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Ageing@Work

Smart, Personalized and Adaptive ICT Solutions for Active, Healthy and Productive Ageing with enhanced Workability

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Ethics Manual

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Executive Summary

The research of Ageing@Work includes research with humans. Amongst others, planned activities include interviews, surveys, physical and psychometric tests, observations, monitoring and tracking of activities at work and in private life. With regard to the ICT solutions to be developed, it can also be assumed that, for example, daily routines are tracked and additional data is collected and processed. The collected data may include age, gender, data on health and lifestyle as well as other data such as workability and physiological, psychometric behavioural and social parameters. Design of these and other solutions of the project will be carried out with **Ethics by Design and by Default** approach. This means that ethical aspects will be considered from the very beginning and ethical aspects will be included in all evaluation activities. In addition, possibly confidential company data on the workplace's design, work processes and other working conditions are to be recorded. This results in special requirements for **data protection**, **confidentiality** and other ethical aspects like **the principle of voluntary participation** based on **informed consent** as well as **integrity** and **dignity of study participants**.

This document presents the **Ethics Manual** for the Ageing@Work project. It provides information on identified challenges and summarises fundamental requirements to deal with ethical, privacy, data protection and other related issues in the project. It must be followed by all beneficiaries to ensure **compliance with ethical and related requirements** during and after the Ageing@Work project. In addition, national legislation must be taken into account if relevant requirements arise. The manual will help beneficiaries to comply with privacy policies and to decide if and for which actions external ethics approvals are necessary. If so, it also outlines the procedure for obtaining such an approval. Furthermore, to deal with such issues an **Ethics Advisory Board (EAB)** of the project was built including members with expertise on ethics. They will assist the project in identifying and solving ethical concerns that might not be identified by the end users or the project group. Members and responsibilities of the Ethics Advisory Board are also named in this document.

Before any activity involving research with humans or the collection or processing of personal data, the **study design** including relevant aspects of data protection must be described in detail. This information is to be send to the EAB of the project before starting the respective activity. Then the EAB can make **recommendations** on whether and to what extent the planned activities should be carried out. In addition, the board recommends whether an ethics approval by an external ethics committee is advisable.

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List of Terms and Definitions

Abbreviation	Definition
AGA	Annotated Model Grant Agreement
AI	Artificial Intelligence
AR	Augmented Reality
Art.	Article
AVC	Ambient Virtual Coach
CIOMS	Council for International Organization of Medical Sciences
CFR	Charter of Fundamental Rights of the European Union
D	Deliverable
DoA	Description of the Action
DoH	Declaration of Helsinki
DPIA	Data Protection Impact Assessment
DPO	Data Protection Officer
EAB	Ethics Advisory Board
ECHR	European Convention on Human Rights
EDPB	European Data Protection Board
EGE	European Group on Ethics in Science and new Technologies
EREC	Network of European Research Ethics Committees
ERP	Ethics Responsible Person
EU	European Union
GDPR	General Data Protection Regulation
H2020	Horizon 2020
ICF	Informed Consent Form
ICT	Information and Communication Technologies
MDR	Medical Device Regulation
QoL	Quality of Life
PB	Plenary Board
T	Task
TFEU	Treaty on the Functioning of the European Union
UDHR	Universal Declaration of Human Rights
VR	Virtual Reality
WHO	World Health Organisation
WP	Work Package

Table 1: Definitions

Preface

This Ethics Manual consists of four sections plus annexes. **Section 1 "Introduction"** introduces the topic and outlines basic principles of ethics in the context of research and makes a relationship to the activities to be undertaken in the Ageing@Work project. **Section 2 "Legal Backgrounds and further Regulations"** lists national and international laws, regulations and codes of conduct related to ethics and data protection which have been identified by the authors and which may be relevant to the project. Further guidelines and sources of information are also mentioned. **Section 3 "Data Protection, Privacy and Confidentiality"** summarises the most important requirements in connection with data protection, which are derived from the *General Data Protection Regulation* (GDPR), and shows ways in which these can be overcome. Finally, **Section 4 "Ageing@Work Ethics Framework"** recommends a basic approach on how to deal with ethics and data protection issues within the Ageing@Work project.

In addition, further information and tools are provided in the appendices. **Appendix 1 "Ageing@Work Ethics Summary Report"** shows a summary of ethical questions which already emerged in the course of applying for the project. **Appendix 2 "Questionnaire on ethical and legal issues"** and **Appendix 3 "Information provided in the questionnaire on ethical and legal issues"** show a questionnaire, which was sent to all project partners for the preliminary identification of further ethical issues within the framework of the project and their feedback. Parts of this questionnaire can also be used in the further course of the project to obtain information as to whether ethics confirmations from external ethics committees are recommendable and whether a Data Protection Impact Assessment (DPIA) is required. **Appendix 4 "Information on a research / study / experimental protocol"** shows recommendations of the *World Health Association* (WHO) and the *Council for International Organization of Medical Sciences* (CIOMS) on information which should be included in a study protocol. **Appendix 5 "Informed Consent Form (ICF) Template from D1.1"** shows a draft or template for an Informed Consent Form (ICF) which can be used for the surveys in the project. **Appendix 6 "WHO Templates for ICFs"** provides supplementary WHO templates for such ICFs. **Annex 7 "List of national Data Protection Authorities"** lists national data protection authorities and Annex 8 "**DPIA Template**" contains a template for carrying out a DPIA.

In order to get a **quick overview of this document**, it is recommended to read **Section 1** and **Section 4** in particular. In this way, it is possible to identify which of the points dealt with are of major interest to the reader. The reader is then directed to other sections relevant to him by means of corresponding references within the document.

Finally it should be noted, that each beneficiary is responsible for compliance with national and international laws and regulations. Information provided by the Ethics Advisory Board and contained in the Ethics Manual are to be understood as a recommendation.

1. Introduction

1.1 Scope of the Deliverable

During and after the project, applicable ethical and privacy standards must be adhered to and possible challenges must be adequately addressed. This Ethics Manual supports the identification of ethical issues associated with the activities planned in the Ageing@Work project. The information provided and procedures described here should ensure this. This refers primarily to the development of the results within the project but also to the further use of these after the end of the project. All involved in the project are encouraged to carefully review the Ethics Manual and to confirm compliance with the proposed practices.

1.2 Relation to other Activities and Deliverables

This deliverable is related indirectly with all the activities that concern studies in humans and data collection (e.g WP2, WP3, WP5 & WP7), data management (e.g. WP9) as well as ethics and other legal requirements (e.g. WP1, WP9). However, in the development of the ICT solutions and the Ageing@Work platform (e.g. in WP4), the requirements of this document are also relevant. This applies in particular if the personal rights of users are infringed or personal data is collected, processed or shared.

1.3 Ageing@Work Project Description

Ageing@Work will develop a novel ICT-based, personalised system to support ageing workers (aged 50+) into designing fit-for-purpose work environments and managing flexibly their evolving needs. Advanced dynamically adapted virtual models of workers will incorporate specificities in respect to skills, physical, cognitive and behavioural factors, being extended from the work context to personal life aspects interacting with workability, health and wellbeing. Virtual workplace models will encode characteristics of the workplace (factory, outdoor work site, home), at both physical and semantic, resource/process levels. On top of the models, computational intelligence will be responsible to (a) assess user specificities and needs i.r.t. work conditions, both in terms of ergonomics, health and safety issues and task assignments, and (b) perform personalized predictive simulations on workability, health and well-being. Recommendations will then be provided both to the worker and company (under strict privacy restrictions), on how the working conditions must adapt. The worker models will be populated by highly unobtrusive worker sensing, both at work, at home and on the move. To foster workability and productivity, highly personalized, intuitive, age-friendly productivity, co-design enhancement tools will be developed, including ones for AR/VR-based context-awareness and telepresence, lifelong learning and knowledge sharing. On top of these, a novel Ambient Virtual Coach (AVC) will encompass an empathic mirroring avatar for subtle notifications provision, an adaptive Visual Analytics –based personal dashboard, and a reward-based motivation system targeting positive and balanced worker behaviour at work and personal life, towards a novel paradigm of ambient support into workability and wellbeing. The

integrated system will be developed following user-centered design methodology and will be evaluated at two pilot sites, related to core Industry 4.0 processes of mining and machines production.[1]

1.4 General Ethical Principles

When implementing Horizon 2020 (H2020) funded projects, beneficiaries must act in accordance with ethical principles – this includes standards of research integrity – and applicable international EU and national laws. Article 34 of the *H2020 - Annotated Model Grant Agreement* (AGA) lists the following basic ethical principles that must be followed [1]:

> *"Respecting human dignity and integrity*
>
> *Ensuring honesty and transparency towards research subjects and notably getting free and informed consent (as well as assent whenever relevant)*
>
> *Protecting vulnerable persons*
>
> *Ensuring privacy and confidentiality*
>
> *Promoting justice and inclusiveness*
>
> *Minimising harm and maximising benefit*
>
> *Sharing the benefits with disadvantaged populations, especially if the research is being carried out in developing countries*
>
> *Maximising animal welfare, in particular by ensuring replacement, reduction and refinement ('3Rs') in animal research*
>
> *Respecting and protecting the environment and future generations"*

Also to be mentioned in this context are requirements for gender equality (Article 33), avoidance or disclosure of conflicts of interest (Article 35) and confidentiality (Article 36) [1]. The aspects mentioned here can also be found in the *Grant Agreement No. 826299* on this project.

Fundamental legal bases include the *Charter of Fundamental Rights of the European Union (CFR)* [2] and the *European Convention on Human Rights (ECHR)* [3].

[1] Paragraph taken from Ageing@Work DoA

The *European Code of Ethics for Research Integrity* [4] identifies and defines the key principles of research integrity as follows:

> *"**Reliability** in ensuring the quality of research, reflected in the design, the methodology, the analysis and the use of resources.*
>
> ***Honesty** in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair, full and unbiased way.*
>
> ***Respect** for colleagues, research participants, society, ecosystems, cultural heritage and the environment.*
>
> ***Accountability** for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts."*

In an article by Emanuel et al. [5] seven basic principles are enumerated, which have to be taken into account in the ethical implementation and evaluation of research.

1. **Value**, which means that research must have benefits for science and society as well as for individuals involved.
2. **Scientific validity**, which means that suitable research methods must be carefully and professionally selected.
3. **Fair subject selection**, which means that this has to be done in a transparent dependence of the research objectives. Discrimination or privileged treatment of individuals has to be avoided, inclusion and exclusion criteria must be formulated.
4. **Favourable risk-benefit ratio**, which means that possible risks must be minimised and the intended benefit must clearly outweigh them.
5. **Independent review**, which means that the intended procedures and the results are transparently described and reviewed by independent bodies.
6. **Informed consent**, which means that stakeholders must be fully informed of the course of action and the consent or refusal to participate is entirely voluntary.
7. **Respect for enrolled subjects**, which means that the well-being of the participants is continuously monitored, their privacy is respected and there is the possibility to revoke the participation without negative consequences.

Although these are originally related to clinical research, they can also be applied to the studies planned within the Ageing@Work project.

1.5 Ethical Issues in Ageing@Work

The principles of research integrity referred to in Section 1.4 and the resulting Good Research Practices [4] certainly apply to all activities within the framework of the Ageing@Work project. The ethical principles listed in the previous section mainly relate to activities in WP1 (*Ethics requirements*), WP2 (*User requirements, system specification and architecture*), WP3 (*Worker and workplace models and orchestration support tools*), WP7 (*Ageing@Work platform integration and validation*) and WP9 (*Project Coordination and Management*), as well as all other processes involving human subjects or including collection, processing or sharing personal data. This applies in particular to the development (and application in pilot studies) of the ICT solutions and the Ageing@Work platform (for example in WP4).

The aim of adhering to these principles is to derive maximum benefit from research activities and to reduce adverse effects and risks for all stakeholders, but in particular for the research subjects, as far as possible. Adverse effects for the research subjects can be characterised in particular by the following points:

- Physical damages (i.e. injuries)
- Major psychological or emotional harms (i.e. stress or anxiety)
- Economic, social or reputational disadvantages (i.e. loss of job or salary, discrimination, stigmatisation or harassment)
- Violation of privacy or misuse / loss of personal data (i.e. non-protection of anonymity, unauthorised transfer of data to third parties or data theft)

The Ageing@Work Ethics Summary Report (see Annex 1) provides a first overview of identified ethics issues. The planned research involves human participants on a voluntary basis. In addition, it is expected that (sensitive) personal data will be collected and processed and that data might be further processed (secondary use). In addition, tracking with sensors and observation of the participants is planned. This is the basis for mainly privacy and data protection requirements. Further requirements arise with regard to the recruitment process of the participants and the informed consent. The participation should be absolutely voluntary. However, most of the envisaged participants are employees of the participating companies, which in turn are involved in the recruitment process, data collection, processing and analysis.[2] This means that the participants are in a relationship of dependence. This results in very special challenges to the recruiting process in order to ensure the voluntariness and avoid adverse consequences of participation. Therefore, the Ethics Summary Report recommends an ethics check of the recruiting procedure. Furthermore, it is required, among other things, to describe the nature and extent of data collection, data processing and data dissemination and to carry them out in accordance with international and national law. An Incidental Findings Policy is required, too.

[2] This occurs only for Siemens not ANEFA as the workers at the quarries are not employees of ANEFA. Nevertheless, it must also be ensured here that participation is absolutely voluntary and that non-participation does not entail any disadvantages.

To address these ethical issues, as part of the submission of the Ageing@Work project, adjustments have already been made in Section 5 (*Ethics and Security*) of Appendix 2, Part B (DoA). In addition, the work package "*WP1 - Ethics requirements*" has been added to the project plan.

In order to identify further possible ethics issues, the authors of this document distributed a template on ethical and legal issues with a questionnaire (see Annex 2) to all beneficiaries. In addition, the activities described in the DoA were analysed in order to uncover further fields of action. Apart from the points already mentioned above, further possible ethical aspects to be considered could be identified. These include, but are not limited to, the prevention of physical (and other) adverse effects on participants, the minimisation of risks, the maximisation of benefits, the safety and adequacy of the equipment and methods used, and the confidentiality of company information. The information provided by the project partners in the questionnaire is presented in Annex 3[3].

Further information on the challenges outlined here and suggested procedures how these can be managed are presented in the following sections. Finally, it should be noted that in the course of the project, even after completion of the Ethics Manual, further ethical issues may arise which cannot yet be identified at the present time. In order to counter this situation, all planned activities must be carried out in close coordination with the Project Management and Ethics Advisory Board.

[3] It should be noted that the questionnaire was submitted to the parties at a very early point in the project. Since the exact procedures and study designs for the planned activities had not yet been finally determined at this stage, the information provided represents a first inventory of possible ethical issues. Additional aspects may arise in the further course of the project, others may not be relevant.

2. Legal Backgrounds and further Regulations

2.1 Preface

This section lists the main legal bases and other relevant directives and possible sources of information. Some of these are briefly summarised, others are merely listed as further readings. The sources listed here are to be understood as an indicative list. It is the responsibility of the individual actors within the project to identify and comply with relevant legal requirements for the planned activities. The Ethics Advisory Board (EAB) of the project can provide support and advice in the process.

2.2 Horizon 2020 Regulations and Guidelines

Fundamental ethical requirements for projects carried out under H2020 are set out in Article 19 of *EU Regulation No 1291/2013* [6], which states:

> *"All the research and innovation activities carried out under Horizon 2020 shall comply with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols.*
>
> *Particular attention shall be paid to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection."*

Further information on identifying and addressing ethical issues in H2020 projects is provided in *Ethics in Social Sciences and Humanities* [7]. Among other things, topics such as the influence of research methodology on ethical aspects, research with (vulnerable) participants, informed consent, incidental findings, data protection, risk assessment and ethics approvals are discussed. Information and procedures to ensure data protection in EU funded projects can be found in the document *Ethics and data protection* [8]. With regard to Ageing@Work, the topic is discussed in more detail in Section 3. Another document issued by the European Commission [9] outlines the tasks and functions of the Ethics Advisory Board (EAB). This is addressed in Section 4.3.

