Project HEROES
Deliverable 3.2: Ethical and legal approvals

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1. Introduction

The number of people aged over 80 will quadruple between 2010-2050 (SilverEco, 2020). Almost 90% of respondents in one European survey (Alber, 2004) felt that social and health care systems should help older people remain in their homes. To do so, they will require assistance - infrequent at first, with daily tasks such as groceries or seeing a doctor. Families - especially adult women in their 40s and 50s - were traditionally helping with these activities, without pay, thus increasing the income inequality for older women. However, family support is rapidly declining due to the breakdown of families into smaller units, children living further away due to professional commitments and rising female labour participation. By 2060, Europe faces a 1.5+ million gap of informal caregivers (Geerts, 2012). The formal sector, while covering the basics, cannot fill in the gap left by the families as they are themselves facing a steep recruiting challenge, needing 4.1m qualified personnel by 2030 (Michel, 2019).

HEROES makes recruiting caregivers faster and cost-effective by outsourcing the screening of candidates to nurses and retirees, who review candidates remotely and online. This solves the problem of finding and recruiting trustworthy caregivers, which cannot be solved without the HEROES platform. The platform is intended for people of all ages, focusing on the challenge to find and recruit trustworthy caregivers. HEROES helps recruit these caregivers by outsourcing the screening of candidates to nurses and retirees, who review candidates online via the HEROES platform.

The HEROES platform builds diverse ecosystems at the community level. The HEROES platform directly engages families and care providers as recruiters, retirees and qualified nurses as reviewers, and, after the commercial launch, potential caregivers as candidates. Indirectly, we will be interacting with local businesses, home care providers, NGOs, retiree and nurse associations and local municipalities, thus bringing together diverse community groups and stakeholders as enablers of more connected, diverse, and caring local communities.

Collecting target group reactions and comments related to the HEROES-App concept is key for a successful product development. Therefore, research with human participants will be carried out as part of the product

development and innovation process. This requires attention be paid to the ethical and legal guidelines that govern such research activities.

1.1 Purpose of the ethical guideline deliverable

This document presents the ethical guidelines for the HEROES project by outlining the moral and legal aspects that need to be considered within the scope of the project. During the co-creation phase and the field trials, data on the end-users will be stored. Thus, it is necessary to consider ethical, privacy, and usage issues regarding the involvement of end-users during the project. In this context, it is essential that the dignity and rights as human beings as well as the right to privacy are upheld during the whole project. All involved partners are responsible for identifying and integrating ethical standards from the very beginning of the project.

The involvement of end-users as co-designers is essential for the project to guarantee a high acceptance of the product amongst the target group. Therefore, all user-related activities including user studies and the development of the system will adhere to this guideline to ensure that the necessary ethical considerations are met. The guideline refers to the main regulations that apply in the European Union and the respective countries of the participating project partners.

1.2 Related documents

As part of the WP 3, this document is closely tied to the D3.1 Work Plan & Componence of the End-User Advisory Board, D3.3 Test and Evaluation Plan, and the D3.4 User Testing and UX KPI Report.

2. Legal Responsibilities

The HEROES project will examine all relevant ethical issues and will comply with the fundamental ethical principles regarding personal data and in the involvement of human subjects in research activities. These principles are reflected in most national and international policies and regulations. The main theme of these policies is that the participation of end-users must be voluntary and conducted in a way that upholds their dignity and safety. Voluntary participation implies that the person(s) must not be coerced or pressured into partaking as a participant. Their decision to join as a participant in the project must be on their own accord. The participant should also be able to discontinue the study or the participation of the project at any time, without any reason given. During the field trials and co-creation phase, it is the researcher's responsibility to ensure that the studies do not cause any physical or mental harm to the participant or anyone else involved in the research. Each study should be fully evaluated beforehand to ensure that there is no risk of harm.

If additional ethical concerns should arise at any time during the project that are not outlined in this document, it is up to the project partner to bring these to the attention of the project coordinator for an ethical review. Any new ethical developments will be considered under the same legal and ethical guidelines as are documented here.

