Abstract: This deliverable provides a preliminary version of the Ethics and Privacy manual that will be followed by the FELICE project. This manual will be consulted over all stages of the project and it includes all relevant information on the adopted procedures for adhering to ethics policies and for ensuring the privacy and the security of data and subjects that this project will handle.

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List of Abbreviations

AI Artificial Intelligence
ALLEA All European Academies
BDSG Bundesdatenschutzgesetz
CETS Council of Europe Treaty Series
D Deliverable
DMP Data Management Plan
DPIA Data Privacy Impact Assessment
DSAnpUG Datenschutz-Anpassungs- und Umsetzungsgesetz EU
DSG Datenschutzgesetz
EPM Ethics & Privacy Manager
ETS European Treaty Series
EU European Union
GA Grant Agreement
GDPR General Data Protection Regulation
KPI Key Performance Indicators
OA Open access
ORD Open Research Data Pilot
REC Research Ethics Committees
UDHR Universal Declaration of Human Rights
UNESCO United Nations Educational, Scientific and Cultural Organization
WFDSAG Datenschutz- Anpassungsgesetz – Wissenschaft und Forschung
WHO World Health Organization
WP Work Package
Executive Summary

This document aims to provide a preliminary version of the Ethics and Privacy Manual for the FELICE project. The structure of this document is as follows:

Initially, we provide an overview of the ethical and privacy considerations to be found in the FELICE project, with respect to the research with human participants that will be conducted during the pilot requirements and evaluation. The methodology to address the ethical considerations consist of a review of EU and national legislations and directives on ethics, privacy, and data protection (Section 2). Further on, we continue by providing the Ethics & Privacy issues that can be encountered in the FELICE project (Section 3). Section 4 of the present document provides the specifications of the appropriate security measures of the project, which entails the basic and specific guidelines and rules that need to be followed towards preserving the privacy of the users, ensuring their safety, and respecting their rights as volunteer test subjects. Finally, a separate section (5) of the Ethics and Privacy Manual presents the FELICE Incidental Findings Policy, providing guidance on the procedures that are to be followed with regard to handling the discovery and report of potential incidental findings during research.

It should be noted that this document will be updated throughout the project in order to reflect up-to-date information. This initial version will guide the consortium in questions of ethics and data privacy. With respect to the initial submission, the document will be updated over the course of the project, until its final version.
1 Introduction

1.1 Purpose of the document

The current Ethics and Privacy Manual aims at the establishment of all the legal regulations and ethical guidelines that need to be taken into consideration during the studies and the demonstrations of the FELICE project, where volunteer participants will be involved and data collection and process will be carried out. This Ethics and Privacy Manual has been composed, including all the necessary ethical and privacy regulations and guidelines, in order to inform all involved parties towards (i) preserving the privacy of the users, (ii) ensuring their physical and personal safety and wellbeing and (iii) respecting their rights as volunteer test subjects.

1.2 Intended readership

D1.3 is a confidential document to be disclosed only to members of the FELICE consortium, including the Commission Services. This document has been intended, first of all, for all project members that participates in the preparation and realization of experiments. Software developers, managerial and technical staff members will carry out their activities in accordance with the guidelines outlined inn this manual. Furthermore, the manual is directed to all people involved in the project and also to the volunteers who will participate in the studies, and who may wish to be further informed about the guidelines followed by the project.

1.3 Relationship with other FELICE deliverables

The Ethics and Privacy Manual will guide the FELICE consortium over all stages of the project. Therefore, it is relevant to all deliverables, as far as it includes all relevant information on the adopted procedures for adhering to ethics policies and for ensuring the privacy and the security of data and subjects that this project will handle, and especially to those of Work Package 2 (WP2) and Work Package 8 (WP8) regarding the preparation and actualization of user studies and user case scenarios of the FELICE project.

Furthermore, the present deliverable outlines and elaborates on the regulatory landscape on which deliverable D10.1 (report concerning the project’s ethics requirements) will rely on. It is also consistent with the provisions made by the Data Management Plan regarding how data will be handled during the project and after the project completion.
Framework on ethics, privacy and data protection

For the purposes of the Felice project, several activities that include data collection, storage and process will take place, in order to assess the technology as well as the effectiveness of the solutions proposed by this project. Thus, human participants will be involved in the user studies and use cases of WP2 and WP8 respectively, and personal data about those participants will be collected. As a result, privacy protection and confidentiality issues for volunteers regarding the collected data need to be carefully handled. Special guidelines are set and presented in this document, to be followed by the partners and the participants involved in all human interaction activities. Furthermore, FELICE will consider the publication of relevant views of datasets produced by the project’s system, to boost research on behavioral health and data science.

In the context of Horizon 2020, article 19 of Regulation 1291/2013 determines that:

“all research and innovation activities carried out under Horizon 2020 shall comply with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols”.

In the FELICE project’s Grant Agreement (GA No. 101017151) this obligation is explicitly acknowledged in art. 7.1 of sec. 1 (“General obligation to properly implement the action”). Accordingly, the consortium carefully considered International, European, and national legislation and directives relevant to the project regarding the data collection, processing and the relevant publications that will take place.

The most important issues based on these policies are:

- Voluntary Participation

All FELICE participants will participate in the project voluntarily, and no pressure will be forced on the employees of the pilot sites for participating in the project’s activities. All participants will be freely and willingly asked to give their informed consent to be engaged to the project’s activities.

- Informed Consent

All volunteers will have to provide informed consent to the consortium before their participation in any activity, in order for the project to assure the human rights personal data. All rules and guidelines specified and defined in this document will be followed throughout the project’s lifetime.

