

Retrospective research: The 2014 legal changes in Switzerland

Trilaterales Treffen der deutschsprachigen Ethikräte

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Outline

1. Definition of LRH retrospective research
2. The old system
3. Characteristics of the new system
4. Three types of consent
5. ... and without consent
6. Role of ethics committees
7. Practical advice

Retrospective research is

Research with:

- Existing data (medical + personal data, including genetic data)
- Existing biological material

preexisting

- Nothing is collected prospectively from the subject
 - Cannot / should not cheat !

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Outside the scope of the new law

- Retrospective research with
 - **anonymous** data
 - ≠ coded data
 - **anonymous** biological material
 - More correctly anonymized biologic material
 - ≠ coded material

= Almost without constraint

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Biobanks

- The legislature decided not to directly regulate them.
 - No good reason given.
- The only (private, but very good) text of the Academy of Science was recently withdrawn.
- Legal vacuum, except for consent rules in LRH.

The old (pre-2014) system

- Mostly based on medical (professional) secrecy
 - Civil Code + Penal Code
- OALSP – Ordinance on the authorizations to lift secrecy
- Cantonal law
- Internal guidelines of hospitals/clinics
- Law on therapeutic product did not cover retrospective research

New (2014) system

- Law on Research on Human Beings (LRH) and its 3 ordinances
 - ORH? Yes.
 - OClin? No, because applies to prospective
 - Org LRH? Yes, for organizational questions
- Little cantonal law (statutes) left.
- Internal guidelines (e.g., hospitals) should be adapted
- Now obsolete: OALSP and its authorizations

Characteristics of the new system

- Centers on the notion of research, not medical secrecy
 - Now of little direct relevance
 - Who collected the data: the treating physician or a third party?
 - To whom data was transferred ?
 - If it's research, it's within the scope of the LRH,
 - Even if the doctor's «own» data
- Centers on subject's consent.

Practical consequences


- You cannot re-use your «own» data (i.e. those of your own patients) for your «own» research-
- Similarly, it's not because the data is being kept within the «same» unit that it can be re-used for its «own» research purpose.

Two pillars

- Subject consent
 - Almost always



and

- Authorization from the ethics committee 
 - Almost, but ...
sometimes «tiny» committee

Subject consent

- It is the rule, but...

- One exception



- Type of consent varies



Three types of consent

- Free and informed **specific** consent
- Free and informed **general** consent
- Non-opposition (**veto**) after receiving information (informed)

Which consent for which research?

- **Specific consent**
 - Biological material *NON-coded*
 - Genetic data *NON-coded*
- **General consent**
 - Biological material *coded*
 - Genetic data *coded*
 - Non-genetic data *NON-coded*
- **Veto right**
 - If non-genetic data *Coded*

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Definitions: coded? anonymized?

- **Coded?** Data is anonymous for recipient, but someone else holds the necessary key to decode
- **Anonymized?** In the beginning, data was collected with personal identifiers, but then those were permanently and completely removed.
 - Possible for biological (genetic) material
- **Collected anonymously?** From the beginning, no personal identifiers were available/collected.

May I anonymize biological material / genetic data

- Yes, but ...
 - Patient must be **informed** (fully) before, **and**
 - He/she has a veto right

No consent if

- For the 3 types of consent, the researcher may seek a waiver from the ethics committee
- He/She must prove that the following conditions are met.

«a. l'obtention du consentement ou l'information sur le droit d'opposition est impossible ou pose des difficultés disproportionnées, ou on ne peut raisonnablement l'exiger de la personne concernée;

b. aucun document n'atteste un refus de la personne concernée;

c. l'intérêt de la science prime celui de la personne concernée à décider de la réutilisation de son matériel biologique ou de ses données.»



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Requirements for the waiver

- Absolutely or *practically* impossible to obtain subject consent (including non-veto).
 - Probably same criteria as in the past: too many subjects (!), subjects now deceased, subjects no longer leaving in Switzerland
 - Possibly: psychologically frail subjects.
 - No waiver: patients are still being medically followed same physician
 - Partial solution? Ask certain, waive those who do not respond.
 - No valid ground: for scientific reasons, all subjects must be included
- No written proof of a prior refusal of the subject
 - Rare in practice
- The interest of science prevails over the subject's interest to self-determine whether to participate
 - Ultimately decided by the ethics committee

Ethical review

- Always mandatory
 - If research within scope of LRH (systematic+ generalizable knowledge + sickness or functioning of human body)
- Number of members varies →
 - Plenum
 - Only 3 members
 - Only the president

How many members for retrospective projects?

- Plenum?
 - Never if retrospective
- 3 membres? (i.e., simplified procedure)
 - If consent waiver
- President only?
 - Everything else !

Advice

- Systematically ask **general** consent to all patients entering the hospital/the clinic
 - Not difficult !
 - Nice brochure
 - But still not done everywhere
- &
- Finish the job: regulate biobanks

More info

- Retrospective research according to new LRH: V. Junod, RevMed (2014)
 - <http://rms.medhyg.ch/numero-417-page-399.htm>
- Retrospective research before LRH: V. Junod et B. Elger, Swiss Medical Weekly (2010)
 - <http://www.smw.ch/for-readers/archive/backlinks/?url=/docs/pdfcontent/smw-12972.pdf>
- Access to Swiss statutes:
 - <http://www.admin.ch/opc/fr/classified-compilation/81.html>

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Thank you!

Questions ?