2.3 Ageing@Work Grant Agreement

Article 34 of the *Grant Agreement Number 826299 - Ageing@Work*, similar to the *AGA* [1], establishes rights and obligations with regard to ethical issues. All beneficiaries in the project are therefore obliged to act in accordance with the principles of ethics and research integrity already mentioned in Section 1.4. In addition, for activities that raise ethical issues, it must be considered whether the opinion or authorisation of an independent ethics committee (ethics approval) should be obtained.

Furthermore Section 5 *DoA* (Part B) lists initial requirements for the recruitment process, informed consent, privacy and protection of personal data, incidental findings and secondary use of personal data.

2.4 EU Regulations and Guidelines

The most fundamental ethical requirements for research projects involving human participants at European level can be traced back to the *Charter of Fundamental Rights of the European Union (CFR)* [2] and the *European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR)* [3].

For privacy and the protection of personal data, the *General Data Protection Regulation* (GDPR) [10] forms the most important legal basis. In this context, the requirements of the *Directive on privacy and electronic communications* [11] and *Directive 2009/136/EC* [28] may also be relevant. However, these must be implemented into national law by each member state of the EU.

If the ICT solutions used or developed as part of the Ageing@Work platform fall within the scope of *Regulation (EU) 2017/745 on medical devices (MDR)* [12], this will result in further demands. According to Art. 2, 1 of the MDR

> *"'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:*
>
> - *diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
> - *[…]".*

If this is the case, the efforts made in the project to test the ICT solutions could be understood as 'clinical evaluation' (see Art. 1, 44) or 'clinical investigation' (see Art. 1, 45). Then, among other things, the requirements of Chapter VI 'Clinical Evaluation and Clinical Investigations' and Annex XIV as well as Annex XV must be considered. In Addition *Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use* [13] may also have to be taken into account. The classification rules for medical devices set out in Annex VIII shall also apply. Under https://www.bfarm.de/EN/MedicalDevices/Differentiation/MedicalApps/_artikel.html (Accessed 23 May 2019), the *German Federal Institute for Drugs and Medical Devices (BfArM)* offers guidance which, for example, helps to decide whether medical apps fall within the scope of the German *Act on Medical Devices* (Medizinproduktegesetz - MPG) [14]. This is the national implementation of inter alia *Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices* and *Directive 93/42/EEC of 14 June 1993 concerning medical devices*. These directives will be replaced by the new MDR. Nevertheless, first decision-making support can be found under the link mentioned above.

The *European Textbook on Ethics in Research* [15] and the results of the European RESPECT project [16, 17, 18] can be recommended as further readings on the subject of ethics and data protection in research.

More information and comments on relevant issues can be found in the opinions, recommendations and statements of the *European Group on Ethics in Science and new Technologies (EGE)*[4], the *Article 29 Data Protection Working Party*[5], the *European Data Protection Board (EDPB)*[6] and the *High-Level Expert Group on Artificial Intelligence*[7]. At this point, we should not forget to mention in particular *Guidelines on Data Protection Impact Assessment (DPIA)* [19], *Guidelines on Automated individual decision-making and Profiling* [20] as well as *EGE Opinion No. 26 - Ethics of Information and Communication Technologies* [21] and *EGE Opinion No. 29 - The ethical implications of new health technologies and citizen participation* [22]. More details on European data protection legislation are presented in the *Handbook on European data protection law* [23].

2.5 International Guidelines and Codes of Conduct

To uphold ethical principles in research, the *Declaration of Helsinki (DoH)* [24] and the *Nuremberg Code* [25] should always be complied with. Both documents contain important cornerstones to ensure research ethics at the international level.

Further guidelines for the observance of ethical principles, issued by the *World Health Organisation (WHO)* and the *Council for International Organizations of Medical Sciences (CIOMS)* respectively, are listed and explained in *International Ethical Guidelines for Health-related Research Involving Humans* [26] and *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants* [27]. The first source is aimed primarily at researchers who plan and carry out research projects with human participants. Among other things, it contains points which should be included in a study protocol and sets minimum requirements for obtaining informed consent. The second source is addressed to research ethics committees as well as to researchers themselves.

[4] https://ec.europa.eu/info/research-and-innovation/strategy/support-policy-making/scientific-support-eu-policies/european-group-ethics-science-and-new-technologies-ege_en#ege-opinions-and-statements
[5] https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/index_en.htm
[6] https://edpb.europa.eu/guidelines-relevant-controllers-and-processors_en
[7] https://ec.europa.eu/futurium/en/ai-alliance-consultation/guidelines#Top

2.6 National Laws and Regulations

This section lists the most relevant national legislations and codes of conduct, broken down by beneficiary's nations. The sources listed here are based on *D1.2 POPD-Requirement No.6* (Ageing@Work) and the responses to the questionnaire in the Template on ethical and legal issues (see Annex 2 and Annex 3).

Belgium

- Act 13 June 2005, Basic federal act for the electronic communications sector
- Act of 6 July 2005 on various legal provisions regarding electronic communications
- Organic Law 03/12/2017, Establishment of Data Protection Authority
- Organic Law 30/7/2018, on Protection of Natural Persons with regard to the Processing of Personal Data (Data Protection Act)
- Organic Law 12/2018, Law establishing the Data Protection Authority (DPA Act)

Cyprus

- Law N. 28 (III)/2001
- Law N.30(III)/2003
- Law N. 112 (I)/2004 about electronic communications and postal services
- Law N. 125(I)/2018, Protection of Natural Persons with regard to the Processing of Personal Data (Data Protection Act)
- Law N. 150 (I) /2001

Germany

- Federal Data Protection Act (BDSG)
- Federal State Data Protection Laws (LDSGs) [Each federal state has its own, see https://www.datenschutz-wiki.de/Landesdatenschutzgesetze]
- Telekommunikationsgesetz (TKG) ["Telecommunication Act"]
- The Act on Medical Devices (Medizinproduktegesetz - MPG)
- Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data

Greece

- Law 2472/1997
- Law 3471/2006
- Law 3783/2009
- Law 3917/2011
- Law 4024/2011
- Law 4070/2012
- Law 4139/2013

Italy

- Legislative Decree n. 196/2003, Italian Data Protection Code
- Legislative Decree n. 101/2018, Provisions for the harmonization of national legislation to the provisions of the GDPR on matters delegated to Member State law

Poland

- Act of 10 May 2018 on the protection of personal data (Journal of Laws of 2018, item 1000, hereinafter referred to as "DPA") - from 25 May 2018;
  http://prawo.sejm.gov.pl/isap.nsf/download.xsp/WDU20180001000/T/D20181000L.pdf
  https://www.uodo.gov.pl/en/514/886
- Communication of the President of the Office for the Protection of Personal Data of 17 August 2018 on the list of types of personal data processing operations requiring an assessment of the effects of processing on their protection;
  http://prawo.sejm.gov.pl/isap.nsf/DocDetails.xsp?id=WMP20180000827
- The Constitution of the Republic of Poland (art. 47, art. 51)
  https://giodo.gov.pl/en/408/2
  https://www.giodo.gov.pl/144/id_art/779

Spain

- Spanish Information Society Services Act (Law 34/2002 on information society services and e-commerce)
- Spanish General Telecommunications Act (Law 9/2014)
- Organic Law 3/2018, Spanish Data Protection of Data Protection and Guarantee of Digital Rights (Spanish Data Protection Act)
- Spanish Patient Act, Clinical Documents and Information (Law 41/2002)
- Spanish Constitutional Law
- Organic Data Protection Law 15/1999, (LOPD)
- Law 14/2007 of Biomedical Research (known in Spanish as LIB)
- Royal Decree 1090/2015 regulating clinical trials with medicinal products

United Kingdom

- UK Data Protection Act 1998
- Data Protection Act 2018

3. Data Protection, Privacy and Confidentiality

3.1 Background

3.1.1 History

The European Union knows two distinct basic rights concerning privacy and personal data protection. The right to respect for private life, called the right to privacy, enshrined first in international human rights law as one of the fundamental protected human rights in the Universal Declaration of Human Rights (UDHR) in 1948. Subsequently, Europe adopted this right in the European Convention on Human Rights (ECHR) in 1950. These laws were passed long before the development of the Internet and other new technologies. Therefore, new rules governing personal data collection and processing were needed. The right to personal data protection was first adopted in different European countries in the 1970s and was later on established at European level in the Convention 108 ("Convention for the protection of individuals with regard to automatic processing of personal data") in 1981. Building on this, the European Union developed the Data Protection Directive (Directive 95/46/EC) in 1995 which was transposed into national law by the individual EU countries.

At present, the protection of personal data in the European Union is guaranteed by Article 8 of the EU Charter of Fundamental Rights (CFR) [2] and Article 16 of the Treaty on the Functioning of the European Union (TFEU) [29]. In the age of advancing technical development and innovations, more and more information and personal data is digitalized and can be retrieved more easily and quickly. This is why the informational self-determination of EU citizens is both important and challenging. The abundance of information and the ease of its storage and combination awaken desires and carry high risks. Data protection is intended to counter these risks preventively. In order to meet the new challenges, the EU recently has introduced the General Data Protection Regulation (GDPR) [10] which is directly applicable in the EU countries since 2018 and replaces the previous Data Protection Directive. Besides, there are other national regulations on data protection on the basis of flexible clauses of the GDPR, e.g. concerning data protection for employees or for scientific research purposes. The EU legislation sets out the principles of the protection of natural persons with regard to the processing of their personal data regardless of their nationality or residence to protect their fundamental rights and freedoms, in particular their right to the protection of personal data in the digital age. In this way the GDPR makes a contribution to the accomplishment of an area of freedom, security and justice as well as to economic and social progress and to the well-being of natural persons in the European Union (Recital 2 GDPR).

3.1.2 Definitions

The GDPR defines some terms that are relevant to data protection in Ageing@Work [10].

- **Personal data** means any information relating to an identified or identifiable natural person (data subject) […] who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person (Art. 4 GDPR).
- **Special categories of personal data** are personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership […] as well as genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation (Art. 9 GDPR).
- **Processing** means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction (Art. 4 GDPR).
- **Profiling** means any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to a natural person, in particular to analyse or predict aspects concerning that natural person's performance at work, economic situation, health, personal preferences, interests, reliability, behaviour, location or movements (Art. 4 GDPR).
- **Pseudonymisation** means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person (Art. 4 GDPR).
- **Consent** of the data subject means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her.
- **Controller** means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data […] (Art. 4 GDPR).
- **Processor** means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller (Art. 4 GDPR).

3.1.3 Data Protection Principles

With regard to data protection according to GDPR, there are seven basic principles (Figure 1) that must be respected when collecting and processing personal data in Ageing@Work (see Art. 5 GDPR) [10].

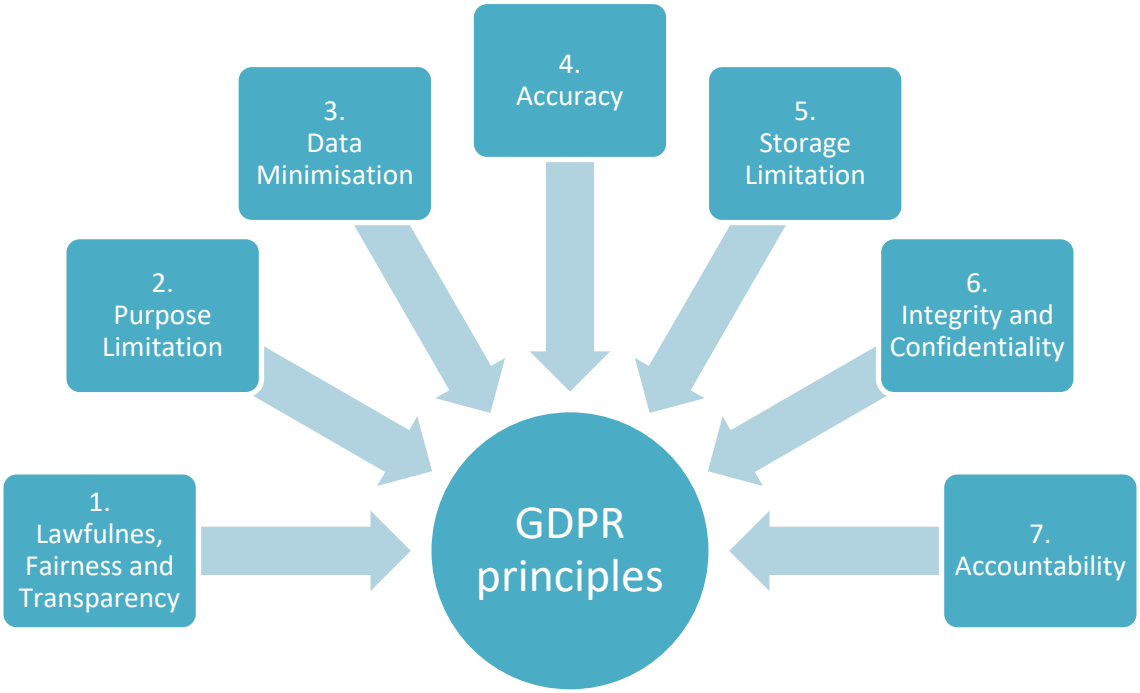

Figure 1: Basic principles of the GDPR

1. **Lawfulness, Fairness and Transparency**
   Personal data must be processed lawfully. The consent to the storage and processing of personal data must be voluntary, specific, unambiguous and based on information. Personal data must be processed fairly and in a manner understandable to the data subject. The principle of transparency assumes that all information is easily accessible and understandable and written in clear and simple language.
2. **Purpose Limitation**
   Personal data must be collected for specified, explicit and legitimate purposes and must not be further processed in a way incompatible with those purposes. Further processing for archiving purposes in scientific research purposes shall not be considered to be incompatible with the initial purposes as long as it is in accordance with Article 89(1) GDPR.
3. **Data Minimisation**
   Personal data must be adequate, relevant and limited to what is necessary for the purposes of the processing. Personal data should be allowed to be processed only if the purpose of the processing cannot reasonably be achieved by other means.
4. **Accuracy**
   Personal data must be accurate and, where necessary, kept up to date. All reasonable steps shall be taken to ensure that personal data which are inaccurate for the purposes of their processing are erased or rectified without delay.

5. **Storage Limitation**
   Personal data must be stored in a form which allows data subjects to be identified for no longer than is necessary for the purposes for which they are processed. Exception: Personal data may be retained for longer periods, to the extent that the personal data are used exclusively for scientific and non-commercial purposes in accordance with Article 89(1) GDPR subject to the implementation of appropriate technical and organisational measures required by the GPDR to protect the rights and freedoms of the data subject.
6. **Integrity and Confidentiality**
   Personal data must be processed in a manner which ensures adequate security of personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage using appropriate technical or organisational measures.
7. **Accountability**
   The controller shall be responsible for and be able to demonstrate compliance with the above principles and GDPR requirements.

Furthermore, from Article 6 of the GDPR the following legal bases result to lawful data processing:

- Consent of a data subject to the processing of personal data;
- contractual necessity;
- legal obligation;
- vital interests;
- public interests;
- legitimate interests.

The data processing is only then lawful if at least one of the requirements is fulfilled.

3.1.4 Rights of the Data Subjects

There are some specific rights of data subjects and duties of controllers concerning data protection according to the GDPR that have to be respected when collecting and processing personal data in Ageing@Work [10].

Right to Information and Access to Personal Data (Art. 13 et seq. GDPR)

When personal data is collected within Ageing@Work, the controller must provide the data subject at least with the following information:

- Identity and contact details of the controller (and the controller's representative);
- contact details of the Data Protection Officer (DPO);
- purposes and legal basis (see Section 3.1.3) of the processing;
- categories of personal data concerned;
- legitimate interests pursued by the controller or by a third party (when processing is based on GDPR Art. 6(1) point (f));
- recipients or categories of recipients of the personal data;

- intention to transfer personal data to a third country or international organisation and the existence or absence of an adequacy decision by the Commission, where applicable;
- period for which the personal data will be stored;
- right to request from the controller access to and rectification or erasure of personal data or restriction of processing concerning the data subject or to object to processing as well as the right to data portability;
- right to withdraw consent at any time;
- right to lodge a complaint with a supervisory authority;
- whether the provision of personal data is a statutory or contractual requirement and whether the data subject is obliged to provide the personal data and the possible consequences of failure to provide such data, where applicable;
- existence of automated decision-making, including profiling, and meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject, where applicable;
- data source, when the personal data are not collected directly from the data subject.

