New electronic informed consent including super safe signing and verification

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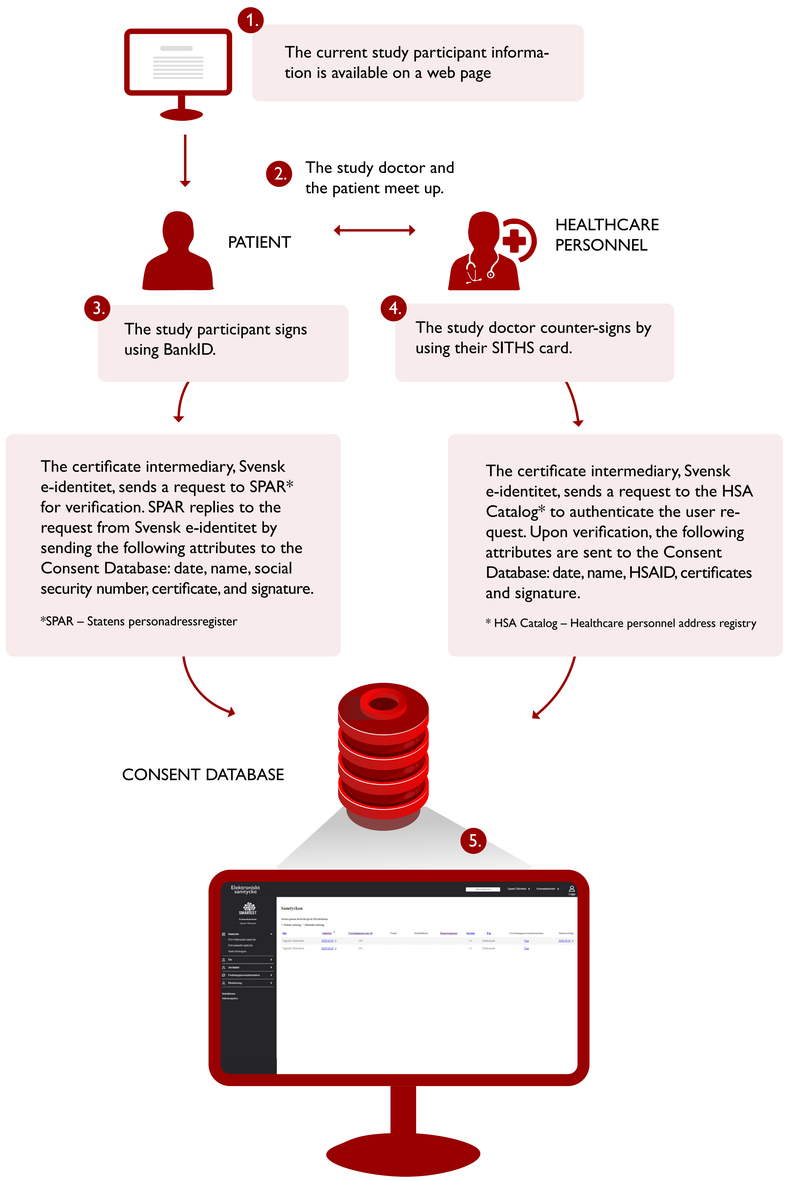
INTRODUCTION

The signing of a consent form for patient participation in research studies is vital in order to comply with regulatory requirements. The method most commonly used today is signature with pen on paper. Since the informed consent is paper based and the signature must be witnessed in order to comply with Good Clinical Practice (GCP), patients must be physically present at the study site in order to sign the consent form, and a study monitor must travel to each study site to verify each signature.

OBJECTIVES

- Develop an electronic informed consent system.
- Utilize a safe identifier, currently in use by healthcare personnel (HSAID and SITHS card).
- Utilize a safe identifier, commonly available for participants/patients (BankID).
- Secure and safe storage for given consents, accessible only with two-factor authentication.
- Online database enables remote monitoring.
- Build in controls to prevent electronically signing a non-valid version of the consent form.
- Build in controls to prevent electronic signatures to the same version, multiple times.
- Allow for re-consent to updated version of the informed consent if required.
- Safe and secure storage of multiple versions of consents with links to the participants/patients electronic signatures.
- Facilitate online/telemedicine inclusions into clinical studies.



ELECTRONIC INFORMED CONSENT WEB APPLICATION

SOLUTION

- The patient reads the study participant information on a web page.
- The study doctor and the patient meet in real life or using telemedicine tools, and the patient can get answers to his/her questions about the study.
- After agreement about inclusion, the study doctor enters the participant's social security number into the electronic consent application.
- The patient consents by entering his/her personal PIN code in the BankID application.
- The study doctor counter signs the consent form, using his/her personal PIN code for the SITHS card.
- The unique signatures, certificates, participant's name, doctor's name, timestamp, and site stored in the database, which can be viewed in the application.
- The patient will receive a PDF copy of the signed consent form electronically, if an email address was provided, or a paper copy.

RESULTS & CONCLUSIONS

An electronic informed consent application has been developed and successfully validated according to GCP-GAMP5. The requirements stated in the objectives are fulfilled. The development process includes classification of information according to GDPR, risk assessments of both the process and the results, specification of user requirements, followed by a transformation of these into technical requirements.

All requirements have been tested and approved according to predefined expected results using a qualification protocol. The code will be available for other studies or projects, through collaborations with Uppsala University.

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