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IOANNA

Integration Of All stores Network & Navigation Assistant

D2.4 Ethical & legal issues

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¹ L = Legal agreement, O = Other, P = Plan, PR = Prototype, R = Report, U = User scenario

² PU = Public, PP = Restricted to other programme participants (including the Commission Services), RE = Restricted to a group specified by the consortium (including the Commission Services), CO = Confidential, only for members of the consortium (including the Commission Services)



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Summary

As the IOANNA application is addressing to elderly people, despite the legal obligation, it is more than essential to keep a high moral standard and code throughout the project for the users of every role being involved to the pilots and afterwards for the users of the IOANNA application. Therefore the IOANNA consortium pays high attention to the implementation of legal and ethical issues.

The Ethical Board will reassure that the procedures taken place in every stage of the project will be consistence with the GDPR and the ethical aspect of the matters that may have to confront. The IOANNA application will integrate the latest technology concerning data protection, security and privacy, confidentiality, anonymity and other relevant matters, under the supervision of the Ethical Board, so as to ensure that the GDPR and the European directives are followed.

During each user study an informed consent form will be presented to the participants. It will describe the objectives of the study, the means of handling private data, information and the associated risks, if any. It will be explained to the participants that they can withdraw at any point from the study (i.e. exit rights and self-determination). If the participants agree with the terms of the informed consent, they will be asked to sign the form. The participants will also be made aware of all information that is collected, stored and processed during the pilot applications, user studies and system design. They will have the right to refuse the use of information; the one judged as private or sensitive. In addition, the project researchers will carefully explain the objectives of the study to the participants, to clarify what is expected from them and what the future technology will be used for.



Abbreviations

D	Deliverable
WP	Work Package
AAL	Ambient Assisted Living



1. Introduction

“What good are empty laws without morality” or in a poetic version “Of what use are the laws, inoperative through public immortality?”

[Lat., Quid leges sine moribus Vanæ proficient?]

Horace - **Quintus Horatius Flaccus** (65 BC – 8 BC), [known in the English-speaking world as **Horace** (leading Roman lyric poet during the time of Augustus (also known as Octavian)]

1.1 Scope & Objectives of this deliverable

IOANNA offers a modern, synchronous, integrated solution that combines various services that can be found in different applications, coupled with some additional innovative ones, into one platform.

Considering users requirements, from Task 2.2, IOANNA platform aims at putting together already successful projects that for various reasons did not hit the market or did not fully unfold their potentials yet. In addition the platform will develop supplementary parts, providing a single product that will get incorporated to everyday life, be intuitively useful, personalized, and take into consideration the life span dimension.

The scope and the objectives of the deliverable D3.1 “Ethical and Legal Issues aims to ensure that the involvement of users, vulnerable or not, is done in a way that the physical, psychological and social safety but also wellbeing of the participants are always the first priority. In addition, attention will be paid to the ethical dimensions of the creation, setup and implementation of the participatory design process and field trials.

The project will consider all relevant ethical issues involved during project lifetime, will be compliant with the fundamental ethical principles in the use of personal data and in the involvement of older adults in the testing activity. Particularly, **IOANNA** project will consider the:

- **Charter of Fundamental Rights of the European Union (EU)**. The Charter introduces general ethical principles as fundamental rights in Europe, such as protection of human dignity and human life, protection of personal data and privacy as well as the environment; and in accordance with community law and international as well as national conventions. Furthermore, national ethics boards will be consulted, especially the countries, namely Slovenia and Spain, where pilot application will take place.



- **International Bill of Human Rights** (the Universal Declaration of Human Rights, Adopted in 1948 and the International Covenant on Civil and Political Rights, 1966).
- International and National regulation for medical purposes, such as **Declaration of Helsinki and Ethical Principles for Medical Research** involving Human Subjects by the World Medical Association.
- **International Code of Medical Ethics** or **Directive 2001/20/EC** on Good Clinical Practice.
- **European Data Protection legislation (Directive 95/46/EC)**, the related legislation of the participating partners' Member States.
- **EU Directive on Privacy and Electronic Communications** (2002/58/EC amended by Directive 2009/136).

