NEWS FROM

swissethics

Schweizerische Vereinigung der Forschungsethikkommissionen
Association suisse des Commissions d'éthique de la recherche
Associazione svizzera delle Commissioni etiche della ricerca
Swiss Association of Research Ethics Committees

SWISSETHICS: BUILDING TRUST AND INCLUDING PATIENTS' PERSPECTIVES IN THE HUMAN RESEARCH PROCESS

Author: **swissethics**

It has been widely proven that involving patients and laypeople throughout the entire human research process provides added value for human research in general, for patients in their everyday lives, and therefore for society as a whole. Public and patient involvement (**PPI**) is possible at the very early stages of research when defining objectives and planning a study, when a study is conducted, and when study results are published. PPI means that patients are treated as active research partners rather than just passive research subjects. This article discusses how swissethics promotes transparency in order to lay the foundation of trust needed for PPI and provides examples of PPI for the regulatory and ethical aspects of human research.

Patients and laypeople can contribute to clinical research in different ways: for example, they can actively participate in a research project or sign a general consent form, thus making their data and samples that are routinely collected in the hospital available to research. In recent years, patient organisations have become increasingly professionalised, and today they offer their services and competencies not only to academia but also to industry, research institutions, and policymakers, among others.

PROMOTING TRANSPARENCY IN HUMAN RESEARCH

swissethics is convinced that involving patients and laypeople in clinical research and tapping into their motivation can generate the desired results only if there is complete trust between patients and laypeople and the researchers, institutions, and authorities involved in clinical research. Transparency and openness regarding the work swissethics does is one of the crucial pillars on which it builds trust. In order to promote this transparency in human research for the general public, researchers, and institutions, swissethics launched the RAPS (Registry of All Projects in Switzerland) portal in Mai 2018. Additionally, since the start of the COVID-19 pandemic, it has regularly published lists of all studies that have been approved and all studies that have been submitted for approval conducted on SARS-CoV-2 and COVID-19 in Switzerland on its website.

INCLUDING PATIENT REPRESENTATIVES IN ETHICS COMMITTEES

Research ethics committees are composed of individuals from different professions, and they function as multidisciplinary panels to fulfil their duties to protect patients' rights and safety. Following the revision of article 53 (related to the composition of ethics committees) of the Human Research Act (**HRA**) that came into effect on 26 May 2021, at least one member of an ethics committee must be someone who represents patients. Even before the recent revision of article 53, ethics committees were well aware of the benefit patient representatives and laypeople bring to the review of research projects and clinical trials. This is why some ethics committees have already been including patient representatives among their members since the HRA came into force in 2014.

MAKING THE INFORMED CONSENT PROCESS MORE PATIENT-FRIENDLY WITH PPI

In a recent initiative of Professor Bernard Hirschel, President of the Ethics Committee Geneva, patient representatives and laypeople were actively involved in completely revising swissethics' templates for patient information and consent forms. In addition, swissethics started an important project in which the short forms of informed consent forms were completely redesigned. This project was based on linguistic work that was carried out by Professor Felix Steiner's team at the Zurich University of Applied Sciences (**ZHAW**) in Winterthur and that was initially funded by the Federal Office of Public Health (**FOPH**). In due time, further interviews with patients, laypeople, and patient organisations will be conducted in order to gather their input on several other templates for informed consent forms. The fundamental objective for this total revision of the templates is to improve comprehensibility in general and to identify the most essential information that patients want to find in the informed consent forms.