



H2HCare

Social robot-based solution for elders' Care management and coaching after discharge from Hospital to Home

D3.1 Code of Conduct



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List of acronyms

Acronym	Description
AAL	Ambient Assisted Living
ALLEA	All European Academies
IPR	Intellectual Property Rights
GCP	Good Clinical Research Practice
GDPR	General Data Protection Regulation
LRH	Human Research Law
OClin	Ordinance on Clinical trials in human research
SME	Small and Medium Enterprises



Executive summary

A Code of Conduct is an agreement on rules of behaviour for the members of that group or organization. With this document, practical guidelines are given to the project partners, which need to be followed in order to complete the project in line with the strategic objectives of the AAL programme. In particular, seven principles are described: reliability, honesty, respect, accountability, transparency, independency and responsibility. The principles stated in this document are generic, and the document complements the consortium agreement.



1 Introduction

1.1 Intended Audience

This document has all project members as its audience. The rules and guidelines shall be followed by all persons involved in the project. All project's members should use the report both as a reference in the project and as a source for input and discussions around these issues. As more ethical issues may arise during the development of the product, this report will be updated throughout the project duration.

1.2 Relations to other activities

The content relates to activities where end-users are involved, and the handling and storage of privacy-sensitive project data. This will include research activities with human subjects to ensure the safeguard of their ethical and privacy rights, as well as privacy regulation concerning data.

1.3 Document overview

AAL funds cross-national projects that involve SMEs, research bodies and end-user organizations. Therefore, this code of conduct follows the recommendations for good research practice from The European Code of Conduct for Research Integrity by ALLEA [1], while taking into account the profession codes for applied research and the basics for good clinical practice rules [2]. The latter because the H2HCare projects involves older frail end-users, namely persons with underlying heart disease conditions. The AAL program has defined the following strategic objectives:

- Efficient usage of public funding resources
- Efficient implementation (time-to-contract, evaluation and selection processes, etc.)
- High involvement of SMEs
- High involvement of end-users
- Strong European cooperation
- Commitment of national funders/sponsors.

In the H2HCare project, the strategic objectives as described in the AAL program are mapped to 7 principles ("Code of conduct") which are aligned with codes for research:

- **Reliability** in ensuring the quality of research, reflected in the design, the methodology, the analysis and the use of resources
- **Honesty** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair, full and unbiased way
- **Respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment
- **Accountability** for the research from idea to publication, for its management and organization, for training, supervision and mentoring, and for its wider impacts [1]
- **Transparency** openness and accessibility
- **Independency** objectivity; impartiality and independence
- **Responsibility** for the scientist and project partners of the future

In the process of writing the H2HCare Code of Conduct, literature has been studied, and guidelines from similar projects have been reviewed. This document presents a selection of guidelines which operationalize the strategic goals, are aligned with the 7 principles as stated above, and which are relevant to the H2HCare project context.



The code of conduct has been written in close collaboration with the project consortium via discussions and feedback rounds and builds on standards as can be found in literature on ethical rules in practice-based research and professional standards for applied sciences.

The remainder of this document describes how the project implements the 7 principles in 5 different themes (in alphabetical order):

- **Collaboration**
- **Compliance**
- **Data storage and management**
- **Interaction**
- **Upholding scientific standards**



2 Implementation of the seven principles

2.1 Collaboration

Research is a common enterprise, carried out in academic, industry and other settings. Research involves collaboration, direct or indirect, which often transcends social, political and cultural boundaries [1].

2.1.1 Accountability

Researchers are accountable for their actions while conducting research.

Researchers will be unbiased in their report whereby they do not selectively exclude research results without sound arguments, researchers will not adjust formulas to match the wishes of the stakeholders, and do not present conclusions that are not based on the data.

Researchers are autonomous in the analysis and ensure that it is not sent by desired outcomes according to the agenda of commercial or political groups.

All partners in research collaborations take responsibility for the integrity of the research [1].

All authors are fully responsible for the content of a publication, unless otherwise specified [1].

2.1.2 Respect

All partners will consider the interests of the stakeholders, the influence that various interest groups can have on the research method during execution and the influence that they have as a project partner in conducting the research in practice. Partners will follow the regulations and protocols which apply in their field of study for doing research. If research with humans imposes any risk, the importance of the research must justify taking that risk. In this case, external experts are asked for advice, such as a medical ethical review committee.

