A, your clinical data and biological samples cannot be used for research.

If you do not sign the consent form, i.e. if you do not respond, the law provides that samples and data can be used for research on an exceptional basis subject to authorisation from the relevant ethics committee. It is therefore important for you to make your wishes clear.

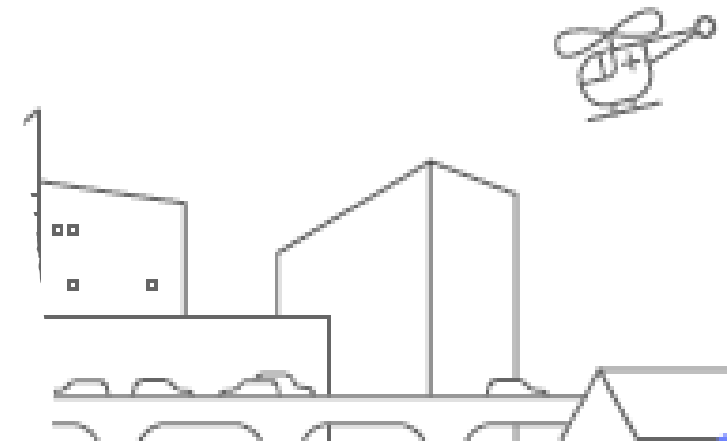
Your decision will not have any effect on your medical treatment.



It is essential that patients position themselves about GC so that their decision could be respected.

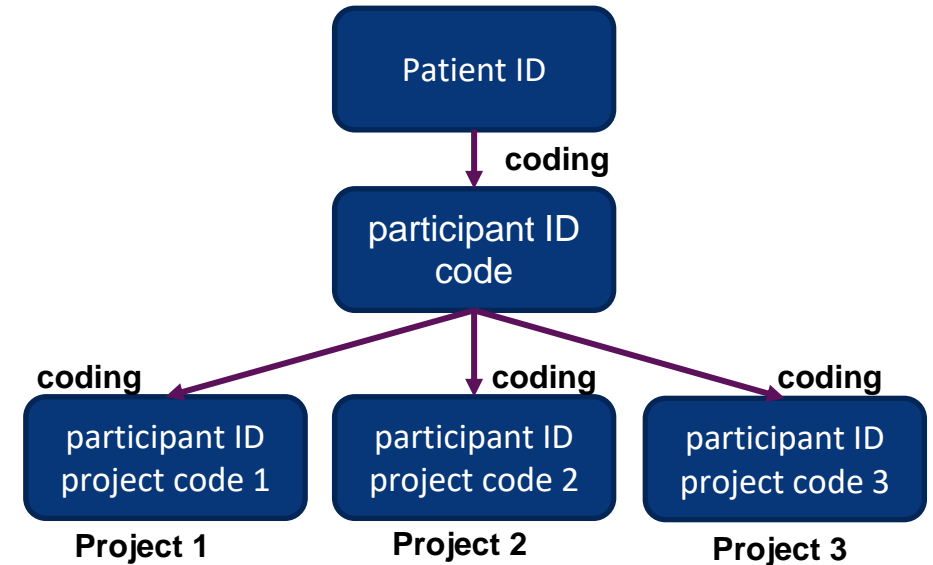
The advantages of General consent

- For investigators
 - ✓ Time saving to set up HRO3 research projects
- For patients
 - ✓ Less solicitations
 - ✓ Transparency and information concerning research with data and samples
 - ✓ Opportunity to participate in biomedical research
- For the institution
 - ✓ Compliance with legal and institutional standards in the use of samples and data in research

