Deliverable 2.4

CleverGuard Ethics Manual

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Abstract

D 2.4 “Ethics Manual” serves to guide the actions of our members consistent with our Consortium values. The Code will serve as a common direction and ethical protocol for all end user organisations helping the Consortium to comply with the ethical principles, standards, national laws in the pilot sites and the existing European Regulations (cite GDPR?) .

What is new in this Version

This is the second version of the CleverGuard Ethics Manual, a major revision of the prior version. AAL guidelines were taken into account.

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Version	Date	Changes	Organization
0.1	Apr 21	Initial Creation	HSLU
1.0	July 21	First release	ICA
2.0	Jan 23	Second release	ICA

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Content

1 Introduction and Scope

This Ethics Manual serves as a comprehensive guide for the CleverGuard R&D Consortium in the ethical development and deployment of the NILM-based application. It outlines the principles, practices, and standards that must be adhered to by all consortium members to ensure the project's alignment with ethical considerations. The Code of Ethics created by the Consortium thus, constitutes the general ethical framework and the common ground for developers and end-users organizations to guide their actions during the project. While the Code cannot answer every question, it can show you where to go for guidance when the answer is not clear.

This manual applies to all members of the CG R&D Consortium, including researchers, developers, project managers, and any other stakeholders involved in the development of the NILM-based application. It covers ethical considerations from the initial stages of research to the deployment and ongoing use of the application.

1.1 Why do we have a Code, and why must we follow it?

Complying with our Code is about creating an open and honest environment where we can achieve our best work legally and with integrity ensuring the honesty, truthfulness and earnestness of our actions . Whenever we become aware of a violation of the Code, Consortium policy or the law, we will act to address the problem and prevent future occurrences. Depending on the circumstances, corrective and preventive steps might include training, counselling and disciplinary actions up to and including termination of partnership.

1.2 Inclusive Decision-Making

Inclusive decision-making is fundamental to the ethical development of the NILM-based application. All decisions within the consortium should involve input from diverse perspectives, taking into account the expertise of researchers, developers, caregivers, and end-users. Regular meetings and forums will be conducted to encourage open dialogue and collaborative decision-making.

1.3 Transparent Communication

Transparency is paramount in maintaining ethical standards. Consortium members are expected to communicate openly about project goals, methodologies, potential risks, and ethical considerations. Any potential conflicts of interest or ethical concerns should be promptly communicated to the consortium for discussion and resolution.

1.4 Interdisciplinary Collaboration

The development of the NILM-based application requires collaboration across various disciplines, including technology, healthcare, and social sciences. Interdisciplinary teams will be formed to ensure a holistic approach to ethical

considerations, incorporating insights from diverse fields to address complex issues associated with the project.

1.5 How to make the right decision

Doing what is right is our goal. If the right thing to do is not clear, we will ask ourselves:

- Is it consistent with our Code?
- Is it legal?
- Does it follow our policies?
- Does it benefit the Consortium as a whole – not just a certain individual or group?
- Would I be comfortable if my actions were made public?

If you can answer "YES" to all of these questions, the action is probably okay. But any "no" or even "maybe" answers are a signal to stop and get advice or ask questions. .

1.6 Who must follow the Code?

It does not matter where you work or what you do for the Consortium – you have a responsibility to use good judgement and follow our Code. That includes every full-time or part-time contributor at every level of the Consortium.
People managers have additional responsibilities to serve as a positive role model in every respect and to help people review, understand and apply the Code.

1.7 Continuous Ethical Evaluation

Ethical considerations is continuously evaluated throughout the project's life-cycle. Regular ethical reviews will be conducted during regular project meetings to assess the impact of project activities on end-users, caregivers, and other stakeholders. This ongoing dynamic evaluation process will allow the consortium to adapt and implement changes to address emerging ethical concerns.

1.8 Every member's responsibility

To fulfil our responsibilities and maintain and enhance our culture and reputation, we rely on our people to help enforce the Code. We thus believe it's every collaborators' responsibility to signal whether they recognized any potential violations to Code, or in case they think think an activity or behaviour could lead to a violation.

1.9 Reporting Concerns

Consortium members have the responsibility to raise concerns in situations n that they believe may violate or lead to a violation of the Code, Consortium policy or the law or in case they are aware of any potential threats to the Code.

Maybe the consortium members sense that something is not right at work, or you saw something or heard about an act that may violate our Code, our policies or the law. If so, the person has a responsibility to share her concerns by reporting right away – even if she is not sure that a Code violation has occurred. When someone reports concerns, the person helps the consortium handle issues properly, fix problems before they occur and remedy situations that have already happened. It helps build trust with each other and with other stakeholders.

CleverGuard require compliance with the law, as well as ethical conduct. If someone feel sthese standards have not been met, need access to policies, or have any questions, please ask for guidance or voice concerns by contacting any of the following resources:

- info@cleverguard.care
- CLEVERGUARD c/o CLEMAP AG, Lavaterstrasse 66, 8002 Zürich, Switzerland

2 General Principles

The Code of Ethics is based on a number of General Principles that express the basic tenets of ethical and professional behaviour and conduct. Observance of these General Principles is central to the public interest.

2.1 Co-Creation and Participatory Design

The principles of co-creation and participatory design is integral to the development of the NILM-based application. End-users, especially seniors living alone, will actively participate in the design process, ensuring that the application meets their needs, preferences, and expectations. Workshops, focus groups, and usability testing sessions will be conducted to facilitate user involvement.

2.2 Informed Consent and Privacy

Prior to their involvement in the project, users will be provided with detailed information about the purpose, scope, and potential risks of the NILM-based application. Informed consent will be obtained from all participants, and their privacy will be rigorously protected throughout the project. Data anonymization and encryption protocols will be implemented to safeguard user information.

2.3 Accessibility and Inclusivity

The application will be designed to be accessible and inclusive to users with diverse abilities and needs. Consortium members will adhere to the accessibility requirements outlined in EN 301 549 to ensure that the application is usable by individuals with varying levels of physical and cognitive abilities.

3 Ethical Issues and Risk Management

3.1 Identifying Ethical Issues

The consortium will actively identify potential ethical issues associated with the development and deployment of the NILM-based application. This includes but is not limited to, issues related to data privacy, user autonomy, and potential societal impacts. A designated ethics committee will be responsible for monitoring and addressing these issues.

3.2 Risk Assessment and Mitigation

A comprehensive risk assessment is conducted to identify potential risks associated with the project. This assessment is covering ethical, technological, and social risks. Mitigation strategies will be developed to address these risks, and the consortium will implement necessary changes to minimize potential harm.

3.3 Continuous Monitoring and Adaptation

The project's risk management plan includes continuous monitoring mechanisms to ensure that the identified risks and ethical considerations are addressed in real-time. The consortium will remain adaptable, ready to implement changes based on ongoing assessments and external feedback.

4 Respecting Autonomy, Right to Choose, and Dignity

4.1 Empowering User Autonomy

The NILM-based application will be designed to empower user autonomy. Users will have the option to customize their preferences, set notification thresholds, and control the level of information shared with caregivers. The consortium is committed to respecting the autonomy of seniors living alone while providing them with tools for enhanced safety and well-being.

4.2 Informed Decision-Making

Consistent with the principles of informed consent, users will be provided with accurate and comprehensible information to facilitate informed decision-making. This includes information about the application's functionalities, potential benefits, and any associated risks. The consortium will actively engage with users to address any questions or concerns they may have.

4.3 Cultural Sensitivity and Respect for Dignity

The consortium recognizes the importance of cultural sensitivity and will ensure that the NILM-based application respects the cultural backgrounds and values of users. The application's interface, communication methods, and notifications will be designed with cultural diversity in mind, fostering an environment that respects the dignity of each individual.

5 Ethical Dialogue

5.1 Open Channels of Communication

Open communication is essential for addressing ethical concerns effectively. Consortium members are encouraged to actively communicate and express any ethical concerns or insights they may have. Regular meetings, both formal and informal, will be conducted to facilitate an open dialogue among team members, ensuring that ethical considerations are woven into the fabric of the project.

5.2 Stakeholder Involvement

Stakeholder involvement is crucial to understanding diverse perspectives and potential impacts. The consortium will actively engage with stakeholders, including caregivers, healthcare professionals, and representatives from relevant communities, to gain insights into their unique ethical considerations. This involvement will be instrumental in shaping ethical decisions and ensuring the project's alignment with societal expectations.

5.3 Regular Ethical Reviews and Discussions

Ethical reviews are conducted at the regular project meetings to evaluate the project's ethical standing. These reviews will involve the project board, stakeholders, and external experts, when necessary. Ethical discussions will be scheduled to address emerging ethical concerns, assess the impact of project activities, and make any necessary adjustments to ethical guidelines and practices.

6 Compliance with AAL Guidelines for Ethics

6.1 Alignment with AAL Ethical Standards

The project will adhere to the ethical standards outlined by the AAL Guidelines for Ethics. Consortium members are expected to familiarize themselves with these guidelines and ensure that the project's ethical framework aligns with and complements the principles set forth by AAL.

6.2 Integration of AAL Principles into Development

AAL principles are integrated into the development process to ensure that the NILM-based application not only meets ethical standards, but also aligns with the broader goals and values of AAL. The consortium will actively seek opportunities to contribute to the advancement of AAL ethical guidelines and participate in collaborative efforts within the AAL community.

6.3 Ethical Review Board Engagement

In case of an arising ethical issue, an external ethical review board will be engaged to provide independent oversight and validation of the project's ethical practices. The review board will assess the project's adherence to AAL ethical guidelines, provide

recommendations, and ensure that ethical considerations are robustly integrated into the project's development and deployment.

7 Data Privacy and Security

7.1 Adherence to Data Protection Regulations

Consortium members will adhere to local and international data protection regulations, including GDPR and other relevant laws. Data protection will be a priority throughout the project, and the consortium will implement measures to ensure the lawful and ethical handling of user data.

7.2 Secure Data Handling and Storage

Protocols for secure data handling and storage will be implemented to safeguard user information. This includes encryption methods, access controls, and secure storage practices. Consortium members will regularly review and update these protocols to address evolving security threats.

7.3 User Consent and Control over Data

User consent will be obtained transparently, and users will have control over their data. The consortium will provide clear information about data collection, processing, and storage practices. Users will have the option to modify their consent preferences and exercise control over the sharing of their data with caregivers or other parties.

8 Adherence to standards

The consortium members are familiarizing with the following standards, and wherever appropriate and applicable they adhere to them.

8.1 ISO TC314 Ageing Societies

ISO TC314 focuses on standardizing aspects related to ageing societies. It provides guidelines to address the challenges and opportunities associated with an ageing population.

The consortium will align with ISO TC314 by integrating principles that consider the unique needs and preferences of seniors living alone. The development process will incorporate features that enhance the quality of life for older adults, recognizing the diversity within this demographic.

The consortium will actively engage with experts in gerontology, healthcare professionals, and representatives from relevant communities to ensure that the application caters to the holistic well-being of seniors in an ageing society.

8.2 EN 301 549 Accessibility Requirements for ICT Products and Services

EN 301 549 outlines accessibility requirements for Information and Communication Technology (ICT) products and services. It aims to make technology accessible to users with diverse abilities.

The consortium will respect EN 301 549 to ensure that the NILM-based application is accessible to users with varying levels of physical and cognitive abilities. This includes the design of user interfaces, navigation, and overall usability.

Usability testing will be conducted with individuals representing a diverse range of abilities to identify and address accessibility challenges. Regular accessibility audits will be performed to maintain compliance with the standard.

8.3 CEN-ISO/TS 82304-2:2021 Health and Wellness Apps – Quality and Reliability

CEN-ISO/TS 82304-2 focuses on quality and reliability in health and wellness apps, providing guidelines for ensuring the effectiveness and safety of such applications.

