CARE

CARE ABOUT CARE

Report on ethical & legal considerations

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1 Introduction

The following ethical and legal considerations are based on the *AAL Guidelines for Ethics, Data Privacy and Security* (Dantas et al., 2020) with adaptations due to COVID and associated contact restrictions as well as on the approach used in the CiM project (Schneider et al., 2016).

1.1 Purpose of this document

This document represents the official deliverable D10 of the AAL project C^C – Care about Care. In projects where, older people are involved in different project phases (co-creation, co-design, field tests), ethical and legal issues have to be considered. This document describes the partial application of the ethics and privacy dialogues (Dantas et al., 2020) as far as COVID allowed it as well as ethical and legal issues related to end user involvement in different project phases (Schneider et al., 2016).

1.2 Definitions, acronyms and abbreviations

AR	Augmented reality
C^C	Care about Care
DoW	Description of Work
EPD	Ethics and privacy dialogue
FHWN	Fachhochschule Wiener Neustadt
GDPR	General Data Protection Regulation
HWN	Hilfswerk Niederösterreich
JCA	Joint Controller Agreement
KOR	Korian
LTC	Long-term care
MR	Mixed reality
SHD	Stëftung Hëllef Doheem

1.3 Relationship with other documents

This deliverable relates to task T2.8 Ethical and legal considerations of the DoW. It also addresses D17.x Study designs, the Joint Controller Agreement signed by all project partners and consent forms for project phases involving users.

1.4 Document structure

This document begins with a brief reflection on the need for ethical and legal considerations (Section 2). Section 3 describes the application of the Ethics and Privacy Dialogues (EPDs). Section 4 to 7 deal with trial participants their rights and obligations.

2 Importance of ethical and legal considerations

The main target group in AAL projects normally cannot be considered as tech-savvy. Thus, rules and processes are needed for considering ethical and legal issues when involving these people in different project phases – to ensure user acceptance. In concrete rules, processes and information strategies regarding ethical and legal issues are needed for dealing with our co-creation/co-design workshop participants (pre-intervention phase) and trial participants (intervention/field trial). Moreover, ethical and legal issues are relevant in system design and development.

Since the C^C consortium takes ethical issues seriously, we seek a vote from the ethics committees/boards in Austria, Luxembourg and Belgium. For Austria, the study has already been positively reviewed by the ethics board of the University of Applied Sciences and we received the vote for it on September 3, 2021. A vote for Belgium is still pending. In Luxembourg, the submission for ethical approval is still pending.

Having a clear understanding of rights and responsibilities of co-creation/co-design workshop and trial participants, as well as rules and procedures for dealing with them – at different stages of the project – clarity and transparency on ethical and legal issues will be provided to all project partners and co-creation/co-design and trial participants involved in the project (Schneider et al., 2016).

3 Ethics and Privacy Dialogues – EPD

In the proposal phase we decided to follow the EPD. In autumn 2021 we had to follow an adapted form of the EPD. The reason was COVID and the fear among older people to participate in workshops, thus we tried to keep the field exposure low and use already planned workshops to also talk about ethical and legal issues.

The first dialogue was part of the project kick-off in June 2021, before the co-creation phase. Scenarios were presented and discussed for each characteristic. Based on the results of this dialogue, the study design was prepared for submission to the ethics committees. We were also able to plan the co-creation and co-design phases and the consent forms required for these.

In autumn, when the second dialogue was planned, we had to be flexible due to COVID and have unceremoniously integrated the dialogue into the co-creation workshops. Specific questions on ethical and legal aspects were fitted into the Walt Disney Method, especially in the realist/maker and critic phases. The results of this dialogue enabled us gain insights which legal and ethical challenges people with care needed, relatives and care workers see in the individual features. Based on the outcomes of the ethical and legal parts of the co-creation workshops the system architecture was designed (encrypted transmission, storage

of as little data as possible, hosting in Europe). Additionally, the workshop supported the preparation of a Joint Controller Agreement (according to GDPR) and the identification of the necessary processing activities of each party.

Currently, three more dialogues are planned. The third dialogue should take place during or after the pilots to inform the pre-trials. After the pre-trials the fourth dialogue should help us make improvements for the trial. During the trial a last dialogue is planned to inform further development in the direction of the market.

4 Rights and responsibilities of co-creation/co-design workshop participants

Care receivers, care service providers and informal carers are part of the target group for the co-creation and co-design workshop. Their task is to participate in various activities for developing the features of the **care cockpit** as well as the **remote care assist**. With their participation and feedback, the participants are supporting the project team in developing user-centred and user-friendly ICT-solutions.