2.1.3 Intellectual property

European directives on intellectual property converge with professional good practice in requiring project partners to pay attention to ensuring necessary permissions, correct attribution of authorship, acknowledgement of sources, correctness of references and the avoidance of plagiarism [3].

All partners formally agree at the start of their collaboration on expectations and standards concerning research integrity, on the laws and regulations that will apply, on protection of the intellectual property of collaborators, and on procedures for handling conflicts and possible cases of misconduct [1].

2.1.4 Honesty and transparency

Revenues in the future should be discussed in advance, by the project team. The H2HCare project supports the IPR regime on the basis of Regulation No. 1290/2013 which establishes the rules for participation in Horizon 2020 research framework. IPRs, pre-existing know-how, agreement on exploitation rights and clarification of each individual's right and obligations are included in the Consortium Agreement document.



2.1.5 Communication

In task collaboration, partners will involve members in the following order: task members, work package lead and project lead. Furthermore, partners are constructive, pragmatic and concrete. Partners respect the individual targets but also share the common goal.

2.2 Compliance

Research should comply with the laws of the countries in which they are based or in which they are carrying out research. In the case of international collaborations or online research, the laws of additional countries may also apply [3].

Project partners shall examine which national laws apply, especially in international co-operations [3].

Project partners shall pay due respect to the fact that materials used in research are predominantly protected by intellectual property rights such as copyright, database and software protection [3].

2.3 Data storage and management

Research often involves the collection and other further processing of (personal) data. Therefore, the processing of personal data is regulated by law [3]. Project partners have the duty to be transparent and make their work available to colleagues. It's important to be aware of the necessity to make their work transparent while considering the careful handling of (personal) data and to make a well-considered decision that involves the rights of intellectual property.

2.3.1 Protocol for sharing and storing privacy-sensitive project data

In view of EU regulations and the GDPR [6], the H2HCare project partners have defined a protocol which describes how privacy-sensitive project data is shared and stored. This protocol aims to minimize the risk of data breaches and aims to make sure any privacy sensitive data is handled in a correct manner. The protocol can be found in the Appendix A.

2.3.2 Transparency and honesty

Researchers, research institutions and organizations ensure that any contracts or agreements relating to research outputs include equitable and fair provision for the management of their use, ownership, and/or their protection under intellectual property rights [1].

Authors ensure that their work is made available to colleagues in a timely open, transparent, and accurate manner, unless otherwise agreed, and that they are honest in their communication to the general public and in the traditional and social media [1].

Researchers, research institutions and organizations provide transparency about how to access or make use of their data and research materials [1].

Project partners publish results and interpretations of research in an open, honest, transparent and accurate manner, and respect confidentiality of data or findings when legitimately required to do so [1].

2.3.3 Integrity and reliability

Project partners will collect the data only for specified, explicit and legitimate purposes [3].



Project partners should comply with the conditions for communication of personal data to third parties or recipients, bearing in mind that it is only lawful to transfer data if the purpose is compatible with that for which the data were originally collected [3].

Project partners should respect the rights of data subjects to access personal data, rectify incomplete or inaccurate data, and to object to the processing under the stipulated circumstances [3].

Appointments and agreements made within the project team should be complied on time.

If not deviation of the time should be answered with solid arguments and reported to the project partners.

2.3.4 Carefulness

Project partners should take technical and organizational measures to ensure the security and confidentiality of personal data (including encryption where necessary) [3].

The quality of data collection, data entry, data storage and data processing are well monitored. Correct reporting of all steps and monitoring of the execution is imperative.

2.3.5 Accountability

Project partners justify themselves for the way in which data are collected, as well as the way in which various interest groups are involved in the data collection.

Project partners justify themselves for the way data has been analysed, as well as the way in which various interest groups are involved in validating the data analysis.

By correct source listing, project partners will justify the intellectual origin of the cited or paraphrased texts. This also applies to information from the internet and from anonymous sources. Without the source, no texts or results of research from others are used.

2.4 Interaction

Interaction with individuals or organizations during research requires clear agreements. The following codes prevent any harm done to participating individuals or organizations.

