



HAAL

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Ethics/gender and data protection compliance protocol
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1 Executive summary

This deliverable presents the key elements and regulations to take into account regarding ethics, gender and data protection. The first section describes ethics considerations, the second one presents how to address gender issues and the last one identifies data protection regulations to follow. All of the considerations are based on the guidelines as described in the deliverable D1.3 of the HAAL project which is titled ‘Ethical and legal manual’.

List of abbreviations (in order of their frequency)

Abbreviation	Definition
PwD	People with dementia
HAAL	Healthy Ageing Ecosystem for People with Dementia
DP	Deliverable
QoL	Quality of Life
MCI	Mild cognitive impairment
IT	Italy
INRCA	IRCCS Istituto Nazionale di Ricovero e Cura per Anziani
DN	Denmark
NCKU	National Cheng Kung University
NL	Netherlands
TW	Taiwan
WP	Work package
YZU	Yuan Ze University
AI	Artificial Intelligence
GDS	Global Deterioration Scale
ADL	Activities of daily living

2 Ethics

The HAAL project includes several research methods to examine user needs and conduct usability. The research methods include interviews, focus groups, meaningful tryouts, co-creation sessions, usability tests and field test. With respect to ethics and data privacy of the participants during the phases of co-creation, ethical guidelines are taken into account during the research activities affiliated with the HAAL project. The ethical guidelines are described in depth in deliverable D1.3, stating the ethical and legal manual for the project.

2.1 AAL Guidelines

The AAL Programme encourages researchers to aim for ethical excellence, and remind, in their AAL Guidelines [1], that it is not a “nice to have” but a “must have”. The research activities must then be compliant with ethics regulations and standards. The HAAL project coordinator Vilans participated in the AAL webinar on Friday February 12, 2021, on AAL Guidelines for Ethics, Data privacy and Security. All information and knowledge from the guidelines and the webinar are implemented in the HAAL project. Following AAL guidelines, the framework for ethics compliance involved four steps. These steps are illustrated in the picture below :

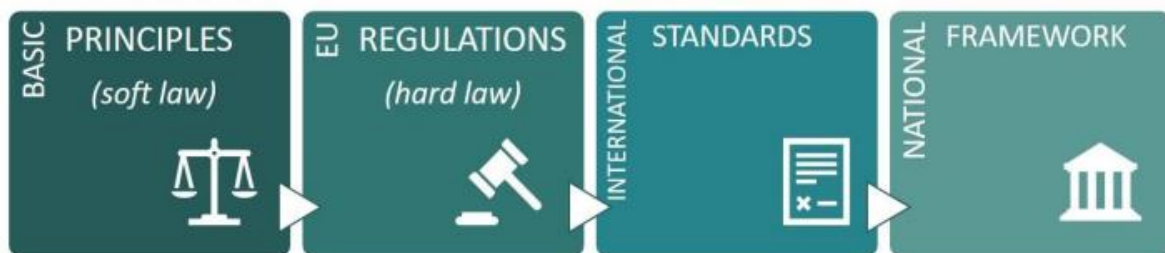


Figure 1: Framework for compliance. Source: AAL Guidelines for Ethics, Data Privacy and Security.

2.1.1 Basic principles

“Fundamental Ethical principles indicate that an intent to do good or provide help must always be the underlying motive for action. However, intent to do good is not sufficient. The potential for good must sufficiently outweigh the potential for harm. This soft law concept includes a series of ethical codes of conduct, texts and principles to guide the protection and respect of the human rights and dignity of human beings, based on 4 principles (beneficence, non-maleficence, autonomy and justice).” Cited from AAL Guidelines for Ethics, Data Privacy and Security [1].

2.1.2 EU Regulations

“This area refers to a set of constructed legal directives and regulations to enforce the protection of any endeavor involving human beings (i.e. Convention of Oviedo) or the data privacy and security (i.e. GDPR General Data Protection Regulation). The European Data Protection concern is not new, it is an ongoing reform process continuously adapting and based on 3 main principles:

- to build on the previous Data Protection Directives since 1995 (95/46/EC),
- to increase transparency and accountability of the data processing,
- to enhance the data protection rights of the individuals.