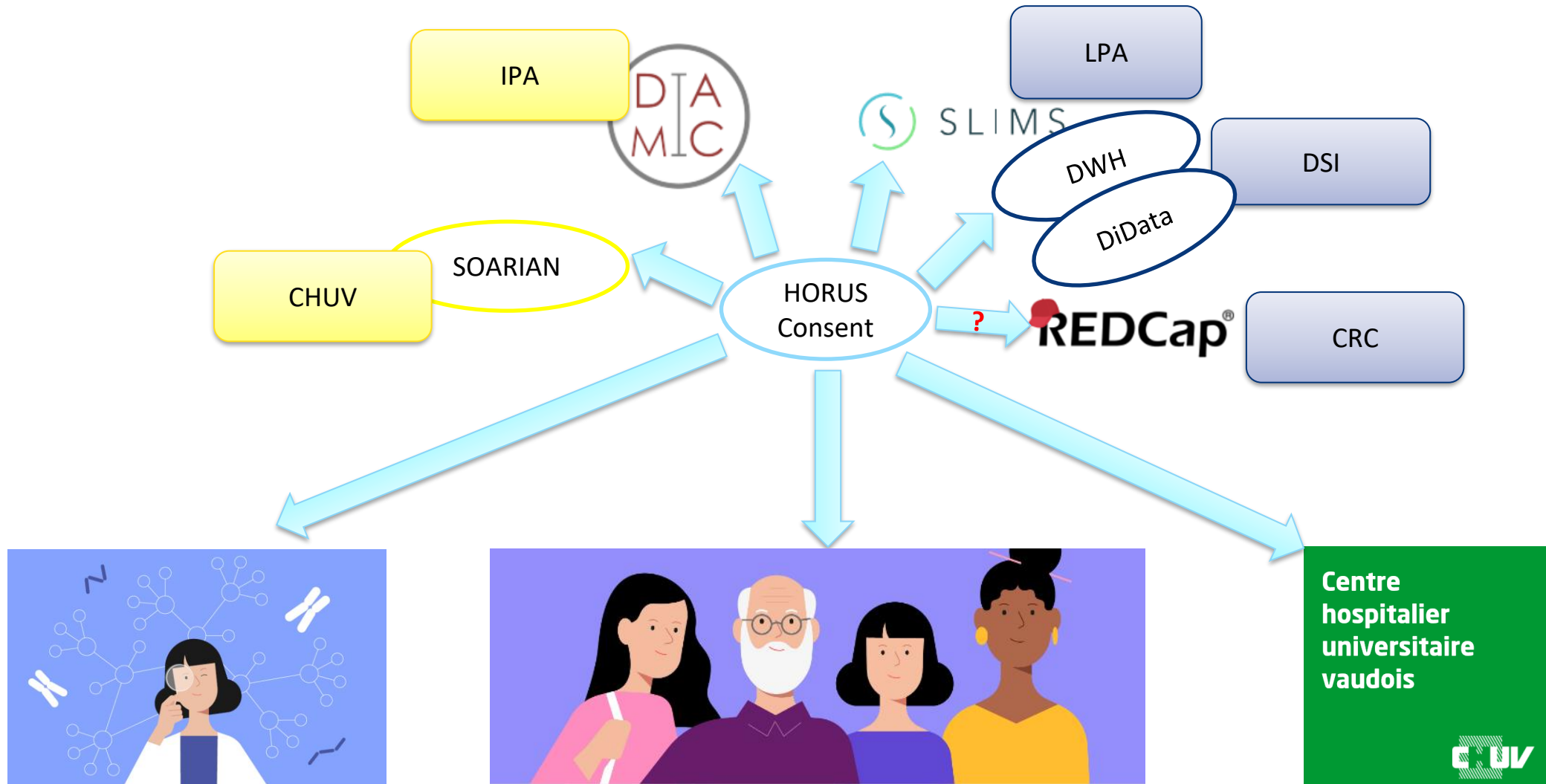


Several functionalities:

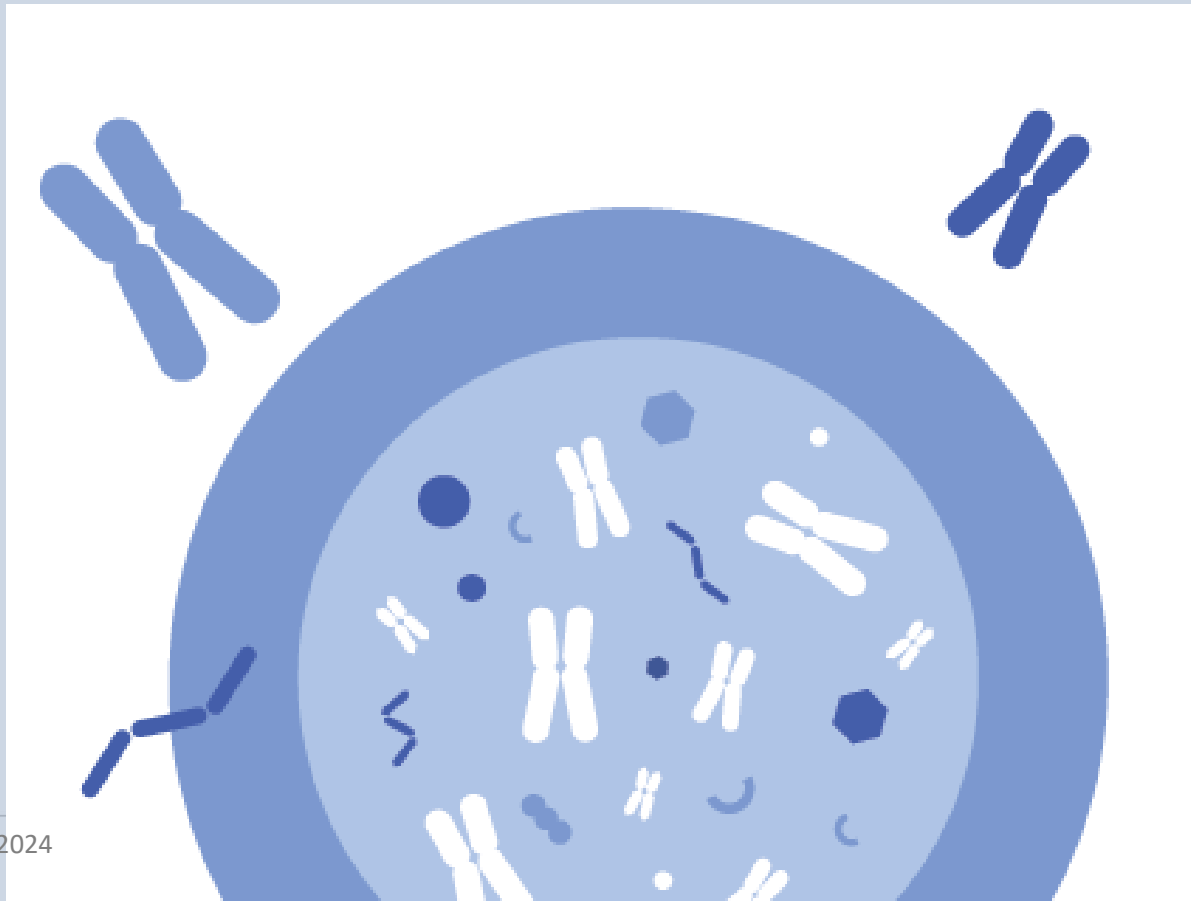
1. General consent management
 - GC mailing to not-yet informed patients: edition functionalities
 - GC forms registration: Using an optical scan to save the information of the received general consent forms
 - Synchronizing data with the different clinical applications.
2. Documenting research projects
3. Management of specific consent forms
4. Management of consent revocation (specific and/or general)
5. Coding management of patient ID (for research purposes)
 - Coding of patient ID: participant ID code
 - Coding of patient ID per research project : participant ID project code