2.4.1 Respect and integrity

Project partners should respect the anonymity, privacy and confidentiality of individuals participating in the research, and ensure that the presentation of data and findings does not allow the identity of individuals participating in a study, or informants, to be disclosed or inferred. Project partners should also ensure that this is also the case in the presentation of findings by contractors, funding agencies or colleagues. In cases where disclosure of the identity of a subject (whether an individual or an organization) is central and relevant to the research, such confidentiality cannot always be guaranteed. In such cases the problem should be addressed in open discussion with research subjects, with the aim of obtaining informed consent to any disclosure [3].

Project partners handle research subjects, be either human, animal, cultural, biological, environmental or physical, with respect and care, and in accordance with legal and ethical provisions [1].

Project partners have due regard for the health, safety and welfare of the community, of collaborators and others connected with their research [1].



Project partners consider the interests and privacy of all concerned and their organizations as well as the copyrights of other authors.

2.5 Upholding scientific standards

Researchers have a responsibility to take account of all relevant evidence and present it without omission, misrepresentation or deception. This means making sure that the selection and formulation of research questions, and the conceptualization or design of research undertakings, does not predetermine an outcome, and does not exclude unwanted findings from the outset. Data and information must not knowingly be fabricated or manipulated in a way that might lead to distortion.

Integrity requires researchers to strive to ensure that research findings are reported by themselves, the contractor or the funding agency truthfully, accurately and comprehensively.

2.5.1 Reliability

Researchers ensure factual accuracy and avoid misrepresentation, fabrication, suppression or misinterpretation of data.

Researchers demonstrate an awareness of the limitations of the research, including the ways in which the characteristics or values of the researchers may have influenced the research process and outcomes, and report fully on any methodologies used and results obtained (for instance when reporting survey results, mentioning the date, the sample size, the number of non-responses and the probability of error).

Researchers critically question authorities and assumptions to make sure that the selection and formulation of research questions, and the conceptualization or design of research and undertakings, do not predetermine an outcome, and do not exclude unwanted findings from the outset.

Researchers ensure the use of appropriate methodologies and the availability of the appropriate skills and qualifications in the research team.

2.5.2 Respect

Researchers take account of the work of colleagues, including research that challenges their own results, and acknowledge fully any debts to previous research as a source of knowledge, data, concepts and methodology.

Researchers ensure fair and open recruitment and promotion, equality of opportunity and appropriate working conditions for research assistants whom they manage, including interns and research students.

2.5.3 Independence

Researchers declare any conflict of interest that may arise in the research funding or design, or in the scientific evaluation of proposals or peer review of colleagues' work.

Researchers ensure that research findings are reported by themselves, the contractor or the funding agency truthfully, accurately, comprehensively and without distortion. In order to avoid misinterpretation of findings and misunderstandings, researchers have a duty to seek the greatest possible clarity of language when imparting research results.



2.5.4 Responsibility

Researchers ensure that research results are disseminated responsibly and in language that is appropriate and accessible to the target groups for whom the research results are relevant.

Researchers honour their contractual obligations to funders and employers.

2.5.5 Transparency

Researchers declare the source of funding in any communications about the research.

Researchers report their qualifications and competences accurately and truthfully to contractors and other interested parties, declare the limitations of their own knowledge and experience when invited to review, referee or evaluate the work of colleagues, and avoid taking on work they are not qualified to carry out.

Researchers ensure methodology and findings are open for discussion and full peer review [3].



3 Rights and ethics in research activities

During the H2HCare project, several research methods will be used to design, test and validate the tool developed in the project. To protect the participants involved in these research activities, each activity must take into account ethical aspects and human subjects' rights.

3.1 Ethical approval

Following the GCP [2], some research activities that include participation of human subjects need to be reviewed and receive approval from Ethics Committee. Especially for the following types of study:

- “Studies of a physiological, biochemical, or pathological process, or of the response to a specific intervention – whether physical, chemical, or psychological – in healthy subjects or in patients;
- Controlled studies of diagnostic, preventive or therapeutic measures, designed to demonstrate a specific generalizable response to these measures against a background of individual biological variation;
- Studies designed to determine the consequences for individuals and communities of specific preventive or therapeutic measures;
- studies concerning human health-related behaviour in a variety of circumstances and environments;
- Studies that employ either observation or physical, chemical, or psychological intervention. Such studies may generate records or make use of existing records containing biomedical or other information about individuals who may or may not be identifiable from the records or information. The use of such records and the protection of the confidentiality of data obtained from those records are discussed in the “International Guidelines for Ethical Review of Epidemiological Studies” (CIOMS, 1991, currently being updated). “ [2]

Depending on the functionalities that will be developed in the H2HCare project, the pilot test trials may enter in one of the above categories. If so, each trial site will have to submit the protocol to their Ethical Committee and receive approval. In case of doubt, whether an ethical approval or not is needed, each trial site will check with their Ethical Committee and/or ask for an exemption from ethical approval process.