2.1 International policies and European union regulations

Ethical aspects of research, especially research involving human participants, have been under careful scrutiny in the past 100 years. Driven by concerning historical events, the need to protect participants in research has become clear. Such events resulted in many reports and guidelines, identifying issues to be considered when preparing for research with humans. One such document that greatly contributed to ethics in research involving humans is the Nuremberg Code of 1949. Within this document, 10 essential principles should be

considered when conducting research with human participants.

1. Voluntary consent is essential.
2. The results of the research should be used to better society.
3. The study should be designed that the anticipated results justify the means.
4. Avoidance of all unnecessary physical and mental suffering and injury is essential.
5. No experiment should be conducted where there is a risk of death or disabling injury.
6. The degree of risk should never exceed that of the importance of the problem to be studied.
7. Facilities where the studies take place should be prepared in a way to eliminate even remote possibilities of injury, disability, or death.
8. Studies should only be carried out by responsible, qualified persons.
9. Participants must have the right to leave the experiment at any time.
10. Those conducting the study must be prepared to end the experiment at any time if there is reason to believe the continuation is likely to result in injury, disability, or death to the subjects participating in the study.

The Nuremberg Code impacted, and continues to influence, research involving human participants. Since then, many more international ethical guidelines have been developed to supplement the 10 principles for diverse situations. The Declaration of Helsinki (1964); Food, Drug, & Cosmetics Act (1962); and many others have contributed to basic ethical guidelines in research with human subjects. Importantly, the Belmont Report (1979) contributed to the standard of well-controlled studies, including respect for persons through the requirement for informed consent.

2.2 Data processing of individuals

In May 2018, the General Data Protection Regulation (GDPR) was launched and applies to all individuals within the European Union. Under the GDPR, citizens should regain control over their personal data by unifying the regulations. Under the GDPR, personal data is defined as any information that could be used, on its own or in conjunction with other data, to identify an individual. This data includes IP addresses, mobile device identifiers, and geolocation and biometric data (fingerprints, retina scans, etc.). The GDPR also covers data related to an individual's physical, psychological, genetic, mental, economic, cultural, or social identity.

Accordingly, any collection, storing or processing of personal data must be clearly disclosed and the purposes thereof be declared. In addition, the length and purpose of data storage must be clearly stated. It must be also clearly stated in the case that the data is shared with other parties. Data subjects have the right to request a portable copy of the data collected by a processor in a common format, and the right to have their data erased. No personal data may be processed unless it is done under a lawful basis specified by the regulation, or if the data controller or processor has received explicit, opt-in consent from the data subject. The data subject has the right to revoke this permission at any time.

The HEROES project field trials may require the participants to create personal profiles and/or exchange information through a trial version of the platform during which data will be collected, stored and processed. HEROES also requires some information to be exchanged between participants (i.e., candidate profiles and application data will be made available to reviewers and recruiters). Therefore, GDPR regulations will be upheld and ensured by the respective consortium partners. This also includes the communication of data

subjects' rights regarding their data as stipulated by the GDPR [Article 15]:

- The right to information
- The right to be informed about any third party transfers of information or data
- Right to access, erasure, rectify or restrict data
- Right to data portability to other data controller
- Right to object against further processing

2.3 National Laws and Regulation

Beyond the international standards, partners will act according to community law as well as national conventions. User studies will take place in Austria, Romania, and Switzerland. Each respective partner will ensure that they are adhering not only to the legal regulations and guidelines presented by the European Union, but also to the standards to their country of operations. This includes national regulations regarding ethics and data protection.

2.2.1 Austria

Authorities:

Ethikkommission der Stadt Wien (Ethics Commission of the City of Vienna) - The Ethics Committee of the City of Vienna assesses whether the rights and integrity of the subjects participating in a particular clinical trial or new medical method are adequately protected, taking into account the "Guideline for Good Clinical Practice" and the Declaration of Helsinki.

Main regulations:

- Vienna Hospitals Act 1987 - Wr. KAG, LGBl. für Wien No. 23/1987, as amended from time to time.
- Federal Act on Hospitals and Sanatoria - KAKuG, Federal Law Gazette No. 1/1957, as amended from time to time.
- Medicinal Products Act - AMG, Federal Law Gazette No. 185/1983, as amended from time to time.
- Medical Devices Act - MPG, Federal Law Gazette No. 657/1996, as amended from time to time.