1.2 Structure of the Deliverable

The deliverable is structured as follows:

- Introduction
- EU regulation & directives – GDPR
- Data protection
- Ethical issues
- Establishment of Ethical Board
- Conclusion
- Appendix

2. IOANNA - Guidance to Privacy Protection and Confidentiality

2.1 Security and Privacy Issues - Privacy Protection and Confidentiality

In the certain section, security and privacy issues are analysed, from a technical aspect. It describes the techniques and means, as well as the domains and the components that the architecture and design of IOANNA has taken into consideration, concerning the specific matters and its achievement, while developing the mobile application along with the platform.

- **Security**

At least, there are five critical security requirements that need to be satisfied:



- *Authentication*, the method with which an entity is uniquely identified, and its identity verified.
- *Integrity*, the method that ensures that every system, resource, file and information in general can be modified only by authorized entities.
- *Confidentiality*, the method by which access to the content of information is available only to authorized recipients.
- *Non-repudiation*, the method that produces cryptographic data that ensure that an entity cannot repudiate its actions.
- *Availability*, the method that ensures that a system can fulfil its purpose with a given degree of success.

IOANNA platform will satisfy the security requirements by using the set of security mechanisms and a set of security services. Security mechanisms are stand-alone instances of components that are directly embedded within an enterprise platform service, addressing a security requirement based on a policy. Security services on the other hand, are independent services within an architecture that are available to any enterprise service wishing to perform a security goal as part of a policy. Security services integrate security mechanisms and in our case in IOANNA platform will interact with other security services as part of their operation. Security mechanisms will also interact with security services to send and receive information.

- **Privacy**

Privacy in massively inter-connected environments and its social acceptance from end-users require totally novel approaches to identity and manage privacy issues. These must adopt trustworthy interfaces, considering multiple requirements (e.g. anonymity, pseudonymity, link-ability / unlink-ability) and data protection regulations in place, enabling:

- End-users to administrate and control their identities on their own, and easily e-access advanced business services
- Organizations to harmonize their authentication / authorization procedures, enhancing the majority of their infrastructures by easily plug-in them to a core Identity & Access Control Management (IAM) system and to effectively secure and manage their enterprises.

We believe that a synchronous approach such as IOANNA should recognize the need for broader e-solutions, in which the notion of federation is expanded, and the relationship of each user with the framework is established, guaranteed and monitored by a trusted third entity. A user-centric and federated solution will allow for clean separation between each service and the associated authentication and authorization procedures required.



- **Disclaimer Information**

One of the measures that IOANNA will implement, in order to be in accordance with the recommendation of GDPR, is related to the use of Disclaimers for the use of cookies. The disclaimer will inform and explain the use of the cookies and the way that the gathered information is processed. Additionally, it will provide the right of the certain choice to the end user. *“Only the GDPR is liable to create rights and obligations for individuals”, as mentioned at the “Rules for Business and Organisation”, regarding the Data Protection.*

2.2 EU regulation & directives – GDPR

2.2.1 Data Protection

According to the GDPR rules, the project team should be aware when processing personal data relating to an individual. The responsibility to guarantee for the GDPR to be applied, burdens the national administrations, which will support regional and local administration, respectively.

Most of the personal data held is usually processed on the basis of a legal obligation or insofar as it is necessary to perform tasks carried out in the public interest or in the exercise of official authority vested in it.

The following principles have to be considered and respected, when personal data are processed by a private and public administration:

- fair and lawful processing;
- purpose limitation;
- data minimization and data retention.

The law should be the guardian and the trustee of the above principles (e.g. the types of data, storage period and appropriate safeguards). Moreover, the individuals must be informed about the processing, such as its purposes, the types of data collected, the recipients, along with their data protection rights and consent before the action.

In the future, when IOANNA will be functioning within the frame of a national or international limits, according to the GDPR, it will be required to appoint a Data Protection Officer (DPO) to ensure the implemented measures for the protection of the personal data.



2.2.2 Data collection, processing, storage

According to the GDPR, the type and amount of personal data an organisation may process depends on the reason for processing it and the intended use. Moreover, when the key rules processing data are transparency, to be collected for a specific reason, to collect only data which fulfill a specific purpose, to be stored for the necessary period of time, and have appropriate technical and organizational safeguards.