The controller has the duty to provide this information with the data subject to ensure fair and transparent processing in respect of the data subject. The information should be provided within the informed consent form that is submitted to the data subjects before participation.

Right to Rectification and Erasure (Art. 16 et seq. GDPR)

The data subject has the right to obtain from the controller at any time the rectification and completion of data that is inaccurate or incomplete. Data that is no longer required must be deleted immediately. The data subject has the right to obtain from the controller the erasure of personal data unless there is a legal basis for storing the data. The controller has the duty to erase personal data when one of the following reasons applies:

- The personal data are no longer necessary in relation to the initial purposes.
- The data subject withdraws consent on which the processing was based.
- The data subject objects to the processing pursuant to Art. 21 GDPR.
- The personal data have been unlawfully processed.
- The personal data have to be erased for compliance with a legal obligation in Union or Member State law to which the controller is subject.

The right of erasure can be restricted where processing is necessary for archiving purposes in scientific research in accordance with Art. 89 GDPR, to the extent, that the right of erasure is likely to make it impossible or seriously impair the achievement of the objectives of that processing.

Right to Object and Non-automated Individual Decision-making (Art. 21 et seq. GDPR)

The data subject has the right to object, on grounds relating to his or her particular situation, at any time to processing of personal data concerning him or her which is based on point (e) or (f) of Article 6(1) GDPR, including profiling based on those provisions. The controller shall no longer process the personal data

unless the controller demonstrates compelling legitimate grounds for the processing which override the interests, rights and freedoms of the data subject or for the establishment, exercise or defence of legal claims. Where personal data are processed for scientific research purposes pursuant to Article 89(1) GDPR, the data subject, on grounds relating to his or her particular situation, shall have the right to object to processing of personal data, unless the processing is necessary for the performance of a task carried out for reasons of public interest.

The data subject shall have the right not to be subject to a decision based solely on automated processing, including profiling, which produces legal effects or similarly significantly affects the data subject. This right can be limited if the decision is authorised by Union or Member State law to which the controller is subject and suitable safeguard measures are taken to protect the data subject's rights, freedoms and legitimate interest.

Duties of the Controller (Art. 24 et seq. GDPR)

The controller is responsible for compliance with the regulations and the protection of the rights of data subjects. Taking into account the state of art, the cost of implementation and the nature, context, scope and purposes of processing as well as the severity and likelihood of risks to the rights and freedoms of natural persons, the controller has to observe or perform the following:

- Implementation of appropriate technical and organisational measures (e.g. Pseudonymisation);
- review and update of these measures;
- implementation of appropriate data protection policies;
- data protection by design and by default.

3.1.5 Data Protection Officer

According to Article 37 GDPR, the controller and the processor shall designate a data protection officer (DPO) in any case where:

- the processing is carried out by a public authority or body, except for courts acting in their judicial capacity;
- the core activities of the controller or the processor consist of processing operations which, by virtue of their nature, their scope and/or their purposes, require regular and systematic monitoring of data subjects on a large scale; or
- the core activities of the controller or the processor consist of processing on a large scale of special categories of data pursuant to Article 9 GDPR and personal data relating to criminal convictions and offences referred to in Article 10 GDPR.

The DPO shall be appointed on the basis of professional qualities and expert knowledge of data protection laws and practices and the ability to perform the duties referred to in Article 39 of the GDPR. The DPO may be an employee of the controller or processor or perform the tasks on the basis of a service contract. The controller or processor shall publish the contact details of the data protection officer and communicate them to the supervisory authority (Art. 37 GDPR).

The DPO shall have at least the following tasks (Art. 39 GDPR):

- to inform and advise the controller or the processor and the employees who carry out processing of their obligations pursuant to the GDPR and to other Union or Member State data protection provisions;
- to monitor compliance with the GDPR, with other Union or Member State data protection provisions and with the policies of the controller or processor in relation to the protection of personal data, including the assignment of responsibilities, awareness-raising and training of staff involved in processing operations, and the related audits;
- to provide advice where requested as regards the data protection impact assessment and monitor its performance;
- to cooperate with the supervisory authority;
- to act as the contact point for the supervisory authority on issues relating to processing, including the prior consultation and to consult, where appropriate, with regard to any other matter.

The responsible DPOs of the project partners, if any, are listed in Annex 3.

3.2 Risk Assessment

3.2.1 Risk-based Approach

The GDPR includes a risk-based approach to data protection and privacy. Controllers are obliged to assess the severity and likelihood of risks to the fundamental rights and freedoms of data subjects and, in response to their data processing activities, to take protective measures corresponding to the level of risk. According to GDPR, controllers must perform risk assessments within the framework of Data Protection Impact Assessments (DPIA) where there are high risks involved in data collection or processing. Therefore the data protection requirements described above must be taken into account, e.g. data security, data protection by design, fair processing, legitimate interest, purpose limitation etc.

To standardise the risk assessment procedure in Ageing@Work, the individual steps are explained in more detail below. The legislation demands data controllers to ensure a level of security proportionate to the risk involved in collecting and processing of personal data in Ageing@Work. Controllers can comply with this requirement by first identifying the risks, before implementing the appropriate level of technical and organisational measures to mitigate the risks.

There is no clear definition of the term “risk” in the GDPR, but it can be derived for example from the Recital 75. Therein it means that risks to the rights and freedoms of natural persons may result from personal data processing which could lead to physical, material or non-material damage. In particular, the following impacts are highlighted:

- discrimination;
- identity theft or fraud;
- financial loss;
- damage to the reputation;

- loss of confidentiality of personal data protected by professional secrecy;
- unauthorised reversal of pseudonymisation;
- any other significant economic or social disadvantage;
- discrimination in their rights and freedoms;
- prevention from exercising control over their personal data;

The GDPR distinguishes between risks and high risks. To evaluate risks on the basis of an objective assessment, the severity and likelihood of the risks to the rights and freedoms of data subjects should be determined by reference to the nature, scope, context and purposes of the data processing (Recital 76).

Below sets out a non-exhaustive list of activities that represent a potential high risk for data subjects:

- processing of special categories of personal data such as racial or ethnic origin, political opinions, religion or philosophical beliefs, trade union membership, genetic data, data concerning health or data concerning sex life or criminal convictions and offences;
- evaluation of personal aspects, in particular analysing or predicting aspects concerning performance at work, economic situation, health, personal preferences or interests, reliability or behaviour, location or movements, in order to create or use personal profiles;
- processing of personal data of vulnerable natural persons (which may be also employees due to their hierarchical relationship to the employer [30]);
- processing involves a large amount of personal data and affects a large number of data subjects;
- processing using new technologies (big data, automated processing, profiling, …);
- systematic monitoring of a publicly accessible area.

In order to decide whether there are high risks, the table on risk assessment in the Annex 2 (Section VI. “Risk Assessment”) may be used. It contains risk assessment questions which serve to identify possible risks arising from the planned research activity. If the result does not reveal any risk, no additional measures other than the usual compliance measures need to be taken. If any question is answered with "Yes", a full risk assessment as part of a DPIA must be carried out. The GDPR requires in certain cases a DPIA and a prior consultation of a supervisory authority, depending on the risks of the data processing and the measures taken by the controller to mitigate the risks. Figure 2 shows the general procedure to decide whether a DPIA and a prior consultation are necessary. But note that even if no DPIA is mandatory, there may be a need to assess risks and take protective measures.
There are exemption clauses in which no DPIA has to be performed (see Figure 2). This is the case if the supervisory authority has placed the processing operation on a published list or if there is a legal basis in Union or Member State law to which the controller is subject, which regulates that there is no DPIA required for certain processing operations because the DPIA has already been implemented as part of a general impact assessment (Art. 35 GDPR).

To ensure security of processing operations, the controller or processor should assess the risks associated with the processing and implement measures to mitigate those risks, e.g. pseudonymisation or encryption. Appropriate measures depend on the context and the specific risks of the processing operations. Those measures should ensure an adequate level of security, including confidentiality, taking into account the state of the art and costs of implementation in relation to the risks and nature of the personal data to be

protected. The assessment of the data security risk should take into account the risks arising from the processing of personal data, such as accidental or unlawful destruction, loss, alteration, unauthorised disclosure or access to personal data transmitted, stored or otherwise processed which may in particular lead to physical, material or non-material damage.

Where the processing may present a high risk to the rights and freedoms of natural persons, the controller should be responsible for the implementation of a DPIA, which shall in particular assess the origin, nature, particularity and severity of that risk. The outcome of the assessment should be taken into account when determining the appropriate technical and organisational measures. If a DPIA finds that processing operations pose a high risk that the controller cannot mitigate by appropriate measures in relation to the available technology and costs of implementation, the supervisory authority (see Annex 7) should be consulted prior to the processing (Recital 83 et seq. GDPR).

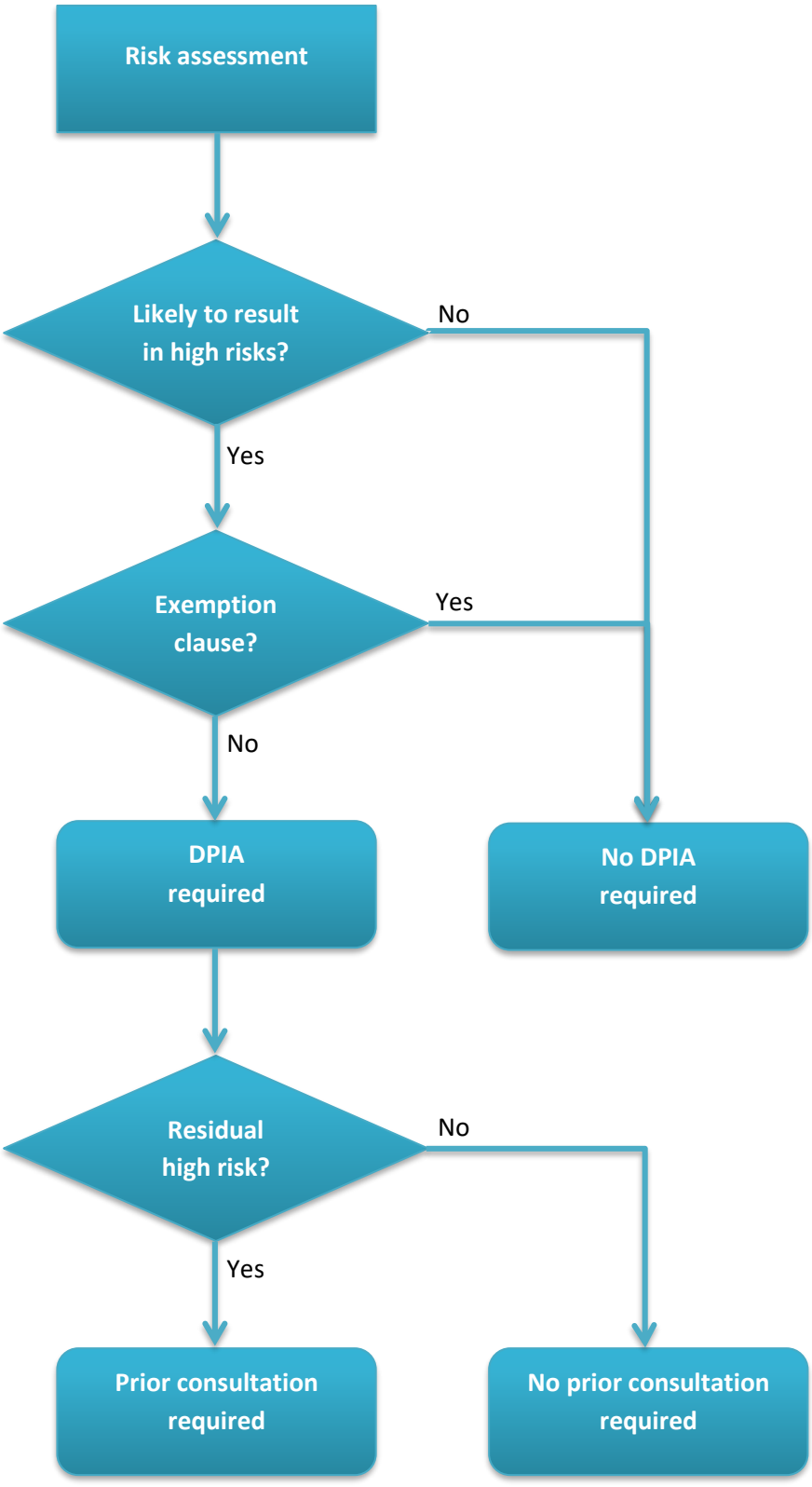

Figure 2: Flow chart for the decision about DPIA and prior consultation

3.2.2 Data Protection Impact Assessment (DPIA)

According to Article 35 GDPR, the controller shall carry out an assessment of the impact of the envisaged processing operations on the protection of personal data prior to the processing where it is likely to result in a high risk to the rights and freedoms of natural persons (see Section 3.3.1). In general a DPIA concerns a single data processing operation. A single assessment may address a set of similar processing operations that present similar high risks. The controller shall have recourse to the assistance of the DPO where necessary.

The assessment shall contain at least:

- a systematic description of the envisaged processing operations and the purposes of the processing, including, where applicable, the legitimate interest pursued by the controller
- an assessment of the necessity and proportionality of the processing operations in relation to the purposes
- an assessment of the risks to the rights and freedoms of data subjects
- the measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of personal data and to demonstrate compliance with the GDPR taking into account the rights and legitimate interests of data subjects and other persons concerned

The relevant controllers or processors should take into account the codes of conduct (see Art. 40 GDPR) when assessing the impact of processing operations carried out by those controllers or processors. The controller shall seek the advice of the DPO, where designated, when carrying out a DPIA. The DPO may provide advice and monitor the performance of the DPIA. In addition, the controller shall seek the views of the data subjects or their representatives on the intended processing, without prejudice to the protection of commercial or public interests or the security of the processing, where appropriate [10].

The legislation does not specify the method by which a DPIA is to be conducted, but there are criteria that it must include. Figure 3 shows the general cycle process for carrying out a DPIA. As it is an iterative process, it is likely that each of the phases will be repeated several times before the DPIA can be completed. According to Article 35 GDPR, the controller shall carry out a review to assess if processing is performed in accordance with the data protection impact assessment at least when there is a change of the risk represented by processing operations. In principle, a DPIA should be continuously reviewed and regularly re-evaluated in order to establish good practice.

