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Developing innovative procedures for obtaining informed consent: Three solutions underway

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The Swiss Personalized Health Network (SPHN), a national initiative funded by the State Secretariat for Education, Research and Innovation (SERI), was designed to promote the development of personalised medicine and personalised health in Switzerland. The SPHN aims to develop infrastructure projects that will make health-related data interoperable and shareable at the national level. Accordingly, certain projects related to informed consent (IC) were funded and are described in this article: the Electronic General Consent (e-GC), the Citizen Centered Consent: Shared, Transparent and Dynamic (the so-called C3-STuDY), and the proactive management tool of consent for research (in French so-called “Gestion Proactive des Consentements de Recherche”, GPCR).

Introduction

In the current, rising era of biomedical research that increasingly wants to access and use big data, the conditions for acquiring consent to research from patients must evolve in accordance with ethical, legal, and societal imperatives.

Many stakeholders are involved in implementing various principles, laws, rules, techniques, and procedures to cope with such a rapidly evolving environment. In order to meet these imperative requirements and to be practically able to manage massive access to sensitive health-related data, we need suitable technical innovations and validated solutions. Among those stakeholders involved is the Swiss Personalized Health Network (SPHN), a national initiative funded by the State Secretariat for Education, Research and Innovation (SERI) that was designed to promote the development of personalised medicine and personalised health in Switzerland. The SPHN aims to develop infrastructure projects that will make health-related data interoperable and shareable, at the national level. Accordingly, certain projects related to informed consent (IC) were funded and are described in this article: the Electronic General Consent (e-GC) and the C3-STuDY Citizen Centered Consent (referred to as C3-STuDY). Additionally, a third, also new consent management tool, rounds off this article: Gestion Proactive des Consentements de Recherche (GPCR, meaning proactive management of consent for research).

e-GC: a nationwide, harmonised, interactive tool

According to the Swiss Human Research Act (HRA) and its ordinance (Human Research Ordinance, HRO), further use of biological material and health-related personal data for research purposes requires the consent of patients. So far, as of 2017, a paper-based GC process with a handwritten signature has been established at all five Swiss university hospitals. Presenting paper consent forms to patients, however, calls for considerable resources: printing, explaining to patients, collecting, and transferring the consent forms into the electronic health record system.

Therefore, if more effort went into creating an easier distribution of the GC, such as by facilitating patient access to the consent form, the GC patient pool would be likely to increase and more research initiatives in personalised health would be likely to succeed.

The goal of the e-GC project is to extend the GC process by offering patients a flexible, patient-centric, and admission-independent electronic consent pathway. All five Swiss university hospitals agreed in late 2019 to participate in the testing of an electronic consent pathway at their institution.

Based on the national GC template (V2/2019), a user-interface prototype for the collection of the GC was developed by the Department of Clinical Research, University of Basel (mid-2018). The prototype was evaluated in different settings at the five Swiss university hospitals. Two options of giving consent were explored: using 1) patients' mobile phones, without any involvement of hospital personnel; and 2) a hospital device (a tablet) requiring explicit confirmation of patient identity by hospital personnel. Issues were documented by respective recruiters in each hospital and feedback from patients was collected through a survey, directly after the usability testing. The evaluation of the usability testing is ongoing and results should be released in the course of the year 2020.

C3-STuDY: shared, transparent, and dynamic exchange

The C3-STuDY project proposes moving towards a new model of consent for research, applying a more interactive, transparent, and dynamic approach, focused on the citizen rather than the patient. This revised approach promotes a proactive exchange of information between data providers and users. It aims to strengthen the transparency and traceability of all these processes, for which the responsibility should be

better shared between citizens and researchers.

The project, based on innovative communication channels, might guarantee this two-way exchange of information. Better informed, citizens can make more independent choices, follow the evolution of the research in which they participate, change their preferences over time, and feel more engaged in such consent processes. As for researchers, they will be able to document their research in a more dynamic and transparent manner. This transparent and continuous exchange of information serves to strengthen the informational and societal value of research; it involves a change of role from a passive research subject to an active, interested, and valued participant.

This generic, transparent, dynamic, non-retractable but revocable and traceable consent management system was developed at the Hôpitaux Universitaires Genève (HUG) and uses a computer protocol called smart contracts. Thanks to a web tool or an App, citizens will be able to accept or refuse consent, and even revoke consent previously granted. The system will also allow researchers to find those participants who have already agreed to have their data used for research projects. The web interface and the Apps allow them at any time to consult the status of their consent and the recruitment rate of their studies or to launch information campaigns to call out and recruit participants.

A first version of the C3-STuDY tool was made functional in March 2019. As of early 2020, it was being tested for technical and security aspects, and discussions have started among certain university hospitals to clarify the architectural and technical constraints, envisaging production to start later in the course of the year 2020.

GPCR: a new consent management tool underway

Because legal and ethical requirements concerning data and sample reuse are very strict, university hospitals face some issues concerning research projects and data protection. Challenges include:

- How can personal data be disassociated from samples, yet remain linked?
- How can investigators systematically generate codes for participants in their research projects?
- Could a given institution centralise consent management in a single tool, without raising confidentiality issues?
- Can a given institution inform each patient about research projects in which their samples or data are or have been used?
- How can investigators access patient GC status, to find out whether they can reuse samples or data for each patient they would like to include?

To solve these issues, the Lausanne University Hospital (CHUV) has developed a consent management application, GPCR, which started being applied in April 2019.

GPCR helps investigators to manage participant recruitment. Once investigators have obtained the ethics committee’s approval, they can identify their study in the application and list each recruited patient and the associated signed consent. For studies reusing data and/or samples, the GC status is automatically visible once a participant is added to a project in the application.

GPCR optimises the management of the GC. This application can help increase the number of informed patients significantly, while optimising data capture, quality, and security. Overnight, the application automatically generates mailing documents (such as cover letters and consent forms) for 1) all non-informed patients who have an appointment at the hospital within two weeks; and 2) all patients who have had an appointment within the past two weeks, and who did not get the chance to receive the documents ahead of

time (in case of emergency, for instance). The GC forms that patients fill out completely and return, are then automatically registered by optical scanning. In case a patient decides later to revoke its GC, GPCR sends an e-mail notifying all investigators who have included that particular patient in their study.

GPCR also enables institutional coding system for research, which is centralised. Each patient added to GPCR receives a unique patient ID code. When a patient is then included in a research study, the application generates a new, specific patient-project ID code. Those codes are the keys for access to study data.

To conclude, GPCR as a consent management tool aims to address multiple objectives at the hospital level. It serves to fulfil some of the specific and emerging needs and concerns – of the institutional sponsors, investigators, participants, GC teams, and data scientists – regarding regulatory, security, confidentiality, data availability, and use for research-related activities.Show more Hide

Conclusion

The management of research consent is a major challenge in the era of personalised medicine. The three projects presented here build on the possibilities arising from digitalisation; they propose new technical solutions to current GC information, notably in an understandable way. By taking into consideration the Swiss legal requirements, the specific needs of the university hospitals involved, as well as the values and preferences of patients and citizens, these projects may significantly advance the development of digital solutions. They offer the promise of feasible methods that can be used to tailor GC, being a fundamental prerequisite for research by facilitating data exchange, sharing and interoperability. The remaining regulatory obstacles (eg. the use of electronic signature) might be solved in the future with the revision of the HRO.