3.2 Informed consent

Following the Charter of fundamental rights of the European union [7] and the article 3 “In the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law”. Therefore, in all research being performed, each participant needs to agree with the research and give their consent. The format of the consent form may vary following the different national regulations of each site test and the type of the research.

Switzerland (HUG)

In Switzerland, one of the research and pilot sites, the informed consent format is defined by the LRH (Human research law) [8] and the OClin (Ordinance on clinical trials in human research) [9], if the study enters in the category of clinical trials.

In case of a research on human beings except clinical trials, the informed consent must include the following information (LRH):

- the nature, purpose, duration and procedure of the study
- foreseeable risks and constraints
- benefit for the participants



- measure to ensure the protection of his personal data
- rights of the participants

In case of a clinical trials, the informed consent must include the additional information (OClin):

- possible alternatives to the intervention submitted to the clinical trial when this allows a direct benefit to be expected;
- charges and obligations that arise from participation in the clinical trial; vs.
- the right she must refuse to participate in the clinical trial or to revoke her consent without having to justify her decision and without being prejudiced in relation to her medical treatment;
- consequences of a revocation of the consent on the continuation of the medical treatment as well as on the subsequent use of the personal data collected before the revocation and the biological material taken before the revocation;
- their right to receive information at any time on matters relating to the clinical trial;
- the right she must be informed of the results concerning her health or to refuse to receive this information, or to designate a person who takes this decision for her;
- arrangements made to cover any damage related to the clinical trial, including the procedure in the event of damage;
- the sponsor and the main sources of funding for the clinical trial;
- other elements necessary for her to make her decision.

Norway (SN):

In Norway, the Rights and Cautions within the scope of this project will be covered by the general codes of conduct of this document and specifically of the referenced documents under point [4]. There will be no clinical trials for Norwegian participants.



4 References

- [1] ALLEA All European Academies (2017). *The European Code of Conduct for Research Integrity Revised Edition*. Advised on 15-05-2017, from: <https://allea.org/>
- [2] World Health Organization. (2005). Handbook for good clinical research practice (GCP): guidance for implementation.
- [3] RESPECT project. (2004) *Intellectual property*. Advised on 15-05-2017, from: <http://www.respectproject.org/code/clegal.php?id=#2>
- [4] Norwegian National Data Security Entity requirements apply in Norway: <https://www.datatilsynet.no/personvern-pa-ulike-omrader/forskning-helse-og-velferd/leverandorer-og-utviklere-i-helse-og-omsorgssektoren/>
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- [5] Project number AAL-2012-5-033 Project acronym and name: PIA Personal IADL Assistant: http://www.aal-europe.eu/wp-content/uploads/2019/12/Deliverable_3.1_Code_of_Conduct.pdf
- [6] GDPR General Data Protection Regulation: <https://gdpr-info.eu/>
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- [8] LRH, <https://www.admin.ch/opc/fr/classified-compilation/20061313/index.html>
- [9] OClIn, <https://www.admin.ch/opc/fr/classified-compilation/20121176/index.html>



Appendices

A: H2HCare protocol for collecting, storing and sharing privacy sensitive project data

In view of EU regulations, the H2HCare project partners need to properly define how privacy-sensitive project data is collected, stored and shared. This protocol aims to minimize the risk of data breaches and aims to make sure any privacy sensitive data is collected and handled in a correct manner.

With **privacy-sensitive project data** we refer to any information collected or generated in the context of the H2HCare project, which can be linked to an individual who participates in any kind of H2HCare project activities.