4.1 Rights of the workshop participants

- **all the ethical and legal information** stated in the informed consent, **signed by the workshop participants** of the co-creation and co-design workshops, **applies**
- **processing of personal data** for the purpose of the research project "Care about Care" only (name, contact details, telephone number / email address), gender, year of birth, care allowance level, type of restrictions, mobility aids, number of visits of the care organisation per week, contract duration, use of electronic devices and the information given in the workshop)
- data will only be used by project partners as part of the research project, **personal information will not be passed** on to persons outside the project team, except for the purpose of reviewing the project by the project-financing national and European bodies
- the **published research results** (e.g. publications, research reports) **do not show any personal reference** and therefore do not allow any conclusions to be drawn about the participants identity
- **consent is given voluntarily**, participants can revoke at any time with effect for the future
- the **European Data Protection Regulation (GDPR) applies**, as stated in the informed consent, signed by the participants, this includes primarily, Art 6 Abs 1 lit a (consent) and Art 9 Abs 2 lit j (research purposes in the public interest) in connection with the Austrian Research Organization Act (FOG)

4.2 Responsibilities of the workshop participants

If individuals decide to participate in the workshops, they will sign an informed consent and agree to participate in the C^C project on a voluntary basis. Their tasks are to involve in the

co-creation and co-design workshop, to give feedback, to fill out the questionnaire and to test the features.

4.3 Information strategies, processes and rules

In the Care about Care-Project care receivers, informal carers and care givers are directly involved in the project phases. The following section describes information strategies, processes and rules for user involvement in the co-creation and co-design workshop.

Information strategy:

- Participants have been informed about the workshop by employees of the end user organisation
- They get a written invitation for the workshop and additional information about the project

Rules:

- Oral invitation
- Written invitation
- Information about project and project progress
- Informed consent for tape recording if needed
- Workshop aims
- Announcement of further appointments

Process:

- Potential participants will be informed about the workshop by employees of the end user organisation
- Written invitations will be delivered 2 weeks before the workshop appointment by the end user organisation
- Participants will be reminded personally by the end user organisation before the workshop: if needed, the transport to the workshop is organized
- Workshop
    - People are informed about the project (progress)
    - People are informed about the aims of the workshop
    - People are informed about further appointments

5 Rights and responsibilities of pilot participants

Care receiver and care service providers are part of the target group for the first pilot in March in Austria. Their task is to participate in order to help develop the features for AR and the expert center part of the **remote care assist**.

For the pilot in May and June 2022, care receiver and care service providers as well as informal carers will participate to help test the **care cockpit**. With their participation and

feedback, the participants are supporting the project team in developing user-centred and user-friendly ICT-solutions.

5.1 Rights of the pilot participants

- **all the ethical and legal information** stated in the informed consent, **signed by the pilot participants, applies**
- the **European Data Protection Regulation (GDPR) applies**, as stated in the informed consent, signed by the participants, this includes primarily, Art 6 Abs 1 lit a (consent) and Art 9 Abs 2 lit j (research purposes in the public interest) in connection with the Austrian Research Organization Act (FOG)
- **processing of personal data** for the purpose the research project "Care about Care" (name, contact details (telephone number / email address), gender, year of birth, care allowance level, type of restrictions, mobility aids, number of visits of the care organisation per week, contract duration, use of electronic devices and the Information given in the workshop)
- data will only be used by project partners as part of the research project, **personal information will not be passed** on to persons outside the project team, except for the purpose of reviewing the project by the project-financing national and European bodies
- the **published research results** (e.g. publications, research reports) **do not show any personal reference** and therefore do not allow any conclusions to be drawn about the participants identity
- **consent is given voluntarily**, participants can revoke at any time with effect for the future
- care receiver is informed in detail within the framework of the care, therapy and support measures and goals carried out
- documentation of the measures carried out (and the possibility of inspecting the documentation)
- care receivers can name confidants if desired in the context of the pilot
- all individuals present with a care receiver, taking part in the pilot are sworn to secrecy
- rights laid down in the patient charter with regard to service providers (agreement to ensure patient rights, **Federal Law Gazette I No. 42/2006)**: right to respect human dignity and integrity, right not to be discriminated, right to be polite and respectful, right-on self-determination, information and documentation
- reacting accordingly if the state of health of the participants changes during the pilot (e.g. dementia symptoms, ...)
- video chat via AR glasses should only be available to the defined group of individuals, no new individuals are brought in without consultation with those involved
- live broadcast will not be saved
- care receiver can cancel at any time, if not feeling comfortable

5.2 Responsibilities of the pilot participants

If individuals decide to participate in the pilot, they will sign an informed consent and agree to participate in the C^C project on a voluntary basis. By signing the informed consent, the participants agree that all actions necessary to test the features for the C^C project are carried out during their booked period of care provided by HWN.

