SCTO PLATFORMS

# General consent: swissethics' point of view

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swissethics considers the concept of General Consent (GC) a highly useful tool for making patient data and samples available for research. An essential prerequisite for using GC agreements is that patients are informed in a fair and ethical manner with the GC form. Towards this statement, numerous technical options exist, depending on the type of data and encryption involved. Only after patients have received information that is both legally accurate and ethically conveyed, and have given their consent, their data and samples may be used in research.

Making data and samples available should provide long-term benefits to society – and potentially to the involved individuals as well – by allowing for the generation of knowledge per se and for the advancement of medicine and science as a whole. These benefits to the individual and society are both medically useful and desirable from an ethical standpoint.

However, every information document and consent form includes the dilemma: how to convey information ethically and in an intelligible, concise and easy way, while at the same time ensuring its legal accuracy and completeness? This dilemma is notoriously difficult to solve. To address this issue, swissethics and unimedsuisse elaborated version 2.0 of their GC template in February 2019. Since then, this template has been adopted by several university and non-university hospitals.

swissethics supports introducing a uniform, universally accepted national GC template. Its implementation would substantially contribute to the improvement of a number of key national research infrastructures such as the Swiss Personalized Health Network (SPHN) and the Swiss Biobanking Platform (SBP). Further efforts should therefore be made to implement a commonly accepted version of this document that balances comprehensibility with legal requirements.

swissethics has added **short summaries in plain language which succinctly outline essential information at the beginning of many information sheets**. Such a brief and visually appealing summary depicting the essential information for participants could be added at the beginning of the GC form as well. Also, in line with increasing technical possibilities, concrete plans need to be made for using e-consent and for relaying it via digital channels.

Introducing e-consent, including in the context of GC, requires amending legislation related to the Human Research Act (HRA) – a measure swissethics has long supported. Together, implementing such measures will determine whether and to what extent research participants are really involved in the research community in the future.