In sharing and/or storing any privacy-sensitive project data, the following guidelines will need to be adhered to in the context of the H2HCare project:

END USER PARTNERS (namely: HUG, SN):

- a) **Will gather privacy-sensitive data** according to the Code of Conduct that defines how to collect privacy-sensitive data, specifying the application of the current EU regulation (GDPR). In short, the end-user partners will clarify and explain, in an easy-to-understand way (according to the transparency principle), to the participants the H2HCare project, the partners involved, and their role. **All privacy-sensitive data gathered shall be encrypted and anonymized.** They also will inform the participants about their rights (including access rights, rectification and the right to withdraw. This will also include the right of insights into the log of access and use of the data).
- b) **Will store privacy-sensitive data on a secure location in line with national and EU regulations (GDPR) on data privacy.**
Only people that need to work with personal data will have access to this information.
- c) **Will not share any digital or non-digital files with patients' personal data.**
Privacy-sensitive information will never be sent through email in an unencrypted state. Privacy-sensitive data can **only** be shared with written consent of the participants involved.
- d) **Will be responsible for adhering to local (national) data protection rules.**
The end-user partner will be the "*controller*" of the personal data according to the current EU Regulation. The H2HCare Ethics Manager supervises the "*controllers*" in the participating countries.

ALL PROJECT PARTNERS:

Will have shared access to privacy-sensitive project data in the anonymized form. GDPR applies in all cases.

1. The Code of Conduct is defined on article 40 of regulation (EU) 2016/679 of the European Parliament on the protection of natural persons with regard to the processing of personal data.
2. Controllers as defined on article 24 of regulation (EU) 2016/679 of the European Parliament on the protection of natural persons with regard to the processing of personal data.



SPECIFIC PEOPLE THAT NEED TO KNOW PERSONAL DATA (including formal caregivers, informal caregivers, H2HCare technicians):

- a) Will have access to the H2HCare platform databases only according to the Participants decision.
- b) Will have access to the H2HCare platform databases only using an individual and personal account.
- c) The H2HCare platform databases will be stored on a location which properly adheres to the EU regulations and GDPR on data privacy.

B: End-user participation Consent Declaration

Consent form: H2HCare

The H2HCare system aims to support seniors with heart failure in their transition from acute (hospital) to community (home) care by providing robot-based coaching for helping them to deal with post discharge recommended treatment plan and lifestyle changes.

The H2HCare project is executed under the EU AAL funding scheme. AAL funds cross-national projects that involve small and medium enterprises (SME), research bodies and end-user organizations.

This project is about finding out how the H2HCare system works for you.

Please tick the box below if you agree:

- I have received understandable information about the H2HCare project and the purpose of my participation in the H2HCare project
- I participate voluntarily in the H2HCare project
- I understand that I may, at any time, drop out of the H2HCare project
- I understand that if I drop out of the project, I do not have to express any reason for my decision
- I understand that I will be granted access and with rights to alterations to my personal collected data upon my request
- I understand that I will be granted access to the log files for changes to my collected personal data upon my request
- I understand that all of my personal collected data will be encrypted for safeguarding
- I understand that all of my personal collected data will be anonymized

Please put ticks in the boxes below if you are happy to:

- Use the H2HCare system in laboratory and test settings
- Use the H2HCare system in your home
- Grant access to all of my personal collected data to formal and informal caregivers
- Talk to us about yourself and your experiences of using the H2HCare system
- Allow us to use structured and semi-structured questionnaires to register your usage of the H2HCare system and your opinions of it



- Allow us to look at the computer logs to find out how and when you have been using H2HCare system and its applications
- Allow us to take photographs of you using the H2HCare system
- Allow us to video you using the system and talking about the H2HCare system
- Allow the encrypted and anonymized data to be stored post project for scientific use

Please put ticks in the boxes below if you are happy for anonymous non-confidential information you tell us about you, and what you tell us about your experience with the H2HCare system, along with photographs and video, to be used in:

- reports
- at conferences
- on the web

If you are not happy with any of the points above – please tell us now.

Your name: _____

Your address: _____

Your signature: _____

Today's date: _____

We will not use your whole name or address in any of our publicity. We request these details only for our records.

Signature of H2HCare controller: _____

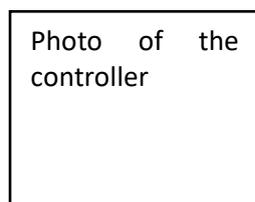


Photo of the controller

For more information speak to
Contact details: