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D 1.6

USER INTERACTION ETHICAL REVIEW REPORT

Supporting Active Ageing through Multimodal coaching

DISCLAIMER

AKNOWLEDGEMENT

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Supporting Active Ageing through Multimodal coaching

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☒	Approved by the WP Leader
☒	Approved by the Technical/Exploitation Manager[1]
☒	Approved by the Coordinator
☒	Approved by the PSC

[1] Choose Technical Manager for Deliverables in WP1-7,10 and Exploitation Manager in WP 8-10

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In this deliverable, applicable legal regulation, at the international, European and domestic level are first reviewed. After, ethical standards, guidelines and best practices in relation to project SAAM are reviewed. The project's target groups are presented and the project research ethical and governance implications and management approach are summarised. The present document is compiled with the aim to present all Consortium partners with the ethics dimensions of SAAM and to serve as a reference during the development of the project in time.

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HISTORY OF CHANGES

For updating the Deliverable after submission to the EC if applicable

Version	**Date**	**Change**
V2.0	28.01.2020	Added section with guidelines, risks and checklists for ethical management, added communication plan for pilots and reference to D8.1. Methodology of the Pilot Study (section 6). Added conclusions.

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Supporting Active Ageing through Multimodal coaching

PROJECT DOCUMENTATION SHEET

Project Acronym:	SAAM
Project Full Title:	Supporting Active Ageing through Multimodal coaching
Grant Agreement:	GA № 769661
Call identifier:	H2020-SC1-2017-CNECT-1
Topic:	Personalised coaching for well-being and care of people as they age
Action:	Research and Innovation Action
Project Duration:	36 months (1 October 2017 – 30 September 2020)
Project Officer:	Jose Albacete VALVERDE
Coordinator:	Balkan Institute for Labour and Social Policy (BILSP)
Consortium partners:	Jožef Stefan Institute (JSI) University of Edinburgh (UEDIN) Paris-Lodron Universität Salzburg (PLUS) Scale Focus AD (SCALE) Interactive Wear AG (IAW) Univerzitetni rehabilitacijski inštitut Republike Slovenije (SOČA) Nacionalna Katolicheska Federacia CARITAS Bulgaria (CARITAS) Bulgarian Red Cross (BRC) Eurag Osterreich (EURAG)
website:	saam2020.eu
social media:	#saam2020, #saamproject

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ABBREVIATIONS

AAL	Ambient Assisted Living
D	Deliverable
GDPR	General Data Protection Regulation
T	Task
SAAM	Supporting Active Ageing through Multimodal Coaching

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CONTENTS

TABLE OF FIGURES

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 769661

1. INTRODUCTION

Ethics considerations underlie any research and they are particularly relevant if the research involves humans. Ethics is referred to, and sometimes codified, in documents with diverse scope, legal power, stringency, and geographical coverage. In our review of ethics for the purposes of SAAM, we distinguish between the following documents categories:

- Applicable legal regulations (international, EU-level, and domestic);
- Ethical standards;
- Ethical guidelines;
- Ethical best practices.

Documents from all the categories above have their effect on SAAM project research.

In project SAAM, we are aware that ethical and good governance principles related to research practice, interaction with the users, and the developed technological solution all have implications for the Consortium, for project participants, and for SAAM users beyond the end of the project. To develop sensitivity about these ethical issues, we clearly identify and get to know the different target groups of the project. We continuously examine the ethical and governance implications, since we are aware that the issues will be constantly revealing as the project progresses.

In this deliverable, we first review applicable legal regulations, at the international, European and domestic level[2]. After, we review ethical standards, guidelines and best practices in relation to project SAAM, we present the project's target groups, and we summarise the project research ethical and governance implications, including guidelines, risks and checklists for ethical management. The present document is compiled with the aim to present all Consortium partners with the ethics dimensions of SAAM and to serve as a reference during the development of the project in time.

2. APPLICABLE LEGAL REGULATIONS

2.1 International provisions

Provisions of international law treat primarily the rights of humans and the issue of involving human beings in (scientific) research. The **Universal Declaration of Human Rights** is the document setting "common standards of achievement for all peoples and all nations" (United Nations, 1948). Its 30 articles are a set of inalienable rights of persons that are valid at all times and in all situations. Thus, in the context of SAAM, the Declaration fully applies. SAAM Consortium partners uphold the rights

[2] The domestic level here is reviewed in the three countries where work is executed in the field.

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to human dignity (Art. 1) and to non-interference with privacy, family or home (Art. 12) as crucial values.

Involving humans in research is a particular situation, which affects human rights. The Council of Europe's 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 (Council of Europe, 1997), also known as the **Oviedo Convention**, **and its Additional Protocol** to the Convention on Human Rights and Biomedicine, **concerning Biomedical Research**, are set out to "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" (Art. 1 of the Convention). SAAM is a research project that falls outside of research in biology and medicine; however, it involves research and interventions related to health and welfare with very limited, if any, risks for the person concerned. This is why Chapter II – Consent and Chapter III – Private life and right to information of the Oviedo Convention apply to our research. The General rule (Art. 5) stipulates that "An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time." Information collected from and information given to individuals included in research is subject to Article 10: "Everyone has the right to respect for private life in relation to information about his or her health. 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." A principle related to SAAM research is the Protection of persons not able to consent (Art. 6), which is as follows: "…an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit." SAAM is not intended to have direct benefits for people unable to give informed consent due to illness or disability. SAAM research results would not differ if research is carried out solely in groups of seniors who are able to give informed consent in comparison with research groups involving seniors able and not able to give informed consent. This is why **individuals who are unable to give informed consent will not be included in research activities.** From the Consortium countries, only Bulgaria and Slovenia are parties to the Oviedo Convention and its Additional Protocol concerning Biomedical Research; however, the principles from the Convention reviewed above are more a matter of ethics rather than legislation, thus the whole Consortium will adhere to them.

2.2 European legislation

At the European level, regulations become more specific. The **Convention for the Protection of Human Rights and Fundamental Freedoms** (Council of Europe, 1950) to which all SAAM Consortium countries are signatories, together with the **Charter of Fundamental Rights of the European Union**

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(European Parliament, Council of the European Union and European Commission, 2000), include the following rights, freedoms and principles relevant to SAAM research and technology:

- Human dignity;
- Right to the integrity of the person;
- Right to liberty and security of person;
- Respect for private and family life;
- Protection of personal data;
- Non-discrimination;
- Equality between men and women;
- The rights of the elderly;
- Integration of persons with disabilities;
- Health protection (part of Article 35);
- Environmental protection;
- Consumer protection.

As stipulated in Article 51 of the Charter: "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."

This is why there are legal regulations relevant to project SAAM both at the EU level, and at the national level. A list of relevant EU-level legal provisions with short commentary on each document is presented in the table below:

Table 1: SAAM relevant EU-level legal provisions

Document	**Principle, right or freedom concerned**	**Field of application**	**Note**
Regulation (EU) 2016/679 (GDPR)	• Respect for private and family life • Protection of personal data	Protection of natural persons with regard to the processing of personal data and on the free movement of such data.	*Currently in transition period. Comes into full force on 25 May 2018.*
Directive 95/46/EC	• Respect for private and family life • Protection of personal data	Protection of individuals with regard to the processing of personal data and on the free movement of such data.	*In force until 25 May 2018.*
Directive 2006/24/EC	• Protection of personal data	Retention of data generated or processed in connection	*N/A*

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		with the provision of publicly available electronic communications.	
Regulation (EU) 1290/2013	• All	Laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)"	*N/A*
Regulation (EU) 1291/2013	• All	Establishing of Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)	*N/A*

Table 1 includes EU legislation that is directly related to project SAAM, the research it produces and SAAM technology. Table 2 below indicates legal provisions that will be applicable to SAAM technology, in particular.

Table 2: SAAM end-product relevant EU legislation

Document	**Principle, right or freedom concerned**	**Field of application**	**Note**
Directive 2001/95/EC	• Health protection • Consumer protection	General product safety.	*N/A*
Directive 2002/21/EC	• Health protection • Environmental protection • Consumer protection	Common regulatory framework for electronic communications networks and services.	*Framework directive.*
Directive 2002/58/EC	• Protection of personal data	Processing of personal data and the protection of privacy in the electronic communications sector.	*Also known as Directive on privacy and electronic communications.*
Directive 2009/136/EC	• Protection of personal data	Amending Directive 2002/58/EC	*N/A*
Directive 2014/53/EU	• Health protection • Consumer protection	Harmonisation of the laws of the Member States relating to the making available on the market of radio equipment	*N/A*
Council Directive 93/13/EEC	• Consumer protection	Unfair terms in consumer contracts	*N/A*

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Directive 1999/44/EC	• Consumer protection	Certain aspects of the sale of consumer goods and associated guarantees	*N/A*
Directive 2011/83/EU	• Consumer protection	Amending Directive 1999/44/EC	*N/A*
Directive 2000/31/EC	• Consumer protection	Legal aspects of information society services, in particular electronic commerce, in the Internal Market	*Also known as Directive on electronic commerce.*

SAAM research is not medical research, the intended SAAM solution is not designed nor intended to be a medical device. However, should the need arise, Consortium partners should be aware of the provisions that affect medical research and medical devices at the EU level. An overview of these is given in Table 3 below:

Table 3: EU legal provisions in medical research and concerning medical devices

Document	**Principle, right or freedom concerned**	**Field of application**	**Note**
Regulation (EU) 536/2014	• Right to the integrity of the person • Respect for private and family life • The rights of the elderly • Protection of personal data • Non-discrimination • Equality between men and women • Health protection	Clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.	*N/A*
Council Directive 93/42/EEC	• Health protection	Medical devices.	*N/A*
Directive 90/385/EEC	• Right to the integrity of the person • Health protection	On the approximation of the laws of the Member States relating to active implantable medical devices.	*N/A*

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2.3 Domestic legislation

SAAM research with humans (WP1 and WP8) will be carried out in three of the five Consortium countries, namely Austria, Bulgaria, and Slovenia. The partners involved are EURAG Österreich and PLUS (Austria); BILSP, Caritas and BRC (Bulgaria); JSI and SOČA (Slovenia).

Relevant domestic legislation of all three countries is shortly reviewed in the sections below. It is the responsibility of partners to follow their obligations under domestic law in relation to SAAM research. Whenever needed, Consortium partners are at liberty to modify SAAM instruments, so that these are fully compliant with their domestic laws.

2.3.1 Austria

There is no national ethics board in Austria, only regional and university ethics boards. The regional ethics boards handle medical and clinical research only; the respective university ethics board handles all academic research. In accordance with the Helsinki Declaration, any medical research must be submitted for consideration to the respective regional ethics board. As the SAAM system is not a medical device and none of the Austrian partners involved will be conducting clinical studies, there is no need to seek approval of regional ethical bodies.

PLUS follows the code of conduct of the University of Salzburg and follows the rules of good academic practice. Following PLUS regulations (University Statutes §§144-145), approval by the university ethics committee (Ethics Committee of the Paris-Lodron University Salzburg) is required only for research on humans which bears a possibility to affect the physical or psychological integrity of subjects or their right to privacy or other important rights and interests of the subjects or their relatives (§145 (1)). Deciding whether or not any particular study falls in this category, and therefore requires approval, is within the responsibility and authority of the study lead (§145(2)), who has to coordinate this decision with the head of the Centre for HCI. For pilot studies in WP8, PLUS foresees consulting the Ethics Committee of the Paris-Lodron University Salzburg. All other studies conducted within SAAM in Austria are not expected be subject to the requirements outlined in §145(1).

EURAG follows the Medical University of Vienna's standard for Good Scientific Practice, which is applicable to pre-clinical and clinical trials. In its Section 3.2, it is stated that "[i]n accordance with Austria's legislation and the international guidelines, all research projects on humans must be submitted for approval to the Ethics Committee. This concerns all measures on patients and/or trial subjects, on identifiable human material (e.g. blood, serum, tissue samples, DNA) or data (e.g. medical histories) that are used with the purpose of obtaining knowledge and/or that do not exclusively serve the health benefits of the patients and/or of the trial subject on whom said measures are applied." (Medical University of Vienna, 2013) This definition excludes research and user involvement within project SAAM, as it concerns users' needs and satisfaction with the SAAM system, getting target insights about product appeal and market requirements as part of a product development process.

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Regardless of ethical approval procedures, both PLUS and EURAG will ensure to guarantee established standard rights (the right to withdraw from any study at any point, the right to be informed of the study purpose, the right to give explicit consent, the right to remain anonymous, etc.) to all study participants within the SAAM project. All study data will be anonymised and handled in compliance with the Austrian adaptation (Datenschutz-Anpassungsgesetz 2018) of the EU General Data Protection Regulation (Regulation (EU) 2016/679), in order to protect the privacy and anonymity of all study participants. Additionally, the pilots' methodology as outlined in D8.1 underwent a review by the ethics committee of University of Salzburg.

2.3.2 Bulgaria

In Bulgaria, provisions on issues such as personal data handling, confidentiality, ownership of data, access, future uses of data, and consent can be found in the Law on Personal Data Protection (Закон за защита на личните данни, 01.01.2002) and its sub-delegated legislation.

The law regulating biomedical research on human subjects (only in cases of clinical trials) in the country is the Law on Medicines in Human Medicine (Закон за лекарствените продукти в хуманната медицина, 13.04.2007). It also contains provisions for the consultation of Commissions on Ethics in cases of clinical trials. This law, however, is not applicable to project SAAM since it only covers human medicine. This was corroborated in consultation with the Central Commission on Ethics (Централна комисия по етика).

This is why the ethical review process in Bulgaria, with the respective ethical approval procedures, is set at the level of the partner organisations as follows:

- BRC – ethical commission of BRC;
- Caritas Bulgaria – Management Board;
- BILSP – ethical commission of BILSP.

2.3.3 Slovenia

The Oviedo Convention has been in force in Slovenia since December 1, 1999. In Slovenia, the current practice in assuring observance of ethical principles in biomedical research largely relies on the Helsinki Declaration, on the Oviedo Convention and the provisions of the Additional Protocol to the Oviedo Convention, on biomedical research.

The National Medical Ethics Committee (NMEC) is the main body responsible for ethics of biomedical research in the country and reviews most research with human subjects in the country. After consultation with the partner SOČA and the External Advisory Board (one of its members is Mr. Božidar Voljč who is the chair of NMEC), SAAM research activities are subject to ethics approval from NMEC. The timing for ethical approval from NMEC, after submission of an application to the commission, is no longer than 2 months.

Other related laws and guidelines are:

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- Law on Health Services (Zakon o zdravniski sluzbi), Ur.l. RS, No.:98/99 and 67/02;
- The Helsinki Declaration of the World Medical Association continues to provide an essential guidance for researchers, drafters of protocols of clinical studies, and for ethical review, and has in Slovenia a de facto status of obligatory guideline;
- Personal Data Protection Act (Zakon o varstvu osebnih podatkov), Ur.l. RS, No.:59/99, 57/01, 59/01 and 52/02. The researchers are obliged to observe the provisions of paragraphs 2 and 3 of Article 10 of the Oviedo Convention
- University of Ljubljana's Code of ethics for researchers.

2.4 Data handling

Ethical data handling and protection of personal data is a very important and sensitive issue. Therefore, European Union and its Member States put a lot of attention to this topic and cover it with a relatively stringent legislation. SAAM Consortium partners are committed to not only meeting the minimum requirements for data protection, but also, whenever possible, to conduct the project research in accordance with the highest standards of ethical data handling.

For the duration of the project, data will be handled in accordance with the Data Management Plan (D10.2), European and domestic law. Depending on the data after the project end, all personal data will be anonymised through the deletion of the files in which personal identification of the volunteers is stored or it will be aggregated.