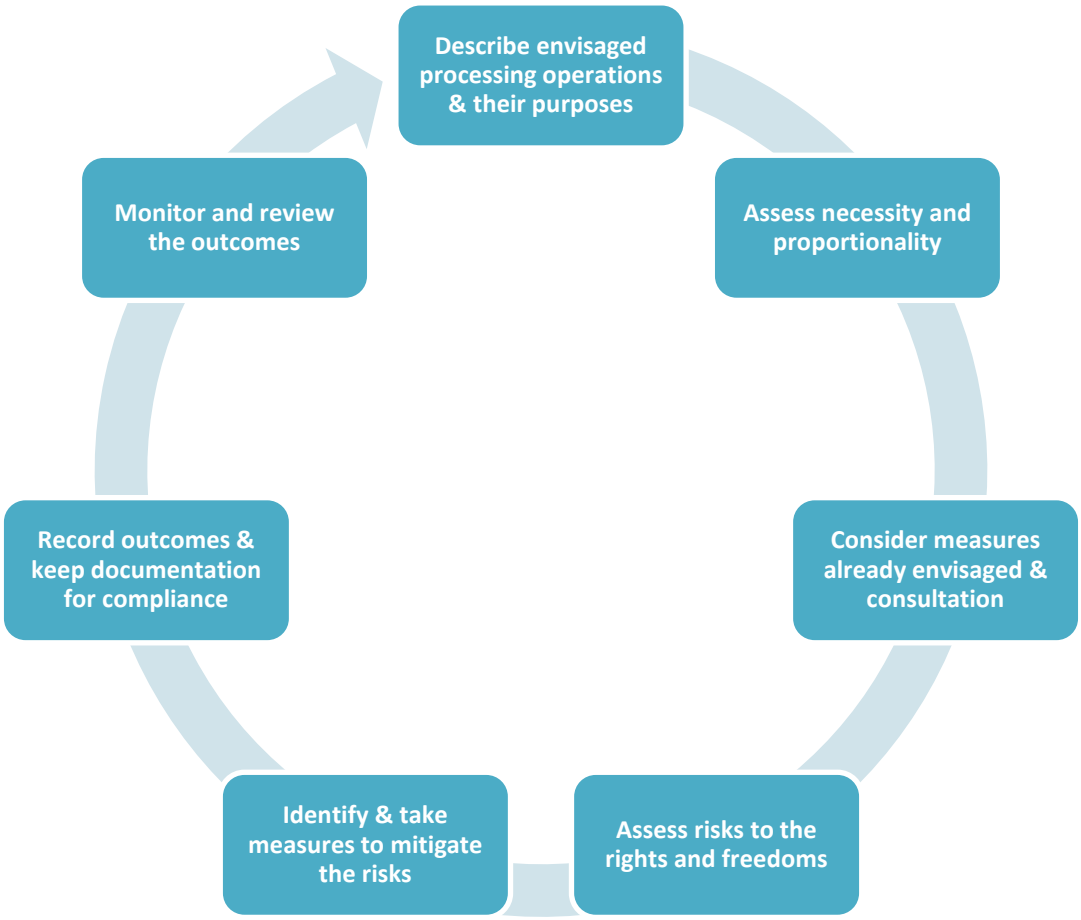

Figure 3: General iterative process of a DPIA

On the basis of the DPIA, appropriate technical and organisational measures must be taken to mitigate risks to the rights and freedoms of individuals. Risk reduction does not mean eliminating the risk, but reducing it as far as possible, taking into account the desired benefits and the appropriate economic and technological parameters. The DPIA must be well documented and retained as evidence of compliance.

Where the processing operation is carried out by joint controllers, they must clearly define their respective obligations. Their DPIA should set out which party is responsible for the various risk management measures and for protecting the rights and freedoms of the data subjects. Each data controller should express his or her needs and provide useful information without either compromising secrets (e.g.: protection of trade secrets, intellectual property, confidential business information) or disclosing vulnerabilities. A DPIA may also be useful for assessing the data protection impact of a technology product, e.g. hardware or software, if it is likely to be used by different data controllers to perform different processing operations. Of course, the data controller using the product remains obliged to perform its own DPIA in relation to the specific implementation, but this may be communicated by a DPIA created by the product provider [30]. It is to expect that also in the context of the Ageing@Work project processing operations are carried out by joint controllers (see Section 3.3.2).

3.2.3 Prior Consultation

According to Article 36 GDPR, the controller shall consult the supervisory authority prior to processing where a DPIA indicates that the processing would result in a high risk in the absence of measures taken by the controller to mitigate the risk. That means, this only applies if the company does not take appropriate measures to contain the risk. A list with the competent data protection authority for each country can be found in the Annex 7 and at the following link: https://edpb.europa.eu/about-edpb/board/members_en.

Where the supervisory authority is of the opinion that the intended processing would infringe the regulations of the GDPR, in particular where the controller has insufficiently identified or mitigated the risk, the supervisory authority shall give written recommendations to the controller and to the processor, where applicable. A period of up to eight weeks is provided for this, which the authority may extend by up to six weeks on account of the complexity of the intended processing.

The controller must provide the supervisory authority with all necessary information and documentation that it has requested for the purposes of the consultation, especially:

- where applicable, the respective responsibilities of the controller, joint controllers and processors involved in the processing, in particular for processing within a group of undertakings;
- the purposes and means of the intended processing;
- the measures and safeguards provided to protect the rights and freedoms of data subjects pursuant to the GDPR;
- where applicable, the contact details of the DPO;
- the results of the DPIA;
- any other information requested by the supervisory authority.

3.3 Data Protection and Privacy Policy

3.3.1 Data Usage in Ageing@Work

In the current deliverable the main elements of the data privacy policy of Ageing@Work are presented. This policy will then be given concrete form in D9.2 “Data Management Plan & Ethics”, where the management of data and relevant data protection issues will be explained in detail and a coherent strategy will be developed.

Ageing@Work, in essence, seeks to develop a series of adaptive, personalised ICT tools that will help the effective establishment of key measures to counteract for crucial issues hindering the ageing workers’ workability and well-being. The project will take advantage of the recent advances in ICT technologies and various sensors. The objective is to develop an integrated platform of advanced, personalized and adaptive ICT tools, which on one hand, will help tailoring the workplace to the evolving needs and specificities of the ageing workers, both in terms of ergonomics and in terms of work processes and task assignments and on the other, will support the ageing worker’s active and healthy ageing at work and at home, as well as workability, by means that will include personalized physical and mental health support ICT tools, as well as telepresence and productivity enhancement tools, based on advanced AI, AR, VR and virtual assistant

technologies, and with particular emphasis on flexible management of work, along with worker QoL support. In order to achieve the research and development of such a personalized system, personal data of ageing workers will have to be collected and processed, including in some cases sensitive personal information. Among other things, personal data collection will be performed during the system user requirements analysis phase (WP2), during the data collection campaigns of WP3, as well as during the pilot trials of WP7. Personal data (name and email) will also be collected when subscribing to the newsletter on the project homepage (https://ageingatwork-project.eu). The Ageing@Work Consortium is fully aware of this and the related challenges in terms of research ethics and, more specifically, data protection.[8]

In this context, it is pointed out that all data processed within the framework of Ageing@Work comply with the data protection principles described above, e.g. all data are relevant and limited to the purposes of the research project (data minimisation principle). All beneficiaries involved in Ageing@Work will adhere to these principles. Ageing@Work will essentially collect mandatory data to support its research activities.

All consortium members have agreed that in Ageing@Work, participants' personal data will be safeguarded as follows:

- No unnecessary data collection activities will be performed within the project's lifetime.
- Personal data that have been collected for analysis will be handled discretely and with anonymity.
- No personal data will be collected without definite permission of the human participants.
- Every personal data collected throughout the project will be treated with respect to the protection of fundamental human rights (e.g. separating general and personal data, handling encrypted personal data and identities, erasing irrelevant personal data).
- The participants will be granted with the right to access their personal data and the analysis and user models made based on it. [9]

Compliance with data protection principles such as data minimisation should be guaranteed prior to data collection and processing. To this end, Table 2 lists the most important questions and their criteria for assessing whether compliance with these standards has been achieved.

[8] Paragraph taken from Ageing@Work DoA
[9] Paragraph taken from Ageing@Work DoA

Basic Questions	Concretising Criteria
What is the purpose of the activity?	• What needs to be achieved?
Does personal data need to be processed?	• Is it necessary? • Is there another way?
What is the legal basis?	• Consent? (freely given, informed) • Public interest? (national law required) • Legitimate interest? (justify, explain) • Consider all relevant bases
How much personal data is needed?	• Minimum to achieve the purpose • Proportionate and necessary
What are the risks to the data subjects?	• Screening questions • Data Protection Impact Assessment (DPIA) • Mitigate risks / consult / report
Are appropriate security measures in place?	• Consider resources and severity of risk • Technical and organisational measures
Does the personal data need to be retained?	• What security measures required? • Minimum amount for minimum time • Review and justify retention periods
Will the personal data be shared?	• Recipient standards must align • Minimum necessary for the purpose
Will the data be used for a further purpose?	• Consider anonymisation • Compatibility test (linked purpose) • New legal basis if different purpose
Does research include profiling or automated individual decision-making?	• Provide information on reason, nature and extent • Provide explanation how data subjects will be informed, possible consequences and safeguards of fundamental rights

Table 2: Questions to consider before each research activity

3.3.2 Data Protection in Collection and Processing

Within the Ageing@Work project, there are several partners who collect and process personal data of different kinds and from different sources. Since each of these partners makes its own decisions about what personal data to collect and process and which methods to use, each of them is its own data controller. As all the partners work on the same project with the same objectives, the project as a whole consists of joint controllers. It is important that each partner is individually responsible for compliance with current legislation. This includes in particular their personal responsibility to carry out their tasks in a way that ensures compliance with the Ageing@Work approach of data protection by design and by default.

In some cases it is likely that the processing of personal data in Ageing@Work raises risks concerning ethics and data protection, e.g. the processing of sensitive health data of employees or the usage of new technologies as automated data collection with electronic devices, profiling, tracking or the combination of data from different sources. In order to counter and mitigate these risks, ethical and legal issues have to be identified and analysed and appropriate technical and organisational measures must be taken in advance of data collection and processing. These could be for example:

- the pseudonymisation or anonymisation of personal data;
- data minimisation;
- applied cryptography (e.g. encryption and hashing);
- using data-protection focused service providers and storage platforms;
- arrangements that enable data subjects to exercise their fundamental rights, e.g. access to their personal data and consent to its use or transfer.

Further information can be found also in the document *Ethics and data protection* drafted by a panel of experts at the request of the European Commission [8].

If the collection and processing of data may lead to high risks for the rights and freedoms of natural persons, a DPIA shall be carried out prior to processing in order to assess the impact of the envisaged processing operations on the protection of personal data. The DPIA should be launched as early as possible in the design of the processing operation, even if some of the processing operations are still unknown. Updating the DPIA throughout the life cycle of the project ensures that data protection and privacy are taken into account and creates solutions to promote compliance. It may also be necessary to repeat individual steps of the evaluation during the development process, as the selection of certain technical or organisational measures may influence the severity or likelihood of the risks associated with the processing.

The controller is responsible for ensuring that the DPIA is carried out. It can be done by someone else, but the controller remains ultimately responsible for this task. In addition, each data controller must keep a record of the processing activities for which he is responsible (accountability principle) including the purposes of the processing, a description of the categories of data and recipients of the data and a general description of the technical and organisational safeguard measures. Different methods of assessing the impact on data protection and privacy could be used to support the implementation of the essential requirements laid down in the GDPR. A possible template can be found in Annex 8 [31] but each partner can decide on its own which method to use for the risk assessment. In case the controller considers a processing operation not to be likely to result in high risks, the controller should document the reasons for not carrying out a DPIA and include the views of the DPO or a suitably qualified expert [30].

To assure data protection and security of the research and to reduce risks and discomfort for the participants, necessary measures must be implemented which contain, inter alia, the following points:

- Informed consent: Informed consent is required for data collection, data storage, data processing and publication of raw or processed data. Before consent is sought, information must be given, specifying the alternatives, risks, and benefits for those involved, in a way users understand.

- Voluntary participation: Participation is on a voluntary basis.
- Participation of disable people: It is essential that the consortium project team considers other issues of an ethical nature, such as the personal autonomy and integrity of the person and respect for rights and especially confidentiality aspects.
- Minimal risk: Participants should not be exposed to more than minimal risk.
- Anonymity: Volunteers have the right to remain anonymous. All data analyses are performed on an anonymous basis.
- Feedback: Participants shall be provided with the possibility to retrieve feedback on the results of research.
- Privacy: Researchers must ensure that the manner in which research outcomes are reported does not contravene the right to privacy and data protection.
- Confidentiality: Confidentiality is different from the participant's right to privacy; it refers to how data about the participants will be stored.
- Data control: The data subject has the right to access all data processed about him or her, and has the right to demand the rectification, deletion or blocking of data that is incomplete, inaccurate or isn't being processed in compliance with the data protection rules.
- Informed stakeholders: Informing stakeholders in detail on ethical aspects of research and evaluation/validation in reporting activities.[10]

Where possible, data should be collected in anonymous form so that it no longer relates to identifiable individuals, e.g. statistical data. A data collection is considered anonymous only if the anonymisation process starts directly at the time of data collection, so that there is no personal data actually processed. If anonymisation takes place at a later stage, the raw data are still personal data which have to be protected until they are rendered anonymous. Fully anonymized data is not subject to data protection law. However, the data collection may still raise significant ethical issues due to the origins of the data or the applied method to obtain the data [8].

While anonymised data is no longer considered as personal data, anonymisation processes are challenging, especially for large datasets with a wide range of personal data. It is very difficult to create completely anonymous datasets that contain the detailed information needed for research purposes [32]. It also may be important to have the possibility to re-identify the research subjects to their personal data. In these cases data should be pseudonymised in order to protect the data subject's privacy and minimise the risk to their fundamental rights in the event of unauthorised access. Therefore all participants should be assigned an identification code so that the different actions of the participants during data collection can be mapped. The pilot site person collecting and issuing the data should not participate in the evaluation or come into contact with the test participants and their performance in the tests. The managers of the pilot sites must take responsibility for ensuring that training procedures, supervision, and data security arrangements are sufficient to prevent unauthorised breaches of confidentiality.

The relationship between the identification code and the participant is captured in the repository and stored separately and securely. This file is accessible only to the appropriate leader of each pilot site. The

[10] Paragraph taken from Ageing@Work DoA

key to associate the participant's name with the code that identifies the data file is not made available to anyone and the privacy of the data is protected. In addition, the data is retained for the shortest period of time necessary to achieve the project objectives. Each access to the collected data is password protected and is only granted to authorised partners for data processing. In addition, access to information will also be restricted to the partners involved in the respective task to ensure their confidentiality. Information technologies will be used to securely store, provide and access data and to manage the rights of users.

3.3.3 Data Protection during Storage and Destruction

Within Ageing@Work the identification information is stored separately from all evaluation data. Data from electronic records is stored on secure servers that are backed up daily. In addition there are technical measures in place such as firewalls, regularly updated virus protection and access restriction by password protection. Non-electronic files are stored in locked file cabinets in non-public areas. Files containing information that could identify a study participant are kept separate from research files in locked cabinets. All areas are reviewed regularly to ensure that confidential information is not omitted in open areas.

Every participant has the right to be forgotten, which means that the data subject has the right to ensure that his or her personal data are erased and no longer processed if he or she has withdrawn the consent to the processing. All data from the project pilots and studies that are considered confidential will be discarded by the end of the project, while only the public models and respective datasets described in detail in the Ageing@Work Data Management Plan will be made open. This plan also reports on the strategy of open data storage and destruction in research and on the limits of its secondary use and disclosure to third parties. A number of critical factors relevant to data retention will be taken into account, e.g. the purpose of data retention, the type of open data collected, the policies for access to open data, security measures, confidentiality and anonymity of data. Since hard disk drives are used for data storage, existing methods and tools for permanent and irreversible data destruction are used, e.g. completely overwriting and formatting hard disks.

Further processing of the personal data collected previously ("secondary use") is not envisaged. In the unlikely event that such a need arises during the course of the project, the Ageing@Work consortium will take all necessary steps to ensure explicit confirmation that the beneficiary has a legitimate basis for processing and that appropriate technical and organisational measures have been taken to protect the rights of data subjects. In addition, it will be ensured that the secondary data used in Ageing@Work remain anonymous.

