

Recommendations concerning the application of the General Consent version 2019

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Working Group General Consent unimedsuisse

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This document describes the recommended application of the General Consent version 2019 in the institutions. It follows the Swiss legal regulations.

1. Concerning the General Consent version 2019

The General Consent version 2019 (below GC) [1] consists of an obligatory written information (1.5 pages) and the decision form, which has to be signed by the patient or legal representative, if applicable.

The template GC has been approved of by all Ethics committees, swissethics, Swiss Academy of Medical Sciences (SAMW) and unimedsuisse. This national approval is only valid, if the template of the GC is applied without changes.

To implement the template in a specific institution the institutions' logo and contact-address for further information or withdrawal is added. Institutions are free to use their own corporate design, as long as they do not change the wording. If an institution (in most cases a hospital) changes the wording of either information or decision form, the used form has to be submitted to the responsible ethics committee for re-approval.

Additional information is possible, if desired by the institution (e.g. extended, interactive general consent online information or a brochure). The according information has to be in line with the national GC information and the procedures of the institution. It is recommended that all additional information to the patient is submitted to the Ethical Committee concerned.

The template of the GC is available in 4 languages [2]. Download is possible under www.unimedsuisse.ch. Further Languages are available within the university hospitals.

Please note, that the specific research project itself, that uses the data/samples, needs still an approval by the ethics committee.

2. Data and samples concerned

The GC covers the further use of coded genetic and non-genetic data and/or samples for research according to the Human Research Ordinance (HRO) Art. 29, 30, 32. [3]

The scope applies only to data and samples collected during the hospital stay and may include data from research projects. It does not cover additional data/sample collection (HRO, chapter 2), such as additional examinations or sampling of additional blood.

3. Significance of the patients' decision

The national GC template applies the opt-in approach, meaning that the patient or his/her representative has to say yes to data/samples use, otherwise data/sample use is not possible. The opt-out regulation (meaning: if no objection is given by patient, but patient was informed, using coded non-genetic data or anonymization of samples is allowed) is not accepted within the GC even though it is allowed according to the Human Research Act (HRA).

There are three major reasons for this decision:

- A transparent and clear information is crucial for the decision-making process of the patient.
- Not all institutions are able to document which patients received the information concerning GC (either through mailings or face-to-face).
- The opt-in approach ensures consistency with is conform to the EU General Data Protection Regulation (GDPR) [4] resulting in harmonized processes in international projects.

To make the patients' decision valid, the decision form has to indicate the decision (Yes/No) and has to be signed by the patient and/or his/her legal representative, if applicable. The legal representative is defined according to Article 378(1) of the Swiss Civil Code (ZGB) [5] (see appendix). The situations of application of a legal representative are described below (see Chapter 6).

Statement Status «Yes»

If a patient gives his/ her consent (ticks «Yes»), further use of data and samples collected during the stay in the institution is allowed until consent is withdrawn. The consent is valid for data and samples collected before consent and for future collected data and samples.

The documented consent remains valid after the death of the patient.

If no documented consent or refusal of a deceased person is available, the next of kin or a trusted person designated during the lifetime of the deceased person is allowed to give consent (HRA, Article 36).

Further use of data and samples is allowed according to the following patient statement status to the single question on the GC form:

Status	Further use allowed of/after
Yes	coded genetic data & samples (HRO Art.29)
Yes	coded non-genetic data (HRO Art.32)
Yes	Anonymization* of genetic data & samples (HRO Art.30)
Yes	Anonymization* of non-genetic data (not part of HRA-regulation)
Yes	Anonymously collected data & samples* (not part of HRA regulation)

* Note: there is a difference between anonymous data/samples and the anonymization of data/samples. The use of anonymously collected data and samples/extracted data and anonymization of non-genetic data is allowed (these data are not regulated by the HRA). The anonymization of genetic data & samples is possible if there is a status Yes.

Statement Status «No»

«No» means an objection and refusal to further use of data/samples for research.

If the patient ticks «No», the following further uses of data and samples are not allowed:

- Coded non-genetic data
- Coded genetic data & samples
- Anonymization of genetic data & samples**

**Note: In order to provide a clear and fair information to the patients, the anonymization of non-genetic data should not be allowed, even though this part is not regulated by the HRA.

Status	Further use allowed of
No	Anonymous data/samples (not part of HRA-regulation)

No Statement

If there is no decision on the GC form, data are not allowed to be used (except of anonymous data/samples). Even if the GC documentation was handed over to the patient and his/her decision is pending, it means that no consent has been given.

Status	Further use allowed of
No signature, informed or <u>not</u> informed	Anonymous data/samples (not part of HRA-regulation) Anonymization of non-genetic data

4. Withdrawal

The consent can be withdrawn at any time without giving a reason. Contact information for withdrawal has to be provided on the obligatory written information sheet and the consent form. Data and samples are not allowed to be used for new projects from the moment on, at which the consent was withdrawn. The patient decision has to be updated in the administrative system of the institution.