- Data protection

For the private data collection and process that are necessary to meet the project’s scope, the legislations and directives of the European Union will be followed. An overview of all related legislation that will be followed is provided in the following sections of this document.

Furthermore, the FELICE project intends to address during all of its activities gender and age diversity and acceptability. Respect for equality shall be reflected to FELICE research’s

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policy. By ensuring that all studies will be equally inclusive to men and women participants from different ages (provided that they are adult fully capable of consent), so that the research will meet in an unbiased manner the needs of all citizens. The gender and age dimension of FELICE will be further elaborated on D10.1 (WP10), which will guide the research teams through the recruitment process of human research participants during the pre-pilot and pilot evaluation studies.

2.1 International, EU and National Legislation & Directives

In this section, International, EU and National Legislation & Directives relevant to the project ethics and privacy issues are delineated. Since the scope of the respective regulations and guidelines is substantially wide, it is of paramount importance to provide text excerpts and relevant clarifications on the key issues they address, in relevance with the project’s scope and envisioned activities.

2.1.1 Universal Declaration of Human Rights

The Universal Declaration of Human Rights (UDHR) [1], representing a milestone document of human rights since its proclamation by the United Nations General Assembly in 1948, states on its preamble that:

“the recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world”.

All members pledge to uphold universal respect for and observance of human rights as described by 30 articles to this Declaration. These fundamental rights apply to all human endeavors, including FELICE project. However, the activities carried out in FELICE project present no particular threat above and beyond any other workplace environment with respect to the rights defined by the Declaration. Therefore, the specific articles of the Declaration will not be described here in details.

2.1.2 World Health Organization guidelines on standards and operational guidance for ethics review of health-related research with human participants

The World Health Organization (WHO) guidelines on standards and operational guidance for ethics review of health-related research with human participants [2], as it revised the 2000 WHO relevant publication on 2011, has been developed for individuals and organizations involved in health-related research with human participants, including biomedical, behavioural, social science, and epidemiological research. Apart from its aim to provide guidance to the research ethics committees (RECs) on which organizations rely to review and oversee the ethical aspects of a research, it also intends to provide basic guiding rules to the researchers who design and carry out health research studies.
Adherence to these guidelines helps to promote the ethical conduct of research and enhances and protects the rights and wellbeing of research participants and communities.

Although the FELICE research does not consist of a health-related research per se (i.e., it is not a medical research), its scope involves the promotion of the workers well-being, and its research agenda involves the collection and process of health-related data. Hence, special notation must be given here to the respective guideline’s Chapter V, under the title “Standards and guidance for researchers”. This chapter refers to the researchers’ responsibilities regarding the submission of the research application for review by the competent Ethics Committees (and the obligation to proceed in compliance with the approved protocol, report on safety issues and to author ongoing reports and follow-ups on the research’s status), as well as with the researchers’ obligation to provide all the necessary information to research participants, to keep the research participants and their communities informed of the progress of the research by appropriate means (at suitable time-frames in simple and in a non-technical language), as, for example, when the research study is terminated or cancelled, when any changes occur in the context of the research study that alter the potential benefits or risks, when the research project is completed, or when the results of the research are available.

2.1.3 UNESCO Universal Declaration on Bioethics and Human Rights

The Universal Declaration on Bioethics and Human Rights [3], adopted by the United Nations Educational, Scientific and Cultural Organization in October 2005, addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions. (Article 1). The declaration is a non-binding instrument and, according to Article 2, aims amongst others to:

(a) to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics;

(d) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while stressing the need for such research and developments to occur within the framework of ethical principles set out in this Declaration and to respect human dignity, human rights and fundamental freedoms;

(b) to guide the actions of individuals, groups, communities, institutions, and corporations, public and private;

To this end, the declaration proclaims amongst others the following principles and methods for their application:

Article 3 – Human dignity and human rights

1. Human dignity, human rights and fundamental freedoms are to be fully respected.
2. The interests and welfare of the individual should have priority over the sole interest of science or society.

**Article 4 – Benefit and harm**
In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

**Article 5 – Autonomy and individual responsibility**
The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.

**Article 8 – Respect for human vulnerability and personal integrity**
In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected, and the personal integrity of such individuals respected.

**Article 9 – Privacy and confidentiality**
The privacy of the persons concerned, and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected or consented to, consistent with international law, in particular international human rights law.

**Article 10 – Equality, justice, and equity**
The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.

**Article 11 – Non-discrimination and non-stigmatization**
No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.

**Article 12 – Respect for cultural diversity and pluralism**
The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.

Application of the principles

Article 18 – Decision-making and addressing bioethical issues
1. Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular declarations of all conflicts of interest and appropriate sharing of knowledge. Every endeavor should be made to use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues.
2. Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis.
3. Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted.

Article 20 – Risk assessment and management
Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.

Article 21 – Transnational practices
1. States, public and private institutions, and professionals associated with transnational activities should endeavor to ensure that any activity within the scope of this Declaration, undertaken, funded or otherwise pursued in whole or in part in different States, is consistent with the principles set out in this Declaration.
2. When research is undertaken or otherwise pursued in one or more States (the host State(s)) and funded by a source in another State, such research should be the object of an appropriate level of ethical review in the host State(s) and the State in which the funder is located. This review should be based on ethical and legal standards that are consistent with the principles set out in this Declaration.

[...]
The spirit of the declaration and the entailed to it ethical principles regarding scientific research (also contained in relevant EU conventions and guidelines as well as in national legislations) are shared by the FELICE project, which intends to respect and promote them.
2.1.4 Charter of Fundamental Rights of the European Union (2012/C 326/02).

The Charter of Fundamental Rights of the EU Union (2012/C 326/02) [4], which was signed concurrently with the Treaty of Nice (2000) and has been subsequently revised, places the individual at the heart of its activities, by establishing the citizenship of the Union and by creating an area of freedom, security, and justice. The Union therefore recognizes the rights, freedoms and principles set out hereafter.

**Article 1 - Human dignity**

Human dignity is inviolable. It must be respected and protected.

**Article 3 - Right to the integrity of the person**

1. Everyone has the right to respect for his or her physical and mental integrity.

**Article 8 - Protection of personal data**

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.

**Article 21 - Non-discrimination**

1. Any discrimination based on any ground such as sex, race, color, ethnic or social origin, genetic features, language, religion, or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation shall be prohibited.

2. Within the scope of application of the Treaties and without prejudice to any of their specific provisions, any discrimination on grounds of nationality shall be prohibited.

**Article 51 - Field of application**

1. The provisions of this Charter are addressed to the institutions, bodies, offices, and agencies of the Union with due regard for the principle of subsidiarity and to the Member States only when they are implementing Union law. They shall therefore respect the rights, observe the principles and promote the application thereof in accordance with their respective powers and respecting the limits of the powers of the Union as conferred on it in the Treaties.

**Article 53 - Level of protection**
Nothing in this Charter shall be interpreted as restricting or adversely affecting human rights and fundamental freedoms as recognized, in their respective fields of application, by Union law and international law and by international agreements to which the Union or all the Member States are party, including the European Convention for the Protection of Human Rights and Fundamental Freedoms, and by the Member States' constitutions.

**Article 54 - Prohibition of abuse of rights**

Nothing in this Charter shall be interpreted as implying any right to engage in any activity or to perform any act aimed at the destruction of any of the rights and freedoms recognized in this Charter or at their limitation to a greater extent than is provided for herein.

**2.1.5 Oviedo Convention, 4.IV.1997 (ETS No. 164) and its Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research, 25.I.2005 (CETS No. 195)**

The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (4.IV.1997, ‘Oviedo Convention’, ETS No. 164) [5] is the only international legally binding instrument on the protection of human rights in the biomedical field. It draws on the principles established by the European Convention on Human Rights, in the field of biology and medicine. It is a framework Convention aiming at protecting dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms regarding the application of biology and medicine. In what follows, certain of its articles on which due regard shall be given in the context of the FELICE project are being highlighted:

**Chapter I – General provisions**

**Article 1 – Purpose and object**

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

Each Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention.

**Article 2 – Primacy of the human being**

The interests and welfare of the human being shall prevail over the sole interest of society or science.

**Article 4 – Professional standards**

Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.

**Chapter III – Private life and right to information**

**Article 10 – Private life and right to information**
1. Everyone has the right to respect for private life in relation to information about his or her health.

2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.

Chapter V – Scientific research

Article 15 – General rule

Scientific research in the field of biology and medicine shall be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being.

Article 16 – Protection of persons undergoing research.

Research on a person may only be undertaken if all the following conditions are met:

(i) there is no alternative of comparable effectiveness to research on humans;

(ii) the risks which may be incurred by that person are not disproportionate to the potential benefits of the research;

(iii) the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability;

(iv) the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection;

(v) the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

The Oviedo Convention was supplemented in the following years of its adoption by Additional Protocols devoted to special topics. In this context, the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (CETS No. 195) [6] was signed in 2005 and entered into force in 2007. Its purpose is to define and safeguard fundamental rights in biomedical research, in particular of those participating in research. The fundamental principle for research involving human beings, as in the Convention itself, is the free, informed, express, specific, and documented consent of the person(s) participating. The Protocol addresses issues such as risks and benefits of research, consent, protection of persons not able to consent to research, scientific quality, independent examination of research by an ethics committee, confidentiality and the right to information, undue influence, safety and duty of care.

2.1.6 General Data Protection Regulation (GDPR) 2016/679

The General Data Protection Regulation (‘GDPR’) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data forms the currently applicable regulation that is governing processing
wholly or partly by automated means and processing other than by automated means of personal data at EU level (Article 2 GDPR), and is horizontally applicable across all EU Member States and hence relevant for all partners of the FELICE project involved in the relevant activities, either consisted in public or private sector organizations. In what follows, emphasis will be placed on specific provisions and the key concepts that trigger its application.

Chapter I – Article 4

According to the definitions given under Article 4 of the GDPR, ‘personal data’ means any information relating to an identified or identifiable natural person (‘data subject’); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, psychological, genetic, mental, economic, cultural or social identity of that natural person.

Furthermore, ‘processing’ means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

Chapter II – Article 5

Principles relating to processing of personal data

1. Personal data shall be:

   • processed lawfully, fairly and in a transparent manner in relation to the data subject (‘lawfulness, fairness and transparency’);
   • collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes (‘purpose limitation’);
   • adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed (‘data minimization’);
   • accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay (‘accuracy’);
   • kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organizational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject (‘storage limitation’);
• processed in a manner that ensures appropriate security of the personal data, including protection against unauthorized or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organizational measures (‘integrity and confidentiality’).

