Draft Project plan for the CEN Workshop on "Digital health innovations – Good practice guide for obtaining user consent for personal health information"

Requests to participate in the Workshop and/or comments on the project plan are to be submitted by
15th July 2022 to
madlen.schmudde@din.de[1]

Recipients of this project plan are kindly requested to name all patent rights known to them to be relevant to the Workshop and to make available all supporting documents.

Berlin, 7th June 2022 (Version 1)

[1] Applications for participating in the Workshop and comments on the project plan that are not received by the deadline do not need to be taken into consideration. Once constituted, the Workshop will decide whether or not to consider the comments received in good time.

Contents

Summary

Within a variety of European Research and Innovation (R&I) projects in the health and care sector obtaining consent for collecting and processing personal health data for the development, deployment, testing and evaluation of digital health innovations is a crucial point. This CWA aims to combine the experience of various R&I projects regarding this topic in some kind of a best practice guide on how to obtain user consent for personal health information. This will not only make it easier for R&I projects but also for other market participants outside of R&I projects to consider the different topics that consent is needed for.

1 Status of the project plan

Draft project plan for public commenting (Version 1.0)

This draft project plan is intended to inform the public of a new Workshop. Any interested party can take part in this Workshop and/or comment on this draft project plan. Please send any requests to participate or comments by e-mail to **madlen.schmudde@din.de**.

All those who have applied for participation or have commented on the project plan by the deadline will be invited to the online kick-off meeting of the Workshop on **22th July 2022**.

2 Workshop proposer and Workshop participants

2.1 Workshop proposer

Person or organisation	Short description and interest in the subject
Prof. Dipak Kalra The European Institute for Innovation through Health Data Unit of Medical Informatics and Statistics dipak.kalra@i-hd.eu Phone: +32 9 332 40 67 Webpage: https://www.i-hd.eu	The European Institute for Innovation through Health Data is a not for profit organisation focusing on multi-stakeholder engagement to co-create good practices and approaches to scaling up the trustworthy use and value from health data, to improve care and accelerate research. Dipak Kalra has a 30 year history in European projects on electronic health records, and of CEN & ISO standards development.

2.2 Other potential participants

This CWA will be developed in a Workshop (temporary body) that is open to any interested party. The participation of other experts would be helpful and is desired. It is recommended that:

- Representatives of organizations in the health and care sector sector, including health and care providers, the health ICT sector and patient organisations
- Participants in related Technical Committees, especially those focused on data protection and information security
- Participants in related Research Projects, especially those developing or piloting digital health innovations

take part in the development of this CWA.

2.3 Participants at the kick-off meeting

The following persons or organisations already signed up to the kick-off meeting prior to the publication of the draft project plan.

Person	Organisation
Workshop proposer: Prof. Dipak Kalra	The European Institute for Innovation through Health Data, Belgium
Matthias Pocs	Stelar Security Technology Law Research
Luc Nicolas	ETHEL
Itziar Alkorta	University of the Basque Country
Lola Verdoy	Kronikgune Institute for Health Services Research
Nuno Garcia	Universidade da Beira Interior
Ana Ortega	Kronikgune Institute for Health Services Research
Erika Rovini	University of Florence
Gianna Vignani	UP Umana Persone impresa sociale R&S
Eleftheria Iliadou	National & Kapodistrian University of Athens
Filippo Cavallo	University of Florence
Idoia Landa	Medicines Optimisation Innovation Centre
Fabio Guasconi	UNINFO
Workshop secretariat: Madlen Schmudde	DIN e. V.

3 Workshop objectives and scope

3.1 Background

The motivation for this Workshop came from multiple European research projects and large-scale pilots that found that they were all needing to identify the most suitable lawful basis for collecting and processing personal health data for the development, deployment, testing and evaluation of digital health innovations. In many cases they could see the potential value for reusing that data later, after the project, but this potential could be for research questions that had not yet been identified. They therefore needed a multi-layered lawful basis, potentially multi-layered consent, and found that they were all reinventing similar wheels, encountering similar problems and could benefit hugely by learning from each other. After some initial exchanges it was clear that the body of projects collectively had quite a bit of useful learning that could be shared with others to avoid them reinventing those wheels or making mistakes.

Therefore, it is time to consolidate the learning and experience of several projects and large scale pilots regarding the nature of data subject consent for the development, piloting and evaluation of digital health innovations intended for use in the health and care sector. This will help the current projects with obtaining the most appropriate consent for their needs, or with understanding the implications of consent they have already obtained. But primarily this guide for obtaining user consent for personal health information will be a resource to future projects and large scale pilots as some kind of a checklist. The resulting specification from this workshop will make it easier for Research and Innovation (R&I) projects as well as market participants outside of R&I projects to also consider the different topics that consent is needed for.

Regarding the legal environment the proposed specification has to be in accordance with the EU General Data Protection Regulation (GDPR) which went into effect in 2018.[2,3] There are also other guidelines published by the European Commission addressing relevant topics like data protection which also have to be considered when a guide for obtaining user consent is developed. One of them is the Guidelines on Transparency under Regulation 2016/679.[4] Furthermore the work (e.g. opinions[5]) of the *Article 29 Working Party*[6] which is an independent European working party dealing with the protection of privacy and personal data has to be taken into account.

3.2 Scope

The planned CEN Workshop Agreement (CWA) will define a guideline for obtaining the most suitable consent for the use of digital health innovations. The guideline will describe which aspects should be considered when asking for consent. It will also cover the usability of a consent form especially regarding the patient-friendly presentation of informed consent choices. Another aspect of this CWA will focus on how to handle the subject's access requests or withdrawal during a pilot evaluation.

The planned CWA is intended to be used as a guideline for R&I Project and other market participants when consent is needed for the use of digital health innovations.

3.3 Related activities

The subject of the planned CWA is not at present the subject of a standard. However, there are committees, standards and/or other technical specifications that deal with related subjects and thus need to be taken into account - and involved, where necessary - during this Workshop:

- ISO/TC 215 Health informatics
  - ISO/TS 17975:2015 Health informatics – Principles and data requirements for consent in the Collection, Use or Disclosure of personal health information
  - ISO/TS 14265:2011 Health Informatics – Classification of purposes for processing personal health information
  - ISO/TR 18638:2017 Health informatics – Guidance on health information privacy education in healthcare organizations
  - ISO 13940:2015 Health informatics – System of concepts to support continuity of care
- CEN/TC 251 Health informatics
- CEN/WS 102 CEN Workshop on guidelines for introducing tele-medical and pervasive monitoring technologies balancing privacy protection against the need for oversight and care
- CEN/TC 431 Service Chain for Social Care Alarms (dormant)

4 Workshop programme

4.1 General

The kick-off meeting is planned to take place on 22th July virtually via web conference. All meetings are intended to be executed online. If a physical meeting is convened, the possibility of online participation will be granted.

A draft for public commenting will be published for 30 days.

A total of 6 Workshop meetings via web conference will be held (including the kick-off meeting), during which the content of the CWA will be presented, discussed and approved.

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[2] https://gdpr.eu/ [accessed: 2022-03-04]

[3] https://www.gov.uk/government/publications/consent-privacy-policy/consent-policy#:~:text=Consent%20should%20be%20separate%20from,and%20conditions%20('unbundled')&text=Consent%20must%20be%20'easy%20to,and%20how%20to%20do%20so [accessed: 2022-02-17]

[4] https://ec.europa.eu/newsroom/article29/items/622227 [accessed: 2022-03-04]

[5] https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2014/wp216_en.pdf [accessed: 2022-03-04]

[6] https://edpb.europa.eu/about-edpb/more-about-edpb/article-29-working-party_en [accessed: 2022-03-04]

The CWA will be drawn up in **English** (language of meetings, minutes, etc.). The CWA will be written in **English**.

4.2 Workshop schedule

Table 1: Workshop schedule (preliminary)

CEN Workshop	May 2022	Jun 2022	Jul 2022	Aug 2022	Sep 2022	Oct 2022	Nov 2022	Dez 2022	Jan 2023	Feb 2023	Mar 2023	Apr 2023	May 2023	Jun 2023	Jul 23
Initiation															
1. Proposal form submission and TC response															
2. Project plan development															
3. Open commenting period on draft															
Operation															
4. Kick-off meeting															
5. CWA(s) development															
6. Open commenting period on draft															
7. CWA(s) finalised and approved by															
Publication															
8. CWA(s) publication															
Dissemination															
Milestones			K + V		V		V					V	V + A	P	D

K Kick-off
M Workshop meeting
V Virtual Workshop meeting
A Adoption of CWA
P Publication of CWA
D Online distribution of CWA

4.3 Work already delivered

This workshop is based on the experience of different European research projects regarding how to obtain user consent for personal health information. Therefore, during several exchanges beforehand an idea was developed on what this CWA should probably include:

- Deciding when consent is the most suitable legal basis, and the alternatives to be considered
  - What would digital health innovators seek consent for?
  - Consent as a legal basis, and other legal bases, under the GDPR
  - Consent as the basis for processing personal data
  - Alternative legal bases for processing personal data
  - Ethical consent vs GDPR consent in the research context
- GDPR good practices when collecting consent
- Consent requirements when introducing a novel digital health tool
- Consent for data reuse and data sharing
- Data altruism (broad consent)
- Obtaining consent from vulnerable patients
- Avoiding coercion
- Points to include in a transparency notice and Informed Consent Form
- Appropriate consent form wording
- The process of collecting consent
- The scope of personal data
- Information security safeguards

5 Resource planning

The administrative costs of the CEN Workshop will be covered by the PHArA-ON (Pilots for Healthy and Active Ageing) project, which received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857188.

All costs related to the participation of interested parties in the Workshop's activities have to be borne by themselves. The PHArA-ON project aims to reach an agreement with CEN CENELEC Management Centre to make the CWA freely downloadable from the CEN Website. The copyright of the final CEN Workshop Agreement will be at CEN. The final document will include the following paragraph: "Results incorporated in this CEN Workshop Agreement received funding from the European Union's HORIZON 2020 research and innovation programme under grant agreement number 857188 (PHArA-ON)".

6 Workshop structure and rules of cooperation

6.1 Participation in the Workshop

The Workshop will be constituted during the course of the kick-off meeting. By approving this project plan, the interested parties declare their willingness to participate in the Workshop and will be formally named as Workshop participants, with the associated rights and duties. Participants at the kick-off meeting who do not approve the project plan are not given the status of a Workshop participant and are thus excluded from further decisions made during the kick-off meeting and from any other decisions regarding the Workshop.

As a rule, the request to participate in the Workshop is closed once it is constituted. The current Workshop participants shall decide whether any additional members will be accepted or not.

Any new participant in the Workshop at a later date is decided on by the participants making up the Workshop at that time. It is particularly important to consider these aspects:

a. expansion would be conducive to shortening the duration of the Workshop or to avoiding or averting an impending delay in the planned duration of the Workshop;
b. the expansion would not result in the Workshop taking longer to complete;
c. the new Workshop participant would not address any new or complementary issues beyond the scope defined and approved in the project plan;
d. the new Workshop participant would bring complementary expertise into the Workshop in order to incorporate the latest scientific findings and state-of-the-art knowledge;
e. the new Workshop participant would actively participate in the drafting of the manuscript by submitting concrete, not abstract, proposals and contributions;
f. the new Workshop participant would ensure wider application of the CWA.

All Workshop participants who voted for the publication of the CWA or its draft will be named as authors in the European Foreword, including the organisations which they represent. All Workshop participants who voted against the publication of the CWA, or who have abstained, will not be named in the European Foreword.

6.2 Workshop responsibilities

The Workshop Chair is responsible for content management and any decision-making and voting procedures. The Workshop Chair is supported by the Workshop Vice-Chair and the responsible Workshop secretariat, whereby the Workshop secretariat will always remain neutral regarding the content of the CWA. Furthermore, the Workshop secretariat shall ensure that CEN-CENELEC's rules of procedure, rules of presentation, and the principles governing the publication of CWA have been observed. Should a Workshop Chair no longer be able to carry out her/his duties, the Workshop secretariat shall initiate the election of a new Workshop Chair. The list below covers the main tasks of the Workshop Chair. It is not intended to be exhaustive.