With the emerging digital age – e.g. big data, Internet of Things, automation/robotics, artificial intelligence, machine learning and blockchain – some very relevant legislation for AAL was approved, as the 2018 General Data Protection Regulation No. 679/2016 (GDPR) and the text currently under discussion: the new EU ePrivacy Regulation, supplementing GDPR for electronic communication of personal data.” Cited from AAL Guidelines for Ethics, Data Privacy and Security [1].

2.1.3 International Standards

“The European Union has established a system of standards and rules for bringing innovation, services and products safely to the market, in full respect of its citizens’ rights and privacy. They directly apply to the functioning and general security measures of the product or service itself, such as the label “CE” or “ISO”, but also concern the privacy and security of personal data. There are some relevant standards to be considered for the AAL community:

- ISO TC314 | Ageing Committees - <https://www.iso.org/committee/6810883.html>
- ISO 82304-2 | Health and wellness apps - <https://www.iso.org/standard/78182.html>

As for CE marking (https://ec.europa.eu/growth/single-market/ce-marking_en), it applies to specific products, indicating that the manufacturer declares compliance of that product with the relevant European product safety legislation. It is, in principle, a self-certification process. Only for a few products it is required to have the product tested and certified by a Notified Body.” Cited from AAL Guidelines for Ethics, Data Privacy and Security [1].

2.1.4 National framework and regional regulations

“After ensuring that a product or service is complying with the different international regulations - and eventually adding value to it by conforming to standards or achieving the CE mark -, it is still necessary to ensure that it also obeys to the national or regional regulations of the countries where it will be used or commercialised. For the development phase this usually implies the need to acquire ethical approval for studies; when going to the market it may be required to have specific authorisation from municipalities, regions or national agencies.” Cited from AAL Guidelines for Ethics, Data Privacy and Security [1].

2.2 Ethical principles

Ethical principles that must be followed during the project are listed and explained in the deliverable D1.3 Ethical and legal manual. These principles are derived from General guidelines for research ethics [2]. Four principles will be followed throughout the HAAL project: 1. Respect; 2. Good consequences; 3. Fairness; 4. Integrity.

2.3 Rights and ethics

2.3.1 Human and fundamental rights

This section describes the human and fundamental rights of European citizens according to European laws that must be guaranteed for all participants involved in the project.

Right to respect for private and family life, European Convention on Human Rights, article 8 [3]

1. Everyone has the right to respect for his private and family life, his home and his correspondence.
2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

Protection of personal data, Charter of Fundamental Rights of the European Union, article 8 [4]

1. Everyone has the right to the protection of personal data concerning him or her.
2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.
3. Compliance with these rules shall be subject to control by an independent authority

Because of the collaboration between European and Taiwanese project partners, also Taiwanese human- and fundamental rights should be incorporated in the guidelines of the HAAL project. Therefore, all partners should also adhere to the following principles:

In Taiwan, the rights of human subjects in research projects are protected according to the Act on Human Subjects Research (Human Subjects Research Act, announced on Dec. 28, 2011 and amended on Jan. 02, 2019) [5]. The Act stipulates that “Human subject research should respect the autonomy of the human subjects, and ensure balance of the risks and benefits from conduct of the research, minimizing invasiveness to the human subjects, and securing equitable distribution of research burdens and results, while protecting human subject’s rights.” (Article 2). In addition, “Research protocol shall obtain the consent of participating research subjects as approved by the ethics review committee.” (Article 12) According to the act, the committee should be set up by the research institute.

2.3.2 Informed consent

The article 3 of the Charter of fundamental rights of the European union [4], specifies the need for “the free and informed consent of the person concerned, according to the procedures laid down by law”. Therefore, for each research being performed in the project, researchers will ensure that each participant receives the necessary information about the research and give its consent. A common template of information sheet and consent form (Annexe 1) were created and shared with all partners. These templates and their content follow the European Commission requirements [5]. The content of the information sheet and the consent form may vary following the type of the research and the different national regulations that may be concerned.

2.3.3 National laws and ethical committee’s approvals

National laws regarding ethics and research were identified for each end-user site and are described in the deliverable D1.3 Ethical and legal manual. Each end-user site will follow and respect their respective national laws.

2.3.3.1 The Netherlands

The national laws that will be respected in the Netherlands are the following:

- The Netherlands Code of Conduct for Academic Practice (2014)
- Code of conduct for research and statistics (Gedragscode voor Onderzoek en Statistiek, 2010)
- Handleiding voor verwerkers van persoonsgegevens: Wet bescherming persoonsgegevens (2002). (Manual for processors of personal data: Data Protection Act) Sauerwein en Linneman. Publisher: Ministerie van Justitie. www.justitie.nl
- Handleiding voor de toetsing van medisch-wetenschappelijk onderzoek met mensen (2002). (Manual for the review of medical research involving human subjects) Publisher: centrale commissie mensgebonden onderzoek (CCMO). Available via www.ccmo.nl
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- Privacy bij wetenschappelijk onderzoek en statistiek. Kader voor gedragscode. Hooghiemstra, 2002. (Privacy in scientific research and statistics.) Available via College Bescherming Persoonsgegevens, www.cpbweb.nl
- Nederlandse Gedragscode Wetenschapsbeoefening (Dutch Academic Integrity VSNU) VSNU: <http://www.vsnu.nl/Media-item/Nederlandse-Gedragscode-Wetenschapsbeoefening.htm>
- Gedragscode voor gebruik van persoonsgegevens in wetenschappelijk onderzoek VSNU: (Code of conduct for use of personal data in research) <http://www.rug.nl/Bureau/expertisecentra/abjz/producten/pdf/gedragscodeWetenschappelijOnderzoekEnPersoonsgegevens.pdf>

Description of national requirements for privacy and data protection

- Wet Bescherming Persoonsgegevens (WBP)
- Richtlijn 95/46/EG (October 24, 1995)
- General Data Protection Regulation (GDPR, Regulation (EU) 2016/679)

2.3.3.2 Italy

The national laws that will be respected in Italy are the following:

- The Italian Legislative Decree 30 June 2003, 196, in compliance with the EU Law.
- The Italian Personal Data Protection Code in compliance with the EU GDPR (as of per May 2018).
- The Criminal Code and the Criminal Procedure Code on the subject of computer crime (Law n. 547, 23th December 1993).
- The issue of transparency, acknowledging the right of access of citizens to administrative institutions and to administrative proceedings, including the use of consultation and active participation action (Law n.150, 7th June 2000).
- The issue of accessibility, intended as the “ability of computer systems, in the manner and to the extent permitted by technological knowledge, to provide services and usable information, without discrimination, even for those who, because of personal disabilities, require assistive technology or special configurations (Legge Stanca, Art. 4, 9 January 2004).
- Public Administration Digital Code” (The Italian Legislative Decree 7 March 2005, n. 82). [6]

2.3.3.3 Taiwan

The national laws that will be respected in Taiwan are the following:

- Human Subjects Research Act, announced on Dec. 28, 2011 and amended on Jan. 02, 2019 [5]

- The Act of Personal Data Protection (National Development Council, 2015) [7].
- The Taiwan Code of Conduct for Research Integrity (2020) [8] [9].
- The Enforcement Rules of the Personal Data Protection Act (National Development Council, 2016) [10].

2.3.4 Ethics committee approval

In respect to ethical approval; ethical committees can be formed in different institutions, with an overarching committee in HAAL and Vilans will take part of the HAAL internal ethical committee and ensure ethical supervision in The Netherlands. Vilans has an expert on human and clinical data management and data protection who is fully aware and authorized to handle the data management plan for the HAAL results. The data manager will supervise the data storage and handling and comply with national and European legislations. In addition, local and/or regional Medical Ethical Committees will be involved for the alpha & beta testing.