2. The controller shall be responsible for, and be able to demonstrate compliance with, paragraph 1 (‘accountability’).

Chapter II – Article 6

Lawfulness of processing:

1. Processing shall be lawful only if and to the extent that at least one of the following applies:

   • the data subject has given consent to the processing of his or her personal data for one or more specific purposes;
   • processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract;
   • processing is necessary for compliance with a legal obligation to which the controller is subject;
   • processing is necessary in order to protect the vital interests of the data subject or of another natural person;
   • processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;
   • processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child.

Chapter II – Article 7

Conditions for consent:

1. Where processing is based on consent, the controller shall be able to demonstrate that the data subject has consented to processing of his or her personal data.

2. If the data subject's consent is given in the context of a written declaration which also concerns other matters, the request for consent shall be presented in a manner which is clearly distinguishable from the other matters, in an intelligible and easily accessible form, using clear and plain language. Any part of such a declaration which constitutes an infringement of this Regulation shall not be binding.
3. The data subject shall have the right to withdraw his or her consent at any time. The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal. Prior to giving consent, the data subject shall be informed thereof. It shall be as easy to withdraw as to give consent.

4. When assessing whether consent is freely given, utmost account shall be taken of whether, inter alia, the performance of a contract, including the provision of a service, is conditional on consent to the processing of personal data that is not necessary for the performance of that contract.

2.1.7 Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (ETS No.108)

The Council of Europe Convention for the Protection of Individuals with Regard to Automatic Processing of Personal Data (“Convention 108”) [8] aims to protect the right to privacy, as recognized in Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms. The rights to privacy and to data protection are also enshrined in Article 7 and 8 of the EU Charter of Fundamental Rights and Article 16 of the Treaty on the Functioning of the European Union.

Convention 108 was opened for signature in 1981, long before the era of the internet and electronic communications. In order to address privacy challenges from new technologies and to strengthen enforcement an effort for its review was initiated in 2013. In 2018, this resulted in a proposal to modernize Convention 108 (the “Amending Protocol”).

The field governed by the Amending Protocol is now largely covered by the European Union’s data protection legislative framework. The General Data Protection Regulation (EU) 2016/679), applicable since 25 May 2018, provides for a comprehensive system of rules in the field of data protection and ensures at least equivalent, and – in many cases – a higher standard of protection. According to Article 13 of the Amending Protocol, parties may namely grant data subjects a "wider measure of protection than that stipulated in this Convention", thus leaving them free to adopt stronger protections.

2.1.8 ePrivacy Directive 2002/58/EC, concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)

The ePrivacy Directive 2002/58/EC [9] of the European Parliament and of the Council of 12 July 2002) concerns the processing of personal data and the protection of privacy in the electronic communications sector and deals with the regulation of a number of important issues such as security in the processing of personal data, the notification of personal data breaches, and confidentiality of communications.

The main principles embodied in the e-Privacy Directive are the following:

1) Where the e-Privacy Directive provides for a specific rule applicable to natural and legal persons in relation to processing in connection with the provision of publicly
available electronic communications services in public communication networks, it prevails over the general rule set out by the GDPR (Principle of Specialty).

2) Electronic Communication Services and Networks must be secured through appropriate technical and organizational measures. (Security)

3) The confidentiality of communications and the related traffic data by means of a public communications network and publicly available electronic communications services, must be ensured (Confidentiality)


Directive 2009/136/EC of the European Parliament and of the Council of 25 November 2009 (EU Cookie Directive) introduces several provisions regarding the electronic communications networks and services to end-users. The EU Cookie Directive requires websites to obtain informed consent from visitors before they store information on a computer, or any web connected device. This storage is mostly done by cookies, which can then be used for tracking visitors to a site. With the EU Cookie Directive, the user of a site will now be required to opt-in when using a website containing cookies.

The EU Cookie Directive could be used to protect the privacy of the FELICE project’s electronic communications networks. The cookie policy is also relevant to the FELICE project’s website. In compliance with the data protection legislation and the EU Cookie Directive it will clearly explain to users what the cookies do; the potential consequences of allowing the cookies; and why FELICE is using them. FELICE will also obtain informed consent from users prior to using these cookies.


The Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 (into force since August 2016) concerning measures for high common level of security of network and information systems across the Union (NIS Directive) lays down measures with a view to achieving a high common level of security of network and information systems within the Union so as to improve the functioning of the internal market (Article 1). Relevant to the NIS Directive is: (i) the Commission Implementing Regulation (EU) 2018/151 of 30 January 2018, laying down rules for application of Directive (EU) 2016/1148 of the European Parliament and of the Council as regards further specification of the elements to be taken into account by digital service providers for managing the risks posed to the security of network and information systems and of the parameters for determining whether an incident has a substantial impact, and
states was required by May 2018. The scope of the directive focuses on putting in place measures to enhance security of network and information systems which include devices, infrastructure, network, and data, thereby taking an all-encompassing overview of the connected ecosystem.\(^6\)

Given that the Consortium partners of the FELICE project, especially those involved in the project pilots, will be using a variety of connected devices and infrastructure for the purpose of the project and that personal data will be imported in a pseudonymized form onto the FELICE platform, the relevance of the NIS Directive should be examined.

The Directive imposes security obligations on essential and digital services. A digital service is described as "any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services"\(^7\), including cloud computing service, which is further defined as “a digital service that enables access to a scalable and elastic pool of shareable computing resources” (NIS Directive, Art. 4 p.19). Those computing resources include resources such as networks, servers or other infrastructure, storage, applications, and services. Article 5 of the NIS Directive defines an essential service as "a service essential for the maintenance of critical societal and/or economic activities depending on network & information systems, an incident to which would have significant disruptive effects on the service provision". Accordingly, the Directive is directed, firstly, to operators of essential services—including the health, energy, water and transportation sectors and, secondly, to digital service providers—including online search engines, cloud computing services and online marketplaces.

