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| Acronym: | VITAAL |
| Name: | Walking speed, variability and personalised interventions on Geriatric Giants |
| Call: | AAL JP Call 2017 |
| Contract nr: | aal-2017-066 |
| Start date: | 01 May 2018 |
| Duration: | 36 months |

# D2.1 Ethical Roadmap

Nature[1]: R
Dissemination level[2]: PU
Due date: Month 2
Date of delivery: Month 7
Partners involved (leader in bold): **ETHZ**, KULEUVEN, UMONTREAL
Authors: ETHZ

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

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

# Partner list

| Nr. | Partner name | Short name | Org. type | Country |
|---|---|---|---|---|
| 1 | Dividat AG *(coordinator)* | DIVIDAT | SME | Switzerland |
| 2 | Fraunhofer AICOS | AICOS | R&D | Portugal |
| 3 | ETH Zurich | ETHZ | R&D | Switzerland |
| 4 | Université de Montreal | UMONTREAL | R&D | Canada |
| 5 | Universitair Psychiatrisch Centrum KU Leuven | KULEUVEN | END-USERS | Belgium |
| 6 | ProCare (Belgium) | PROCARE | SME | Belgium |
| 7 | Physio SPArtos | SPARTOS | SME | Switzerland |

# Revision history

| Rev. | Date | Partner | Description | Name |
|---|---|---|---|---|
| 1 | 09.07.2018 | ETHZ | Created the first version | Alexandra Schättin |
| 2 | 18.07.2018 | ETHZ | Comments and additions | Alexandra Schättin |
| 3 | 06.08.2018 | ETHZ | Comments and additions | Alexandra Schättin |
| 4 | 09.11.2018 | ETHZ | Integration of comments and further revision | Melanie Thalmann |
| 5 | 11.11.2018 | ETHZ | Comments and additions | Yu Imaoka |
| 6 | 12.11.2018 | ETHZ | Final revision | Melanie Thalmann |

| | 19.11.2018 | Approved by (Partner) |
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# Table of contents

# 1. Introduction

This document is part of *Task 2.1: Ethical roadmap* within *Work package 2: User Requirements and Specifications*. The lead partner of this work package and task is ETH Zurich (ETHZ). The document describes an ethical roadmap which is a strategic plan containing the basic ethical principles and agreements that all project partners need to comply with during the VITAAL project.

During the project, this ethical roadmap needs to be the foundation on which many other documents are based. These could be for example questionnaires, leaflets, informed consent, study protocols etc.

When necessary in the course of the project, the document will be updated.

This document is subdivided into eleven sections, containing a short description of the project, current legislation on international and national level, internal ethical review board, VITAAL's general ethical principles and their practical application, inclusion and exclusion criteria, recruitment of participants, informed consent, privacy and data protection, risks and safety, reporting and publishing and benefits for society and individual participants.

# 2. Overview

The VITAAL project's main goal is to bridge the gap between assessment and intervention. The main focus of VITAAL is to develop a gait assessment via IMU sensors and use this gait assessment as simple geriatric assessment to identify training needs of older adults. This holistic approach wants to capture the gait pattern of older adults suffering from fall events (mobility impairment), neurocognitive disorders and/or incontinence. The identified training needs will be used to adjust and individualise the training content (emphasising balance, strength, coordination, cognition, etc.) of the technology-based exergame training (being based on the existing Active@Home exergames). A training adapted to an individual is expected to be more effective in counteracting disabilities than a "one size fits all" approach. The home-based intervention will focus on physical but also on cognitive aspects. This video game-based training intends to be challenging, motivating and captivating by considering training principles.

The user interaction and investigation within the VITAAL project will be carried out in three phases:

1. *Understanding and conceptualizing phase (Investigation phase):* In the first phase, senior citizens will play an active role for VITAAL to get a clearer picture of users' needs, attitudes and expectations towards technology-based body function' assessment tools and its usage to individually adapt exergame training. The method used will be a survey/questionnaire with about 15 elderly people participating in every involved VITAAL partner country (Switzerland, Belgium, and Canada). In parallel to the survey, a focus group with stakeholders will be conducted in every country, in order to gain useful knowledge for the promotion of the technology-based gait assessment and its usage to individually adapt exergame training and its

future exploitation. The main goal of this first phase is to get profiles of archetypical end-users and stakeholders who are expected to provide a solid basis for the development phase.

2. *Developing phase (Development phase):* In the second phase, small groups of users will be involved during the system development stage to help creating and defining a working prototype of the gait assessment and the adaptable exergame intervention (including exercise for balance, strength, cognition, and pelvic floor muscles strength). The developed exergame will be based on experiences gained in the previous AAL Active@Home project that led to an interface. IMU sensors from Active@Home will be improved, and the movement evaluation algorithms will be adjusted to needs from VITAAL. User-centred design techniques will be applied to define and validate the assessment tools and the game user interface and to guarantee that the target group can easily understand all aspects. End-users may also actively participate in the construction of a dataset of movements that will then be used to develop algorithms for signal processing so that movement and body function evaluation techniques can be created on top. The main goal of this phase is a user-centred system and design development.

3. *Validation and testing phase (Trial phase):* In the third phase, the developed gait assessment tools and the exergame will each be tested for aspects of reliability, validity, feasibility, usability and effectiveness by using a two-step approach. Before the field trials, technical validation of the assessment tools and the exergame training system will be performed. After that, the technology will be tested by about 20 independently living older adults per study site (Switzerland, Belgium, Canada) recruited from the community for each trial phase. Additionally in the second trial phase, about 20 older adults per involved country will be recruited as control group. Trials will be organized into two consecutive stages. Participants will be able to use the system during an extended period of time in real life conditions to ensure realistic environments (at home). In the first (shorter) stage, users will validate the system from a technical point of view. In the second (longer) stage, the main goal is evaluating the training program by measuring key performance indicators with the assessment tools.

# 3. Legislation and general ethical principles

The members of the Consortium declare that the VITAAL project will comply with the current legislation and regulations of the countries in which the research is to be carried out. Moreover, the project will comply with all relevant European Union (EU; Belgium), Swiss and Canadian legislation, especially the legislation below:

## 3.1 The European Charter of Fundamental Rights

The EU is founded on a common ground of shared values laid out in the European Charter of Fundamental Rights. The Charter acknowledges a range of personal, civil, political, economic and social rights. The Cologne European Council of June 1999 [http://www.europarl.europa.eu/summits/kol1_en.htm] entrusted the task of drafting a charter to a convention. The Lisbon Treaty incorporates the Charter into the Treaty on the European Union,

giving the charter an equal legal effect, and states that all European legislation needs to conform to the principles of the Charter. Consequently, this also applies to the European research policy.

The European Charter of Fundamental Rights contains several principles which can be relevant in the context of research. These principles form the basis of important ethics guidelines but also support the conduct of research. The most important articles are mentioned here (shortened to the relevant parts):

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

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

*In the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law.*

*Article 7 – Respect for private and family life*

*Everyone has the right to respect for his or her private and family life, home and communications.*

*Article 8 – Protection of Personal Data*

*Everyone has the right to the protection of personal data concerning him or her.*

*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.*

*Compliance with these rules shall be subject to control by an independent authority.*

## 3.2 New EU regulation on data protection

According to the European Charter of Fundamental Rights, natural persons have the fundamental right to the protection of personal data concerning him or her.

The European Commission adopted new legislation on this subject. **The Regulation (EU) 2016/679 (General Data Protection Regulation)**, repealing Directive 95/46/EC, entered into force on 24 May 2016 and was applied from 25 May 2018. **The Directive (EU) 2016/680 (Data Protection Directive)** entered into force on 5 May 2016 and was applied from 6 May 2018.

The Eurobarometer survey on protection and personal data, conducted among 28'000 EU citizens in March 2015 reveals concern among EU citizens. For example, a majority agrees that "providing personal information is an increasing part of modern life" (71%), "that their explicit approval should be required in all cases before their data is collected and processed" (69%), or "that they would want to be informed should their data ever be lost or stolen".

Further, eight out of ten EU citizens feel that they do not have complete control of their personal data. However, General Data Protection Regulation applies adapted regulations, which build and maintain trust. The overall change concerns the same data protection rights across EU. This means for businesses that the single, pan-European law for data protection build consistency between 28

countries. Moreover, one-stop shop involves one single supervisory authority (Data Protection Authority, DPA), which will promote clarity and make it cheaper for companies to do business in the EU. Same rules apply when goods and services are offered on the EU market. By means of a risk-based approach, rules will be tailored to risks and therefore avoid one-size-fits-all obligation. Rules incentivize businesses to innovate, by means of data protection by design, meaning to build data protection safeguards into products and services from the earliest stage of development. Techniques as 'anonymization', 'pseudonymization' and 'encryption' are promoted to protect personal data (important in terms of big data) and thereby enable big data innovation. Transparency is core to the adapted version on data protection, stating that organization should publish transparent and easily accessible data protection policies. Simple icons on a website could explain how, by whom and under whose responsibility personal data will be processed.

All in all, red tape will be reduced, meaning that no more notifications (fees for processing data) need to be provided to supervisory authorities. Small- and medium-sized businesses are for example also able to charge a fee for providing access to data (every penny counts). Data protection officers do not need to be appointed by the large majority of small- and medium-sized businesses. However, when the core activities involve "regular and systematic monitoring of data subjects on a large scale" a data protection officer need to be appointed. Only very risky data processing activities will need to carry out data protection impact assessments. Thereby, a privacy-friendly environment will be created.

In terms of controlling personal data and in order to build and maintain trust in online environment, the adopted Regulation states that easier access to personal data is ensured. Also, EU citizens have the right to data portability, which means that data can be transferred between services by the user. Thereby, trust is strengthened and fair competition created: especially small- and medium-sized businesses can compete giants within the single market. The right to be forgotten means that if requested, data must be deleted. Moreover, users have the right to know when data has been hacked. Thus, by means of clear affirmative actions, meaning that users give their consent for processing personal data. In case of data breaches, the data protection authority of each Member State as well as the user need to be informed as soon as possible – where feasible within 72 hours.

All in all, the adapted Regulation ensures:

- Enhancing transparency
- Fostering consumers' trust
- Boosting competition through new right of data portability
- Creation of a level playing field for all companies active in the single market

## 3.3 The Canadian Charter of Fundamental Rights

The Canadian Charter of Rights and Freedoms is one part of the Canadian Constitution. The Constitution is a set of laws containing the basic rules about how our country operates. The Charter sets out those rights and freedoms that Canadians believe are necessary in a free and democratic society. The principles included in the Charter are general and not really relevant in the context of research.

In Canada, federal, provincial and territorial laws govern all public sector institutions within each of their respective jurisdictions. The province of Québec (where the research is held in Canada) has civil law that also provides individuals with more specific rights and freedoms under the Québec Charter of human Rights and freedoms and the Civil Code of Québec.

### 3.3.1 Québec Charter of human rights and freedoms

The "Commission des droits de la personne et des droits de la jeunesse" has the mission to ensure that the principles set forth in this Charter are upheld. Again, some principles of the Charter can be relevant in the context of research. The most important ones are mentioned here.

*Article 4 – Every person has a right to the safeguard of his dignity, honour and reputation.*

*Article 5 - Every person has a right to respect for his private life.*

*Article 9 - Every person has a right to non-disclosure of confidential information.*

*Article 10 - Every person has a right to full and equal recognition and exercise of his human rights and freedoms, without distinction, exclusion or preference […].*

### 3.3.2 Civil Code of Québec

The Civil Code of Québec, in harmony with the Charter of human rights and freedoms and the general principles of law, governs persons, relations between persons, and property. It came into effect on January 1, 1994. The most relevant articles in the context of research are: 10, 13, 15, 20-22, 24, 25, 35, 37 and 1474. They are summarized here below.

Every person is entitled to the integrity of his person and a person of full age who is capable or incapable of giving his consent may participate in research that could interfere with the integrity of his person provided that the risk incurred, taking into account his state of health and personal condition, is not disproportionate to the benefit that can reasonably be anticipated. For a person incapable of giving his consent, there are however some conditions to respect. If a person of full age is incapable of giving consent to care required for his or her state of health, consent is giving by his or her mandatary, curator or tutor or by a person who shows special interest in the person of full age. Consent to medical care is not required in case of emergency.

Also, every person has a right to the respect of his reputation and privacy. The privacy of a person may not be invaded without the consent of the person or without the invasion being authorized by law. Every person who establishes a file on another person shall have a serious and legitimate reason for doing so. He may gather only information which is relevant to the stated objective of the file, and may not, without the consent of the person concerned or authorization by law, communicate such information to third persons or use it for purposes that are inconsistent with the purposes for which the file was established. In addition, he may not, when establishing or using the file, otherwise invade the privacy or injure the reputation of the person concerned. Finally, a person may not exclude or limit his liability for material injury caused to another through an intentional or gross fault. He may not in any way exclude or limit his liability for bodily or moral injury caused to another.

### 3.3.3 Data protection

Concerning, data protection, each Canadian jurisdiction – federally, provincially and territorially – has its own independent Information and Privacy Commissioner who reports to their respective legislature and oversees the relevant data protection laws applicable in that jurisdiction. In Québec, the Commission d'accès à l'information du Québec is responsible for overseeing and enforcing the following provincial access and privacy laws:

1) *Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information, Québec's public sector privacy law;*

The most relevant articles in the context of research in this Act are: 53-56, 59, 59.1, 60, 60.1, 63.1, 64 and 125. They are summarised here below.

In any document, information concerning a natural person which allows the person to be identified is personal information. The name is not personal information, except where it appears in conjunction with other information concerning him, or where the mere mention of his name would disclose personal information concerning him. Personal information is confidential, except in the following cases: (1) the person to whom the information relates consents to its disclosure (2) where it relates to information obtained by a public body in the performance of an adjudicative function; the information remains confidential, however, if the body obtained it when holding a sitting in camera or if the information is contemplated by an order not to disclose, publish or distribute. A public body shall not release personal information without the consent of the person concerned except in some specific cases only and under strict conditions. In those cases, before releasing personal information, a public body must ascertain that the information is necessary for the purposes of a prosecution or proceedings contemplated in the Act. The public body that releases information may only release such information as is necessary to achieve the purposes for which the information is released. Where information is so released, the person in charge of the protection of personal information within the public body must record the release in a register kept by the person for that purpose.

Also, a public body must take the security measures necessary to ensure the protection of the personal information collected, used, released, kept or destroyed and that are reasonable given the sensitivity of the information, the purposes for which it is to be used, the quantity and distribution of the information and the medium on which it is stored. No person may, on behalf of a public body, collect personal information if it is not necessary for the exercise of the rights and powers of the body or the implementation of a program under its management. The Commission may, on a written request, grant a person or an agency the authorization to receive communication of personal information contained in a personal information file, for study, research or statistics purposes, without the consent of the persons concerned, if it is of the opinion (1) that the intended use is not frivolous and the ends contemplated cannot be achieved unless the information is communicated in nominative form; (2) that the personal information will be used in a manner that will ensure its confidentiality. The authorization is granted for such period and on such conditions as may be fixed by the Commission. It may be revoked before the expiry of the period granted if the Commission has reason to believe that the authorized person or body does not respect the confidentiality of the information disclosed or the other conditions.

2) *Act Respecting the Protection of Personal Information in the Private Sector, Québec's private sector privacy law that has been deemed "substantially similar" to the federal private sector privacy law;*

The Act applies to such information whatever the nature of its medium and whatever the form in which it is accessible, whether written, graphic, taped, filmed, computerized, or other. It also applies to personal information held by a professional order to the extent provided for by the Professional Code. The most relevant articles in the context of research in this Act are: 1, 2, 4-6, 8, 11-15, 17, 18, 18.1, 21.1, 30 and 31. They are summarised here below.

Any person carrying on an enterprise who may, for a serious and legitimate reason, establish a file on another person must, when establishing the file, enter its object and may collect only the information necessary for the object of the file. Such information must be collected by lawful means. Any person collecting personal information relating to another person may also collect such information only from the person concerned, unless the latter consents to collection from third persons. However, he may, without the consent of the person concerned, collect such information from a third person if the law so authorizes. A person who collects personal information from the person concerned must, when establishing a file on that person, inform him (1) of the object of the file; (2) of the use which will be made of the information and the categories of persons who will have access to it within the enterprise; (3) of the place where the file will be kept and of the rights of access and rectification.

Furthermore, every person carrying on an enterprise must ensure that any file held on another person is up to date and accurate when used to make a decision in relation to the person concerned. Once the object of a file has been achieved, no information contained in it may be used otherwise than with the consent of the person concerned, subject to the time limit prescribed by law or by a retention schedule established by government regulation. No person may communicate to a third person the personal information contained in a file he holds on another person, or use it for purposes not relevant to the object of the file, unless the person concerned consents thereto or such communication or use is provided for by this Act. Consent to the collection, communication or use of personal information must be manifest, free, and enlightened, and must be given for specific purposes. Such consent is valid only for the length of time needed to achieve the purposes for which it was requested. Consent to the communication of personal information by a third person may be given by the person concerned to the person who collects the information from the third person.

Every person carrying on an enterprise in Québec who communicates personal information outside Québec or entrusts a person outside Québec with the task of holding, using or communicating such information on his behalf must first take all reasonable steps to ensure (1) that the information will not be used for purposes not relevant to the object of the file or communicated to third persons without the consent of the persons concerned, except in cases similar to those described in sections 18 and 23; (2) in the case of nominative lists, that the persons concerned have a valid opportunity to refuse that personal information concerning them be used for purposes of commercial or philanthropic prospection and, if need be, to have such information deleted from the list. If the person carrying on an enterprise considers that the information will not receive the protection mentioned before, the person must refuse to communicate the information or refuse to entrust a

person or a body outside Québec with the task of holding, using or communicating it on behalf of the person carrying on the enterprise.

Finally, a person carrying on an enterprise may, without the consent of the person concerned, communicate personal information contained in a file he holds on that person in only specific cases. The Commission d'accès à l'information may, on written request and after consulting the professional orders concerned, grant a person authorization to receive communication of personal information on professionals regarding their professional activities, without the consent of the professionals concerned, if it has reasonable cause to believe (1) that the communication protects professional secrecy, especially in that it does not allow the identification of the person to whom the professional service is rendered, and does not otherwise invade the privacy of the professionals concerned ; (2) that the professionals concerned will be notified periodically of the intended uses and the ends contemplated and will be given a valid opportunity to refuse to allow such information to be preserved or to allow such information to be used for the intended uses or the ends contemplated ; and (3) that security measures have been put into place to ensure the confidentiality of personal information. Such authorization shall be granted in writing. It may be revoked or suspended if the Commission has reasonable cause to believe that the authorized person is not complying with the prescriptions of this section, the intended uses or the ends contemplated.

3) An Act to amend the Act respecting health services and social services, the Health Insurance Act and the Act respecting the Régie de l'assurance maladie du Québec, Québec's privacy laws relating to health records.

Only the Act respecting health services and social services is presented here. The health services and social services plan established by this Act aims to maintain and improve the physical, mental and social capacity of persons to act in their community and to carry out the roles they intend to assume in a manner which is acceptable to themselves and to the groups to which they belong. The most relevant articles in the context of research in this Act are: 1, 19, 19.0.1, 19.1, 19.2, 23, 24, 27.3, 28, 34, 107, 233, 233.1. They are summarised here below.

The record of a user is confidential and no person may have access to it except with the consent of the user or the person qualified to give consent on his behalf. Information contained in a user's record may, however, be communicated without the user's consent in some specific cases only. Consent to a request for access to a user's record for study, teaching or research purposes must be in writing; in addition, it must be free and enlightened and given for specific purposes. Otherwise, it is without effect. The consent is valid only for the time required for the attainment of the purposes for which it was granted or, in the case of a research project approved by an ethics committee, for the period determined, where that is the case, by the ethics committee. The director of professional services of an institution or, if there is no such director, the executive director may authorize a professional to examine the record of a user for study, teaching or research purposes. Before granting such authorization, the director must, however, ascertain that the criteria determined under section 125 of the Act respecting Access to documents held by public bodies and the Protection of personal information are satisfied. The authorization must be granted for a limited period and may be subject to conditions. It may be revoked at any time if the director has reason to believe that the authorized professional is violating the confidentiality of the information obtained or is not complying with the

conditions imposed or with generally accepted standards of ethics and scientific integrity. Also, at the request of a user, an institution must send a copy or summary of, or an extract from, the user's record as soon as possible to another institution or to a professional. However, where the request of the user is made for study, teaching or research purposes, the institution may require consent in writing.

Regarding the complaint procedure, it must enable a user to address a verbal or written complaint to the local service quality commissioner regarding the health services or social services the user received, ought to have received, is receiving or requires from the institution. If an institution carries on research activities, the procedure must also enable any person, whether or not a user, who participates in research to make a complaint concerning the research.

Finally, every institution at the request of the Minister or the agency, must take part in the assessment of the overall performance of the health and social services system. An institution may use the name, address and telephone number contained in a user's record to carry out surveys to ascertain user expectations and satisfaction with respect to the quality of the services offered by the institution. A local authority may do the same to ascertain the level of user satisfaction with the organization of services and the results obtained. A user may at any time request the institution or local authority to use no longer the information concerning the user for such a purpose. Every institution must adopt a code of ethics, which shall set out the rights of the users and the practices, and conduct expected, with respect to the users, from the employees, the trainees, including medical residents, and the professionals practising in a centre operated by the institution.

## 3.4 Other relevant laws and regulations

- Declaration of Helsinki of the World Medical Association (WMA) adopted by the 18th WMA General Assembly in June 1964 (latest version October 2013)
- EU-ICH-Guideline for Good Clinical Practice E6(R1) of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use of 10 June 1996
- Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use
- International Ethical Guidelines for Biomedical Research Involving Human Subjects by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the Word Health Organization (WHO) signed in Geneva in 2002
- Convention of the Council of Europe on Human Rights and Biomedicine signed in Oviedo on 4 April 1997
- Additional Protocol to the Convention of the Council of Europe on Human Rights and Biomedicine concerning Prohibition of Cloning Human Beings signed of 12 January 1998
- Additional Protocol to the Convention of the Council of Europe on Human Rights and Biomedicine concerning Biomedical Research of 25 January 2005

- Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (there will be a new Directive apply from 25 May 2018, see above)

Nothing in the VITAAL project may conflict the opinions of the European Group of Advisors on the Ethical Implications of Biotechnology (1991-1997) and the opinions of the European Group on Ethics in Science and New technologies (as from 1998).

Within the VITAAL project, the research using participating elderly people is mainly conducted in Switzerland, Belgium and Canada. Therefore, the prevailing regulations will apply to these countries. Furthermore and very importantly, all project activities need to be approved by the respective Ministry of Health/the respective ethics authority. These authorities and the organization, procedure and time course/deadlines may vary in the different countries involved. Below the national specifications are described. The information sent to the respective ethical committee include objectives of the research project, methodology of the study, description of intervention and their potential benefits and risks and informed consent template.

**Switzerland:**
In Switzerland, there is the local ETHZ's ethical committee where submissions (study protocols) can be sent. Answers from this committee can normally be expected within 2 months following submission. There is also a cantonal ethical committee (Kantonale Ethikkommission Zürich). Answers from this ethical committee can normally be expected within 3 months after submission. The Ethics Committee of the Canton of Zurich (KEK) and the Ethics Commission of ETH Zurich (ETH-EK) divide labour roughly as follows: Studies on diseases, structure, and functions of the human body that are conducted in Switzerland are evaluated by KEK; All other studies with human subjects are evaluated by ETH-EK.

Beyond the international EU regulations mentioned above there are some Swiss regulations and guidelines:

- Federal Act on Research involving Human beings, Human research act (HRA) of 30 September 2011 (status as of 1 January 2014)
- Ordinance on Clinical Trials in Human Research (ClinO) of 20 September 2013 (status as of 1 January 2014)
- Ordinance on Human Research with the Exception of Clinical Trials (HRO) of 20 September 2013 (status as of 1 January 2014)
- Federal Act on Data Protection (FADP) of 19 June 1992 (status as of 1 January 2014)

**Portugal:**
In Portugal, there are national authorities that need to be contacted if a new system (software and exercise protocol used) is to be considered a clinical trial: a) The Portuguese Authority for ethical purpose is CEIC (National Ethics Committee for Clinical Research) ; b) Infarmed (National Authority of Medicines and Health Products) and c) CNPD (Portuguese Data Protection Authority). There are also local ethical committees where submissions can be sent (e.g. at Universities).

In the case of VITAAL the purpose is to develop a training software, not a clinical trial, so the new system must be only compliant with Portuguese Data Protection Requirements published by CNPD and according Portuguese Law 67/98 (Data Personal Protection Law). The project needs to obtain an authorization from CNPD to capture, process, store and present or disseminate personal information from users. The Portuguese Law 67/98 is consistent with Directive 95/46/CE issued by European Parliament in October 25th, 1995.

**Belgium:**

In Belgium, there is an independent Medical Ethics Committee of UZ Leuven and the Ethics Committee of the UPC KU Leuven (campus Kortenberg) that will approve the study execution. Beyond the international EU regulations mentioned above, there are some Belgian regulations and guidelines:

- Belgian law of May 7th 2004 on experiments of humans (permission for participation is requested from the legal representative)
- Article 29 of the Belgian law of May 7th 2004 (insurance)
- Act of December 8th 1992 on the protection of privacy with regard to the processing of personal data

**Canada:**

In Canada, the institutions that conduct research are responsible for its review. As a result, most academic centres have their own research ethics committee. In Montréal, there is a local ethical committee attached to the Centre de recherche de l'Institut universitaire de gériatrie de Montréal (CRIUGM) which is also affiliated with the Université de Montréal. As a first step, the project is submitted to the evaluation committee, which consists of three subcommittees. These three subcommittees ensure:

- The relevance and the scientific validity of the project
- The safety, the dignity and well-being of research participants and to ensure respect of their rights
- That all direct costs of research are provided for in the research budget

At the same time, the research project is also subject to an institutional suitability assessment by the direction of the research centre. Finally, the person formally mandated to authorize the carrying out of research in the establishment transmits is decision to the researcher. This whole process takes about 1 month from the deposit date of submission.

Also, in Canada, any institution that receives funding from one of the three federal granting agencies – the Canadian Institutes of Health Research, the Social Sciences and Humanities Research Council, and the Natural Sciences and Engineering Research Council of Canada —must ensure that all research involving humans conducted at that institution complies with the Tri-Council Policy Statement – Ethical conduct for research involving humans, 2010.

## 3.5 General ethical principles of VITAAL

Based on the above mentioned legislation, the VITAAL project will uphold the following five general ethical principles:

1. Respect for the integrity and dignity of persons: protecting them from being used for any other purpose than stipulated.
2. Follow the "do no harm" principle: clearly communicating any potential risks to the elderly person involved.
3. Acknowledge the rights of individuals to privacy, personal data protection and the freedom of movement.
4. Honour the requirement of informed consent and continuous dialog with elderly constructively and transparently.
5. Respect the principle of proportionality: not imposing more than is necessary on the subjects, nor going beyond stated objectives (mission creep).

# 4. Internal ethical review board

All the ethical issues should be supervised by an internal ethical review board. The supervision by an internal ethics committee should help to ensure the project's full adherence to the important ethical aspects. The internal ethical board has the following members:

- Eling de Bruin (ETHZ)
- Chantal Dumoulin (UMONTREAL)
- Davy Vancampfort (KULEUVEN)
- Bujar Badalli (DIVIDAT)

All issues with an ethical content should receive first the approval of the ethical review board of VITAAL. The internal ethics committee is especially responsible for:

- Evaluation and approval of inclusion and exclusion criteria
- Supervision of the recruitment process of participants
- Support of developing the informed consent document
- Evaluation and approval of rules for privacy and data protection
- Evaluation of potential risks and analysis of safety issues
- Approval of all documents containing ethical issues (especially reports)
- Supervision and support of the approval by the national ethical committees especially defining the timeframe for writing and submitting to the relevant authorities at the national level

# 5. Target group and inclusion/exclusion criteria

The main target group of this project is represented by elderly people aged around 60 years and older without severe illness/disability. Of special interest in this project are older adults suffering from previous falls, mild cognitive impairment, neurocognitive disorders and/or incontinence.

Elderly with mild mobility impairments will not be excluded. But it's necessary that participants are able to stand and move without any aid. People with acute behavioural problems will be excluded. Concerning neurocognitive disorders people with an MMSE score less or equal 10 have to be excluded.

The elderly involved in the different project phases will be more precisely described in the methodology definitions (e.g. which procedures are used to secure the determined criteria). In following work packages, the target groups will be more precisely formulated resulting in different scenarios/use cases which will define the elderly involved and the trial-environment in the three different countries.

# 6. Recruitment of participants

User groups will be selected and recruited in Switzerland, Belgium and Canada.

Potential participants can be addressed in many different ways (face-to-face, advertising, publicity, homepage etc.). They have to be informed about research goals and methods/procedures. This information will be handed out in writing (e.g. information letter, leaflet) and orally. Potential participants will be notified in their own language and in a comprehensible way.

The researchers will make future participants aware that their participation is completely voluntary, that they have the right to refuse to participate and that if they agree to participate, they can still terminate their participation at any time and without any given reason for their decision. The researchers will inform participants on a number of important factors which could influence their decision to participate (like risks/benefits, potential inconveniences or adverse consequences, restrictions to confidentiality etc.). Participants should get ample opportunity to read through the information, to ask the researcher any question and to consider their potential participation.

The VITAAL project will not approach people who are unable to give their informed consent (see chapter 7). In case such a situation would accidentally occur, the approach will be terminated immediately.

In order to recruit participants, no suitable high financial compensations or any other rewards may be used. It is nonetheless allowed to give participants a small and suitable present (costs have to be paid by the organization conducting the research).

# 7. Informed consent

Declared one of the most important principles in research ethics in many international conventions and guidelines, informed consent is meant to guarantee the voluntary participation in research and is probably the most important procedure regarding integrity and privacy issues.

Informed consent consists of three important components: adequate information, voluntariness and competence. This implies that, prior to consenting the participation, participants should be clearly informed about research goals and procedures, potential risks and the possibility to refuse participation or withdraw from research at any time and without consequences. It's important that participants are competent to understand the information and should be fully aware of the consequences of their consent. Therefore, people incapable of making their own choices will not be approached for the VITAAL project.

Participants will be asked for their informed consent by signing the informed consent document on the basis of the provided information. Numerous anthropological studies have pointed out that participants rarely recall what they agreed to when just signing an informed consent form. That's why a more interactive approach would be desirable and could address this issue (e.g. elaborating the written information and the informed consent document verbally).

In each phase of the VITAAL project the respective information and informed consent needs to be adapted to the research goal.

**To summarize, the informed consent document covers:**

- Goals of the project and research
- Research methods and procedures
- Potential risks and discomfort
- Anticipated benefits to participants and society
- Gratuity for participation
- Data protection, privacy and confidentiality
- Use and publication of data
- Withdrawal of participation
- Emergency care, compensation for injury or damage
- Identification of investigators (e.g. for further questions/information)
- Rights and duties of research subjects

# 8. Privacy and data protection

Privacy is a fundamental right which needs to be protected at all time. Privacy can mean many different things in different contexts. Not all people have the same notion of the right of privacy, but most people want to maintain control over personal information and communication. If personal information is disclosed, we expect this information to be treated confidentially. Data protection is meant to guarantee our right to privacy. It includes both measures with regard to access to data and the conservation of data. Data protection refers to the technical framework and security procedures designed to guarantee that all personal data are safe from unforeseen and unintended use.

Within the VITAAL project with four study sites, it is unavoidable that data will travel across borders inside the EU and between the EU and Canada. As a result, data concerning the citizens of one member state are sometimes processed in another member state of the EU or Canada. Therefore, regulations on data transfer become necessary and are implemented and observed in the VITAAL project.

For the member states of the EU, the directive to follow during the project until May 2021 is the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. All personal health data will be treated as 'sensitive personal data'. As a result, the personal data of all citizens will have equivalent protection across the EU. The member states of the EU are required to bring their national legislation in line with the provisions of this directive. From May 2018, the project will comply with Regulation (EU) 2016/679 (General Data Protection Regulation), updated in 27 April 2016 and applied in May 25, 2018. According to Regulation (EU) 2016/679, the same data protection rights across the European Union apply in the European-wide project VITAAL. For Canada the directive to follow is coming from the Commission d'accès à l'information du Québec as previously described in chapter 3.3.3 Data Protection. For the privacy and data protection between Europe and Canada, the more restrictive criteria of the legal systems concerned will be complied with.

Data protection and privacy are fundamental rights, which need to be respected. Privacy covers the right to manage one's personal information, while being free from secret surveillance. Data protection entails the integrity and control of one's data with regard to the purposes of data processing. It has to be stated explicitly that data will be transferred from one partner to another within the EU and Canada only after it was made anonymous. The international laws include the obligation to process data always fairly and in a secure manner and use it only for explicit and legitimate purpose. National laws also guarantee a series of rights for individuals, such as the right to be informed when personal data has been processed and the reason for this processing, the right to access the data and if necessary, the right to have the data amended or deleted.

The project will work as much as possible according to the principle of 'Design by default': The design of the system will automatically apply privacy settings. In other words, no manual change to the privacy settings should be required on the part of the user.

**Some principles of privacy and data protection in VITAAL: How to handle personal data**

*Personal data is understood as any piece of data regarding an identified or identifiable natural person.*

- VITAAL consortium will handle personal data in an appropriate way and is bound to the applying rules and regulations.
- The privacy of all of the participants is respected: personal data is treated as confidential sensitive data. Personal data that may lead to the identification of a participant will be disconnected from the research data.
- Within the VITAAL research, personal data will be used for its assigned goals, as determined beforehand, or for targets that are consistent with the goals mentioned.
- Members of the VITAAL consortium will not hand over any personal data to any third party without the participant's prior consent. Passing personal data to any third party is only allowed if this would serve scientific research.
- If a systematic database, with directly identifiable personal data, would eventually be constructed within the project, the researchers must provide its registration according to national rules.
- The researchers will take all suitable precautionary technical and organizational measures to prevent any loss of data or illegitimate access or processing.

# 9. Risks and safety

If there would be any risks for elderly people participating in the VITAAL project, these would be encountered most likely in the testing phase or in the developing phase.

As the project wants to develop and test gait assessment and a video game containing physical exercise, the highest risks seem to be included in the movements because there is always a risk of injury as in any other daily life movement and especially sport games and sports in general. It has to be stated that the assessments and physical exercise tasks are not very complicated and will be designed specifically for elderly people, taking into account the specificities of this target group. Participants will be well introduced, instructed and supervised by the researchers.

The potential risks will be well clarified to the participants during the recruitment process and they will be specified in the informed consent.

A plan should be designed (including insurance cover) for emergency situations that might occur during the testing.

# 10. Reports and data publication

The dissemination and publication of the results obtained are an important goal of the scientific research. Publishing research results also involves a conflict between the privacy interests of individual participants and the need for free exchange between scientific experts. There are a number of good practice codes and regulations that guide researchers in handling this conflict. The Helsinki Declaration in its latest version states the following:

*"Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication."*

All partners in the VITAAL project will adhere to the Declaration of Helsinki. For statistical analysis only data that is anonymized is used and results will only be published as summary statistics in order to prevent re-identification of individual participants.

# 11. Applying the ethical principles to the VITAAL project in the different phases

In this chapter, practical applications for the ethical principles in the different research phases are described.

## 11.1 Investigation phase

*Goal: It is essential that elderly people participate in this phase in order to get insights in the end-users' needs, attitudes and expectations. The goal is to fulfil their needs in the best possible way while developing the VITAAL systems. Another goal is to describe the archetypical stakeholders.*

| Ethical principle | Specification |
|---|---|
| Inclusion/exclusion criteria | Healthy independently living elderly people aged around 60 years and older. Of special interest in this project are older adults suffering from previous falls, mild cognitive impairment, neurocognitive disorders and/or incontinence (no severe mobility impairment). |
| Recruitment of participants | Questionnaire (end users): about 15 per involved country<br>Focus group (stakeholders): one group per involved country |
| Informed consent | Questionnaire: written informed consent depending on the regulation of countries where survey is conducted<br>Focus group: general hearing through discussion without informed consent |
| Privacy and data protection | Taking part in the questionnaire will be anonymous. The participants will be asked whether they'd like to participate in the following research. In case participants want to, then the personal data which is minimally required for this will have to be registered like name and email address. Research publication will always be anonymized. Any data transfer between the participating countries will take place without personal data. The filled out questionnaires within the VITAAL project will be destroyed six months after the project has ended. Destruction will be carried out by the project coordinators in the respective countries. |
| Risks and safety | There are no risks for the participants at all in this phase. |

| | |
|---|---|
| Reports and data publication | Reports will be situated within the project. |

## 11.2 Development phase

*Goal: It is necessary to have elderly people participating in this phase in order to get sufficient feedback especially on the user interaction with the VITAAL system so that adjustments to the final system can be made.*

| **Ethical principle** | **Specification** |
|---|---|
| Inclusion/exclusion criteria | Healthy independently living elderly people aged around 60 years and older. Of special interest in this project are older adults suffering from previous falls, mild cognitive impairment, neurocognitive disorders and/or incontinence (no severe mobility impairment). |
| Recruitment of participants | Development phase will include a small number in the main country of development procedure (Portugal, Switzerland, Belgium and Canada). |
| Informed consent | Written informed consent (adjusted for this subsection) that needs to be signed by the participants. |
| Privacy and data protection | All data will be anonymized. |
| Risks and safety | Risks because of body function assessment and physical exercising but it will be in a controlled environment and there is always at least one project member for support |
| Reports and data publication | Reports will be situated within the project. |

## 11.3 Trial phase

*Goal: Having elderly people involved in this phase is very important in order to get some final feedback on technical aspects of the system and also to evaluate the promising effect of the new developed program through the measurement of key performance indicators.*

| **Ethical principle** | **Specification** |
|---|---|
| Inclusion/exclusion criteria | Healthy independently living elderly people aged around 60 years and older. Of special interest in this project are older adults suffering from previous falls, mild cognitive impairment, neurocognitive disorders and/or incontinence (no severe mobility impairment). |
| Recruitment of participants | Intervention group: about 20 per involved country<br>Control group: about 20 per involved country |
| Informed consent | Written informed consent form with all the detailed information that needs to be signed by the participants, information will also be given orally and any questions will be answered, participants should get enough time to make their decision. |
| Privacy and data | In the methodology definition the access, storage and data safety will be |

| | |
|---|---|
| protection | discussed. |
| Risks and safety | Risks because of body function assessment and physical exercising but tasks will be designed specifically for elderly people, taking into account the specificities of this target group. |
| Reports and data publication | Reports will be situated within the project and results may be published in respectively research journals and thereby be open to the public. |

# 12. Benefits of the project

VITAAL is a solution for examining individual bodily restrictions, e.g. regarding falls, mild cognitive impairment, neurocognitive disorders and incontinence, using a gait assessment method. This assessment tool may help to formulate individualized interventions and therefore, increase the training effects on the individual level. It is well-known that falling, mild cognitive impairment and incontinence constitute a major problem to our society with serious consequences not only for the health care system but mainly also for the seniors and their families who suffer on an individual level from the consequences. The VITAAL project is aimed to have benefits not only on the individual level but also for the society at large.

## 12.1 Benefits for the individuals

Falling, mild cognitive impairment, neurocognitive disorders and/or incontinence can lead to different injuries, restrictions of movement, loss of independence, social isolation, depression and a general decrease in well-being and quality of life of the affected senior depending on each restriction. As a consequence of a fall, mild cognitive impairment, neurocognitive disorders and/or incontinence, the older adults become often dependent on their family members and caregivers who become highly involved and frequently suffer themselves from a reduced quality of life. The proposed user-centred solution will increase end-users' physical activity, strength, balance, coordination and also motor-cognitive-interplay and thereby counteract the risk of falling, mild cognitive impairment, neurocognitive disorders and/or incontinence and improve independence, well-being and the quality of life. Indirectly, there will also be an improvement in life quality of family members and caregivers. Therefore, the approach of the proposed user-centred solution is based mostly on the counteraction of falls, mild cognitive impairment and incontinence and their consequences but also on supporting and motivating elderly towards healthier and more active lifestyles, which will allow them to fully experience their advanced ageing and retirement years, maintaining their independence and full control of their lives. Moreover, VITAAL uses an assessment pool to understand the individual health condition more precisely and quantitatively and to individualize a motivating and user-centred exercise program.

## 12.2 Benefits for the society

Any intervention aiming to counteract the occurrence of these events (falls, mild cognitive impairment, neurocognitive disorders and incontinence) may also result in a reduction of the direct costs related to the medical services and also the indirect costs related to other health and care

pathways (due to the lack of independence, social isolation, depression among others). Considering that there is also an evaluation phase included in the project, impactful results together with analysis of the costs associated to the installation requirements and equipment may be sufficient to influence health care funders, community organizations and even public policies toward more appropriate management of falls, mild cognitive impairment and incontinence in the older age. The evaluation will be conducted in different European countries and Canada, taking into account the differing social and organizational needs across the countries. The VITAAL project can result in a positive influence on current strategies for falls, mild cognitive impairment neurocognitive disorders and incontinence management.