4. Ageing@Work Ethics Framework

4.1 Ethical Strategy

All participants in the project are committed to ensuring their adherence to the ethical principles set out in Section 1.4 and to acting in compliance with the laws and codes of conduct set out in Section 2. Any other applicable laws, regulations and recommendations must also be complied with. Particular attention must be paid to data protection, compliance with the requirements of the GDPR (see Section 3) as well as protection of confidentiality and anonymity of participants involved. An Ethics / Privacy by Design approach is pursued within the framework of the project. This means that ethical and data protection issues are to be considered and observed during the planning and implementation phase for the entire duration of the project and beyond. If necessary, the approval of external national / regional / institutional ethics committees (Ethics Approvals, see Section 0), data protection authorities and other supervisory bodies must be obtained in advance for all planned activities. Recruitment of participants is based on pre-defined rules. Participation is completely voluntary for all participants and is based on informed consent. The Ageing@Work Ethics Advisory Board (EAB, see Section 4.3), the responsible persons from WP9 ('*Project Coordination and Management*', most importantly T9.3 '*Data management, Ethics and Standardization*') as well as the project management are available to provide advice and support. In the end, however, each beneficiary is responsible for acting in accordance with the rules referred to above. Risks arising from the activities carried out within the framework of the project are to be mitigated. Possible residual risks must be borne by each responsible party. In addition, the procedures contained in Section 5 (Ethics and Security) of Appendix 2, Part B (Ageing@Work DoA) must be followed.

Before starting research activities with human participants or the collection of personal data, the planned procedures shall be described in detail in a research / study / experimental protocol. Appendix 4 contains a recommendation of the information that should be included. In addition, an Informed Consent Form (ICF) tailored to the survey must be prepared. More detailed information can be found in Section 4.7. Both documents should then first be submitted to the EAB so that it can make recommendations and identify possible unidentified ethical and data protection issues.

In addition, it must be decided whether an external ethics committee should be consulted and whether a Data Protection Impact Assessment (DPIA) is necessary. With regard to the ethics vote, the guiding questions from Section V. (*Ethics Checklist*) of the *Questionnaire on ethical and legal issues* (see Annex 2) can be used. The need for a DPIA can be derived from the requirements in Section 3.2 and the key questions in Section VI. (Risk Assessment) of the questionnaire (see Annex 2). The EAB can also be consulted on these points in order to make a recommendation based on the information provided.

Within the framework of the project, the responsible developers must carefully examine whether and if so which of the ICT solutions fall within the scope of MDR [12] (see Section 2.4) and related national or international regulations. Any resulting requirements must be adhered to.

The activities under T9.3 'Data management, Ethics and Standardization' will also make a very important contribution to compliance with ethical principles and to ensuring data protection and privacy. In this task *"special attention will be given to ethical issues wherever these arise by implementing principles such as data protection and privacy awareness. This task will take responsibility for the specification and preparation of necessary legal documentation (for agreement with participants). Privacy & Ethics approval for each pilot will be secured by the relevant consortium member from the relevant authorities. The key output of this task will be a document that will guide the project consortium to comply with EU data protection and privacy principles and regulations along with issues relating to privacy and security [Authors' note: D9.3 'Data management plan & ethics']. This document will be revised if relevant new information arises during the project development."*[11] Activities in this task should be carried out in close coordination with the responsible ERPs, the project's EAB and the Ageing@Work project management.

The procedure described in *Ageing@Work DoA part B* Section 3.2.1.2 is recommended for ethical, privacy and conflict resolution decision-making.

4.2 Ethics Responsible Persons (ERP)

Each institution involved in the project nominates an Ethics Responsible Person (ERB). This person is responsible for ensuring that all activities of the respective institution take place in conformity with applicable law, that basic ethical principles are observed and that the anonymity of the participants and the confidentiality of their data are protected. The ERP is also responsible for ensuring that necessary documents (e.g. research / study / experimental protocols) are correctly prepared, that participation is based on informed consent (confirmed in writing) and, if necessary, that the approvals of external ethics committees or data protection supervisors are obtained before activities begin. The documents required to demonstrate compliance with applicable ethical and privacy laws shall be prepared and retained in accordance with the requirements of WP9 ('Project Coordination and Management', most importantly T9.3 'Data management, Ethics and Standardization'). Furthermore, each ERP is responsible for communication and coordination with Ageing@Work project management, Plenary Board (PB) and EAB.

It is important that each institution involved in the project has to name an ERP, even if no direct research with human subjects or collection of personal data takes place. For instance such a responsible person is also required for the mere processing or analysis of such data.

In the following the ERP for each beneficiary are specified:

Centre for Research and Technology Hellas (CERTH), Greece
Ethics Responsible Person (ERP): Dr. Sofia Segkouli

Universidad Politécnica de Madrid (UPM), Spain
Ethics Responsible Person (ERP): Dr. María Fernanda Cabrera-Umpiérrez

[11] Description taken from: Ageing@Work DoA part A

Siemens AG (SAG), Germany
Ethics Responsible Person (ERP): Markus Dubielzig

MYSPHERA SL (MYSPHERA), Spain
Ethics Responsible Person (ERP): Dr. Sergio Guillen Barrionuevo

University of Patras (UPAT), Greece
Ethics Responsible Person (ERP): Assoc. Prof. Konstantinos Moustakas

Samsung Electronics (UK) Ltd (Samsung), United Kingdom
Ethics Responsible Person (ERP): Kit Lam

Centralny Instytut Ochrony Pracy – Państwowy Instytut Badawczy (CIOP-PIB), Poland
Ethics Responsible Person (ERP): Dorota Żołnierczyk-Zreda

Institute for occupational medicine, safety and ergonomics (ASER), Germany
Ethics Responsible Person (ERP): Hon.-Prof. Dr.-Ing. Hansjürgen Gebhardt

KU Leuven (KUL), Belgium
Ethics Responsible Person (ERP): Prof. Siegfried Dewitte

Q-Plan International Advisors PC (Q-Plan), Greece
Ethics Responsible Person (ERP): Evangelia Tsagaraki

Asociación Nacional de Empresarios Fabricantes de Áridos (ANEFA), Spain
Ethics Responsible Person (ERP): Rosa Carretón Moreno

MultiMed Engineers srls (MMW), Italy
Ethics Responsible Person (ERP): Sergio Copelli

HIT Hypertech Innovations Ltd (HIT), Cyprus
Ethics Responsible Person (ERP): Dr. Christopher Ververidis

4.3 Ethics Advisory Board (EAB)

The Ethics Advisory Board (EAB) of the project supports the consortium partners in identifying ethical, privacy and related issues. It helps and advises the project partners in ensuring compliance with ethical principles, the rights of study participants and conformity with applicable law in the areas of ethics, data protection and related issues. It can also help decide which activities within the project should be subject to an ethics approval by external ethics committees. It can also provide assistance in obtaining such a vote. In order to fulfil these tasks, it is important that the Board has an overview of all activities relevant to its area of responsibility and that it is provided with the necessary information and documents in good time. The ERPs of the involved partners are responsible for this. This is the only way to identify and address potential problems and dilemmas in a timely manner.

The EAB consists of project members with expertise in ethics and data protection in research, legal experts from the participating industrial and pilot-site partners (ANEFA and Siemens) and representatives of the project management. A chairperson and an assistant chairperson will be appointed. They can speak on behalf of the EAB in the project consortium. The procedure described in *Ageing@Work DoA part B* Section 3.2.1.2 will be used for decision making and conflict resolution within the board as well as between the parties involved. On the basis of the information and documents on the planned research and development activities provided by the project partners, the EAB will form an opinion in joint consultation and on this basis can make recommendations and advice to the partners involved. The EAB works closely with the project management and the ERPs involved. The recommendations and advice given by the EAB are based exclusively on the information provided by the project partners on planned activities and are to be regarded as non-binding. Compliance with ethical principles, the protection of participants and conformity with relevant laws (e.g. on data protection) is ultimately the responsibility of the responsible persons of the implementing and involved partners.

The members of the EAB are listed below. As discussed at the project meeting in Madrid, the leadership of the board will be taken over by ASER. If necessary, additional members from the project consortium can be admitted at a later date, a withdrawal is also possible. The admission of external experts is also possible. The approval of the previous members of the EAB and the project management is required for these actions.

Chairperson:

- Hon.-Prof. Dr.-Ing. Hansjürgen Gebhardt
  Head Manager; Institute for occupational medicine, safety and ergonomics (ASER), Germany

Assistant-Chairperson:

- Patrick Serafin
  Researcher; Institute for occupational medicine, safety and ergonomics (ASER), Germany

Members:

- Andreas Schäfer
  Researcher / DPO; Institute for occupational medicine, safety and ergonomics (ASER), Germany
- Dr. Sofia Segkouli
  Centre for Research and Technology Hellas (CERTH), Greece
- Rosa Carretón Moreno
  Asociación Nacional de Empresarios Fabricantes de Áridos (ANEFA), Spain
- Markus Dubielzig
  Siemens AG (SAG), Germany

4.4 Ethics Approvals

As Ageing@Work planned activities include research with human participants and the collection and processing of (sensitive) personal data, it may be necessary to obtain the consent of independent ethics committees before starting research. The key questions from Section V. (*Ethics Checklist*) of the *Questionnaire on ethical and legal issues* (see Annex 2) can provide some preliminary information to make a decision. In addition, the EAB may be consulted. Moreover, national legislation may require an approval. If such ethics votes are required, they should usually be submitted to an ethics committee from the country/region where the research is being conducted. In the case of transnational multicentre research projects, it may also be advisable to submit an additional vote in the country where the researchers come from [26]. If ICT solutions developed and tested within the framework of the project fall within the scope of application of the MDR [12] (see Section 2.4) as well as related national or international regulations, a vote of an ethics committee may also be necessary.

According to the preliminary assessment of the authors of this manual, it seems reasonable to obtain a vote in Spain and Germany for the research activities taking place there. In principle, it is possible for those responsible for the individual activities to submit separate applications for such a vote. It may, however, be more economical to apply for a joint ethics vote in Spain and in Germany. This requires the coordination of the ERPs of the partners involved in order to determine who is primarily responsible for this. An application for an ethics approval inter alia requires a detailed description of the study design, the data collected and the processing of this data. The modalities and content of the application may vary depending on the country and ethics committee. Essentially, however, this will be information on a research / study / experimental protocol, which is listed in Annex 4, based on recommendations from the World Health Organisation (WHO). In addition, in the country where the research takes place, a responsible ethics committee, which can approve the planned research, is to be identified. The Network of *European Research Ethics Committees* (EREC) provides a list of national ethics committees on its homepage (http://www.eurecnet.org/information/index.html).

The EAB can advise on the selection of competent ethics committees and on the submission of applications for an approval.

4.5 Privacy and Data Protection

First of all, the data protection principles must be taken into account when collecting and processing personal data in Ageing@Work. Personal data must be processed lawfully, fairly and transparent. Personal data must be collected only for the specified purposes of the project and limited to what is necessary to achieve the objectives of Ageing@Work. Personal data must be accurate, kept up to date and stored only for the relevant time according to the corresponding purposes.

The rights of the data subjects have to be respected while collecting and processing personal data. All participants have to be provided with adequate information about the project's objectives and the purposes of data processing. Personal data may not be collected if the data subject has not given prior

consent. In addition, the data subject has the right to rectification and erasure of personal data that is inaccurate, no longer required or if he or she withdraws consent.

According to the GDPR, severity and likelihood of risks to the fundamental rights and freedoms of data subjects have to be assessed and appropriate protective measures have to be taken. Therefore controllers must perform risk assessments and in case where it is likely to result in high risks carry out a Data Protection Impact Assessment (DPIA). If there are high risks identified in the DPIA that the controller cannot mitigate by appropriate measures, the supervisory authority should be consulted prior to the processing.

Data should best be collected in anonymous form so that it no longer relates to identifiable individuals. Then the anonymised data is not subject to data protection law but the data collection may still raise significant ethical issues due to the origins of the data or the applied method to obtain the data. If anonymisation is not possible, personal data should be pseudonymised in order to protect the participants' privacy and minimise the risk to their fundamental rights. It works in such a way that an identification code is assigned to all participants so that the different actions of the participants during data collection can be mapped. The relationship between the identification code and the participant is stored separately and securely and is only accessible to defined persons.

Upon completion of the project, all data from the project pilots and studies that are considered confidential will be discarded. Only the public models and respective datasets described in detail in the Ageing@Work Data Management Plan will be made open. In depth information on the general data protection processes is given in Section 3.

4.6 Recruitment of Participants

Several of the studies planned within Ageing@Work with different objectives involve human participants. All people that will be actively participating in the above processes and/or being affected by their execution, will take part in a thorough recruitment and informed consent procedure, that will be particularly stringent to ensure that participation is voluntary and no coercion (not even soft or indirect) is exerted. The specific criteria for the selection of the volunteer participants will be determined by the pilot requirements, while there will be participants with various roles. Furthermore, specific measures to protect the participants from any kind of harm, a breach of privacy/confidentiality and potential discrimination will be applied. Clear inclusion and exclusion criteria shall be established for participation. Discrimination or privileged treatment of individuals has to be avoided. For each data collection, a tailored and detailed informed consent procedure will be developed and applied. The participants concerned are to be informed about, among other things, the objectives of the project, the persons responsible, the methods used, the data collected, the handling and processing of this data, possible benefits and risks as well as the possibility of withdrawing their participation. Further information on informed consent will follow in the next Section 4.7.

Since the participants are employees of the pilot companies involved and are therefore in a relationship of dependence, they are to be regarded as vulnerable [7, 26]. This results in special requirements for

recruitment and the procedure of informed consent in order to ensure absolute voluntariness and to exclude direct or indirect consequences from participation or non-participation. For example, the companies involved (or their management) should not know which employees participated and which employees did not. It must also be carefully clarified whether and in what form the participating companies (or their management) are given insight into the study results in order to ensure that no conclusions can be drawn about individual employees or small groups of employees. This is particularly true as the project will also collect data on health status, lifestyle or work ability. There is thus a risk that knowledge of such data may result in disadvantages (e.g. job loss, discrimination, poorer career opportunities). Appropriate measures must be taken to protect the participants and to eliminate or mitigate such risks. In any event, participants must be fully informed of such risks, should they exist. On the other hand, participants should not receive any special advantages or preferential treatment in relation to their job.

4.7 Informed Consent

The consent procedures will be carefully determined and managed by data collection and pilot-specific tasks (within WP2, WP3 and WP7) that will manage the trials which will be performed in selected data collection areas. Thus, it will require the enrolment of people voluntarily declaring their consent to participate in each of the data collection process and the pilot use cases. However, the design of the observational study will be prepared in strict collaboration with the EAB of the Ageing@Work consortium, in order to respect privacy and ethical issues implied by the data to be collected and analysed. The consent procedure for all data collection processes and the pilot use case realisation at each of the selected pilot sites (e.g. in WP2, WP3 and WP7 respectively), will be obtained through a two stage procedure:

a. Initially the study/data collection responsible or the pilot trial leader will orally present the purpose of the study or pilot to people that will be involved, carefully describing the level of privacy infringement that the execution of each of the process involves. In the event that someone cannot/does not wish to participate in the presentation, he/she will be excluded from the study or pilot. This must not result in any other disadvantages (except non-participation) for the person concerned.
b. Secondly, after a few days, subjects will be required to read and sign an Informed Consent Form (ICF) that will explain in both plain English and in local language what the study/trial leader has already orally explained. The informed consent forms in English and in local language to be used will be sent to the European Commission and included in the experimental protocol.

The data collection and pilot-specific tasks (as parts of the activities performed in WP2, WP3 & WP7) will follow typical consent procedures that will manage the trials. Volunteers will participate in data collection processes including the pilot studies, and thus according to the Ageing@Work ethical protocol regarding the privacy of the personal data and the permission to process those data, all participants will fill in the ICF, either in a digital format (online), or in paper-and-pencil. A first template for an ICF has already been developed under D1.1 and the languages of the prospective study participants have been translated. The English version can be found in Annex 5. The ICF template is structured in three main parts:

- Information Sheet: a short text used to share basic information about the project with participants in the data collection;
- Demographics (and Device Profile Questionnaire): used for collecting basic demographics of the participants like gender and age, but also to collect profile of wearable devices or smartphones possibly used during the data collection;
- Consent Form: this last part of the ICF will be used for signatures in case the candidate participant agrees to participate. The original must be kept under lock and key by the person responsible for the study; a copy will be handed over to the participant.[12]

In the course of the further planning and preparation of the Ageing@Work studies, the ICF template has to be adapted to the requirements of each research activity. Annex 6 shows two WHO ICF templates, one for qualitative studies (e.g. surveys, interviews) and one for clinical studies[13]. These can be used for further information and development of the Ageing@Work ICF template. Depending on the phase of the survey, further adjustments may be necessary, in particular with regard to the following points:

- collection, processing and handling of personal data;
- incidental Findings Policy (see Section 4.8), including limits on confidentiality (e.g. uncovering of criminal activities) and possible findings concerning the participants' own health;
- duration of participation and related time and effort;
- possible risks and benefits for participants.

With regard to data protection and GDPR, the following minimum information shall apply to the ICF [7]:

> *"The identity of the data controller and, where applicable, the contact details of the DPO;*
>
> *the specific purpose(s) of the processing for which the personal data will be used;*
>
> *the subject's rights as guaranteed by the GDPR and the EU Charter of Fundamental Rights, in particular the right to withdraw consent or access their data, the procedures to follow should they wish to do so, and the right to lodge a complaint with a supervisory authority;*
>
> *information as to whether data will be shared with or transferred to third parties and for what purposes; and*
>
> *how long the data will be retained before they are destroyed.*
>
> The data subjects must also be made aware if data are to be used for any other purposes, shared with research partners or transferred to organisations outside the EU (see article 13 GDPR)."

[12] Paragraphs taken from Ageing@Work DoA
[13] Although no clinical studies are planned within the framework of the project, some of the points listed here may nevertheless be relevant (e.g. when carrying out physiological tests).

4.8 Incidental Findings Policy

As orienteering introduction, incidental findings are traditionally defined as results that arise that are outside the original purpose for which the test or procedure was conducted. In the Ageing@Work project, in the event of any incidental finding raising ethical concerns discovered throughout the execution of the project, the following policy will apply:

1. In a first place, these incidental finding will be immediately referred to:
   - the project's responsible partner for the pilot;
   - only if necessary, to the Ethics Advisory Board (EAB).

2. Secondly, the following rules will govern any incidental findings:
   - individuals will give an informed consent to take part in the research;
   - deletion of any incidental findings will be considered by the bodies mentioned in (1);
   - in case of incidental findings that include recording an illegal activity, the consortium will comply with all relevant national and international laws;
   - in case of incidental findings that include any information of public interest, the bodies mentioned in (1) would make a decision about the need, means and timing of their communication to relevant stakeholders, including the national authorities.[14]

In addition to the above-mentioned points, all study participants or other participants should be informed in advance about the handling of random findings in the context of the project as well as the limits of confidentiality (e.g. in the case of the uncovering of criminal activities) within the framework of the Informed Approval Procedure. In addition, the responsible persons should consider including a question in the Informed Consent Form (ICF) on possible findings concerning the participants' own health. The studies foreseeable in Ageing@Work do not contain medical examinations and no medical staff is involved, but the data collected in Ageing@Work may provide indications of possible health problems. The test subjects should therefore be asked whether they would like to be informed in the event of such indications. In this case, they should be provided with the necessary information and advised to have this clarified by a doctor or suitable experts.

The incidental finding policies of Ageing@Work should conform to these basic requirements. These requirements may be revised and adjusted throughout the lifetime of the Ageing@Work project.

4.9 Unidentified Ethical Issues

As already described, the exact procedures in some Work Packages (WP) have not yet been determined at the time of completion of the Ethics Manual. This means that in the course of the project further ethical issues may arise which have not yet been identified. The EAB (see Section 4.3) can provide advice on how to identify and adequately address these issues. To this end, the EAB must be provided with all relevant information (see Section 4.1 and Annex 4) on the planned activities in good time. This is the responsibility

[14] Paragraph taken from Ageing@Work DoA

of the ERP (see Section 4.2) of the partner(s) involved. On the basis of this information and in coordination with the project management as well as the partner(s) involved, the EAB can provide indications as to whether ethical issues exist which were not foreseeable up to now and have not yet been addressed in the Ethics Manual.

In this case, the EAB can, as with all questions of ethics and data protection, provide advice in order to adequately address these points within the framework of the project. Should new information or guidelines arise in the course of this consultation, they will be made available to the entire project consortium. If they are highly relevant, they can also be added to the Ethics Manual (e.g. as a further appendix or other document) and made available to the public. The EAB and the project management, in cooperation with the ERP of the participating partner(s), decide whether this particularly high relevance is present.

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[26] Council for International Organizations of Medical Sciences (CIOMS) (ed.): International Ethical Guidelines for Health-related Research Involving Humans, 2016. ISBN 978-929036088-9. https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf (Accessed 23 April 2019)

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[28] Directive 2009/136/EC of the European Parliament and of the Council of 25 November 2009 amending Directive 2002/22/EC on universal service and users' rights relating to electronic communications networks and services, Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector and Regulation (EC) No 2006/2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws (Text with EEA relevance). https://eur-lex.europa.eu/legal-content/EN/TXT/PDF (Accessed 24 May 2019)

[29] Treaty on the Functioning of the European Union (TFEU) 2012/C 326/01. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012E/TXT&from=EN (Accessed 25 April 2019)

[30] Guidelines on Data Protection Impact Assessment (DPIA) and determining whether processing is "likely to result in a high risk" for the purposes of Regulation 2016/679 17/EN WP 248 rev.01 https://ec.europa.eu/newsroom/document.cfm?doc_id=44137 (Accessed 25 April 2019)

[31] Sample DPIA template, Information Commissioner's Office (ico) in the United Kingdom (UK), https://ico.org.uk/media/about-the-ico/consultations/2258461/dpia-template-v04-post-comms-review-20180308.pdf (Accessed 22 May 2019)

[32] Article 29 Data Protection Working Party: Opinion 052014 on Anonymisation Techniques 0829/14/EN WP216 adopted on April 10, 2014 https://ec.europa.eu/justice/article-29/documentation/opinion-recommendation/files/2014/wp216_en.pdf (Accessed 22 May 2019)

Annex 1: Ageing@Work Ethics Summary Report

Ref. Ares(2018)3828383 - 18/07/2018

Ethics Summary Report

Call Reference	H2020-SC1-DTH-2018-1
Proposal Number	826299
Acronym	AgeingatWork

Ethics Issues

Humans

Does this research involve human participants?	**Yes**
Are they volunteers for social or human sciences research?	**Yes**

Comments

It should be pointed to the beneficiary that the same ethic issues for the trials in WP 6, apply in WP 1 and WP2.

- (WP 1 T1.1.) Required data collection, which should be protected and addressed properly.

The target use cases of the Ageing@Work system will be elaborated, under a prioritization perspective aligned to the one of the requirements. The surveys will be conducted with persons belonging to our target user group (blue collar workers at the age of 50+) in two different sites in Germany (SIEMENS) and Spain (ANEFA), together with persons of their social environment (relatives, friends, and/or health care professionals). Users will be engaged in interviews in each pilot site, based on well-defined criteria and upon written inform concern.

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- (WP 2) Analysis of worker skills, workability, health, safety, human factors and metrics modelling

This task involves collection and analysis of workability, occupational health and safety issues. The methodology established for collecting and analysing the aforementioned end-users requirements and preferences will specify the number and type of users to be involved in this task, and issues like worker skills, gender, expertise with ICTs, health condition, daily routines, etc. Moreover, it will include surveys, interviews and focus groups sessions

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Protection of personal data

Does this research involve personal data collection and/or processing?	**Yes**
Does it involve the collection and/or processing of sensitive personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?	**Yes**
Does it involve tracking or observation of participants?	**Yes**
Does this research involve further processing of previously collected personal data (secondary use)?	**Yes**

Comments

It should be pointed to the beneficiary that the same ethic issues for the trials in WP 6, apply in WP 1 and WP2.

Identified Ethics Issues

The beneficiary has listed the two main ethic issues present in the proposal:
1 – Research with humans, through observation and tracking with sensors
2 – Data protection (from involvement in the project – consent and information forms-, data collection and storage – how content should be anonymous and the use of already existing data).

In addition is listed:
- The consortium to complain with EU and national regulation in force;
- The intended ethics manual to be developed and follow by all consortium partners;
- The protection of the data in the developed platform in detail: Data privacy and security module: The data privacy and security module will contain specific and suitable security safeguards such as the encryption of user's data and appropriate authentication mechanisms to mitigate security risks, making security and privacy in the data storage, communication and management a central issue for the project. A robust security and privacy infrastructure featuring security protocols and privacy preservation mechanisms will be designed and developed to fulfill the end-users' requirements defined in WP1 and to stay aligned with the specifications. In particular, appropriate secure storage protection and data communication (when needed) techniques will be put in place to ensure Ageing@Work bottom-up commitment to security and privacy. A personalised, user-friendly login system together with the enhanced privacy controls will be designed and implemented in this task to support smooth end-user experience, forbidding any interference with their private lives and any unwanted privacy intrusions. The main goal of this task is to develop required infrastructure to support and ensure the necessary control of the services offered to the end-users. For this purpose, we intend to integrate available on the market identity and access management (IAM) system better suited for the needs of this project. Finally we plan to adopt the concept of a Privacy Guaranteeing Execution Container (PGEC) that - by design - provides encapsulation of sensitive data and its deletion after service completion. Finally, the security of the stored sensitive data will be enhanced using industry widely accepted standard cryptographic techniques. This task will contribute to D3.3.

However not all ethics requirements needed are correctly and specifically addressed, as well as the involvement of humans, with data collection, in (WP 1 and WP2).

In addition an incidental policy on finding and avoiding other issues is required to address the collection of data from participants´ homes and habits.

Ethics recommendations

The beneficiary has listed the two main ethic issues present in the proposal:
1 – Research with humans, through observation and tracking with sensors
2 – Data protection (from involvement in the project – consent and information forms-, data collection and storage – how content should be anonymous and the use of already existing data).

In addition is listed:
- The consortium to complain with EU and national regulation in force;
- The intended ethics manual to be developed and follow by all consortium partners;
- The protection of the data in the developed platform in detail: Data privacy and security module: The data privacy and security module will contain specific and suitable security safeguards such as the encryption of user's data and appropriate authentication mechanisms to mitigate security risks, making security and privacy in the data storage, communication and management a central issue for the project. A robust security and privacy infrastructure featuring security protocols and privacy preservation mechanisms will be designed and developed to fulfill the end-users' requirements defined in WP1 and to stay aligned with the specifications. In particular, appropriate secure storage protection and data communication (when needed) techniques will be put in place to ensure Ageing@Work bottom-up commitment to security and privacy. A personalised, user-friendly login system together with the enhanced privacy controls will be designed and implemented in this task to support smooth end-user experience, forbidding any interference with their private lives and any unwanted privacy intrusions. The main goal of this task is to develop required infrastructure to support and ensure the necessary control of the services offered to the end-users. For this purpose, we intend to integrate available on the market identity and access management (IAM) system better suited for the needs of this project. Finally we plan to adopt the concept of a Privacy Guaranteeing Execution Container (PGEC) that - by design - provides encapsulation of sensitive data and its deletion after service completion. Finally, the security of the stored sensitive data will be enhanced using industry widely accepted standard cryptographic techniques. This task will contribute to D3.3.
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However not all ethics requirements needed are correctly and specifically addressed, as well as the involvement of

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humans, with data collection, in (WP 1 and WP2).

In addition an incidental policy on finding and avoiding other issues is required to address the collection of data from participants´ homes and habits.

Ethics Opinion

Conditional ethics clearance (i.e. clearance is subject to conditions, i.e. ethics requirements. The requirements must either be fulfilled before grant signature or become part of the grant agreement)

Pre-Grant Requirements

Humans

2.1. The procedures and criteria that will be used to identify/recruit research participants must be clarified in the grant agreement before signature.

Humans

2.2. The informed consent procedures that will be implemented for the participation of humans must be included in the grant agreement before signature.

Humans

2.8. Details on incidental findings policy must be included in the grant agreement before signature.

Protection of personal data

4.3 Justification for the processing of sensitive personal data must be included in the grant agreement before signature.

Protection of personal data

4.4 The beneficiary must explain how all of the data they intend to process is relevant and limited to the purposes of the research project (in accordance with the 'data minimisation 'principle). This must be specified in the grant agreement.

Protection of personal data

4.8 Description of the anonymysation/pseudonymisation techniques that will be implemented must be specified in the grant agreement.

Protection of personal data

4.13 In case the research involves profiling, the beneficiary must provide explanation how the data subjects will be informed of the existence of the profiling, its possible consequences and how their fundamental rights will be safeguarded. This must be specified in the grant agreement.

Protection of personal data

4.15 In case of further processing of previously collected personal data, an explicit confirmation that the beneficiary has lawful basis for the data processing and that the appropriate technical and organisational measures are in place to safeguard the rights of the data subjects must be included in the grant agreement.

Post-Grant Requirements

Humans

2.3. Templates of the informed consent/assent forms and information sheets (in language and terms intelligible to the participants) must be kept on file

Protection of personal data

4.1 The beneficiary must check if special derogations pertaining to the rights of data subjects or the processing of genetic, biometric and/or health data have been established under the national legislation of the country where the research takes place and submit a declaration of compliance with respective national legal framework(s).

Protection of personal data

4.2 The host institution must confirm that it has appointed a Data Protection Officer (DPO) and the contact details of the DPO are made available to all data subjects involved in the research. For host institutions not required to appoint a DPO under the GDPR a detailed data protection policy for the project must be kept on file.

Ethics Checks

In your opinion, would an ethics check during the project implementation be necessary?	YES

Ethics and privacy issues have been considered and are completed with the requirements listed.
It is clearly stated that participants will be enrolled in a voluntary basis and will have to consent to participate. However, as the study is done in a working environment and the recruiter is the employer, the main concern is the procedures and criteria that will be used to identify/recruit research participants together with its implementation and the use of outcomes measures.

A check of recruitment procedure implementation is advised.

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Annex 2: Questionnaire on ethical and legal issues [15]

I. Beneficiary

Institution / Beneficiary:	Name:	Date:

II. General Ethics

1. Apart from the Declaration of Helsinki, is there any other international or national legislation, which you must follow when performing research with human subjects?
(Please state the legislation and describe it briefly.)

2. Is there an ethics control body in your country?
(If yes, please give a brief description of the procedure.)

3. Is there an ethics control committee in your organisation?
(If yes, please give a brief description of the procedure.)

4. Which ethical control procedures do you follow before performing tests on human subjects? (involvement of other organisations/departments that also control your research activity)
(Please give a brief description of the procedure.)

[15] This questionnaire is an integral part of the "*Template on ethical and legal issues*", which was sent to all project partners prior to the preparation of the ethics handbook and completed by them.

5. Does your organisation have specific expertise in the field of ethics and data protection in scientific research and is there interest in joining the Ethics Advisory Board?
(If yes, please indicate a contact person.)

III. Safety and Hygiene

1. Do you have written procedures for maintaining hygiene in your organisation?
(If yes, please give a brief overview. If no, please explain why or what corrective actions you take.)

2. Do you have written procedures for safety of employees and volunteers in your organisation?
(If yes, please give a brief overview. If no, please explain why or what corrective actions you take.)

3. Do you have expertise and procedures to test the safety of equipment you use or prototypes you develop? (e.g. safety to protect against electrical or magnetic hazards)
(If yes, please give a brief overview. If no, please explain why or what corrective actions you take.)

4. Are you familiar with the formal hygiene and laboratory safety regulations?
(If yes, please give a brief overview. If no, please explain why or what corrective actions you take.)

5. Do you have procedures for conducting risk assessment about safety, breach of privacy and bio-compatibility? (Biocompatible is the term used to describe materials or assemblies that have no negative influence on living organisms in their environment.)
(If yes, please give a brief overview. If no, please explain why or what corrective actions you take.)

6. Is your organisation insured against risks due to invasion of privacy, safety and biocompatibility?
(If yes, please give a brief overview. If no, please explain why or what corrective actions you take.)

IV. Data Protection

1. Is there an established Data Protection Authority in your country which supervises research activities with human subjects and their personal data?
(If yes, please give a brief outline of it. If no, please describe an alternative procedure to review data protection activities.)

2. Do you follow written procedures for protecting privacy (Privacy Policy)?
(If yes, please give a brief outline of it. If no, please explain why or what corrective actions you take.)

3. In addition to the General Data Protection Regulation (GDPR) and the national legislations listed in D1.2 (POPD-Requirement No.6) do you follow or know any official national or international privacy guidelines (especially concerning processing of special categories of personal data for scientific research and employee data protection)?
(If yes, please give references.)

4. Do you tell the participants that all data collected will be treated confidentially and that their anonymity will be preserved?
(If yes, please give a brief outline of it.)

5. Do you have a Data Protection Officer who monitors data protection issues in your organisation?
(If yes, please state the name of your DPO. If no, please explain briefly why.)

6. Does one of your tools as part of the Ageing@Work platform use HTTP cookies stored on the user's computer while usage, tags, pixels or comparable techniques?
(If yes, please describe how you inform the user about this, the consent procedure [e.g. opt-in, opt-out] and the purpose)

V. Ethics Checklist

The ethics checklist serves to figure out if a formal ethics approval is required before performing the planned research activity.

No.	Question	Yes	No
1.	Does your research involve human participants?		
2.	If yes, are they potentially vulnerable individuals or groups? (e.g. children, students, employees)		
3.	Does your research involve the collection of confidential or sensitive information?		
4.	Does your research involve controversial subject matter? (e.g. sensitive, embarrassing or intrusive topics)		
5.	May your research cause any harm to participants, researchers or others? (e.g. invasive techniques, physical interventions)		
If all answers above are "No", then no formal ethics approval is required.			
6.	Has the research activity already approval from an ethics committee?		
7.	Is the research activity part of a larger study that has already received approval from an ethics committee?		
If answer to question 6 or 7 is "Yes" then no further ethics approval is required.			
8.	Have health and safety risks due to the research been considered?		
9.	Are data protection compliance measures taken for any personal data collected by the research?		
If one of the answers to question 1 – 5 is "Yes" and neither 6 nor 7 is "Yes", then a formal verification of the requirement of an ethics approval is advised under consideration of aspects 8 – 9.			

VI. Risk Assessment

The risk assessment questions serve to identify possible risks arising from the planned research activity. If the result does not reveal any risk, no additional measures other than the usual compliance measures need to be taken. **If any question is answered with "Yes", a full risk assessment of data protection (DPIA) must be carried out.**

No.	Question	Yes	No
1.	Does the activity involve the systematic monitoring of publicly accessible spaces?		
2.	Are the persons unaware of the collection and processing of their data?		
3.	Does the activity use automated data collection from open sources?		
4.	Does the activity involve the use of new technologies?		
5.	Is there a combination of a person's data from more than one source?		
6.	Is the personal data used for a purpose other than its original intention?		
7.	Would the processing of personal data be perceived as disruptive in this way?		
8.	Might data processing concern specific categories of personal data? (e.g. health)		
9.	Does the data processing involve decisions or assumptions about individuals?		
10.	Would the data subject consider the processed information to be private?		

VII. Study Description

1. Does your research in Ageing@Work involve human participants and personal data collection or processing?
(If yes, please give the number of the work package and task and describe it briefly.)

2. How will the potential participants be selected (inclusion and exclusion criteria), addressed and recruited (e.g. voluntary participation, informed consent)?
(Please describe it briefly.)

3. Which kind of (sensitive) personal data is collected or processed? (General personal data are any information which are related to an identified or identifiable natural person. Sensitive personal data include genetic, biometric and health data, as well as personal data revealing racial and ethnic origin, political opinions, religious or ideological convictions or trade union membership.)
(Please describe it briefly.)

4. How will the data be collected (what methods, tools, equipment, procedures etc. are applied)?
(Please describe it briefly.)

5. Does your research involve tracking or observation of participants (e.g. special measurements with apps, wearables or sensors)?
(Please describe it briefly.)

6. For what purpose will the data be collected or processed?
(Please describe it briefly.)

7. Does your research involve further processing of previously collected personal data (secondary use)?
(Please describe it briefly.)

8. How will the data be stored and backed up? (anonymisation/pseudonymisation procedure, technical system to implement storage)
(Please describe it briefly.)

9. How will you manage access to the data? Will third parties have access? (identification of persons and their professions who are authorised to have access to the data collected and protection against unauthorized access)
(Please describe it briefly.)

10. Are there any pooled data or the need of access to or transferring of data from different areas/countries?
(Please describe it briefly.)

11. Do you plan to collect any kind of company data / information which might be confidential? (e.g. data on workplace design, work processes and other working conditions among the participating industrial companies)
(Please describe it briefly.)

12. Do you plan any picture, video or sound recordings of involved participants? (in this case a separate consent form for the implementation and use of recordings is required)
(If yes, please describe briefly what kind of recordings, what they are used for and the consent procedure.)

13. Are there any other ethical or legal issues that should be taken into consideration?
(Please describe it briefly.)

Annex 3: Information provided in the questionnaire on ethical and legal issues

Institution / Beneficiary:	Name:	Date:
ANEFA	CESAR LUACES FRADES	25/04/2019

General Ethics

1. International/national legislation

- International Covenant on Civil and Political Rights.
- International Covenant on Economic, Social and Cultural Rights.
- European Convention on Human Rights.
- Spanish Constitutional Law.
- Organic Data Protection Law 15/1999, (LOPD)
- Spanish Society Services information Act (Law 34/2002 on society services information and e-commerce).
- Spanish General Telecommunications Act (Law 9/2014)
- Organic Law 3/2018, Spanish Data Protection Act (Spanish DPA)
- Spanish Patient Act, Clinical Documents and Information (Law 41/2002).

2. Ethics control body in the country

Each company must have an adequate control of its ethical behaviour. In case of failure to comply, the possible liabilities of the civil or criminal jurisdiction that could arise should be clarified.

3. Ethics control committee in the organisation

Yes, ANEFA has an ethics committee, an ethical code and a declaration of principles of good governance.

4. Ethical control procedures

First of all, ANEFA will carry out a detailed analysis of the project to determine if it is consistent with our code of ethics and principles of good governance, and with current legislation.
Secondly, we must make sure that the person on whom the study will be conducted has the capacity to understand the ethical implications of the study and the ability to give valid consent. We will have to inform the subject in writing so that he / she can understand the objective of the study, its phases, the methods that will be used for measurement and the way in which the obtained data will be collected and processed. Finally, the subject must sign the text. A copy will be given to the subject. At any time, he/she can withdraw his/her consent or ask for more explanations in case any of the points was not clear enough. In no case may the data of the subject be shared beyond what is strictly permitted by the subject of the study.

5. Expertise in ethics and Member of Ethics Advisory Board

Yes, ANEFA has legal team well versed in this matter.

Safety and hygiene

1. Written procedures for maintaining hygiene
We do not have as such a written procedure to maintain hygiene, although we are obliged to comply with the obligation to maintain a workplace in conditions of safety and hygiene by law. In addition, we also have with internal rules in the matter.
2. Safety of employees
Yes, we have specific protocols to act in case of accidents, fire or when it is necessary to leave the building for any other reason. We also have a person in charge of safety and hygiene. The workers undergo periodic medical checks through a medical service outside the company.
3. Safety of equipment
As an association, we work in an office and therefore do not handle equipment or prototypes, nor more complex than a computer. The companies we represent have operating manuals for machinery, protective equipment and safety procedures in the event of an accident. They must be inspected regularly by the competent authorities in matters of protection and safety.
4. Formal hygiene and laboratory safety regulations
Yes, we are well informed and advised on the regulation of safety and hygiene.
5. Risk assessment
Yes, as I said, we have a legal team that advises us on these issues.
6. Insurance against risks
Yes, we are insured against multiple risks.

Data Protection

1. Data Protection Authority
Yes, the authority that deals with these issues is the Spanish Data Protection Agency.
2. Privacy Policy
Yes, we are legally informed of our obligations and matters of data protection and we comply with the regulatory requirements.
3. Privacy guidelines
In ANEFA we comply with legal requirements, although respect for data protection is part of our ethical code and principles of good governance.
4. Confidentiality & Anonymity
Yes, it is part of the content of the informed consent that the subjects must sign before the start of the study.
5. Data Protection Officer
Yes, the name of our DPO is María José Gómez.
6. HTTP cookies
No, it does not.

Ethics Checklist

No.	Question	Yes	No
1.	Does your research involve human participants?	✓	
2.	If yes, are they potentially vulnerable individuals or groups? (e.g. children, students, employees)	✓	
3.	Does your research involve the collection of confidential or sensitive information?	✓	
4.	Does your research involve controversial subject matter? (e.g. sensitive, embarrassing or intrusive topics)	✓	
5.	May your research cause any harm to participants, researchers or others? (e.g. invasive techniques, physical interventions)		✓
If all answers above are "No", then no formal ethics approval is required.			
6.	Has the research activity already approval from an ethics committee?	✓	
7.	Is the research activity part of a larger study that has already received approval from an ethics committee?	✓	
If answer to question 6 or 7 is "Yes" then no further ethics approval is required.			
8.	Have health and safety risks due to the research been considered?	✓	
9.	Are data protection compliance measures taken for any personal data collected by the research?	✓	
If one of the answers to question 1 – 5 is "Yes" and neither 6 nor 7 is "Yes", then a formal verification of the requirement of an ethics approval is advised under consideration of aspects 8 – 9.			

Risk assessment

No.	Question	Yes	No
1.	Does the activity involve the systematic monitoring of publicly accessible spaces?	✓	
2.	Are the persons unaware of the collection and processing of their data?		✓
3.	Does the activity use automated data collection from open sources?	✓	
4.	Does the activity involve the use of new technologies?	✓	
5.	Is there a combination of a person's data from more than one source?	✓	
6.	Is the personal data used for a purpose other than its original intention?		✓
7.	Would the processing of personal data be perceived as disruptive in this way?		✓
8.	Might data processing concern specific categories of personal data? (e.g. health)	✓	
9.	Does the data processing involve decisions or assumptions about individuals?	✓	
10.	Would the data subject consider the processed information to be private?	✓	
If any question is answered with "Yes", the need of a full risk assessment of data protection (DPIA) is indicated.			

Study description

1. Human participants & personal data
Yes, the research involves human participants in both of the pilots.
2. Participants selection & recruitment
They will be selected between workers form 45 years old to 62, that do not present any serious mental illness, and that have the capacity to give willingly they informed consent to the trial.
3. (Sensitive) personal data
Biometric and health data.
4. Collection method & tools
With non-invasive devices that can measure vital signs, such as smart wrist band, smart arm bands or heart rate monitors.
5. Tracking or observation
Yes, one of the use cases is based on the measurement and control of the sleep quality, another one is based on the measurement and control of the palpitations, and another one measures the periodicity on which the worker must drink water to stay properly hydrated.
6. Purpose of data collection & processing
Yes, to draw useful conclusions for the user it will be necessary to process the data obtained through the measurement instruments.
7. Secondary use
No, the data will only be used to draw conclusions on a first use. They will not be used for uses other than those agreed upon by the worker.
8. Storage & backup
The decision on how the data will be stored is not part of the competences that have been assigned to ANEFA in this project, so we refer the partners in charge of this WP to give content to the response.
9. Data access
The data will be treated with absolute care, in accordance with legal requirements, avoiding any access to unauthorized persons or third parties and always within the limits authorized by the worker.
10. Pooled data & transferring
The data will be shared among the project partners, within the boundaries of the European Union.
11. Company data & Confidentiality
No, it is not our intention to collect confidential company information.
12. Picture, video or sound recordings
We are not planning on using videos or images obtained from the workers, without prejudice to the fact that they may be necessary for advertising purposes of the project.
13. Other ethical or legal issues
No, as long as the limits of legality and the consent given by the worker are respected.

Institution / Beneficiary:	Name:	Date:
Institute for occupational medicine, safety and ergonomics (ASER)	**AK Wissemann** **P Serafin**	**17/04/2019**

General Ethics

1. International/national legislation

Data protection laws must be observed.

- GDPR
- Federal Data Protection Act (BDSG)
- Federal State Data Protection Laws (LDSGs)
- Telekommunikationsgesetz (TKG) [“Telecommunication Act”]
- Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data

Relevant legal regulations on the subject of research ethics only exist for areas such as drug studies, studies with medical products or radiation (e.g. X-rays).

- The Act on Medical Devices (MPG)
- Medicinal Products Act (AMG)
- Strahlenschutzgesetz (StrlSchG) / Strahlenschutzverordnung (StrlSchV)

2. Ethics control body in the country

There are several local ethics committees in Germany, which are usually located at universities.
In addition, there are various associations and central councils where these are networked.

- The National Council for Ethics: http://www.ethikrat.org/ ("Deutscher Ethikrat")
- Central Ethics Committee of the German Medical Association ("Zentrale Ethikkommission zur Wahrung ethischer Grundsätze in der Medizin und ihren Grenzgebieten bei der Bundesärztekammer [ZEKO]")
- Permanent Working Party of Research Ethics Committees in Germany: https://www.akek.de ("Arbeitskreis Medizinischer Ethik-Kommissionen in der Bundesrepublik Deutschland")
- http://www.eurecnet.org/information/germany.html

3. Ethics control committee in the organisation

There is no such committee within ASER.

4. Ethical control procedures

If necessary for research activities, approvals of appropriate external ethics committees are obtained. For example, that of the University of Wuppertal: https://www.forschung.uni-wuppertal.de/en/ethics-commission.html

5. Expertise in ethics and Member of Ethics Advisory Board

ASER has employees with experience in ethical issues and data protection in research with human participants. Some of them will participate in the EAB of the project.

Safety and hygiene

1. Written procedures for maintaining hygiene
There are written procedures regarding the hygiene and safety of employees. For research participants and volunteers, such rules are drawn up as needed and tailored to the activities in question.
2. Safety of employees
There are written procedures regarding the hygiene and safety of employees. For research participants and volunteers, such rules are drawn up as needed and tailored to the activities in question.
3. Safety of equipment
Usually, only equipment with a CE marking or comparable certificates that prove product safety is used.
4. Formal hygiene and laboratory safety regulations
There are written procedures regarding the hygiene and safety of employees. For research participants and volunteers, such rules are drawn up as needed and tailored to the activities in question.
5. Risk assessment
For general safety and data protection, appropriate risk analyses may be carried out if necessary.
6. Insurance against risks
For past projects, insurance policies were taken out for the test persons.

Data Protection

1. Data Protection Authority
Yes, there is one superordinate data protection authority in Germany: “Die Bundesbeauftragte für den Datenschutz und die Informationsfreiheit”, Husarenstraße 30, 53117 Bonn and all federal states also have their own data protection authorities. https://www.bfdi.bund.de/DE/Infothek/Anschriften_Links/Landesdatenschutzbeauftragte/Landesdatenschutzbeauftragte_liste.html
2. Privacy Policy
Yes, ASER follows written procedures for protecting privacy. “We take the protection of your personal data very seriously. It goes without saying that we always treat your personal data in accordance with the statutory data protection regulations. In the following we would like to inform you about the processing of personal data. […] The ASER Institute collects, processes and uses the user's personal data only to the extent necessary to provide the service offered (pursuant to Art. 6 (1e) GDPR). If the opportunity for the input of personal or business data (email addresses, name, addresses etc.) is given, the input of these data takes place voluntarily and can be revoked at any time. The data marked as mandatory are necessary to assign and answer the request. Further information can be provided voluntarily. Data processing for the purpose of contacting us is carried out in accordance with Art. 6 Para. 1 S. 1 lit. a DSGVO on the basis of your voluntary consent. Your data will only be stored for as long as is necessary for the stated

purpose. You have the right to information, correction, deletion, restriction of the processing of your data. In addition, you have the right to object to the processing and data transfer. […]"

3. Privacy guidelines

In addition to the GDPR, there have to be followed several national legislations, especially:

- Federal Data Protection Act (BDSG)
  Federal State Data Protection Laws (LDSGs) [Each federal state has its own, see https://www.datenschutz-wiki.de/Landesdatenschutzgesetze]

4. Confidentiality & Anonymity

Yes, in case of collection and processing of personal data for research purposes, there is an informed consent form provided, enlightening the participants about their rights and telling them that all data collected will be treated confidentially and that their anonymity will be preserved.