- Content related contact point for the Workshop
- Presides at Workshop meetings
- Ensures that the development of the CWA respects the principles and content of the adopted project plan
- Manages the consensus building process, decides when the Workshop participants have reached agreement on the final CWA, on the basis of the comments received
- Ensures due information exchange with the Workshop secretariat
- Represents the Workshop and its results to exterior

The Workshop secretariat, provided by a CEN/CENELEC national member, is responsible for organising and leading the kick-off meeting, in consultation with the Workshop proposer. Further Workshop meetings and/or web conferences shall be organised by the Workshop secretariat in consultation with the Workshop Chair. The list below covers the main tasks of the Workshop secretariat. It is not intended to be exhaustive.

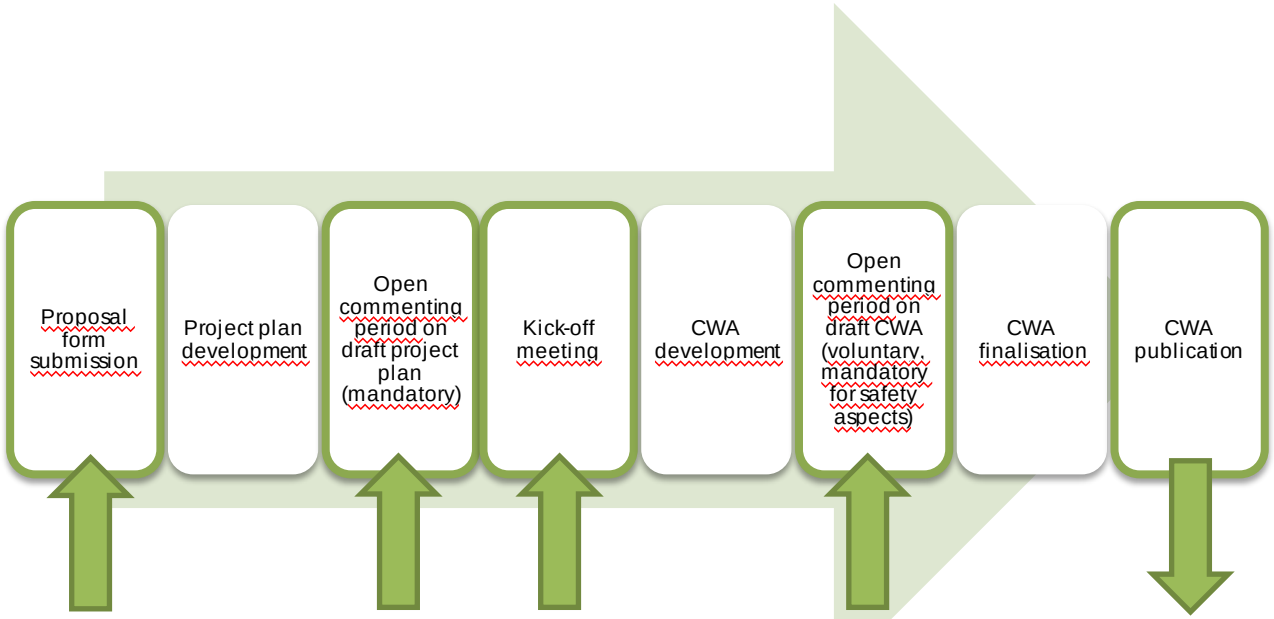
- Administrative and organisational contact point for the Workshop
- Ensures that the development of the CWA respects the principles and content of the adopted project plan and of the requirements of the CEN-CENELEC Guide 29
- Formally registers Workshop participants and maintains record of participating organisations and individuals
- Offers infrastructure and manage documents and their distribution through an electronic platform
- Prepares agenda and distribute information on meetings and meeting minutes as well as follow-up actions of the Workshop
- Initiates and manage CWA approval process upon decision by the Workshop Chair
- Interface with CEN-CENELEC Management Centre (CCMC) and Workshop Chair regarding strategic directions, problems arising, and external relationships
- Advises on CEN-CENELEC rules and bring any major problems encountered (if any) in the development of the CWA to the attention of CEN-CENELEC Management Centre (CCMC)
- Administrates the connection with relevant CEN or CENELEC/TCs