2.2.2 Romania

Authorities:

The National Ethics Council (NEC) of Romania is responsible for the management and tracking of the application regarding moral and professional conduct in research activities.

The faculty of medicine in Timisoara has an institutional ethical committee which is responsible to ensure that ethical codes are followed and complaints received are resolved. This ethical committee has an independent status taking on a consultative role in upholding the rights and safety of the participants during research.

Main regulations:

- The Law No. 206/2004, Art. 9 (1) relating to the good conduct of scientific research, development, technology and innovation

2.2.3 Switzerland

Authorities:

Eidgenössischer Datenschutz- und Öffentlichkeitsbeauftragter (responsible for all issues regarding data security)

Kantonale or eidgenössische Ethikkommission (competence depending on regional scope; must be informed and / or asked to state their opinion in cases in which sensitive medical data of identifiable testing persons shall be handed over to third persons)

Main regulations:

- Bundesverfassung, Art. 13 (Protection of privacy, including the protection of private and family life, home, mail and telecommunication, financial secrecy)
- Bundesgesetz über den Datenschutz (revised 1 March, 2019)
- Verordnung zum Bundesgesetz über den Datenschutz (revised 1 December, 2010)
- Schweizerisches Zivilgesetzbuch, Art. 28-28l
- Bundesgesetz über die Forschung am Menschen (Humanforschungsgesetz, HFG, revised 1 January, 2014)

3. Ethical Issues

3.1 Involved users

More than 50 end-users will take part in the field trials. These end-users will be divided into three groups and act as formal as well as informal caregivers, recruiters and reviewers during the field trials. The participation in the field trials and workshops is voluntarily and participants have the right to withdraw their consent at any time.

3.2 Human-centred design for diverse users

HEROES will follow the human-centred design approach in order to ensure the end-user's point of view during the whole project. According to the ISO 9241-210:2019 standard, human-centred design is defined as follows: "Human-centred design is an approach to interactive systems development that aims to make systems usable and useful by focusing on the users, their needs and requirements, and by applying human factors/ergonomics, and usability knowledge and techniques." Human-centred design research is a well-established practice in health technology research nonetheless, with beneficial effects in terms of increased usability and efficiency of use of the final product of the research and development processes and is a key practice recommended by the Active and Assisted Living Joint Programme, which developed the Youse

instrument for evaluating research projects from the end-user integration level and quality.

AAL Programme also has developed and published sets of guidelines regarding the involvement of end-users in Active and Assisted Living Research Projects: The art and joy of user integration in AAL projects - A White paper for the integration of users, from idea creation to product testing and business model development, and Toolbox: Methods of end user integration - A selection of best practice methods.

HEROES is developed based on the active and extensive involvement of the future users – caregivers (formal and informal) and people in need of care or their families.

In this approach, the end-users are consulted in the evolvement of the app starting at a conceptual idea up to the final product, thus minimising the risks of failure in the introduction of the app on the market. Evaluation sessions, particularly during the field trials, provide objective and subjective feedback from the potential users at the different stages of development of the system.

3.3 Principles for the involvement of human participants

End-users as well as other target groups are actively involved in the HEROES project in order to develop a usable and thus successful application. The inclusion of human participants in this project is important to ensure that there is a positive benefit for the persons affected and that the developments of the platform align with the needs of this target group. The project follows an inclusive, human-centred approach in order to guarantee that the solution is problem solving, accepted and appealing to future users.

As described in the proposal, all end-users should be treated in a dignified and faithful way. Therefore, the field trials involving elderly people from healthy to mildly cognitively impaired will respect the following aspects, which apply to all HEROES project partners for the full duration of the project:

- Fundamental ethical principles, including those reflected in the Charter of Fundamental Rights of the European Union: dignity, freedom, equality, solidarity, citizens' rights and justice.
- European Human Rights Convention (privacy and autonomy). Serious adverse events will be reported within 48 hours after they occurred.
- The right for self-determined living and autonomy of the decision of the test users will not be questioned through the project team members.
- Communication during the whole HEROES project will be reliable, helpful and respectful. There will always be a person of contact. This will be ensured through a group chat. A Whatsapp groupchat will be formed in which the end-users will get quick and context-sensitive support and updates regarding the field trials. Joining the group chat is voluntary and not necessary in order to participate in the field trials.
- Participants will be immediately informed if there are delays in the progression of the field trials or technical developments. They will be given information on the new schedule and will be assured about the following steps and their involvement in the process.