The consortium will take as a guidance the CEN-ISO/TS 82304-2 by integrating quality assurance measures throughout the development life-cycle. This includes rigorous testing, validation, and adherence to industry best practices for health and wellness apps.

The application's functionalities will be designed to enhance the health and wellness of seniors living alone, with a focus on reliability, accuracy, and user-friendly interfaces. Regular assessments will be conducted to verify compliance with the standard.

8.4 Medical device standards

The consortium is aware that the NILM-based application might not be considered as a medical device software at the moment, therefore adhering to the processes outlined in IEC 62304 might only be considered at a later stage.

8.4.1 IEC 62304:2006 Medical Device Software – Software Life-cycle Processes

IEC 62304 outlines the software life-cycle processes for medical device software, providing a framework for the development, maintenance, and risk management of such software.

The consortium is aware that the NILM-based application might not be considered as a medical device software at the moment in accordance to deliverable 6.2, therefore adhering to the processes outlined in IEC 62304 might only be considered at a later

stage. This includes the establishment of a comprehensive software development life-cycle, risk management procedures, and documentation standards.

An emphasis will be placed on risk management, including the identification and mitigation of potential risks associated with the application. The consortium will ensure that the software development life-cycle aligns with the specified processes to guarantee the safety and efficacy of the application.

8.4.2 IEC 62366-1:2015 Medical Devices – Application of Usability Engineering to Medical Devices

IEC 62366-1 provides guidelines for the application of usability engineering to medical devices, emphasizing the importance of user-centred design.

The consortium will be familiarized and respect the IEC 62366-1 by prioritizing user-centred design principles in the development of the NILM-based application. This includes user testing, feedback collection, and iterative design processes.

Usability engineering will be a continuous focus throughout the development, ensuring that the application is intuitive and easy to use for seniors living alone. User feedback will be actively sought and incorporated into design iterations.

8.4.3 ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes

ISO 13485 outlines requirements for quality management systems specific to the design and manufacturing of medical devices.

The consortium will be familiarized and respect ISO 13485 by implementing a robust quality management system tailored to the development of the NILM-based application. This includes procedures for design control, risk management, and post-market surveillance.

Quality management will be an integral part of the development process, ensuring that the application meets regulatory requirements and industry standards. Regular audits and assessments will be conducted to maintain compliance.

8.4.4 ISO 14971:2019 Medical Devices – Application of Risk Management to Medical Devices

ISO 14971 outlines the application of risk management to medical devices, providing a framework for identifying, evaluating, and mitigating risks associated with medical devices.

The consortium will consider ISO 14971 by implementing a comprehensive risk management process for the NILM-based application. This includes the identification

of potential risks, assessment of their impact, and the implementation of risk mitigation strategies.

A risk management plan will be developed and regularly updated throughout the project's life-cycle. The consortium will actively engage with stakeholders to gather insights into potential risks and to ensure a thorough risk assessment.

8.4.5 ISO 14155:2020 Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice

ISO 14155 provides guidelines for the conduct of clinical investigations of medical devices for human subjects, emphasizing good clinical practice.

While the NILM-based application may not undergo traditional clinical trials, the consortium will adhere to the principles of good clinical practice outlined in ISO 14155 to ensure the ethical and responsible deployment of the application.

Ethical considerations and user safety will be prioritized throughout the application's deployment. The consortium will consider user feedback, monitor the application's performance, and address any emerging concerns promptly.

8.5 ISO/IEC 27001:2022 – Information Security Management

ISO/IEC 27001 provides a framework for information security management, ensuring the confidentiality, integrity, and availability of information.

The consortium will adhere to ISO/IEC 27001 by implementing information security management practices for the NILM-based application. This includes data encryption, access controls, and regular security audits.

Data privacy and security will be paramount. The consortium will regularly update security protocols to address emerging threats and vulnerabilities. User data will be handled with the utmost care, and measures will be in place to prevent unauthorized access.

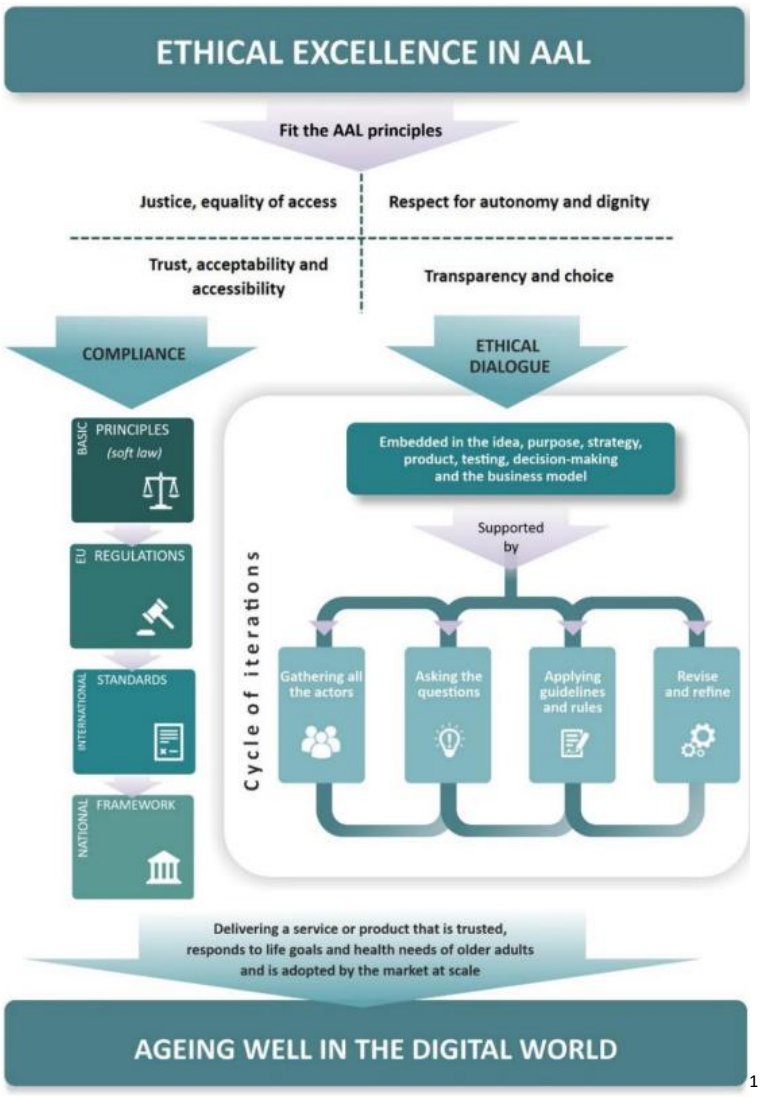
9 Confidentality

The responsibility of respecting privacy applies to CleverGuard members in a particularly profound way. Our technology requires the collection, monitoring, and exchange of personal information constantly, quickly and inexpensively. Therefore, a member should become conversant in the various definitions and forms of privacy and should understand the rights and responsibilities associated with the collection and use of personal information.

We protect and take measures to safeguard the confidential and personal information that we hold, collecting and handling it in compliance with applicable laws, professional obligations, and our own data management policies and practices.

Members should only use personal information for legitimate ends and without violating the rights of individuals and groups. This requires taking precautions to prevent re-identification of anonymized data or unauthorized data collection, ensuring the accuracy of data, understanding the provenance of the data, and protecting it from unauthorized access and accidental disclosure.

Only the minimum amount of personal information necessary should be collected in a system. . Personal information gathered for a specific purpose should not be used for other purposes without the person's consent. Merged data collections can compromise privacy features present in the original collections. Therefore, computing professionals should take special care for privacy when merging data collections.



[1]

[1] http://www.aal-europe.eu/aal-guidelines-for-ethics-data-privacy-and-security/

10 Summary

These principles are to be observed by CleverGuard members at all times. The Code of Ethics is intended to provide guidance to help resolve ethical dilemmas that are likely to be confronted within the course of their employment with CleverGuard. The issues listed in the Code are not exhaustive and do not seek to envisage every potential ethical dilemma. For more information contact info@cleverguard.care.