- Pilot participants are handling equipment/mobile devices used during the pilot (AR glasses) carefully. Any equipment (mobile devices) provided during the pilot is property of FHWN.
- Pilot participants agree that staff members of the project will be physically present during the booked period of care provided by HWN
- Pilot participants agree to keep the scheduled appointments

5.3 Information strategies, processes and rules

In the Care about Care-project care receivers, informal carers and care givers are directly involved in the project phases. The following section describes information strategies, processes and rules for user involvement in the pilot.

Information strategy:

- Participants have been informed about the pilot by employees of the end user organisation
- Participants get a written invitation for the pilot and additional information about the project

Rules:

- Oral invitation
- Written invitation
- Information about project and project progress
- Informed consent
- Announcement of further appointments

Process:

- Participants will be informed about the pilot by employees of the end user organisation
- Written invitations will be delivered before the appointment by the end user organisation
- Participants will be reminded personally by the end user organisation before the pilot
- Pilot
    - People are informed about the project (progress)
    - People are informed about the aims of the pilot
    - People are informed about further appointments

6 Rights and responsibilities of pre-trial participants

Care receiver and care service providers and informal carers are part of the target group for the pre-trial, which will take place in Austria and Luxembourg. Their task is to participate in order to help develop the features for the care cockpit as well as the remote care assist. With

their participation and feedback, the participants are supporting the project team in developing user-centred and user-friendly ICT-solution.

6.1 Rights of the pre-trial participants

- **all the ethical and legal information** stated in the informed consent, **signed by the pre-trial participants, applies**
- the **European Data Protection Regulation (GDPR) applies**, as stated in the informed consent, signed by the participants, this includes primarily, Art 6 Abs 1 lit a (consent) and Art 9 Abs 2 lit j (research purposes in the public interest) in connection with the Austrian Research Organization Act (FOG)
- **processing of personal data** for the purpose the research project "Care about Care" (name, contact details (telephone number / email address/ postal address), gender, year of birth, care allowance level, type of restrictions, mobility aids, number of visits of the care organisation per week, contract duration, use of electronic devices and the Information given in the workshop)
- data will only be used by project partners as part of the research project, **personal information will not be passed** on to persons outside the project team, except for the purpose of reviewing the project by the project-financing national and European bodies
- the **published research results** (e.g. publications, research reports) **do not show any personal reference** and therefore do not allow any conclusions to be drawn about the participants identity
- **consent is given voluntarily**, participants can revoke at any time with effect for the future
- care receiver is informed in detail within the framework of the care, therapy and support measures and goals carried out
- documentation of the measures carried out (and the possibility of inspecting the documentation)
- care receivers can name confidants if desired in the context of the pre-trial
- all individuals present with a care receiver, taking part in the pre-trial are sworn to secrecy
- rights laid down in the patient charter with regard to service providers (agreement to ensure patient rights, **Federal Law Gazette I No. 42/2006):** right to respect human dignity and integrity, right not to be discriminated, right to be polite and respectful, right-on self-determination, information and documentation
- reacting accordingly if the state of health of the participants changes during the pilot (e.g. dementia symptoms, ...)
- video chat via AR glasses should only be available to the defined group of individuals, no new individuals are brought in without consultation with those involved
- live broadcast will not be saved
- care receiver can cancel at any time, if not feeling comfortable

6.2 Responsibilities of the pre-trial participants

If individuals decide to participate in the pre-trial, they will sign an informed consent and agree to participate in the C^C project on a voluntary basis. By signing the informed consent, the participants agree that all actions necessary to test the features for the C^C project are carried out during their booked period of care provided by HWN and SHD.

- Pilot participants are handling equipment/mobile devices used during the pre-trial (AR glasses) carefully. Any equipment (mobile devices) provided during the pre-trial is property of the end-user organisation
- Pre-trial participants agree that staff members of the project will be physically present during the booked period of care provided by HWN and SHD
- Pre-trial participants agree to keep the scheduled appointments

6.3 Information strategies, processes and rules

In the Care about Care-project care receivers, informal carers and care givers are directly involved in the project phases. The following section describes information strategies, processes and rules for user involvement in the pre-trial.