Therefore, the project team will collect data from the participants during the different testing phases in order to gather their feedback on the iterative presented or used. Some personal data will be gathered such as full name, gender, age and country/town. The personal data will be collected to have information on the characteristics of the participants involved during the different phases of the project and observe any potential trends or differences between the participants. The purpose of the data collection will be disclosed to the participants and among other vital information related to the personal data of the participants, thorough information will be provided for data processing and storage.

In particular, the project team will use the data only for the purpose of the project, in particular, for the improvement of the IOANNA app as well as for dissemination purposes, such as publishing scientific articles. However, the identity of the participants will be secured as the participants' feedback as well as other information gathered will be anonymized and only the researchers who conduct the trials and have direct contact with the participants will have access to the participants' personal data. In regards to technical implementations for safeguarding the anonymity of the participants, each participant will be able to register with their e-mail during the trials without revealing their identity. Moreover, the personal data gathered will be stored for 5 years after the project ends, in case of an audit/check/inspection and after that it will be destroyed. All personal data will also be deleted in case the participant wants to withdraw their participation

2.2.3 Information provided to participants

During the recruitment process of participants, a presentation will be given to the participants with general information on IOANNA project, among other topics the presentation will include the overall scope of the project, the most important activities related to the involvement of participants and the expected results and impact. Each potential older person who is interested to participate in the field trials will be provided with a project leaflet which includes information about the participants' involvement (Annex 2). The older people who are willing to take part in the testing phases will receive an informed consent (Annex 1) which includes information about the project, their involvement and their rights, such as right of withdrawal, as well as information about the data processing.

2.3 Ethical Issues

For handling the ethical issues that may arise during the trials, an Ethical Board (EB) is appointed from three project partners, one from each end-user organisation (ANA and Agecare) and one from the responsible partner of the task, SLRO. The EB will



supervise and monitor the project activities with a focus on the trials so as to ensure that the implementation of the trials is aligned with GDPR regulation and the participants' rights are safeguarded. Moreover, the EB will also provide consultation to the end-user partners when needed on how to handle potential ethical issues that may arise as well as preventive actions which can be taken by the end-user organisations.

For this reason, the EB members:

1. have the underlying practical knowledge
2. in case a legal issue arise then the EB will receive legal advice (external consulting)
3. have access to information about implementation of project activities
4. partners have obligation to inform the Committee about the issues that happened;
5. reporting to the General Assembly

2.3.1 Establishment of Ethical Board

IOANNA consortium puts considerable emphasis on ethical and privacy issues. The EB will be dedicated to supervise all project ethical issues. The technology and services to be developed will support autonomy and dignity with respect to the end-users; our vision is to develop the technology in close cooperation with the end-users.

During the 3rd consortium meeting in Bilbao (9th of April 2019), the Ethical Board was defined, which consists of Aggeliki Tsakiri (SLRO, leader), Marina Polycarpou (AgeCare), Mircea Marzan (Ana). The EB will be responsible for ensuring that the research performed in the project conforms to European, national and institutional codes of ethics and legislation. One of the aims of the EB will be to ensure that researchers' interactions with end users are ethical and that the best practice of ethical management has been applied.

2.3.2 Ethical declaration table

The ethical declaration table below has the purpose to provide an overview of the relevant information and suit the special needs of the Ambient Assisted Living paradigm.

Ethics declaration of proposals in the AAL Programme	Described on paragraph
• How is the issue of informed consent handled	3.4
• What procedures does the proposal have to preserve the dignity, autonomy and values (human and professional) of the end-users?	3.4
• If the proposal includes informal carers (e.g. relatives, friends or volunteers) in the project or in the planned service-model - what procedures exist for dealing with ethical issues in this relationship?	3.4



• If the proposal includes technology-enabled concepts for confidential communication between the older person and informal and formal carers, service providers and authorities – what procedures are planned for safeguarding the right to privacy, self-determination and other ethical issues in this communication?	N/A
• What "exit" strategy for the end-users involved in the project?	2.5
• How are the ethical dimensions of the solution targeted taken into account? (Brief description of distributive ethics, sustainability et.al.)	N/A



3. Conclusion

The application itself is aimed at a very sensitive target group, the seniors, for the sensitive matter of not feeling and being excluded from the social life, by activating them to participate and encourage them to be more functional and independent in everyday life, with the help of technology. In spite of the businesses' profit, its purpose of the idea's birth was not limited to, neither activated by that. It was generated from the need to enhance the quality of life of the elderly within the society, with small things. In this case with the help of the technology, through the IOANNA application, so as to proceed, step by step to a mild adjustment. A strong motive, deriving from a sensitive and human angle and perception of the reality for people as ageing.

