CONSEQUENCES OF WITHDRAWAL OF CONSENT

December 10, 2019

1. TOPIC

Our recommendation addresses the question of whether, after withdrawal of consent, biological material may continue to be used in an anonymized form, as the law allows in some circumstances.

2. OUR RECOMMENDATION

SBP recommends that upon withdrawal of consent, biological material should no longer be made available for research, unless otherwise agreed upon by the research participant. Therefore, research participants ought to be offered the option to have their biological material destroyed, and not simply anonymised as allowed by the Swiss law in some circumstances.

SBP's rationale for this recommendation is to avoid the re-identification risk. Since anonymization of biological material cannot be absolutely guaranteed, biological material must be destroyed if the research participant had expressed that choice during the informed consent process, or does express such a choice together with his withdrawal of consent.

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3. LEGAL AND ETHICAL ANALYSIS

FEDERAL ACT ON RESEARCH INVOLVING HUMAN BEINGS (HRA) – 2011

From a legal standpoint, the HRA does not specifically mention the consequences of withdrawal:

"Article 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."

It only provides with the following, in case of post hoc consent:

"Article 31 *Post hoc* or proxy consent

2. If the person concerned refuses to give *post hoc* consent, the biological material and data may no longer be used for the research project."

As well as the following, about anonymisation:

"**Article 32 Further use of biological material and genetic data**

3. Biological material and genetic data may be anonymised for research purposes if the person concerned or the legal representative or next of kin have been informed in advance and have not dissented to anonymisation. For dissent, Articles 22–24 apply *mutatis mutandis*."

ORDINANCE ON HUMAN RESEARCH WITH THE EXCEPTION OF CLINICAL TRIALS (HRO) – 2013

Instead, the consequences of consent withdrawal are dealt with in the HRO, which provides:

"**Article 8 Information**

1. In addition to the points specified in Article 16 paragraph 2 HRA, the persons concerned must receive information on:
   c. the consequences of revoking consent to further use of the biological material and personal data collected up to this point;"

"**Article 10 Consequences of revocation of consent**

1. If consent is revoked, the biological material and health-related personal data of the person concerned must be anonymised after data evaluation has been completed.

2. Anonymisation of the biological material and personal data may be dispensed with if:
   the person concerned expressly renounces this right when revoking consent;
   or
   it is established at the beginning of the research project that anonymisation is not possible and the person concerned, having been adequately informed of this fact, consented to participate (…)."

The Swiss legislation therefore considers anonymization of the biological material and data as the consequence of withdrawal of consent. The legislation does not mention any biological material and/or data destruction options. Still, SBP argues that the option of biological material destruction ought to be offered to research participants.

SBP's rationale is based on the following references:

CIOMS - INTERNATIONAL ETHICAL GUIDELINES FOR HEALTH-RELATED RESEARCH INVOLVING HUMANS - 2016

See Commentary of Guideline 11: Collection, Storage and Use of Biological Materials and Related Data

"Withdrawal of consent. Donors or their legal representatives should be able to withdraw consent for maintenance and use of biological material stored in a biobank. The withdrawal of consent should be formalized by written documentation signed by the donor or their legal representative of the donor, and the samples should either be destroyed or returned to the donor. Future use of the biological materials and related data is not permitted after the withdrawal of consent."

WMA - DECLARATION OF TAIPEI ON ETHICAL CONSIDERATIONS REGARDING HEALTH DATABASES AND BIOBANKS – 2002, AS REVISED IN 2016

Article 15. "Individuals have the right, at any time and without reprisal, to alter their consent or to ask for their identifiable data to be withdrawn from the Health Database and their biological material to be withdrawn from a Biobank. This applies to future use of the data and biological materials."

SPHN - ETHICAL FRAMEWORK FOR RESPONSIBLE DATA PROCESSING IN PERSONALIZED HEALTH RESEARCH VERSION 2 – 2018

1. Respect for Persons

"Guideline g) Participating institutions should have mechanisms in place that ensure revocations of consent are swiftly acted upon across the Network. Upon revocation of consent, personal data and biological material should no longer be made available for research. Personal data should be removed and human biological material should be destroyed if, upon revocation of consent, the research

participant has expressed this preference. However, complete elimination of all human biological material and data may not be possible. Research participants should be informed – during the consent procedures – of this possibility".

NEK/CNE - BIOBANKS FOR RESEARCH - 2015

Revocation of consent

"99. Even though individuals are informed about the risks and benefits of donation when they donate their biomaterials, it must be possible for them to withdraw at any time. Committing oneself for an indefinite period would be excessive and difficult to reconcile with the right to self-determination. Donors must therefore have the right to revoke their consent at any time without being required to give a reason. Withdrawal can take various forms: the donor's samples and data can be destroyed, or they can be merely anonymised and continue to be used – though without further updating – for research purposes. In the former case, the donor's samples and data, together with the code, are to be destroyed; in the latter case, only the identifying code is to be removed. It may be that complete elimination of all samples and data is not possible, particularly because sample components and data already transferred to researchers cannot be recalled or destroyed (cf. Nuffield Council on Bioethics 2015, Sect. 7.9). At the time consent is given, donors are to be informed that, even if it is subsequently revoked, their donation and its consequences cannot be fully reversed."

"**121**. (...) it should be pointed out to donors that, even today, the anonymity of samples and data cannot be absolutely guaranteed."

"**51**. It should also be borne in mind that even anonymised samples and data can possibly – with a certain amount of effort – be re-identified. Anonymised genetic data in particular can be linked to the person concerned if it can be compared with existing – non anonymised – reference data, e.g. in the databases of police authorities and intelligence agencies or even private companies (Bohannon 2013; Nature 2013; Nuffield Council on Bioethics 2015, Sects 4.14 f). Re-identification may, however, also be relatively straightforward with the aid of general biographical details such as region, ethnic origin and occupation, if this information is compared with publicly accessible (e.g. online) data."

"**145**. Under Art. 7 para. 2 HRA, the persons concerned may revoke their consent at any time without giving a reason. This also applies to donors of biological material. If consent is revoked, the material and personal data of the person concerned is to be anonymised after data evaluation has been completed (Art. 10 HRO). As a more radical option, provision could be made for the destruction of the material and data."

"**151**. In addition, the right to revoke consent must not be compromised by the transfer or reorientation of a collection. The right to revoke consent at any time can only be effectively exercised if donors know which biobank is storing their samples and data. This means that donors have to be informed in a general manner about the procedure in question, and that the receiving or reoriented biobank has to fulfil its duties of transparency.

SAMS: RESEARCH WITH HUMAN SUBJECTS - A MANUAL FOR PRACTITIONERS 2015

"If consent to participate in a study is withheld *post hoc* by the patient or by the legal representative, the patient is to be excluded. Biological material already sampled in the course of the study must be destroyed and the data may no longer be used for the research project (Art. 31 para. 2 HRA, Art. 15–17 ClinO). However, if the validity of the study would thereby be compromised in essential respects, failure to evaluate data already collected and publish the results would be ethically problematic. In such circumstances, it is therefore permissible, by way of exception, to use the data in spite of refusal of consent, although the data and any biological material must be anonymised without delay (Art. 17 para. 4 ClinO)."

4. IN PRACTICE

SBP has noticed that, when a withdrawal of consent occurs, several biobanks decide to continue using the related biological material in an anonymized form, without ever offering any destruction options.