Data and samples used for projects before the withdrawal are not affected but should be anonymized, if applicable.

5. Information workflow and documentation

The patient receives the obligatory written information sheet (1.5 pages) and the consent form within the institution or by a notification before/after visiting the hospital. Additionally, oral information by a face-to-face meeting is possible respectively recommended especially for children and adolescents (see chapter 6).

The patient can ask for a copy of the signed consent form. In any case, the written information with contact details of the institution remains with the patient.

The signed consent form is collected and patients' decision is either saved manually or automatically scanned into the documentation system of the institution. The consent form has to be safely archived in a clinical information or a documentation system, according to the archiving guidelines of the institution.

It is recommended to record the following information:

- Statement status (Yes, No, pending)
- Withdrawal (This is depending on the documentation system. If the withdrawal is not triggering the documented decision from «yes» into «no», it needs to be documented separately.)
- Dates of consent/refusal/withdrawal
- History of changes
- PDF of scanned consent form
- Data/samples recipient / Project leader of research project (in order to be able to anonymize data/samples after withdrawal)

6. Application concerning different patient groups

6.1 Judicious adults

For judicious adults the above described general rules apply.

6.2 Additional requirements for particularly vulnerable persons

Research projects based on GC from children, adolescents and adults lacking capacity of judgement have to yield substantial findings which could in the long term be beneficial for the paediatric population or persons with the same disease or disorder, or in the same situation (HRA art 21-24). [6]

6.3 Adults lacking capacity of judgement

Legal representatives (see appendix) of adult patients lacking capacity of judgement receive the same information as the patient. They are allowed to decide and sign for the patient. The adult lacking capacity of judgement should be integrated in the decision process as much as possible. Any refusing attitude of the patient needs to be prioritized.

As soon as the patient recovers capacity and becomes judicious, legal representatives are requested to inform the patient about their decision and the patient is recommended to sign a new consent form. The decision of the legal representative remains valid until the patient eventually signs a new consent form.

If the recovering of capacity is taking place during the hospital stay the institution is recommended to inform the concerned person itself and ask him/her to sign a new consent form.

6.4 Judicious adolescents (14-18 years old)

Legally adolescents receive the same information as adults. They have to sign the form and are authorized to sign alone, but it is recommended to have the signature of the legal representative as well. The decision remains valid after the adolescent turned 18 years.

In all cases, if the adolescent comes back to the hospital when he or she turned 18 years, see section 6.9.

6.5 Adolescents lacking capacity of judgement

Legal representatives (see appendix) of adolescent patients lacking capacity of judgement receive the same information as the adult patient. They are allowed to decide and sign for the adolescent. The adolescent lacking capacity of judgement should be integrated in the decision process as much as possible. Any refusing attitude of the adolescent needs to be prioritized.

As soon as the adolescent recovers capacity and becomes judicious, legal representatives are requested to inform the adolescent about their decision and the patient is recommended to sign a new consent form. If the recovering of capacity is taking place during the hospital stay the institution is recommended to inform the concerned person itself and ask him/her to sign a new consent form.

In all cases, if the adolescent comes back to the hospital when he or she turned 18 years, see section 6.9.

6.6 Judicious children (11-13 years old)

Children (11-13 years old) receive the same written information as adults and their legal representatives, but it is recommended to provide a supplemental oral face to face information or an appropriated written information. Any refusing attitude respectively the decision of the child needs to be prioritized.

The legal signature has to be given by the legal representative.

In all cases, if the child comes back to the hospital when he or she turned 18 years, see section 6.9.

6.7 Children <11 years old

For children under the age of 11 it is recommended to provide an adapted oral information or additional graphical explanations supplementary to the information of the legal representative. The child should be integrated in the decision process as much as possible. Any refusing attitude respectively the decision of the child needs to be prioritized. The legal signature has to be given by the legal representative.

In all cases, if the child comes back to the hospital when he or she turned 18 years, see section 6.9.

6.8 Children lacking capacity of judgement (<14 years old)

Legal representatives (see appendix) of children lacking capacity of judgement receive the same information as the adult patient. They are allowed to decide and sign for the child, but are requested to inform the child together with the institution, inform the child about their decision and offer the option for withdrawing the consent as soon as the child recovers capacity of judgement and/or becomes judicious. The child should be integrated in the decision process as much as possible. Any refusing attitude of the child needs to be prioritized.

In all cases, if the child comes back to the hospital when he or she turned 18 years, see section 6.9.

6.9 Children and adolescents turning 18 years and coming back to the hospital

In all cases, if the child or the adolescent comes back to the hospital when he or she turned 18 years, it is recommended to remind him/her about the general consent decision. The institution is recommended to collect a new consent. The adequate adult procedure is then applied, according to his/her capacity of judgement. Otherwise, in absence of new visit to the hospital, the previous decision remains valid after the child or the adolescent turned 18 years.