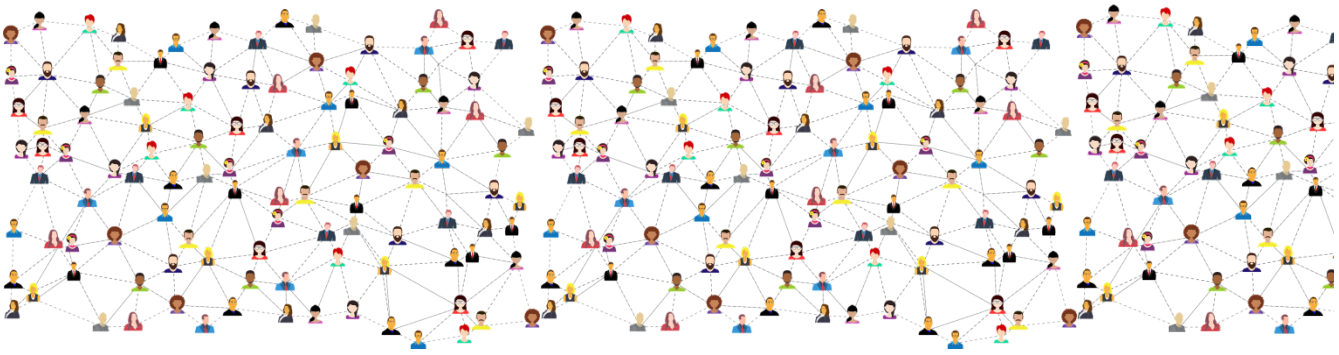
6.3 Decision making process

Each Workshop participant is entitled to vote and has one vote. If an organisation sends several experts to the Workshop, that organisation has only one vote, regardless of how many Workshop participants it sends. Transferring voting rights to other Workshop participants is not permitted. During voting procedures, decisions are passed by simple majority; abstentions do not count.

If Workshop participants cannot be present in the meetings when the CWA or its draft is adopted, an alternative means of including them in the voting procedure shall be used.

7 Dissemination and participation strategy





Proposal form submission

The Workshop proposal will be disseminated to the following relevant stakeholders and bodies for consultation:

- CEN/TC 251 Health informatics

Open commenting period on draft project plan

The project plan will be disseminated to the following relevant stakeholders and bodies for commenting:

- CEN/TC 251 Health informatics
- ISO/TC 215 Health informatics
- CEN/WS 102 CEN Workshop on guidelines for introducing tele-medical and pervasive monitoring technologies balancing privacy protection against the need for oversight and care
- CEN/TC 431 Service Chain for Social Care Alarms (dormant)
- CEN/TC 447 Horizontal standards for the provision of services
- CEN/CLC/JTC 13 Cybersecurity and Data Protection
- CEN/TC 450 Patient involvement in person-centred care

In addition to the CCMC website, the project plan and the date of the kick-off meeting will be advertised on the websites of the R&I projects PHArA-ON, ADLIFE; SHAPES and SMART BEAR as well as on the websites of OPEN DEI, DIN, the European institute for Innovation through Health Data, Kronikgune Institute for Health Services Research, National & Kapodistrian University of Athens (NKUA), University of Florence, UNINFO, UP Umana Persone impresa sociale R&S; AGE Platform Europe and National Research Council of Italy (CNR) to raise awareness. Moreover, the announcement of the CCMC website will be posted in PHArA-ON social media as well as in all the above mentioned partners social media to reach as many interested parties as possible. Interested parties are requested to contribute either through commenting of the project plan (short term) or through Workshop participation (long term).

Open commenting period on draft CWA

The draft CWA will be disseminated to the following relevant stakeholders and bodies for commenting:

- CEN/TC 251 Health informatics
- ISO/TC 215 Health informatics
- CEN/WS 102 CEN Workshop on guidelines for introducing tele-medical and pervasive monitoring technologies balancing privacy protection against the need for oversight and care
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CWA publication

The final CWA will be disseminated to the following relevant stakeholders and bodies:

- CEN/TC 251 Health informatics
- ISO/TC 215 Health informatics
- CEN/WS 102 CEN Workshop on guidelines for introducing tele-medical and pervasive monitoring technologies balancing privacy protection against the need for oversight and care
- CEN/TC 431 Service Chain for Social Care Alarms (dormant)
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8 Contacts

- Workshop Secretariat:

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