- User privacy is subject to extensive formal regulation. Taking this in mind the consortium shows relevant concerns with privacy and ethics issues.

3.3.2 Informed Consent

All project partners conducting field research or co-creation workshops must ensure that the participants have given their informed consent to participate. No participants will take part in the field trials without having signed an Informed Consent sheet. The informed consent of the participants will be collected in written form, digitally or on paper. Information about the study will be handed out to the participants in written form. This includes the objectives of the study, and the rights of the participants during the study and how their information and data is handled, processed and stored. The informed consent must be written in the language of the country where the research activity will be conducted. Therefore, the Informed Consent of Romania must be written in Romanian and the Informed Consent of Austria and Switzerland in German. It is imperative that participants understand their role as participants in the project. Thus, participants will receive information in a way that is easy and accessible to understand. Participants will also be asked for their permission to record data (video/audio) or take photos. This can be declined or accepted freely by the participants. Furthermore, participants are informed that their participation is on a voluntary basis and that they can withdraw freely, without any explanation from the study. Consent forms will be elaborated by each end-user organisation itself according to the requirements of the local ethical committees and explained to the participants prior to the start of the field trials or any research workshops.

3.4 Data protection and privacy

Participants have the right to review and delete their data on request. Data will be generated only in an anonymised form. Therefore, the questionnaires, and other used instruments must not contain questions, which answers could lead to the participant's identity – alone or in combination with other answers. Additionally, the data collected from the field trials will be pseudonymised. During this de-identification procedure, each participant will use a unique number to fill out their questionnaires. This makes the data set less identifiable but still allows for accurate data analysis. This data can be restored in case end-users request to review their data or ask to delete it. This pseudonymisation process complies with the EU's GDPR.

3.5 Potential risks and benefits

3.5.1 Risks

All project partners will follow the ethical and legal guidelines outlined in this document to minimse any risks that might threaten the privacy or dignity of the participants. While the risk for any privacy, legal or ethical breaches remains meagre, data leaks may occur. The Whatsapp group chat entails are the phone numbers of the participants. While we do not condone any participant that might share the numbers with others, it is still possible that this might occur. In the case of inappropriate behaviour of participants or breaches of privacy in the Whatsapp group, the administrators of the group (project partners) will remove the participant from the group and from the field trials. Project partners will offer support to the affected participants to their best abilities.

3.5.2 Benefits

This project views elderly people with rights and responsibilities. This rights based approach, unlike a needs-based approach, appreciates the value elderly people offer to the project and to society as a whole. By including the needs and requirements of elderly people in the recruitment for care workers, the voices of elderly people are heard and incorporated in the development of the product. This contributes to an autonomous sense of self for elderly people. Similarly, the field trials also offers care workers the opportunity to express their needs in the search of work. The participants will be compensated for their consistent efforts during the field trials.

4. Conclusions

As the HEROES project closely works end-users it is necessary that the dignity, rights and privacy of the participants are upheld. By following European data privacy and research guidelines, regulations and laws the HEROES project ensure the wellbeing, dignity and right to privacy of the participants. Each respective partner country will also follow the respective ethical and legal requirements during the project.

5. References

Alber,J.(2004). Health and care in an enlarged Europe. European foundation for the improvement of living and working conditions.

Geerts, J.a. (2012). Projections of use and supply of long-term care inEurope: policy implications. ENEPRI Policy Brief.

Michel, J.-P. K.-S.-W.-M. (2019). Transforming the future of ageing.Berlin:Science Advice for Policy by European Academies

6. Annex

HEROES Project Field Trials Concept (Quick Overview)

September 7, 2021

Project Background and Goals:

The HEROES Project (https://heroesproject.eu/) aims to make recruitment of caregivers fast, reliable, and cost-efficient to meet the care needs in local communities. To reach this objective, we combine the experience of nurses and older people (aged 50 and above) with the advantages of digital technology to create an age-inclusive online recruitment platform.