Within WP1, T1.1, the Consortium partners agreed to follow the identities Coding Protocol (see D1.1, Annex VIII) specifically designed for the needs assessment within the task. This protocol, with some adjustments and refinements, will also be used for the pilot studies in WP8.

3. ETHICAL STANDARDS

Apart from legal regulations, SAAM research is defined by and bound with internationally recognised ethical standards.

3.1 SAAM and the Declaration of Helsinki

The most relevant document in this domain is the World Medical Association's **Declaration of Helsinki** (latest amendment in 2013). It synthesises the achievements of humanity in terms of ethical standards for safeguarding persons and their dignity and operationalises them to a certain extent. This cornerstone declaration is developed for medical research involving human beings and is addressed primarily to physicians, as stated in its Preamble (World Medical Association, 2013). Even though SAAM is not medical research, it involves research with human beings. This is why the

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Consortium follows the guidelines of the Declaration of Helsinki with respect to the research partners do, adapting the Declaration's principles for SAAM research as follows:

- *SAAM research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.*[3]

All partners in the Consortium are committed to this principle.

- *It is the duty of SAAM researchers who are involved in project research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.*
- *SAAM researchers shall consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards.*

Adherence to this principle is manifested in the present document.

- *SAAM research involving human subjects shall be conducted by individuals with the appropriate ethics, scientific education, training and qualifications.*
- *SAAM research involving human subjects shall be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation. Measures to minimise the risks shall be implemented. The risks will be continuously monitored, assessed and documented by the researchers.*

Consortium partners develop their risk assessments continuously and in relation to the separate work packages. In SAAM, the two work packages involving interactions with humans are WP1 and WP8. Continuous risk monitoring is needed, as the interactions with volunteers during WP1 are quite different from those in WP8. The foreseen risks, inconveniences and benefits for the needs assessment in WP1 are clearly stated in the Informed consent forms for primary and secondary users (for further details see Annex V and Annex VI of D1.1 as well as D1.2). A description of the ethical risks identified at the moment of drafting the present deliverable and their management are available in D1.2.

- *Research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group.*

This principle led the Consortium to exclude from the research activities seniors, and any other potential participants, who are unable to give valid informed consent. This is because SAAM is not intended to have direct benefits for people unable to give informed consent due to illness or

[3] The principles are extracted from the Declaration of Helsinki and modified to the nature of project SAAM.

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disability and SAAM research results would not differ if research is carried out solely in groups of seniors who are able to give informed consent in comparison with research groups involving seniors able and not able to give informed consent.

- *Precautions shall be taken to protect the privacy of research subjects and the confidentiality of their personal information.*

The Data Management Plan (D10.2) was carefully designed to respond to this principle. The precautions taken to protect the privacy of research subjects and the confidentiality of their personal information are compliant with Directive 95/46/EC, respectively with Regulation (EU) 2016/679. Within WP1, the practical tool articulating the procedure for privacy protection and personal information confidentiality is the Coding Protocol (D1.1, Annex VIII).

- *Participation by individuals capable of giving informed consent as subjects in SAAM research shall be voluntary.*

The principle was addressed in the design of the Informed Consent forms and guidelines for their usage. The Informed Consent Forms were submitted to domestic ethical commissions (see Section *3. Domestic legislation*) also to verify that they are understandable. Volunteerism is explicitly stated in the Informed Consent Forms for primary and secondary users (see Annex V and Annex VI of D1.1).

- *In SAAM research involving human subjects capable of giving informed consent, each potential subject shall be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study.*

This is explicitly stated in the Informed Consent Forms for primary and secondary users (see Annex V and Annex VI of D1.1). The principle will be followed throughout the project.

3.2 SAAM and the European Code of Conduct for Research Integrity

Another cornerstone document in ethics is the European Code of Conduct for Research Integrity, which applies to research in all scientific and scholarly fields (ALL European Academies (ALLEA), 2017).

In relation to the scientific community and to the wider public, SAAM researchers shall work in a reliable, honest, respectful, and accountable manner. The Consortium shall not tolerate any form of fabrication, falsification, or plagiarism. Apart from these general commitments, individual researchers comply with relevant codes of conduct to their fields of work and follow research and development procedures that are inherently reproducible and traceable.

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4. GUIDELINES AND BEST PRACTICES

Guidelines and best practices act as advice for SAAM researchers with the help of which SAAM research will be conducted and reported and with which the end-solution will comply. These give the way to practical compliance with the ethical principles outlined in the sections above.

The main guidelines that inform the design and execution of SAAM research involving human subjects include:

- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (WHO, 2011);
- Research Ethics in Ethnography/Anthropology (Iphofen, 2013);
- Guide for Research Ethics Committee Members (Council of Europe, 2010);
- Data Protection and Privacy Ethical Guidelines (Experts Working Group on data protection and privacy, 2009);
- Opinion on the Ethical Implications of New Health Technologies and Citizen Participation (EGE in Science and Technology, 2015);
- International Ethical Guidelines for Health-Related Research Involving Humans (Council for International Organizations of Medical Sciences (CIOMS), 2016);
- Options for Strengthening Responsible Research and Innovation (European Commission, 2013);
- Towards Responsible Research and Innovation in the Information and Communication Technologies and Security Technologies Fields (European Commission, 2011);
- Q-SEA – a Tool for Quality Assessment of Ethics Analyses Conducted as Part of Health Technology Assessments (Scott, et al., 2017).