Information strategy:

- Participants have been informed about the pre-trial by employees of the end user organisation
- Participants get a written invitation for the pre-trial and additional information about the project

Rules:

- Oral invitation
- Written invitation
- Information about project and project progress
- Informed consent
- Announcement of further appointments

Process:

- Participants will be informed about the pre-trial by employees of the end user organisation
- Written invitations will be delivered before the appointment by the end user organisation
- Participants will be reminded personally by the end user organisation before the pre-trial
- Pre-trial
    - People are informed about the project (progress)
    - People are informed about the aims of the pre-trail
    - People are informed about further appointments

7 Rights and responsibilities of trial participants

Care receiver and care service providers and informal carers are part of the target group for the trial, which will take place in Austria, Luxembourg and Belgium. Their task is to participate in order to help develop the features for the care cockpit as well as the remote care assist. With their participation and feedback, the participants are supporting the project team in developing user-centred and user-friendly ICT-solution.

7.1 Rights of the trial participants

- all the ethical and legal information stated in the informed consent, signed by the trial participants, applies
- the **European Data Protection Regulation (GDPR) applies**, as stated in the informed consent, signed by the participants, this includes primarily, Art 6 Abs 1 lit a (consent) and Art 9 Abs 2 lit j (research purposes in the public interest) in connection with the Austrian Research Organization Act (FOG)
- **processing of personal data** for the purpose the research project "Care about Care" (name, contact details (telephone number / email address/ postal address), gender, year of birth, care allowance level, type of restrictions, mobility aids, number of visits of the care organizations per week, contract duration, use of electronic devices and the Information given in the workshop)
- data will only be used by project partners as part of the research project, **personal information will not be passed** on to persons outside the project team, except for the purpose of reviewing the project by the project-financing national and European bodies
- the **published research results** (e.g. publications, research reports) **do not show any personal reference** and therefore do not allow any conclusions to be drawn about the participants identity
- **consent is given voluntarily**, participants can revoke at any time with effect for the future
- care receiver is informed in detail within the framework of the care, therapy and support measures and goals carried out
- documentation of the measures carried out (and the possibility of inspecting the documentation)
- care receivers can name confidants if desired in the context of the trial
- all individuals present with a care receiver, taking part in the trial are sworn to secrecy
- Rights laid down in the patient charter with regard to service providers (agreement to ensure patient rights, **Federal Law Gazette I No. 42/2006):** right to respect human dignity and integrity, right not to be discriminated, right to be polite and respectful, right-on self-determination, information and documentation
- reacting accordingly if the state of health of the participants changes during the pilot (e.g. dementia symptoms, ...)
- video chat via AR glasses should only be available to the defined group of individuals, no new individuals are brought in without consultation with those involved
- right to own picture / video recordings (AR glasses, video of living room, sound recording, everyone in the room, private pictures, inventory, pets)

- live broadcast will not be saved
- care receiver can cancel at any time, if not feeling comfortable

7.2 Responsibilities of the trial participants

If individuals decide to participate in the trial, they will sign an informed consent and agree to participate in the C^C project on a voluntary basis. By signing the informed consent, the participants agree that all actions necessary to test the features for the C^C project are carried out during their booked period of care provided by HWN, SHD & KOR

- Trial participants are handling equipment/mobile devices used during the trial (AR glasses) carefully. Any equipment (mobile devices) provided during the trial is property of the end-user organisations
- Trial participants agree that staff members of the trial will be physically present during the booked period of care provided by HWN, SHD & KOR
- Trial participants agree to keep the scheduled appointments

7.3 Information strategies, processes and rules

In the Care about Care-Project care receivers, informal carers and care givers are directly involved in the project phases. The following section describes information strategies, processes and rules for user involvement in the trial.

Information strategy:

- Participants have been informed about the trial by employees of the end user organisation
- Participants get a written invitation for the trial and additional information about the project

Rules:

- Oral invitation
- Written invitation
- Information about project and project progress
- Informed consent
- Announcement of further appointments

Process:

- Participants will be informed about the trial by employees of the end user organisation
- Written invitations will be delivered before the appointment by the end user organisation
- Participants will be reminded personally by the end user organisation before the trial
- Trial
    - People are informed about the project (progress)
    - People are informed about the aims of the trial
    - People are informed about further appointments

References

Dantas, C., Hoogendoorn, P., Kryspin-Exner, I., Stuckelberger, A., & Tijink, D. (2020). *AAL Guidelines for Ethics, Data Privacy and Security*.

Schneider, C., Trukeschitz, B., Eichenberger, R., & Ring-Dimitriou, S. (2016). *Report on ethical issues* (Deliverable 9 of the AAL-Project CareInMovement (CiM)).