3 Gender and minorities

This section describes the importance of considering gender and minorities in research. Its aim is to raise awareness of this issue among the project's partners and to define guidelines to follow. Among the HAAL project, partners will be encouraged to follow Responsible Research & Innovation (RRI) guidelines regarding gender issues [11]. More precisely, HAAL project will follow the advices described in the *Toolkit for Gender in EU-funded research* [12].

3.1 Gender in research

For the European Commission, when applying strategies to promote gender in research, three advices should be taken into account:

1. “Women’s participation in science and research must be encouraged;
2. Research must address women’s needs as well as men’s;
3. There should be research on the gender question itself, to enhance understanding of gender issues in science and research.” [12]

Concretely, to respect gender in research, specific actions should be performed by all project partners, as described below.

3.2 Women’s participation in research

To encourage women’s participation in research it’s then necessary to involve female researchers in working teams and at all levels. It is well known that all around the world, the women gender is less prevalent in the higher positions of the academic field. To cope with gender inequality in the research field, a stronger effort should be place when recruiting [12].

HAAL partners then engage to encourage equal participation of men and women workers in the research teams.

3.3 Gender and minorities dimensions of research

Gender in research is also concerned when addressing the gender dimension of research. Gender should be considered as an entire variable, by assessing the potential gender issues and consequences in the specific research field.

Some gender-specific issues could emerged and should be identified, specifically in health research and healthy ageing. Indeed, studies show that one factor of health inequality and disparities is the gender inequality [13]. Several gender disparities have been identified such as the risk for senior women to be more prone to poverty and isolation [14] and a shorter life expectancy for women [15] due to a higher exposition of chronic illness, cardiovascular disease and mental illnesses [16][17].

Studies show that it is important to consider the different gender and minorities, to ensure quality and generalizability of the results as they may have differences in cultural influences and biological variables [18].

The national institute of health of the United States of America, emphasizes the need to understand how gender may influence the research questions and the research findings [19]. They formulate several advices to guide researchers:

1. Perform a literature review to assess if and how the gender dimensions may affect the research question
2. Take into account the gender of the participants when analyzing the results
3. Report if gender has an influence, or not, on the results

To consider minorities in research, such as transgender and gender nonconforming people but also lesbian, gay and bisexual people, guidelines have been developed by the American Psychological Association to guide researchers [20][21]. If some participants being part of the minorities category are involved in the HAAL project, researchers will be advised to read these two guidelines cited above. These guidelines will help to understand the specificities of these minorities, to know if and how some specific attitudes should be adopted and if some research questions should be further investigated.

To summarize, gender and minorities dimensions can have an influence on health outcome, our findings and can create health disparities. Among the HAAL project, gender variables will be taken into account to explain how the developed solutions meet both men and women needs or expectancies, that may be different. The gender variable could also explain potential differences on the use of the HAAL solution and variables outcomes that are related to health or well-being such as the quality of life for example. Among HAAL project, a specific effort will then be made during the recruitment to involve an equitable number of men and women participants.

4 Privacy and data protection

Regarding data protection, the following national and European laws in force will be respected among the HAAL project:

- Wet Bescherming Persoonsgegevens (WBP) [22].
- General Data Protection Regulation (GDPR, Regulation (EU) 2016/679) [23].
- Act of Personal Data Protection (National Development Council, 2015) [7]

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- The Enforcement Rules of the Personal Data Protection Act (National Development Council, 2016) [10].

4.1 Protocol for collecting, storing and sharing data

This protocol aims to define how personal data will be collected, stored and shared, to make sure that EU regulations are followed and that data are collected and handled in a correct manner. The following guidelines will have to be followed by each partner:

- All the collected data and the results will be anonymized
- Information that contains personal data should be kept confidential, encrypted and not shared outside the group in charge for collecting the data
- Data will be stored on a secure location in line with EU and national regulations
- Data can only be shared among partners in the project with written consent of the participants involved
- Each end-user partner will act as the “controller” of the data they are collecting, according to the EU and national regulations
- The HAAL dashboard must guarantee full confidentiality for personal information at all stage of the R&D process

5 References

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- [4] https://www.europarl.europa.eu/charter/pdf/text_en.pdf
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