HORUS Consent is at the heart of research activities



General Consent at CHUV



01.01.2013 – 02.09.2024

	Adults	Minors
Informed	311'110	29'711
Responded	195'713 (63%)	13'317 (41%)
Consented	155'059 (79%)	8714 (71%)

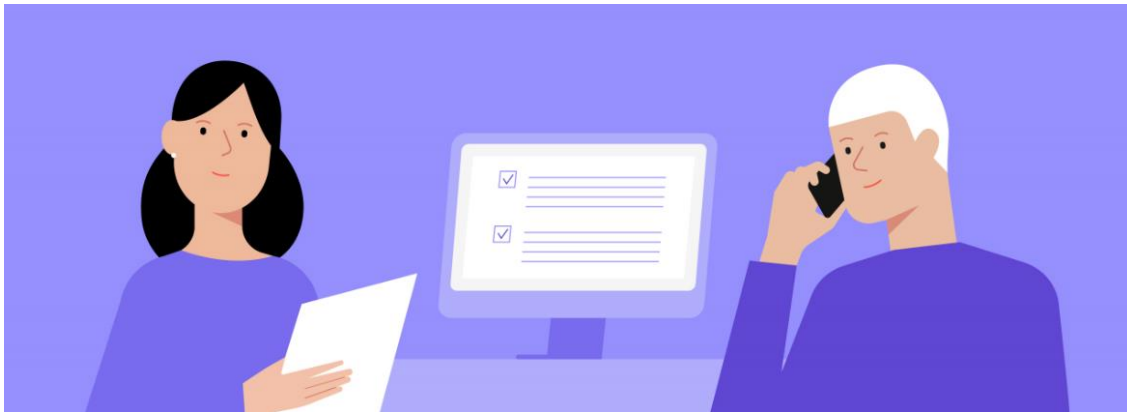
An investigator from abroad is asking for samples and data from patients for his project. Does General consent allow transfer of samples and data abroad?

- No, a specific consent has to be signed.
- Yes
- **Yes if the data protection conditions in the destination country are at least as stringent as those applied in Switzerland.**

If the patients that I want to include in my project have signed GC, I don't need to submit my project to the Ethical Committee.

1. True

2. False



3. Patients and investigators support

The research consent unit (RCU) supports patients for any question about GC. In 2023, RCU received:

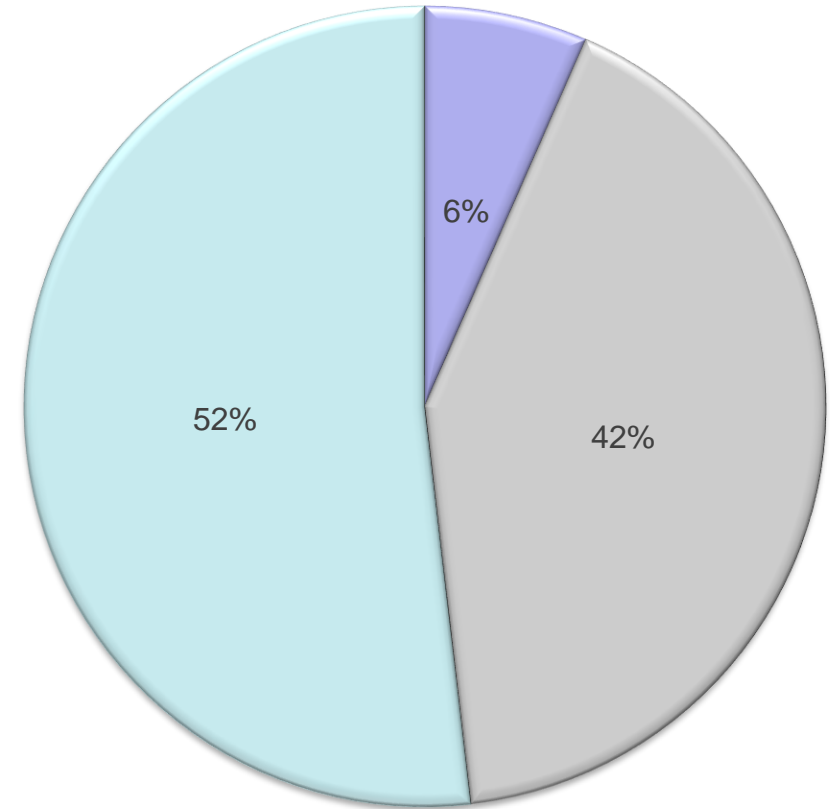
- 696 hotline calls
- 440 comments on GC form
- 99 mails
- 96 e-mails

Contacts were essentially taken by patients (66%) and their relatives (23%).



The research consent unit supports investigators for any question about GC.

In 2023, 380 requests about GC were received



- Targeted GC mailing
- Question
- GC status extraction

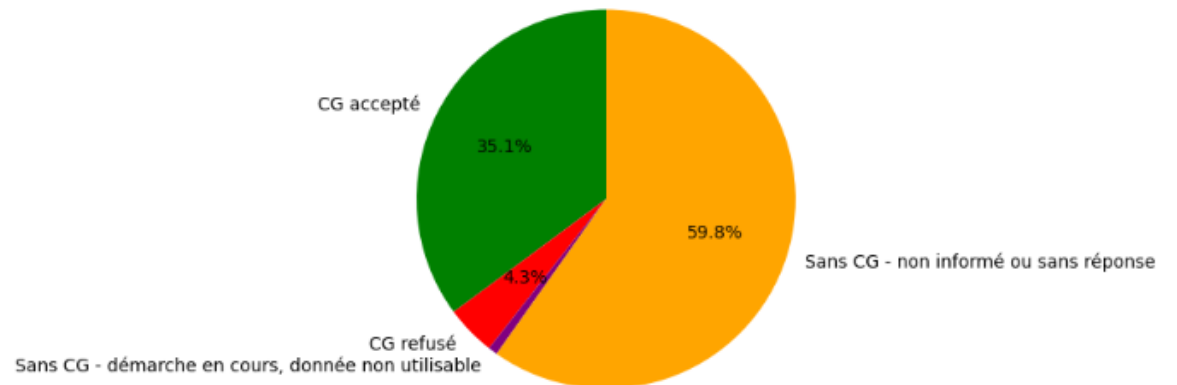
Tailor consent strategy according to feasibility analysis:

- Patients who refused GC : propose a specific consent
- Alive patients not informed about GC: set up a targeted mailing of GC documents
- Unpositionned deceased patients + alive informed unpositionned patients : ask for derogation according to art.34 HRA

NB: GC status may change with the time. It's necessary to check GC status again just before starting data analysis!

	<14 ans	14-17 ans	> 18 ans	Total	
Données utilisables sous le CG	18	4	909	931	Patients positionnés : • CG accepté
Données non-utilisables sous le CG	3	0	110	113	Patients positionnés : CG refusé
Données actuellement non-utilisables sous le CG	7	3	11	21	Démarches en cours
Stratégie à définir avec le BPR	58	19	810	887	Patients non-positionnés : • vivants non informés* • décédés (informés ou non informés) • vivants informés • vivants non contactables • avec démarches CG arrêtées
	3	0	328	331	
	11	1	253	265	
	4	0	96	100	
	1	0	0	1	

* Susceptibles de faire l'objet d'envois ciblés, veuillez contacter l'Unité du consentement à la recherche à support.ucr@chuv.ch pour plus d'informations



If a patient has refused GC, can I propose him a specific consent?

1. No
2. Yes

Take home messages



- Inform patients and obtain their consent.
- Ensure that patients decisions are registered in a manner that enables to respect their decisions anytime
- Write a biobank/register regulation
- Ensure participants data/sample protection and confidentiality
- Submit each research project to the EC



Thank you for your attention!

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