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TNI	**Digitálne a inovatívne zdravotníctvo Návod na správnu prax pri získavaní súhlasu na použitie osobných zdravotných informácií vo výskume a inováciách**	**TNI CWA 17933** 84 9501

Digital health innovations - Good practice guide for obtaining consent for the use of personal health information for research and innovations

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CEN WORKSHOP AGREEMENT

CWA 17933

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English version

Digital health innovations - Good practice guide for obtaining consent for the use of personal health information for research and innovations

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

The formal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN-CENELEC Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation.

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European foreword

This CEN Workshop Agreement (CWA 17933:2023) has been developed in accordance with the CEN-CENELEC Guide 29 "CEN/CENELEC Workshop Agreements – A rapid prototyping to standardization" and with the relevant provisions of CEN/CENELEC Internal Regulations – Part 2. It was approved by the Workshop participants on 2023-05-23, the constitution of which was supported by CEN following the public call for participation made on 2022-06-13. However, this CEN Workshop Agreement does not necessarily include all relevant stakeholders.

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Introduction

There are many kinds of digital health innovation being developed, evaluated, deployed, and used. These include mobile applications that allow patients to enter their health status and monitoring information. Sometimes the data will be collected automatically through wearable sensors or home installed detectors. These solutions might be in continuous or asynchronous connection to healthcare provider systems to enable health and care professionals monitoring of the incoming data streams in real time or periodically. Nowadays significant advances are being made in artificial intelligence (AI) and Internet of Things (IoT) that create a more sophisticated data fusion, analysis and advisory ecosystem. Through these, a care pathway or treatment guidance can be provided to patients and healthy individuals at a granular level, in real time, with professional oversight occurring through escalation (alerting them of readings of concern) or periodically at scheduled review sessions. These are collectively described as digital health innovations. This is a rapidly expanding field for research and product development, and inevitably these developments need to be tested before they can be marketed, approved and widely adopted.

Regardless of the consent, which is needed from the individual patient or healthy person for using well-proven (e.g. on the market) devices for collecting, processing or storing the data, a further layer of consent is needed for innovation solutions since digital health innovations are still under development or in the process of being evaluated. Each patient that uses a digital health innovation is therefore in parallel participating in a study, which goes beyond the purpose of a specific medical intervention. Explicit consent from users of the digital health innovation is often needed for these developmental stages, because the solution is not yet ready to be used as part of the routine healthcare delivery. This is unlike long established CE marked products (such as home glucose monitors, ambulatory blood pressure devices, heart rate monitors) that are issued to patients or purchased by patients directly. The usage of innovations might entail risks or disruptions to the normal pattern of care and might involve the collection of evaluation data such as usability surveys or routine use data. The intended future benefits of using the solution might also not be available to the patient because the advice generated by the solution might not yet be reliable enough to be trusted for care decision-making. It is common in pilot situations to ask the patient and/or their care giver to assess the advice generated for its integrity, plausibility and safety. There is therefore uncertainty about the advisory system under evaluation regarding its trustworthiness as well as intended benefit(s).

It is the experience of many initiatives in the digital innovation field that it is difficult to know what kinds of consent are appropriate in these situations, what permissions should be sought from pilot testing individuals, and how that consent should be framed and transparently explained. It can be challenging to appropriately frame the required consent in order to meet the immediate piloting needs as well as possible future downstream reuses of data for compatible purposes (as defined in the European Data Protection Regulation (GDPR) Art. 5.1.b regarding the compatibility of purpose). It is one challenge to secure ethics committee approval to pilot the use of a digital health innovation, but another more complex challenge is to obtain ethics committee and data protection approval to reuse the pilot data for evaluations, for future innovation enhancements and for further research (which implies the need for consent that permits a broad range of future data use purposes). The different aspects of consent that might need to be covered include:

— **care intervention,** in case the research involves possible changes to care or treatment, or change clinician behaviour, which would require human ethics approval;

— **using a novel digital health tool**, which does not change patient care but changes the methods for collecting data, delivering data or interacting between actors;

— **collecting data to study the research innovation**, including any evaluation data, and sharing amongst consortium partners, potentially cross border, outside EU etc.;

— **the downstream reuse of collected data**, potentially research that might not be anticipated at the time the consent was expected, and possibly involving sharing the data with parties and to countries that were not anticipated.

This CEN Workshop Agreement 17933 has been developed as a good practice guide to help organisations and scientific associations performing research to develop and evaluate digital health innovations to obtain the most appropriate consent that they need from individuals when piloting and evaluating digital health innovations or conducting research.

A recognised challenge is to seek consent for the data gathered through the piloting phase and through evaluation instruments to be reused as a dataset for future research by other organisations, possibly in other countries. If data reuse is intended, which it often should be, then it is appropriate to check if data reuse is covered by the initial consent or if a separate, optional, consent for that data reuse should be requested.

This guide has been produced because many contemporary initiatives have indicated there is a need for understanding as to how to seek consent in an efficient and comparable manner, how to take into account ethical and data protection requirements, word consent forms needed for the study, and obtain ethics committee approval before they begin to conduct a study.

The intention of this guide is to complement a number of European and international standards that deal with more formal considerations regarding consent for the processing of personal data.

Health services and public health research also make use of routinely collected (real-world) data for quality improvement, safety monitoring, public health surveillance and population health strategy. Public and private research organisations make use of real-world data to improve disease understanding, and to develop and evaluate new treatments and other care interventions. If they include the use of personal health data, whether fully identified or pseudonymised, the GDPR requires that these are utilised by an identified data controller or data processor thereof via a legitimate (legal) basis. This legitimate basis is frequently, but not always, informed consent from each data subject. This guide can also serve as a basis for the collection of consent for these research purposes.

1 Scope

Since digital health innovations are still under development or within the evaluation process formal consent is usually needed for all stages of the development cycle. This CEN Workshop Agreement (CWA) defines a guideline for devising, obtaining and documenting the most suitable consent for the use of digital health innovations. The guideline describes which aspects should be considered when asking for consent. It specifies the appropriate consent for different situations and how it should be framed and transparently explained. This includes seeking consent for the future reuse of collected data for additional areas of research. The document establishes how to consider ethical and data protection requirements, the wording of consent forms and obtaining ethics committee approval where applicable. Further, this document focuses on how to handle the subjects access request or withdrawal during (formative and summative) technology evaluation trials. The aim is to support researchers to ensure that the appropriate ICF (informed consent form) elements are considered. This is necessary since the presently adopted consent procedures usually concern only the specific use of data for identified and therefore foreseen purposes and are often challenged to obtain data reuse consent in a suitable way.

This document does not cover the information security safeguards that should be adopted during the data processing.

2 Normative references

There are no normative references in this document.