FELICE is unlikely to be considered as an essential service or a digital service in the meaning of the NIS Directive\(^8\). However, it should be noted that, even though the NIS Directive only explicitly targets essential and digital service providers, suppliers to such providers may also be impacted by the obligations under the Directive as a result of flow down obligations. Moreover, it is important to note that the cloud services providers on which the FELICE pilot research’s partners and the FELICE platform rely on will be considered digital service providers under the NIS Directive. Hence, as a potential supplier to essential and digital service providers, FELICE plays an important role in enabling operators of essential services and digital service providers to secure their network and information systems and, therefore, be subject to the strict requirements of the NIS Directive.

\(^6\) To respond to the growing threats posed with digitalisation and the surge in cyber-attacks, the Commission has submitted a proposal to replace the NIS Directive and thereby strengthen the security requirements, address the security of supply chains, streamline reporting obligations, and introduce more stringent supervisory measures and stricter enforcement requirements, including harmonised sanctions across the EU. The proposed expansion of the scope covered by the NIS2, by effectively obliging more entities and sectors to take measures, would assist in increasing the level of cybersecurity in Europe in the longer term.( [https://www.europarl.europa.eu/RegData/etudes/BRIE/2021/689333/EPRS_BRI(2021)689333_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2021/689333/EPRS_BRI(2021)689333_EN.pdf) )

\(^7\) According to the definition given in point (b) of Article 1(1) of Directive (EU) 2015/1535 to which the NIS Directive Article 4 (5) refers to.

\(^8\) See NIS Directive Recital (50): “While hardware manufacturers and software developers are not operators of essential services, nor are they digital service providers, their products enhance the security of network and information systems. Therefore, they play an important role in enabling operators of essential services and digital service providers to secure their network and information systems. Such hardware and software products are already subject to existing rules on product liability”.  

(ii) the COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL “Making the most of NIS – towards the effective implementation of Directive (EU) 2016/1148 concerning measures for a high common level of security of network and information systems across the Union” toolkit

\(\)
According to the NIS Directive, both operators of essential services and digital service providers must:

- Take appropriate technical and organisational measures to secure their network and information systems;
- Account for the latest developments and consider the potential risks facing their systems; Risk-management measures include measures to identify any risks of incidents, to prevent, detect and handle incidents and to mitigate their impact. The security of network and information systems comprises the security of stored, transmitted and processed data (46);
- Take appropriate measures to prevent and minimise the impact of security incidents and to ensure service continuity; and
- Notify the relevant supervisory authority of any security incident that has a significant impact on service continuity.

2.1.11 Guidelines on FAIR Data Management in Horizon 2020 & Guidelines to the rules on Open Access to Scientific Publications & Open Access to Research Data in Horizon 2020

The guidelines on FAIR Data Management in Horizon 2020 (Version 3.0./26.07.2016) [12] are intended to help the Horizon 2020 beneficiaries make their research data findable (including provisions for metadata), accessible, interoperable, and reusable (FAIR), to ensure it is soundly managed. Under Horizon 2020 a flexible pilot is running (called the “Open Research Data Pilot” - ORD pilot). The ORD pilot aims to improve and maximize access to and re-use of research data generated by Horizon 2020 projects and takes into account the need to balance openness and protection of scientific information, commercialization and Intellectual Property Rights (IPR), privacy concerns, security as well as data management and preservation questions. According to the guidelines, a Data Management Plan (DMP) is required for all projects participating in the extended ORD pilot. A single DMP is to be produced per project, rather than one per dataset as previously. The DMP needs to be updated over the course of the project whenever significant changes arise, such as (but not limited to): (i) new data, (ii) changes in consortium policies (e.g., new innovation potential, decision to file for a patent), (iii) changes in consortium composition and external factors (e.g., new consortium members joining or old members leaving).

The Guidelines on Open Access to Scientific Publications & Open Access to Research Data in Horizon 2020 [13] explain the rules on open access to scientific peer reviewed publications and research data that beneficiaries have to follow in projects funded or co-funded under Horizon 2020. Open access (OA) refers to the practice of providing online access to scientific information that is free of charge to the end-user and reusable. ‘Scientific’ refers to all academic disciplines. In the context of research and innovation, ‘scientific information’ can mean: (i) peer-reviewed scientific research articles (published in scholarly journals) or (ii) research data (data underlying publications, curated data and/or raw data). Open access becomes an issue only if publication is chosen as a means
of dissemination. Moreover, open access does not affect the decision to exploit research results commercially, e.g. through patenting.

FELICE will take into account the Guidelines to the rules on Open Access to Scientific Publications & Open Access to Research Data in Horizon 2020 and the Guidelines on Data Management in Horizon 2020 and consider the publication of relevant views of datasets produced by the system, to boost research on behavioural, health and data science and to create a cornerstone for innovative business models for the private initiative in the area of recommendation and decision support systems, and in personalized care management. Article 29 of the FELICE Grant Agreement sets out detailed legal requirements on open access to scientific publications and to research data. The definition of which information will be published under the open data paradigm, which privacy definitions and related privacy mechanisms will be used to produce sanitized, publishable output that satisfactorily protects personal data will be specified in Deliverable 1.2.