From a legal aspect, companies now are obliged to adhere and be compliant with the GDPR. Therefore, the consortium and more specific, the technical partners are implementing all the necessary technological measures, in order to ensure the security and the protection of privacy, for the personal data and the sensitive information of the applications' end users. The way the above are accomplished, is by embedding it at the application's development, in order to be automated within the mechanism of the programme's procedures and not as work that has to be done by an external user.

On the other hand, there is one more component, equally significant with the legal component. The ethical issue, which is more difficult to be strictly framed, for the rules are general and in circumstances, different matters must be taken into consideration.

The ethical dimension is of high priority within the consortium's perspective and awareness, depicted also in the existence of the Ethical Board in order to defend it and reinforce it. Especially, the companies that are liable for conducting the pilot proceedings, bear the responsibility of ensuring the formality and the legality of the procedures. It will be applied to the groups of elderly participating the pilot at the certain stage of the project's process, explaining the scope of the IOANNA application. Such procedures are the signing of the relevant consent form by the users, to clarify the reasons of the pilot testing, to ensure the respect shown at the users, to be properly informed of their rights, the mild behavior from the people that will approach the users, the patience for a comprehensive explanation and analysis until it is being understood as a whole.

The consortium will continue to do its best to safeguard the legal and ethical issues that may arise and to ensure that is working in accordance with the standards that have been set throughout the completion of the project and after that within the functionality of the application.



4. References

https://ec.europa.eu/info/law/law-topic/data-protection_en

5. Appendix

5.1 Annex 1: Informed consent

I. INTRODUCTION

You have been invited to take part in a research study of the *IOANNA* project. Before making a decision on whether you want to participate or not, please read this document carefully. Please ask all the questions you may have so you can be completely sure that you understand the scope and procedure of the study. You may take a copy of this consent to think about it or talk to your family and friends before making any decision. At all times, we assure the compliance to the current legislation.

II. PURPOSE OF THE STUDY/PROJECT

IOANNA project's main objective is to provide further support on the assistive mobility and social engagement of people over the age of 55 years old, as well as, other citizens which will be achieved through the provision of gathering a number of services in one platform that is called *IOANNA* application. More specifically, *IOANNA* project aims to offer the following services in a user friendly environment for older people:

- 1) Searching engine for commercial offers, stores, stores categories, and specific products of services near the user's location.
- 2) Opportunities for community service in paid or volunteer basis for experienced senior adults or other citizens
- 3) Navigation system aiding senior adults or other citizens to get to their destination with the most convenient way having the option to activate MyCare, so that the senior adult has a more protected support.

We aim to develop an easy to use, intuitive interface in familiar devices and to offer you the means and support to stay active and independent and to keep your habits. The *IOANNA* application will also provide safety for outdoor activities and acts as an emergency system when necessary.

Your family members who care for you and support you in your daily tasks, when needed, will have access to *IOANNA* application in order to ensure that they can help you, if needed.



III. PARTICIPANTS IN THE STUDY AND POSSIBLE PARTICIPATION

We kindly request your voluntary participation in this research project. Please make sure that you are perfectly informed about the purpose of the study and what your participation in it. Please ask to clarify any information you do not understand. Please, do not sign, if you are not sure that you have understood all information provided to you. The participation in this project is totally voluntary and you will not have any financial burden. You can withdraw at any moment without providing explanation or having any consequences

The criteria for participating in this study are as following:

- being over the age of 55 years old and living independently **or**
- being a family member or caregiver of a person over the age of 55 years old

IV. PROCEEDINGS:

The users are involved throughout the project in order to ensure that their needs are met. The involvement of users is required in the following phases: (a) user requirement, (b) mock-up testing, (c) 1st prototype testing, and (d) 2nd prototype testing. You are now invited to participate in the second phase (b) which is the mock-up testing. Therefore, by signing this informed consent you are stating that you are willing to participate in testing only the mock-up phase. In case you are interested in being involved in the upcoming phases, please inform the researcher so as to contact you.