If the patient refused with «No» after he or she turned 18 years, the decision is regulated as defined in the case of a withdrawal. All respective data and samples are not available anymore for new projects.

7. Incidental findings: right to be informed or not to be informed

Patients are informed that they may be contacted in case of incidental findings if they are pertinent for their health and if clinical action is possible. In case of children and patients lacking capacity of judgement the legal representative may be contacted. The institutions are responsible to implement processes how to proceed in such situations and how the contact with patients has to be carried out.

In case of incidental findings, patients will have the occasion to choose to have further information or not on the incidental findings, according to article 8 HRA [7] and according to article 6 of the Federal Act on Human Genetic Testing (HGTA) regarding genetic results [8]. In general, it is the responsibility of the researcher to consider the respective situation.

However, as the institutions cannot guarantee that the patient will not be contacted, patients who do not want to be informed at all about the existence of any incidental findings cannot provide their data and samples. Hence, these patients have to check «No» on the form.

8. Data and sample Governance

Hospitals and research institutions are responsible to establish infrastructure and standardized operating procedures that ensure the protection of patient rights when collecting and processing their data and samples, according to data protection laws and regulations.

It is recommended that these procedures include:

- Data access along standardized procedures. It is recommended that data access is organized by data request to a coordinating point of contact.
- Procedures concerning the coding of data and key keeper responsibility.
- The procedures are in use and all involved parties have been trained.

The governance structure should respect international standards, such as the Declaration of Taipei of the World Medical Association (WMA) of October 2016 [9].

For further use at other institutions or industry within Switzerland or abroad a Data/Sample Transfer Agreement has to be used. For research abroad, it must be ensured that at least the same regulations are followed as in Switzerland.

All research projects have to be authorized by the relevant ethics committee regardless of the consent status. Projects with anonymous (already anonymized) data/samples are not submitted to ethics committee approval (they are not under the HRA regulation).

It is recommended to obtain a jurisdictional inquiry for the anonymization procedures by the ethics committee in terms of future publications («Zuständigkeitsabklärung», «Clarifications des compétences», «Esame della competenza»).

Notes

- 1 Universitäre Medizin Schweiz (unimedsuisse): *Template General Consent 2/2019*
→Link <https://www.unimedsuisse.ch/de/projekte/generalkonsent> [access: 21.5.2019]
- 2 German, French, Italian, English, Shqiptar (Albanian), Arabian, Portugues, Serbian, Somali, Spanisch, Tamil, Thai, Tigrin, Turkish, Russian
- 3 *Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance, HRO)*, status as of 24.4.2018
→Link <https://www.admin.ch/opc/en/classified-compilation/20121177/201804240000/810.301.pdf> [access 21.5.2019]
- 4 *Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)*
→Link <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0679> [access 18.7.2019]
- 5 *Swiss Civil Code (ZGB)*, status as of 1.1.2019;
→Link <https://www.admin.ch/opc/en/classified-compilation/19070042/201901010000/210.pdf> [access 21.5.2019]
- 6 Templates and recommendations from swissethics, Research on and with children: →Link <https://www.swissethics.ch/templates.html> [access 3.9.2019].
- 7 *Federal Act on Research involving Human Beings (HRA)*, status as of 1.1.2014
→Link <https://www.admin.ch/opc/en/classified-compilation/20061313/201401010000/810.30.pdf> [access 21.5.2019]
- 8 *Federal Act on Human Genetic Testing (HGTA)* status as of 1.1.2014. →Link https://www.google.ch/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=2ahUKEwj9c3Vqq3iAhXiwsQBHW6ABI4QFjAAegQIABAC&url=https%3A%2F%2Fwww.admin.ch%2Fch%2Fe%2Frs%2F8%2F810.12.en.pdf&usg=AOvVaw0dH71ffb5LU57EGr4_0oip [access 21.5.2019]
- 9 World Medical Association (WMA): *WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks*, October 2016.
→Link <https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/> [access 21.5.2019].

Appendix: Swiss Civil Code (1.1.2019), Art. 378(1)**«The legal representative**

The following persons are entitled in the following order to represent the person lacking capacity of judgement and to grant or refuse consent to the planned out-patient or in-patient measures:

1. A person appointed in a patient decree or in an advance care directive;
2. A deputy with a right to act as representative in relation to medical procedures;
3. Any person who as a spouse or registered partner cohabits with the person lacking capacity of judgement or who regularly and personally provides him or her with support;
4. Any person who cohabits with the person lacking capacity of judgement and who regularly and personally provides him or her with support;
5. Issue who regularly and personally provide the person lacking capacity of judgement with support;
6. The parents, if they regularly and personally provide the person lacking capacity of judgement with support;
7. Siblings, if they regularly and personally provide the person lacking capacity of judgement with support»