2.1.12 Council Resolution of May 1999 on women and science (1999/C 201/01)

FELICE is a gender-neutral project as there is nothing specific that either promotes or denies inclusion of a specific gender and intends to respect them and take them into consideration both during project design and run time phase. Project planning and activities shall comply with the Council Resolution 1999/C 201/01 [14] which states that:

“The gender mainstreaming of research policy is not limited to promotion of women as research workers but should also ensure that research meets the needs of all citizens and contributes to the understanding of gender-relevant issues”.

To ensure compliance, the gender dimension of the FELICE research involving human participants will also be taken into account in the recruitment of research participants strategy, as elaborated on Deliverable 10.1 (WP10 – Ethics Requirements).

2.1.13 EU Commission documents for guidance on potential misuse of research

As part of the EU Commission H2020 Programme Guidance on “How to complete your ethics self-assessment”9 (version 6.1, February 2019), the “Guidance Note - Potential misuse of research” [15] and the guiding handbook “EU Commission Research Ethics: A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research” [16] will be followed be the FELICE project. Risk assessment and details on measures to prevent misuse of research findings of the FELICE research involving human participants will be further elaborated on Deliverable 10.1 (WP10 – Ethics Requirements).


On 8 April 2019, the High-Level Expert Group on AI of the European Commission presented the Ethics Guidelines for Trustworthy Artificial Intelligence [17]. The Guidelines put forward a set of 7 key requirements that AI systems should meet in order to be deemed trustworthy[^10]:

- Human agency and oversight: AI systems should empower human beings, allowing them to make informed decisions and fostering their fundamental rights. At the same time, proper oversight mechanisms need to be ensured, which can be achieved through human-in-the-loop, human-on-the-loop, and human-in-command approaches.
- Technical Robustness and safety: AI systems need to be resilient and secure. They need to be safe, ensuring a fall-back plan in case something goes wrong, as well as being accurate, reliable and reproducible. That is the only way to ensure that also unintentional harm can be minimized and prevented.
- Privacy and data governance: besides ensuring full respect for privacy and data protection, adequate data governance mechanisms must also be ensured, taking into account the quality and integrity of the data, and ensuring legitimised access to data.
- Transparency: the data, system and AI business models should be transparent. Traceability mechanisms can help achieving this. Moreover, AI systems and their decisions should be explained in a manner adapted to the stakeholder concerned. Humans need to be aware that they are interacting with an AI system, and must be informed of the system’s capabilities and limitations.
- Diversity, non-discrimination, and fairness: Unfair bias must be avoided, as it could have multiple negative implications, from the marginalization of vulnerable groups to the exacerbation of prejudice and discrimination. Fostering diversity, AI systems should be accessible to all, regardless of any disability, and involve relevant stakeholders throughout their entire life circle.
- Societal and environmental well-being: AI systems should benefit all human beings, including future generations. It must hence be ensured that they are sustainable and environmentally friendly. Moreover, they should take into account the environment, including other living beings, and their social and societal impact should be carefully considered.
- Accountability: Mechanisms should be put in place to ensure responsibility and accountability for AI systems and their outcomes. Auditability, which enables the assessment of algorithms, data and design processes plays a key role therein, especially in critical applications. Moreover, an adequate accessible redress should be ensured.

Given that the FELICE consortium will carry out research on and apply methods of robotics and artificial intelligence, it is of outmost importance to comply with the EU ethics guidelines on Trustworthy AI, while, also, consider the any forthcoming developments in view of the European Commission proposal for a Regulation of the

European Parliament and of the Council Laying down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain union legislative acts\textsuperscript{11}.


Given that the FELICE project is funded by the European Commission, within the context of Horizon 2020 programme, an important guide to help the FELICE consortium understand the core subjects of research ethics is provided by the European Commission’s “Ethics for researchers - Facilitating Research Excellence in 7th Framework Programme (FP7)” (2013)\textsuperscript{18}.

Additionally, and in accordance with Article 34.1 of the FELICE Grant Agreement, the revised edition of 2017 of “The European Code of Conduct for Research Integrity”, which was published by All European Academies (ALLEA)\textsuperscript{19} and applies to research in all scientific and scholarly fields, will also be complied with. As stated in its preamble, “the primary purpose of this Code of Conduct is to help realize this responsibility and to serve the research community as a framework for self-regulation. It describes professional, legal, and ethical responsibilities, and acknowledges the importance of the institutional settings in which research is organized. Therefore, this Code of Conduct is relevant and applicable to publicly funded and private research, whilst acknowledging legitimate constraints in its implementation.” The normative framework that the Code provides to guide researchers in their endeavors is formed by four fundamental principles:

- 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.

FELICE acknowledges the importance of the Code and intends to abide by its principles, carefully uphold the guidance it provides regarding good research practices and refrain from any violations of research integrity.

2.1.16 National regulatory framework

National legislations of the partners’ countries (i.e., Greece, Italy, Germany, Austria, Poland, and Ireland) implementing the aforementioned regulatory framework, also need to be complied with (Table 1). Especially regarding the General Data Protection Regulation, the FELICE consortium will, therefore, consider:

\textsuperscript{11} \url{https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1623335154975&uri=CELEX%3A52021PC0206}
• The Italian Legislative Decree no. 101 of 10 August 2018 (amending Legislative Decree no. 196 of 30 June 2003), which entered into force on 19 September 2018, implementing the GDPR in Italian law.