Mock-up is a primitive version of the platform that only has the main and most basic functionalities and features. Buttons and redirections are not fully functional and aims to give the overall feeling of how the final version of the platform will look like

This testing requires from you to test the mock-up which will be provided to you by the researcher. The researcher will explain the procedure that you need to follow during the testing and will support you at any time. You will be required to respond to some questions asked by the researcher in order to gather your feedback on the application you tested.

V. RISKS OR INCONVENIENCE

The only potential inconvenience foreseen at the mock-up phase is that the participants may feel anxiety due to the exposure and adaption to the devices. The project team will provide support to participants so as to use the devices and application provided. You have the right to withdraw at any time you wish.



VI. BENEFITS

Participants will have the opportunity to test and adopt techniques to help them being active and independent. Moreover, the personal benefit from participating in any activity of the *IOANNA* project is that you can make a substantial contribution to the development of future technologies focusing on the enhancement of the quality of life of ageing persons and supporting an independent life-style. In any case, the data collected in this study will lead to a deeper and better knowledge and understanding of the wishes and needs of ageing persons as well as their social environment to enhance future health services.

VII. PRIVACY AND CONFIDENTIALITY

Your registered and/or recorded responses will not include any personal identification information. Hence, it will not be possible to identify you after your participation in any study. Recorded information will be processed during the phase of data analysis and will be included in project internal reports or later in scientific publications. It will not be possible to identify the source of the information. The results of this study may be published in scientific magazines, conference proceedings or books. Complete anonymity of personal data is guaranteed by the *IOANNA* partners.

The authorization for the use of and access to your anonymised data is completely voluntary. This authorization is valid until the end of the study. If you should decide to deny your consent, please contact the research contact person and let her/him know of your intention of leaving the research project. You can contact the research contact person at the address given below (VII CONTACT PERSONS). Please keep in mind that if you do not provide us with your authorization now or if you cancel it in the future, you will not be able to participate in this study.

From the moment, you withdraw from the *IOANNA* project, your data will not be used in any further phase of the project. However, documents that have already been published or are part of the study that have been finished will not be able to be altered.

VIII. CONTACT PERSONS

For further information about your rights as a participant in the investigation, or if you are not satisfied with the way this study is being carried out, or if you have any question or complaint during the investigation, please contact the leading investigator:

>Name of the Local Investigator<

>Name of the Local Institution <



>Full address<

>Telephone Number of Local Investigator<

>Email Address of Local Investigator<

X. CONFIRMATON

I have read the information in this informed consent. All of my questions about the study and my participation in it have been answered. I authorize the use and analysis of my answers to the entity aforementioned for the purposes above indicated. Signing this informed consent does not imply giving up to any legal rights. I accept in a voluntary way to participate in this study.

Name and surname of the participant:

.....

Date:

.....

Signature of the participant

.....

Name and surname of the researcher

.....

Date:


.....

Signature of the researcher:

.....

5.2 Annex 2: Flyers for users

Your input counts!



Try out and test IOANNA application

Contact Us

If you would like more information on how you can contribute to the IOANNA project, please contact us:

<Insert name of your organisation>


<Insert primary address>

<Insert post code>

<Insert country>

<Insert phone number>


<Insert website>




IOANNA project


You can help us develop a suitable application to:

- Further support on the assistive mobility and social engagement of people over the age of 55 years old
- Support people to keep being active and independent



Insert logo





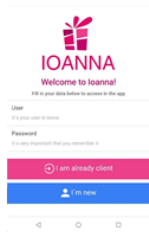
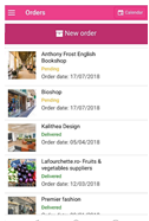

What is IOANNA?

IOANNA is an application (app) which combines a number of services to support people in being active and independent.

How does IOANNA work?

IOANNA includes various functions:

1. Searching engine for commercial offers, stores, products and services near you.
2. Opportunities for community service (paid or volunteered).
3. Navigation system aiding you to get to your destination with the most convenient way and being protected.

Get involved

We would like to ask you to try and test IOANNA if you

- Are over the age of 55 years old or
- Care for a person over the age of 55 years old
- Owner of local business
- Want to help us improve a our application

Step 1

After you give consent we give you the IOANNA application on a device (smartphone, tablet, laptop etc.)

Step 2

Try out the IOANNA app with the support of our researcher.

Step 3

Tell us about your experience.