The platform caters to three main user groups:

To recruiters (companies and families), the platform provides a job posting app where they are matched with existing candidates, post their own job ads and request independent reviews.

To candidates (unskilled helpers or qualified caregivers and nurses), the platform is a job search tool which allows them to apply to job posts through pre-recorded video answers.

To reviewers (older adults and nurses), the platform provides them with an opportunity to review video answers and recommend candidates, thus using their life & work experiences.

Objectives and Measures:

The main objective of the field trials is to evaluate the HEROES platform and gather user feedback for the development of new features as well as the optimization of existing features.

Qualitative feedback will be collected during each evaluation cycle employing a digital experience sampling / diary study approach. Users will perform tasks, try out features and functionalities and report on their observations and experiences in written self-reports. Throughout the duration of the field trials, we plan to stay in touch with our participants through a messenger app on their smartphone. The online survey tool LimeSurvey will be used to facilitate the experience sampling. Participants will receive links to the qualitative experience sampling questionnaire within their messenger app. Moreover, they can use this app to send us their unsolicited observations (photos, screenshots, etc.) and feedback (self-reports).

Quantitative feedback will be collected at the end of each evaluation cycle, (mostly) relying on standardized questionnaires implemented in an online survey tool. The quantitative measures will include questions on

technology acceptance, KPIs of the platform such as matching quality, willingness to pay, and the net-promoter score. Besides these quantitative measures collected during a cycle, participants will also go through a more elaborate questionnaire as part of the initial and final data collection. The quantitative measures at these two measurement points will focus on quality of life, social impact KPIs, the labor framework and work conditions for care persons in the three countries as well as users' value propositions for the HEROES' recruitment platform (i.e., user needs, gains, and pains).

Timeline, Participants and Expected Efforts:

The field trials in the HEROES project will start at the beginning of April 2022 and last until end of March 2023. During these 12 months a total of 75-90 participants — split evenly among the partner countries Austria, Switzerland, and Romania — will take part in the initial data collection, 3 Rapid Evaluation and Development Cycles (RED-C), and a final data collection (see Fig. 1, top). Each RED-C will last for 4 months (or 16 weeks). The actual evaluation with participants takes place in the first 3 weeks per cycle, during which participants are estimated to spend about 5-8 hours evaluating the platform's functionalities and design (see Fig.1, bottom). The initial- and final data collection will take about 30-45 min each. The participants will be recruited from the three main user groups of the platform: reviewers (nurses and people aged 50 and above), recruiters (family members and care organizations), and candidates (helpers and qualified caregivers / nurses).

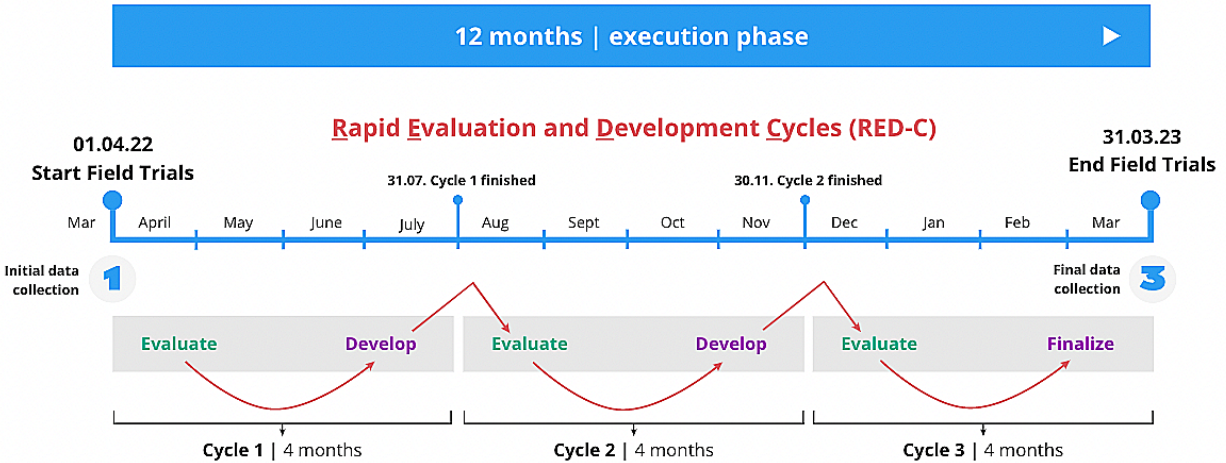
Research Ethics:

As mentioned above, the main objective of the field trials is to evaluate the HEROES platform and gather user feedback for the development of new features as well as the optimization of existing features.

The field trials do not involve any medical interventions. They also do not involve different treatment conditions (e.g., a treatment vs. control group); however, different user groups may be asked to evaluate different features of the platform (e.g., reviewers will be asked to review videos of candidates, while candidates will be asked about their experiences with recording the videos).

Even though we will also collect certain personal information (e.g., on demographics, preferences and attitudes, technology acceptance, work conditions, care needs), all data we collect is intended solely for either informing the development of the platform or measuring its impact (e.g., on quality of life, labor regulations). In addition, all analyses will be conducted only with anonymized or pseudoanonymized data.

The following rights are ensured: (1) Right to an informed consent; (2) Right to withdraw from the research at any time; (3) Protection of participants' privacy and full GDPR compliance.



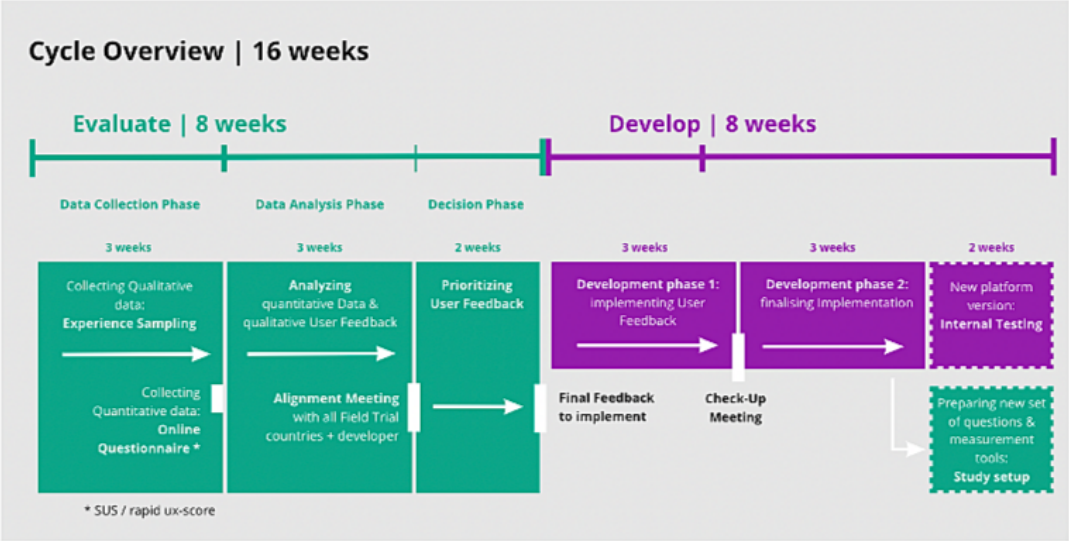


Fig. 1. Rapid Evaluation and Development Cycles (RED-C, top); Cycle Overview (bottom).

Informed Consent Sheet

1. General Information

Thank you for participating in our field trials. At certain times over the next 12 months you will get notifications via the messenger tool that you will be invited to. You will be asked to complete certain tasks within the HEROES app and to give us feedback and tell us your experience.

It is important to know that it is not you who is getting tested, but the app. We are interested in your personal and subjective opinion, there are no right or wrong answers.

If you encounter any technical problems or if you have questions during your participation in the field trials, please don't hesitate to get in touch with your contact person as stated in your booklet on page 3.

On the next page you will find information about the project as well as the field trials. Please read this information

carefully before you agree to participate.

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2. Data protection information

In the following, we inform you about your rights regarding the collection and processing of your personal data. This information is provided in accordance with Articles 13 and 14 of the General Data Protection Regulation (DSGVO). The responsible party (within the meaning of the DSGVO) is the project consortium of the project HEROES.

We care about your privacy and will handle it in a sensitive and appropriate way. We are never interested in your personal information (sex, place of living, ...), but only in your experience of the HEROES app. We only ask for your personal information to find out about certain user preferences and demographics: We are only interested in making the app better, making it more useful, to increase its usability and improve its user experience. The data will be analysed and interpreted only by the partners of the HEROES project consortium (https://heroesproject.eu).

The data that you enter in this and the following survey forms is hosted and processed by rapid user feedback GmbH, only for the purpose of improving the app. The data that you enter in the messenger channels is hosted by these service providers. The messenger tool is only used to communicate with you and to notify you, when a task should be completed. The data will not be processed by us - the project consortium - in any other way then for communication purposes with all participants.

You have the right to the surrender and deletion of your data collected for the purpose of the field trials at any time. The processing is based on your consent (Article 6(1)(a) DSGVO). The data will be processed in a consolidated manner across all participants* so that none of your statements can be traced back to you personally. Until the time of processing, you can have all your statements, information and opinions decidedly deleted. The data will be deleted no later than 7 years after collection.

Project HEROES is funded by the AAL (Active and Assisted Living) Programme's 2020 Call Challenge, project nr. AAL-2020-7-47-CP, with financial support from the European Commission and the national funding agencies of Austria (Österreichische Forschungsförderungsgesellschaft - FFG), Romania (Executive Agency for Higher Education, Research, Development, and Innovation Funding – UEFISCDI) and Switzerland (Innosuisse).

If you have any questions about data protection or the survey itself, please contact your responsible project partner's project manager at any time:
rapid user feedback GmbH, Austria: marco.dellaschiava@user-feedback.at
Fachhochschule Kärnten, Austria: J.Oberzaucher@fh-kaernten.at
TERZ Stiftung, Switzerland: alissa.baer@terzstiftung.ch
IAF OST, Switzerland: katharina.molterer@ost.ch
The Care Hub SRL, Romania: manu.pop@thecarehub.ro

Please check the box underneath with "Yes, I agree with it.", if you agree with our data privacy policy and want to take part in the HEROES field trials:

☐ *Yes, I agree with it.* *Signature:* _____

3. Voluntary participation

Why do we ask you to participate in this year-long test? In human-centric technology development, the potential user - you - are in the middle of every step in the development. That is why the app is tested before release with users just like you. We are interested in your opinion, there are no right or wrong answers. We particularly welcome constructive criticism and comments, and we guarantee that only summarized results will be incorporated into the development of the platform and that individual statements can never be traced back to you personally.

You are participating in the field study completely voluntarily and have the right to stop the study at any time without giving any reason and without any negative consequences.

Please be aware that you will not receive the full allowance available for the complete field study per participant if you decide to stop your participation beforehand.

☐ *Yes, I would like to participate in this field trials voluntarily and have been informed about my personal right to stop the study at any time.*

4. Information on compensation payment

Please confirm that you are participating as a private individual and that you will only receive the compensation payments as a private individual and not as a company.

You are responsible for the proper reporting and taxation of this expense allowance. In Austria, there is a tax-free amount that you may receive as compensation per calendar year, but we cannot accept any liability for this information.

As a compensation for your participation in the Kickoff Meeting you receive a voucher worth 60 EUR (in words: sixty Euro).

☐ *Yes, I participate as a private individual and receive the expense allowance as a private individual.*

Please type in your full Name (Last name, Name). We only need this information to confirm who received the payment compensation.

_____

5. Consent to the publication of photos

I declare my consent to the publication of photos in which I can be seen. Publication may take place without further request. Please tick if you agree to appear in images published for dissemination as part of the project:

☐ *Yes, I agree with it*
☐ *Yes, but blurred*
☐ *No*

6. Information to contact you as a participant of the field trials

During the field study, a field study messenger group will be created to share information about the progress of the study.

Please indicate if you agree to be added to the Field Study Messenger Group.

☐ Yes, I agree to be added to the Field Study Messenger Group and understand that the sole purpose of the group chat is to receive information about the field study. You are not permitted to share other members' contact information or contact them without their consent.

☐ No, I don't use messenger tools in general and I don't want to be added to the messenger group. I would like to receive notifications only by email.

Please type in your phone number, where we can reach you and add you to the field trial messenger groups?

Phone: _____

Please type in your Email address, as an additional way we can reach you during the field trials?

E-Mail: _____