• The Greek National Law 4624/2019, which entered into force on 29 August 2019, implementing the GDPR in Greece’s national legislation,

• The German Federal Data Protection Act (Bundesdatenschutzgesetz – ‘BDSG’), published on July 5, 2017, and entered into force together with the GDPR on May 25, 2018, as well as the Second Data Protection Adaptation and Implementation Act EU (Zweites Datenschutz-Anpassungs- und Umsetzungsgesetz EU – ‘2. DSAnpUG-EU’), which generally entered into force on November 26, 2019, and introduced the adaptation of previous data protection rules to the GDPR.

• The Austrian Data Protection Act (Datenschutzgesetz – “DSG”), which came into force on 25 May 2018 by the Data Protection Amendment Act 2018 (Datenschutz-Anpassungsgesetz 2018), amending the Data Protection Act 2000 (Datenschutzgesetz 2000) and implementing the GDPR in Austrian law. Moreover, amendments to other laws implementing the GDPR in Austrian law were enforced by the Second General Data Protection Adjustment Act, which was passed in June 2018 and applies retroactively. Finally, further regulations were also passed with regard to the cases where a data privacy impact assessment is obligatory (the Obligatory DPIA Ordinance) and the exemptions from the obligation to conduct a data privacy impact assessment (the DPIA Exemptions Ordinance -), as well as the General Data Protection Adjustment Act (Materien-Datenschutz-Anpassungsgesetz 2018) and the research-sector specific Data Protection Adjustment Act – Science and Research (Datenschutz- Anpassungsgesetz 2018 – Wissenschaft und Forschung – WFDSAG 2018).12

• The Polish Personal Data Protection Act of 10 May 2018 (Journal of Laws of 2019, item 1781 which came into force on May 25, 2018, along with the Act on the amendments to sectorial acts accompanying the GDPR of 21 February 2019 (into force since 4 May 2019), implementing the GDPR into the Polish legal order, as well as regulating the matters in which the GDPR leaves a certain regulatory freedom for EU Member States.

• The Irish Data Protection Act 2018, which came into force on 25 May 2018, amending the Data Protection Acts (1988 to 2003), implementing the GDPR in Ireland and addressing procedural aspects of the enforcement of data protection in Ireland.

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Table 1. FELICE partner’s Countries and status of national legislation - EU regulatory framework
3 Ethical and privacy concerns arising during Pilot requirements and evaluation of the FELICE system

The current Ethics and Privacy Manual aims at the establishment of all the ethical guidelines that need to be taken into consideration during the social studies and the demonstrations, where volunteer participants will be involved and data collection and processing will be carried out. This Ethics and Privacy Manual has been composed, including all the necessary ethical and privacy guidelines, in order to inform all involved parties towards (i) preserving the privacy of the users, (ii) ensuring their physical and personal safety and wellbeing and (iii) respecting their rights as volunteer test subjects.

Any ethical issues related to personal data processing and participant’s fundamental rights that may arise during the user studies (WP2 and WP8) will be discussed through the appointed Ethics & Privacy Manager (EPM) and Quality Manager of the project.

European regulations concerning the acquisition of personal data are quite explicit, as seen in Section 2. Of particular interest for the FELICE project is the automatic acquisition of data that could occur without the full knowledge of a participant or observer. And even when the person is aware that data is being acquired, care must be taken to ensure that the acquired data is not used in an inappropriate manner. With these concerns in mind, the following guidelines are issued for the FELICE project:

- No data shall be collected without the explicit informed consent of the individuals under observation. This involves being open with participants about what they are involving themselves in and ensuring that they have agreed fully to the procedures/research being undertaken by giving their explicit consent;
- No data collected should be sold or used for any purposes other than the current project;
- A data minimization policy should be adopted at all levels of the project and should be supervised by the respective ethical/privacy helpdesk of the project. This will ensure that no data which is not strictly necessary to the completion of the current study will be collected;
- Any ancillary personal data obtained during the course of the research should be immediately deleted. However, this kind of ancillary data should be minimized as much as possible in any case.
- Special attention should also be paid to complying with the Council of Europe’s Recommendation R(87)15 on the processing of personal data for police purposes, Art.2:

  “The collection of data on individuals solely on the basis that they have a particular racial origin, particular religious convictions, sexual behaviour or political opinions or belong to particular movements or organizations which are not proscribed by law should be prohibited. The collection of data concerning these factors may only be carried out if absolutely necessary for the purposes of a particular inquiry”. If employees of partner organizations, or university students
serving in any partner university, are to be recruited, specific measures should be in place in order to protect them from a breach of privacy/confidentiality and any potential discrimination. In particular their names should not be made public and their participation should not be communicated to their managers.

### 3.1 Ethical and privacy concerns occurring during Pilot requirements

During FELICE pilot requirements, the project’s partners should provide information regarding:

- the concerns arising during the FELICE use cases and scenarios in the two different iterations, under which the modules and technologies will be used.
- the concerns arising from the integration and combination of FELICE technologies into a single platform with respect to the GDPR requirements, including: (i) the need to minimize the transfer of unnecessary data, (ii) the need to implement rules for ensuring security and the implementation of authentication, authorization, and accounting without compromising privacy.
- how data management and communication across the different modules and heterogeneous sensors will be realized and how the various modules will be interconnected exploiting the necessary mechanisms for security and privacy.