With respect to the intended SAAM system development, publications describing good practices in developing mobile health solutions (mHealth) are very relevant.

In 2014, the European Commission published its Green Paper on mobile Health "mHealth" (European Commission, 2014), covering the following practices with ethical implications:

- ✓ Data protection, including security of health data which is bound by the purpose limitation principle, i.e. (sensitive) personal data can only be processed for the goals for which it was initially collected;
- ✓ Big data mining and the grey zone it represents with respect to the principle of implicit and explicit consent of the data owner; and
- ✓ User safety and transparency of information with respect to who develops the mHealth solutions and whether they have undergone proper reviews.

In a Report of the Working Group on mHealth Assessment Guidelines and as a follow-up of the Green Paper in relation to lifestyle and wellbeing apps, six criteria were determined to be key when

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assessing "the validity and reliability of the data that health apps collect and process" (Working Group on mHealth assessment guidelines, 2017):

1. Privacy
2. Transparency
3. Reliability
4. Validity
5. Interoperability
6. Safety

In view of these criteria and the requirements set out in the GDPR (see above), the SAAM system will be private and secure by design.

For more detailed guidelines on health apps and smart devices SAAM Consortium, partners can turn to the "Good Practice Guidelines on Health Apps and Smart Devices (Mobile Health or mHealth)" (Haute Autorite de Sante, 2016).

5. TARGET GROUPS

SAAM target groups are first described in the project proposal.

For the purposes of WP1, they are specified in D1.1 "Methodology of The Needs Assessment with Set of Data Collection Instruments" and they include "seniors, care providers, close social circle (family, friends, and neighbours), key informants and the community (broader social circle)."

D1.1 also specifies what a SAAM user means within the project. This is "[a] person from the identified target groups (IV.1) who will be testing SAAM or its separate components and will provide feedback to SAAM staff. Depending on the context, a user may also be a person or organisation who would potentially purchase SAAM. Users are grouped in three distinct categories:

- Primary users are senior people whose needs SAAM will cater to
- Secondary users are members of a senior's person social circle (e.g. caregivers, family, friends, neighbours, volunteers, general practitioners)
- Tertiary stakeholders are people or organisations other than the primary and secondary users, who will be affected by SAAM's existence, including those who are potentially business-to-business partners."

The definition of SAAM user has a time component – it revolves around the pilot phase of the project and the time after the end of the project. However, it is applicable by association to the research carried out in WP1, since those SAAM users who will be testing the system or its components will be predominantly members or the population surveyed for the needs assessment in WP1. This stability of the target groups within the project determines the uniform approach towards ethics within the project. The Consortium partners have already set the ethics approach by

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which they will operate within the needs assessment in WP1 involving human beings (see D1.1 and its annexes). Compliance with this approach was set as a minimum requirement for the pilot studies. It was further refined for the purposes of piloting and is thoroughly explained in D8.1.

6. PROJECT RESEARCH ETHICAL AND GOVERNANCE IMPLICATIONS

Ethics is a field that is both stable, with its universality and the moral high ground it holds, and developing together with the issues to which ethical reasoning is applied. This conclusion holds true for research and innovation, and for the specific case of project SAAM.

SAAM project research is being developed not only in view of the innovation, but also with respect to the ethical principles that are reviewed in the present document. By embarking on the project, Consortium partners have agreed not to put the process of innovation in front of the rights and freedoms of their target groups. In terms of governance, this dedication sometimes may slow down the workflow, as the different parts of the project are subject to ethics deliberations within the Consortium, as well as ethics external clearances. However, the ethics commitment is fully embraced by the partners and it is non-negotiable, so the possible slowdowns are internally accepted.

The Consortium partners adopt state-of-the-art governance of ethics issues, with the most obvious issues being protection of personal data and its facets, such as confidentiality, ownership of data, access, future access, privacy, and consent. The Consortium devised the tools for the needs assessment in WP1 being fully conscious of these issues. These tools will be used as a minimum reference for the pilot studies in WP8.

Regarding the end-solution from SAAM project (the SAAM system), protection of personal data is paramount, so every component of the system will be compliant with relevant legislation and the ethical principles set forth in the present document.

Ethics compliance of SAAM research and the SAAM system is ensured through the project governance mechanism adopted within the Consortium. Partners' actions in research and the consequent deliverables are reviewed independently by the Project Steering Committee and the External Advisory Board. This double-checking mechanism is complemented by the country-specific ethics clearance procedures to which research actions within SAAM are undertaken.

The present document is compiled with the aim to present all Consortium partners with the ethics dimensions of SAAM and to serve as a reference during the development of the project in time. With regard to ethics, our focus in the first months of the project was related to inclusion and exclusion criteria, ensuring informed consent and ensuring privacy and confidentiality. However, we are aware that more complex ethical issues will arise during the project. This is why it is crucial for SAAM partners to remain sensitive towards the issue of ethics. We will discuss the ethical aspects in each

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phase of research and system development and ensure that the ethical documentation is updated when the need for that arises.

Furthermore, we have introduced a set of ethical tools as described in D1.2, which were used to produce detailed guidelines for ethical management and risk assessment as provided in Table 4. These aspects treat ethics mostly in light of the long-term pilots as participants in them will be subject to the effects of the system, whereas single sessions and stakeholder feedback gathering activities provide participants only with a glimpse of SAAM.

Table 4 Ethical aspects and respective guidelines

Ethical aspects	**Guideline/action/mitigation**
Respect for autonomy	The system will enable primary users to have a full control over the settings related to autonomy – access to data, limiting the number of messages, selecting coaching actions, leaving the pilot, temporarily discontinuing the pilot, and actively participating in determining personalised pilot goals.
Non-maleficence/ beneficence	Trained researchers will monitor pilots; the goals for mobility and activity domains will be set by therapists/caregivers and not by primary users. Activities that might be potentially dangerous or an uncertainty exists whether a particular pilot participant could perform it safely will not be included among the goals.
Privacy and data protection	A detailed privacy policy is devised (leading partner Scale), which is presented to all (potential) participants of the pilots in WP8.
Ethical tools (providing more information, responding to complaints)	During pilots, the participants will be able to interact continuously with researchers/recruiters running the pilots, to ask questions, to seek assistance in resolving unforeseen issues, etc. Researchers/ recruiters, on the other hand, have detailed pilots methodology guidelines to handle various foreseen situations (D8.1). Following the elaboration of D8.1, several tools were provided to partners to be used by recruiters and field researchers (see Annexes I – X in D1.2). These tools are meant to be used as a reference primarily by recruiters and field researchers; however, they are also fit to be used by all project partners. For all unforeseen situations, the principal investigators running the pilots should consult with the ethical committee that approved running of a particular pilot.

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Ethical aspects	Guideline/action/mitigation
Right to switch-off a monitoring system	The primary users will be in full and independent control over the entire system in terms of suspending its operation temporarily or permanently.
Solutions to avoid dependence	Selection of participants based on their prior self-reported inclinations to developing dependence on various things (technology, drugs, etc.). During the pilots execution we will be observant of potential development of dependency and, if necessary, a pilot can be interrupted, paused or stopped. In the everyday use of SAAM, partic
False security	Careful selection of participants based on their prudence and due diligence to select only goals that can be achieved in a safe way. When delivering information regarding participation in the pilot studies, we will specifically explain to seniors that we are piloting/testing/investigating a system under development and not offering them a 100% working solution that is sold on the market. We refer to the system as being 'dumb' in this sense. Therefore, we will advise them to take coaching obtained with a reasonable pinch of salt. Also, we stress that the emergency module (if any is deployed during pilots) is not the focus of the system as SAAM aims at halting negative developments and improving life, wherever possible, over the long run and not immediately. We stress there are alarm systems specifically designed for emergencies that are sold on the market.
Feeling of surveillance	The primary users will be able to control fully the system, thus also the use of various features. The users will have the possibility to disable a particular feature temporarily.
How to avoid distorting experiment due to observation of lonely people	While this is a valid concern, it is difficult to forecast to what extent the pilot participants will change their behaviour due to the intrusion in their homes by technical systems/solutions and SUs/researchers. This is something that will be addressed in D1.5 where the experience from pilots can be used to identify additional ethical issues that are not visible at this stage of project. In addition, part of the target group is lonely people who would like to have their social activity improved. Thus, it is important that we observe lonely people and this will not result in distorting the experiment, but in the actual experiment.

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Ethical aspects	Guideline/action/mitigation
Traceability in data access	The system has an authentication authorisation procedures set in place and will support extensive logs to allow for traceability of the data access. The DB Split between an Azure DB where the PII will be hosted and on-premises Mongo DB where the sensors data will be stored also allows for a more granulated traceability of data accessing.
Limiting profile abuse	The Social Module of the SAAM Platform is set up in a way that prevents anyone outside of the Social Circles of the Primary user to contact them. In addition, a support e-mail will be provided where claims against a SAAM user with inappropriate / malicious behaviour can be reported and if needed removed from the Platform.
How to avoid the increase in loneliness after the pilot	SAAM will disrupt everyday life as rarely as possible, only when needed (i.e. the system is unobtrusive). Interactions with field researchers are designed to be as few as possible during the piloting stage (in accordance with the research protocol in D8.1). At the time of recruitment and during participation, it is underlined that the piloting is limited in time and that the SAAM system will be removed after the end of the piloting. There will be interactions between recruiters/field researchers and pilot participants during the long-term pilots. Interactions are planned to happen as few times as possible - during the system installation on site, during troubleshooting or repairs as needed, during the research sessions according to D8.1, and when the pilot participants request assistance with SAAM or further information. On the other hand, the social partners engage primarily people from their staff to act as recruiters and field researchers. These are usually people who know or who have communicated with the pilot participants in everyday life. Pilot participants are/will mostly be part of the networks of social partners (SOČA, EURAG, BRC, and Caritas). The involvement of seniors in the activities of these organisations will not halt when they end their participation in the pilot studies. Social partners, at own discretion, should ensure pilot participants stay engaged after the end of the project – this is a measure to show gratitude and appreciation for the participation.

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Ethical aspects	Guideline/action/mitigation
Exit strategy	The participants can in any time end their participation in pilots without any consequences for them.
Opening the platform to third parties	The system will not be open to third parties.
Ethical guidelines for all participants in the pilots	Ethical guidelines are an integral part of all the ethical applications to various ethical committees in Bulgaria, Slovenia, and Austria. In addition, all ethical questions deemed to be relevant for SAAM project are considered in the pilots' methodology development including the detailed guidelines for the participants (D8.1) and will be revisited throughout the pilots.
User-centred design/ planned iterations	The primary users will determine in which theme/domain (Social Activity, Sleep, Activity, Mobility) they want to participate. Their choice will be facilitated by testing demo installations. Furthermore, participants will be able to set goals/targets for themselves, especially in those domains where there are no medical standards involved (e.g., in the social activity domain, participants will be able to choose how many times a week they would like to speak over the phone). They will be also able to choose how they want to receive coaching from the system – themselves personally, through a secondary user, or both. Participants will also be able to choose how the coaching action is rendered to them depending on their preferences. In long-term pilots, feedback from the participants will be gathered on the system and its impact on their lives through field research sessions with the corresponding tools outlined in D8.1. In single sessions and stakeholder feedback gathering activities, the feedback from the users will be, among other things, central to determining the goals for coaching actions and the SAAM application specificities, as depicted in D8.1.

Ethical principles and concepts relevant for the SAAM project as detailed in Table 4 will be/were adhered to during the development of technical system and coaching models and actions.

Furthermore, the items listed within Table 4 were strictly followed during the process of pilots' methodology development thus the identified ethical questions were adhered to and are reflected in the detailed guidelines for the pilot participants, as detailed in D8.1.

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A need for a communication map was identified for the pilots. This issue is addressed in the Methodology for pilots (D8.1). Here we provide excerpts of available points on communication in the Methodology, as well as the supporting materials for recruiters (provided in D8.1, Annex III):

- Reporting procedures between field researchers and the Consortium - see Methodology (D8.1), p. 63, Section "Quality Assurance'.
- Communication between recruiters and (potential) users - see Methodology (D8.1), p. 88.
- The option for users to contact the Consortium directly is also outlined in the last sections of all Information sheets - there are the contacts of the Local contact point, Local SAAM partner and the Coordinator. The information sheets also contain hypotheses on what matters users can contact us - those are all questions and comments related to the piloting, to their participation in it and to the processing of their personal data.
- Communication between field researchers and users follow the same logic as the guidelines above - the only communication difference is that for withdrawal or any other serious events field researchers are supposed to redirect users to their recruiters.

We have also addressed the following questions relevant for the smooth execution of the pilots, as well as for addressing any ethical questions that may arise during the execution of pilots:

- How and to whom to redirect queries from users? – To their recruiters.
- How and to whom to redirect queries from recruiters? – To the principal investigator leading a pilot in each country.
- How and to whom to redirect queries from field researchers? – To the principal investigator leading a pilot in each country.
- How and to whom to direct queries on reporting/requests for information from recruiters (e.g. how many volunteers do we already have, what domains have they chosen, etc.) and from field researchers (e.g. how did interviews go, when are the next interviews planned, etc.)? – To the principal investigator leading a pilot in each country.

7. CONCLUSION

The present deliverable gives an overview of legal regulations and ethical standards applicable for project SAAM and the parties involved in it. It translates those regulations and standards into operational guidelines for the Consortium. The deliverable should be read in conjunction with D1.2 SAAM Ethics Review Codex, Informed Consent Procedures and Templates and D8.1 Methodology of the Study with Sets of Data Collection Instruments. It can and should be used by SAAM Consortium partners and can be used as a reference for ethical discussion that emerge within the Consortium throughout the project and in view of the SAAM system. The SAAM system (in its entirety and its separate components) is designed/integrated in a way that addresses the potential concerns identified by partners. However, a thorough and substantiated discussion on the understandings and concerns about the ethical and governance implications of the SAAM coach and an evaluation of the potential for future implementation of SAAM from the point of view of ethics and the existing policies can only be done once we have experience and results from pilots. Such an evaluation will be a part of D1.5 Ethics Policy, which is postponed from M24 to M36.

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8. REFERENCES AND RECOMMENDED LITERATURE

3rd World Conference on Research Integrity. (2013). *Montreal Statement on Research Integrity in Cross.* Retrieved from http://www.researchintegrity.org/Statements/Montreal%20Statement%20English.pdf

ALL European Academies (ALLEA). (2017). *The European Code of Conduct for Research Integrity: Revised Edition.* Retrieved from https://ec.europa.eu/research/participants/data/ref/h2020/other/hi/h2020-ethics_code-of-conduct_en.pdf

Council for International Organisations of Medical Sciences (CIOMS). (2016). *International Ethical Guidelines for Health-Related Research Involving Humans.* Retrieved from https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

Council of Europe. (1950). *Convention for the Protection of Human Rights and Fundamental Freedoms.* Retrieved from https://rm.coe.int/1680063765

Council of Europe. (1953). *European Convention on Human Rights.* Retrieved from http://www.echr.coe.int/Documents/Convention_ENG.pdf

Council of Europe. (1997). *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.* Retrieved from https://www.coe.int/en/web/bioethics/oviedo-convention

Council of Europe. (2010). *Guide for Research Ethics Committee Members.* Retrieved from https://www.coe.int/t/dg3/healthbioethic/activities/02_biomedical_research_en/Guide/Guide_EN.pdf

Donaldson, T., & Werhane, P. H. (-). *Introduction to Ethical Reasoning.* Retrieved from http://faculty.tuck.dartmouth.edu/images/uploads/faculty/adam-kleinbaum/introduction_to_ethical_reasoning.pdf

EGE in Science and Technology. (2015). *Opinion on the Ethical Implications of New Health Technologies and Citizen Participation: Executive Summary and Recommendations.* Retrieved from https://ec.europa.eu/research/ege/pdf/opinion-29_ege_executive-summary-recommendations.pdf

EIP on AHA. (2017, 1 15). *Blueprint: Digital Transformation of Health and Care for the Ageing Society.* Retrieved from https://ec.europa.eu/digital-single-market/en/blueprint-digital-transformation-health-and-care-ageing-society

Ethical Review in FP7. (-). *Guidance for Applicants: Informed Consent.* Retrieved from http://ec.europa.eu/research/participants/data/ref/fp7/89807/informed-consent_en.pdf

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 769661

European Commission. (2011, 11 21). *Towards Responsible Research and Innovation in the Information and Communication Technologies and Security Technologies Fields.* Retrieved from https://publications.europa.eu/en/publication-detail/-/publication/60153e8a-0fe9-4911-a7f4-1b530967ef10/language-en

European Commission. (2013). *Options for Strengthening Responsible Research and Innovation.* Retrieved from https://ec.europa.eu/research/science-society/document_library/pdf_06/options-for-strengthening_en.pdf

European Commission. (2014). *Green Paper on mobile Health.* Retrieved from https://ec.europa.eu/digital-single-market/news/green-paper-mobile-health-mhealth

European Parliament, Council of the European Union and European Commission. (2000). *Charter of Fundamental Rights of the European Union.* Retrieved from http://www.europarl.europa.eu/charter/pdf/text_en.pdf

Experts Working Group on data protection and privacy. (2009, 9 18). *Data Protection and Privacy Ethical Guidelines.* Retrieved from http://ec.europa.eu/research/participants/data/ref/fp7/89827/privacy_en.pdf

Frauenberger, C. (2015). *Disability and Technology: A Critical Realist Perspective.* Retrieved from http://outsidethebox.at/files/criticalrealist.pdf

Haute Autorite de Sante. (2016, 10). *Good Practice Guidelines on Health Apps and Smart Devices (Mobile Health or mHealth).* Retrieved from https://www.has-sante.fr/portail/upload/docs/application/pdf/2017-03/dir1/good_practice_guidelines_on_health_apps_and_smart_devices_mobile_health_or_mhealth.pdf

Iphofen, R. (2013). *Research Ethics in Ethnography/Anthropology.* European Commission.

Kacelt, J., & Maresova, P. (2016). *Legislative and ethical aspects of introducing new technologies in medical care for senior citizens in developed countries.* Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4959584/

Keller, D. R., & Gampel, E. H. (2008). *Ethical Reasoning.* Retrieved from http://www.blackwellpublishing.com/content/BPL_Images/Content_store/Sample_Chapter/9781405170987/9781405170987_001.pdf

Kuhse, H., Singer, P., Rickard, M., Cannold, L., & van Dyk, J. (1997). Partial and impartial ethical reasoning in health care professionals. *Journal of Medical Ethics*, 226-232.

Medical University of Vienna. (2013). *Good Scientific Practice: Ethics in Science and Research Guidelines of the Medical University of Vienna.* Retrieved from http://www.meduniwien.ac.at/files/7/8/goodscientificpractice.pdf

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 769661

OECD Global Science Forum. (2007). *Best Practices for Ensuring Scientific Inte.* Retrieved from https://www.oecd.org/sti/sci-tech/40188303.pdf

Presidential Commission for the Study of Bioethical Issues. (2016). *For Researchers: Incidental and Secondary Findings.* Retrieved from https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/Researcher%20Primer%20Incidental%20Findings%2010.30.16.pdf

RESPECT Project. (2004). *RESPECT Code of Practice for Socio-Economic Research.* Retrieved from http://www.respectproject.org/code/respect_code.pdf

Scott, A. M., Hofmann, H., Gutiérrez-Ibarluzea, I., Bakke Lysdahl, K., Sandman, L., & Bombard, Y. (2017). *Q-SEA – a tool for quality assessment of ethics analyses conducted as part of health technology assessments.* Retrieved from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5352988/

TU Delft. (2016). *Responsible Innovation: From MOOC to Book.* Retrieved from https://www.google.bg/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&ved=0ahUKEwjE3_3r-77ZAhXCKlAKHVAzAdMQFggzMAI&url=https%3A%2F%2Frepository.tudelft.nl%2Fislandora%2Fobject%2Fuuid%3A2aad6105-4723-437e-9814-06a55054d986%2Fdatastream%2FOBJ%2Fdownload&usg=AOvVaw

United Nations. (1948). *Universal Declaration of Human Rights.* Retrieved from http://www.un.org/en/udhrbook/pdf/udhr_booklet_en_web.pdf

WHO. (2011). *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants.* Retrieved from http://www.who.int/ethics/publications/9789241502948/en/

Working Group on mHealth assessment guidelines. (2017). *Report of the Working Group on mHealth assessment guidelines.* Retrieved from https://ec.europa.eu/digital-single-market/en/news/report-working-group-mhealth-assessment-guidelines

World Medical Association. (2013). *Declaration of Helsinki: Ethical Principles for Medical Research.* Retrieved from https://www.wma.net/wp-content/uploads/2016/11/DoH-Oct2013-JAMA.pdf

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 769661