### 3.2 Ethical and privacy concerns occurring during Pilot evaluation

During FELICE pilot evaluation, the project’s partners should provide information regarding:

- Specifications of the concerns related to the analysis and exploitation of heterogeneous data to ensure GDPR compliance, during the evaluation phase of each iteration (e.g. sanitization of sensitive information before its further processing).
- The implementation of authentication mechanisms with the aim of mitigating security risks.
4 Specification of the appropriate security measures

4.1 Privacy by design and by default in the FELICE system

The term ‘privacy by design’ can be broadly understood as a privacy governance model or a “process map for putting the essential elements of accountability into effect”\(^{13}\). In order to manage personal data responsibly and meet ethical requirements regarding respect of individual autonomy of the persons whose data is being processed (their rights and freedoms, and in particular their right to data protection), as well as to address the data protection principles (i.e. legitimacy, data minimisation, purpose limitation, transparency, data integrity, data accuracy), the developing technologies should make use of robust and innovative methods for assuring data protection, privacy, and security. Apart from technical solutions, this aim pertains to organizational procedures as well.

The GDPR, in the light of the accountability principle, has legislatively introduced in Article 25 (as well as in the Recital 78) the concepts of privacy by design and privacy by default, as core values that developers of technology must implement and adhere to. The terms ‘by design’ and ‘by default’\(^{14}\), although being referred to consecutively in the law’s text, are complementary concepts and, in essence, mean that legal requirements should be kept in mind since the beginning of the design process. In other words, “data subjects will benefit more from data protection by default if data protection by design is concurrently implemented – and vice versa”\(^{15}\). In alignment with the requirements set by Article 25 and Recital 78 of the GDPR, the FELICE project will ensure the implementation of technical and organizational measures, at the earliest stages of the design of the processing operations, in such a way that:

(i) privacy and data protection principles (as determined in Article 5) are implemented in an effective manner and are safeguarded by measures that are built into the processing right from the start

(ii) only personal data necessary for each specific purpose will be collected and processed (taking into account the amount of data, the extent of processing, the storage period and accessibility of data), and that personal data isn’t made accessible to an indefinite number of persons.

These technical and organizational measures shall be suited to achieve their purpose, namely, ensuring that the data protection principles are implemented effectively. Such measures may vary, from technical solutions to the training of the FELICE research personnel. For the FELICE’s controller to be able to demonstrate that all relevant


\(^{14}\) In the EDPB Guilines 4/2019, the term ‘by default’ when processing personal data, refers to making choices regarding configuration values or processing options that are set or prescribed in a processing system, such as a software application, service or device, or a manual processing procedure that affect the amount of personal data collected, the extent of their processing, the period of their storage and their accessibility

principles have been maintained, documentation of the implemented technical and organizational measures should be kept. Appropriate key performance indicators (KPI) to demonstrate the effectiveness of the technical and organizational measures may be determined for this purpose. Once the processing has started, the controller has the obligation to maintain, review and update, as necessary, the processing operation, i.e. the continued effective implementation of the principles in order to protect the rights, staying up to date on the state of the art, reassessing the level of risk, etc. This obligation also extends to any processing carried out by means of data processors.

4.2 The envisioned technical and organizational measures at project level

In the context of the relevant work packages of the FELICE project, the following specification shall be made regarding:

- the technical and organizational measures which are designed to implement the data protection principles at the FELICE system (encryption, pseudonymization, anonymization etc.);
- the measures to ensure the confidentiality, integrity, availability and resilience of processing systems and services;
- the ability to restore the availability and access to the data in a timely manner in case of a technical incident;
- the processes for testing and evaluating the effectiveness of technical and organizational measures in order to ensure the security of the processing.
5 Incidental Findings Policy

Incidental findings are of increasing importance in human participant research and have been defined as “observations of potential clinical significance unexpectedly discovered in research participants and unrelated to the purpose or variables of the study”\textsuperscript{16}. An incidental finding, as an unexpected abnormal finding, may occur in many medical, behavioral, and psychological research settings, including cognitive research (e.g., unexpectedly low memory scores in a control participant). Findings such as these have potentially serious implications for a participant’s medical health, psychological well-being, employment, and insurance coverage. Incidental findings policy as an ethic issue is addressed in the Commission’s guidance entitled “how to complete your ethics self-assessment”\textsuperscript{17}. The possibility of an incidental finding thus raises issues of an investigator’s responsibility to screen for, identify, and properly communicate unexpected abnormal findings to the research participant and other designated parties.

In case of incidental findings during the FELICE research activities, the research team will share this information with the participant according to the Council of Europe recommendation, in Article 27 (“Duty of care”) of the Additional Protocol to the Convention on Human Rights and Biomedicine, Concerning Biomedical Research (Council of Europe, 2005), which states that: “if research gives rise to information of relevance to the current or future health or quality of life of research participants, this information must be offered to them. That shall be done within a framework of health care or counselling. In communication of such information, due care must be taken in order to protect confidentiality and to respect any wish of a participant not to receive such information”. The procedures to handle discovery, reporting of incidental findings and to inform participants should be carried out only by researchers/or affiliated professionals who have the skills and training to reach such decisions.

Moreover, the FELICE research partners will inform the research participants -through the information sheets- on the existence of Incidental Findings Policy, on their right to know in the event of unexpected or incidental finding and that certain procedures will be followed. The procedures will be communicated to the participants before the start of the study. FELICE will determine the potential for incidental findings occurring in the user evaluation study at the outset of planning for the study (Task 8.1), and not after the study has started (first cycle of evaluation planned during M17-M22).


6 Conclusions

This document aims to define and report the basic ethical and privacy guidelines that will be followed throughout the FELICE project. Thus, a thorough analysis of the European, national and international legislations and directives regarding ethics and data privacy has been accomplished. This Ethics and Privacy Manual will be used as a toolkit and a template to be consulted by all partners that will be involved with volunteers for the purpose of this project.
References