5. Data Protection Officer

Yes, our data protection officer is Andreas Schäfer (info@institut-aser.de).

6. HTTP cookies

No.

Ethics Checklist

No.	Question	Yes	No
1.	Does your research involve human participants?		✓
2.	If yes, are they potentially vulnerable individuals or groups? (e.g. children, students, employees)		✓
3.	Does your research involve the collection of confidential or sensitive information?		✓
4.	Does your research involve controversial subject matter? (e.g. sensitive, embarrassing or intrusive topics)		✓
5.	May your research cause any harm to participants, researchers or others? (e.g. invasive techniques, physical interventions)		✓
If all answers above are "No", then no formal ethics approval is required.			
6.	Has the research activity already approval from an ethics committee?		
7.	Is the research activity part of a larger study that has already received approval from an ethics committee?		
If answer to question 6 or 7 is "Yes" then no further ethics approval is required.			
8.	Have health and safety risks due to the research been considered?		
9.	Are data protection compliance measures taken for any personal data collected by the research?		
If one of the answers to question 1 – 5 is "Yes" and neither 6 nor 7 is "Yes", then a formal verification of the requirement of an ethics approval is advised under consideration of aspects 8 – 9.			

Risk assessment

No.	Question	Yes	No
1.	Does the activity involve the systematic monitoring of publicly accessible spaces?		✓
2.	Are the persons unaware of the collection and processing of their data?		✓
3.	Does the activity use automated data collection from open sources?		✓
4.	Does the activity involve the use of new technologies?		✓
5.	Is there a combination of a person's data from more than one source?	✓	
6.	Is the personal data used for a purpose other than its original intention?		✓
7.	Would the processing of personal data be perceived as disruptive in this way?		✓
8.	Might data processing concern specific categories of personal data? (e.g. health)	✓	
9.	Does the data processing involve decisions or assumptions about individuals?		✓
10.	Would the data subject consider the processed information to be private?	✓	

If any question is answered with "Yes", the need of a full risk assessment of data protection (DPIA) is indicated.

Study description

1. Human participants & personal data
ASER is not involved in the collection of personal data in Ageing@Work but we may have access to already collected data to help processing the personal data for the purpose of achieving the project's objectives.
2. Participants selection & recruitment
As the collection of personal data takes place at the two pilot sites (ANEFA and Siemens), ASER is not involved in the selection and recruitment of participants.
3. (Sensitive) personal data
If ASER cooperates in data processing, sensitive data in the form of data concerning health could be processed.
4. Collection method & tools
ASER is not involved in the selection of data collection methods and tools.
5. Tracking or observation
There is no tracking or observation on ASER's part.
6. Purpose of data collection & processing
ASER may be involved in the processing of personal data with the purpose to offer personalised services to employees/companies in respect to health and well-being in workplaces in accordance to the project's objectives and goals as described in the Ageing@Work Description of Action.
7. Secondary use
ASER will not further process previously collected personal data after the completion of the project.

8. Storage & backup
Data is stored and backed up in a database on servers. The personal data is stored in anonymised or pseudonymised form and protected against unauthorised access.
9. Data access
Only the employees directly involved in the project have access to any personal data. No third parties will have access to personal data.
10. Pooled data & transferring
Data transfer takes place exclusively within the borders of the EU between the project partners. ASER may have access to data collected in Germany (Siemens) and in Spain (ANEFA).
11. Company data & Confidentiality
ASER does not collect any kind of company data / information which might be confidential.
12. Picture, video or sound recordings
ASER does not take any picture, video or sound recordings of involved participants.
13. Other ethical or legal issues
No.

Institution / Beneficiary:	Name:	Date:
CERTH /ITI	ETHNIKO KENTRO EREYNAS KAI TECHNOLOGIKIS ANAPTYXIS	9/5/2019

General Ethics

1. International/national legislation
Apart from the Declaration of Helsinki which is a cornerstone on human research ethics, the Greek Laws 2472/1997 and 2472/1997, define a specific regulatory framework which is dedicated to privacy, data retention and data protection.
2. Ethics control body in the country
There is a Data Protection Control body in Greece which is the Personal Data Protection Authority (http://www.dpa.gr/). However there is not a unique control body regarding ethics. According to Law 4521/2018, there are Ethics Committees in each Research Center that evaluate all biomedical research involving human interventions or the use of their biological samples.
3. Ethics control committee in the organisation
Yes. Currently there is an ethics control body in CERTH (The Bioethics committee).
4. Ethical control procedures
Within the Ageing @Work project, an Ethics Advisory Board (EAB) has been established to undertake ethics, legal and privacy issues that will probably emerge during the lifecycle of the project. The role of EAB is to assist the project partners in identifying and solving ethical concerns that might not be identified by the end users or the project group during the whole duration of the project and provide proper advice and solutions on ethics, privacy and socio-economic issues. Furthermore, the project's Ethics Protocol will be drafted and applied to address the ethical and legal issues that will potentially arise during the lifecycle of the project. Ethical control procedures according to performing tests on human subjects have to be addressed mainly by the pilots of the project. In particular pilot sites should submit an application to the ethical committee in order to receive the approval for pilots' operation. Ethical control refers also to proper certificates of devices. At Ageing@Work project, sensors and healthcare devices (medical devices) that will be used, will be properly certified. Moreover standards and regulations will be applied in Apps development. Moreover a number of organizational and technical measures is provisioned to be adopted in order to address potential ethical and legal risks. Particularly, in alignment to the new regulation (GDPR), consent form is one of the seven legal grounds that have to be followed in terms of personal data processing in respect to the European Data Protection Directive (95/46/EC). For this reason a detailed informed consent will be carefully prepared for each data collection process and pilot trial, at each pilot site, fully outlining the scope of the process/trial and its purposes along with the data collected and analysed. Special emphasis will also be placed on user data privacy and security, taking concrete measures for worker data protection.
5. Expertise in ethics and Member of Ethics Advisory Board
CERTH has participated in a number of European projects that had to cope with ethics challenges related to big data. In particular CERTH has been participated in Large scale projects (LSPs), working specifically on data ethics (e.g. VERITAS, myAirCoach, SatisFactory, ACTIVAGE etc.). This critical task

has been assigned to persons with expertise and /or knowledge in human behaviour and social science.
Yes, there is interest from the side of CERTH to join the Ethics Advisory Board.

Safety and hygiene

1. Written procedures for maintaining hygiene

An audit committee is dedicated to periodically assess the rules for health prevention. This assessment includes recommendations for maintaining safety at work including indoor and outdoor cases.

2. Safety of employees

Written report of Hazards regarding safety and health of employees.

3. Safety of equipment

In the context of the stature of CERTH, general guidelines are followed from the receipt of the equipment and during the usage of it. A quality control and validation of the equipment as well as the testing of its safety is conducted to maintain basic rules of safety.

4. Formal hygiene and laboratory safety regulations

At CERTH we are familiar with the main hygiene and laboratory safety regulations.

5. Risk assessment

The main procedure for risk assessment in the context of research is carried out through a DPIA in order to apply the proper remedial measures.

6. Insurance against risks

CERTH has a civil liability insurance. Also there is provision for insurance in respect to the equipment used. Furthermore CERTH provides a health insurance program for its personnel which is valid at national level.

Data Protection

1. Data Protection Authority

Yes, the Hellenic Data Protection Authority (HDPA) (www.dpa.gr).

2. Privacy Policy

CERTH as an organization set ups and follows strictly concrete ethical and legal strategies in respect to data processing. Proper consent management, core principles as data minimization principle and anonymization transparency and other proper measures will be used according to the advanced worker and workplace models that will be developed and used in terms of the Ageing@Work research.

3. Privacy guidelines

As it is has been already mentioned in the D1.2, CERTH follows the main regulations listed below:

- Law 2472/1997
- Law 3471/2006
- Law 3783/2009
- Law 3917/2011
- Law 4024/2011
- Law 4070/2012
- Law 4139/2013

4. Confidentiality & Anonymity
Data confidentiality and anonymity could protect individuals from potential exposure, more specifically in respect to sensitive information handling. CERTH, in order to be compliant with these principles, enclose terms of confidentiality and anonymity in the templates of consent forms indicated by the consortium to be provided to pilots' participants. Terms of data confidentiality and anonymity are enclosed in the template of the consent form provided to all partners as quoted below: 'The information that will be collected from this research project will be kept confidential and will be destroyed 60 months after the termination of the project'. 'Only the researchers will know what your real name is and we will lock that information up with a lock and key. It will not be shared with or given to anyone else except researchers of the consortium - if asked. In such a case, any information about you will have a number on it (user id) instead of your name'.
5. Data Protection Officer
CERTH has assigned the role of DPO to Mr. Chalinidis Ioannis who has a high level expertise justified by the following qualifications: MSc in Information Security, Royal Holloway, and University of London.
6. HTTP cookies
CERTH will use HTTP cookies for the user input in the Ageing@Work platform, in order to store the user credentials and enable user convenience while logging and navigating into the platform.

Ethics Checklist

No.	Question	Yes	No
1.	Does your research involve human participants?	✓	
2.	If yes, are they potentially vulnerable individuals or groups? (e.g. children, students, employees)	✓	
3.	Does your research involve the collection of confidential or sensitive information?	✓	
4.	Does your research involve controversial subject matter? (e.g. sensitive, embarrassing or intrusive topics)	✓	
5.	May your research cause any harm to participants, researchers or others? (e.g. invasive techniques, physical interventions)		✓
If all answers above are "No", then no formal ethics approval is required.			
6.	Has the research activity already approval from an ethics committee?		✓
7.	Is the research activity part of a larger study that has already received approval from an ethics committee?		✓
If answer to question 6 or 7 is "Yes" then no further ethics approval is required.			
8.	Have health and safety risks due to the research been considered?	✓	
9.	Are data protection compliance measures taken for any personal data collected by the research?	✓	
If one of the answers to question 1 – 5 is "Yes" and neither 6 nor 7 is "Yes", then a formal verification of the requirement of an ethics approval is advised under consideration of aspects 8 – 9.			

Risk assessment

No.	Question	Yes	No
1.	Does the activity involve the systematic monitoring of publicly accessible spaces?		✓
2.	Are the persons unaware of the collection and processing of their data?		✓
3.	Does the activity use automated data collection from open sources?	✓	
4.	Does the activity involve the use of new technologies?	✓	
5.	Is there a combination of a person's data from more than one source?	✓	
6.	Is the personal data used for a purpose other than its original intention?		✓
7.	Would the processing of personal data be perceived as disruptive in this way?		✓
8.	Might data processing concern specific categories of personal data? (e.g. health)	✓	
9.	Does the data processing involve decisions or assumptions about individuals?	✓	
10.	Would the data subject consider the processed information to be private?	✓	

If any question is answered with "Yes", the need of a full risk assessment of data protection (DPIA) is indicated.

Study description

1. Human participants & personal data
CERTH as a technological provider will be involved only in pseudoanonymized data processing activities.
2. Participants selection & recruitment
CERTH does not participate in the pilot trials participants' recruitment process. In case that experiments are performed at CERTH, in the context of the project's R&D tasks during the project, proper ethical and legal guidelines according to the new regulation will be strictly followed.
3. (Sensitive) personal data
CERTH as a technological provider will be involved only in pseudoanonymized data processing activities. The R&D efforts of CERTH will involve collection and processing of personal, biometric and health data.
4. Collection method & tools
Data will be collected by approved equipment at the place of the pilot sites and transferred anonymised to servers controlled by CERTH. In case that experiments are performed at CERTH, in the context of the CERTH R&D tasks during the project, there is the possibility to collect human activity tracking data, derived from wearable sensors (e.g. accelerometers, biosignals), from IoT sensors (e.g. environment state, temperature, humidity, lighting etc.) and also from RGB-D and acoustic sensors. All these data will be properly pseudoanonymized and be safely kept in dedicated PC units of the CERTH research group.

5. Tracking or observation
Yes. Wearable computers will be used to collect basic biometric data (e.g health rate) and also cameras, IoT environment sensors and acoustic sensors will be used for observing employees while operating machines.
6. Purpose of data collection & processing
Data will be collected and processed in order to develop personal profiles of employees and offer personalised services in respect to health and well-being in workplaces in accordance to the project objectives and goals as described in the Ageing@Work DoA.
7. Secondary use
It is possible that previous collected data from HR departments of the pilot sites will be used.
8. Storage & backup
Data will be stored and backed up in a database (DB) in servers. The data of each individual will be associated with a numerical code, while only the PI (Principal Investigator) will have the information on the mapping between these codes and the names of participants; this information will be kept properly locked to ensure data safety and confidentiality.
9. Data access
Third parties will not have access. Access to the pseudoanonymized data will be given only to authorised personnel based on user authentication techniques and mechanisms to avoid unauthorised access.
10. Pooled data & transferring
The data will be gathered in the pilot sites' places (Spain and Germany). CERTH may also collect data within its premises during its R&D efforts. Data access is allowed only inside the EU and in consistency with the security and privacy measures defined by the consortium.
11. Company data & Confidentiality
Yes. Data in respect to workplace design, work processes and other working conditions will be collected within the Project but with the consent of the company.
12. Picture, video or sound recordings
Yes, all of the above means will be used. For this reason a separate consent form is provisioned to be drafted and handed –out to participants in order to state their free choice to participate in the research.
13. Other ethical or legal issues
No, from CERTH's side there is no other ethical or legal issue that should be taken into consideration.

Institution / Beneficiary:	Name:	Date:
CIOP-PIB	**Centralny Instytut Ochrony Pracy – Państwowy Instytut Badawczy/Central Institute for Labour Protection - National Research Institute**	**19.04.2019**

General Ethics

1. International/national legislation
The Declaration of Helsinki is the main legislation in force in Poland which we must follow when performing research with human subjects .
2. Ethics control body in the country
Yes, there are Ethics and Bioethics Committees in Poland.
3. Ethics control committee in the organisation
No, there is not.
4. Ethical control procedures
Institutions that perform tests on human subjects are required to report to the relevant Ethics Committee to evaluate the research and obtain approval for its implementation.
5. Expertise in ethics and Member of Ethics Advisory Board
No, our organisation hasn't specific expertise in the field of ethics and data protection in scientific research, we aren't also interested in joining the Ethics Advisory Board.

Safety and hygiene

1. Written procedures for maintaining hygiene
Yes, the procedures concerning the observance of hygiene in the organization are included in the Occupational Health and Safety Regulations of the Central Institute for Labour Protection - National Research Institute. Each employee confirms in writing that they have read the regulations and undertakes to comply with them.
2. Safety of employees
Yes, the procedures concerning the observance of safety by employees and volunteers in the organization are included in the Occupational Health and Safety Regulations of the Central Institute for Labour Protection - National Research Institute. Each employee confirms in writing that they have read the regulations and undertakes to comply with them.
3. Safety of equipment
Yes, in the Institute we have internal procedures to test the safety of equipment we use, as well as prototypes we develop. Our workers are required to familiarise themselves with the terms and conditions of safety and use of equipment.
4. Formal hygiene and laboratory safety regulations
All CIOP-PIB laboratories have their own regulations and instructions for use. In order to use the laboratory, employees are obliged to familiarize themselves with the requirements.
5. Risk assessment
No, we don't have such procedures.

6. Insurance against risks
Yes, our organization is insured against risks due to invasion of privacy, safety and biocompatibility. Insurance covers research and development work in the field of technical and life sciences, leading to new technical and organizational solutions in the field of occupational health and safety, occupational health and ergonomics, adaptation of the results of research and work to practice, dissemination of the results of such research and work, expertise, analysis, assessment of the effectiveness of occupational health and safety projects, analysis, health and safety advisory services.

Data Protection

1. Data Protection Authority
Yes, there is the Personal Data Protection Office in Poland.
2. Privacy Policy
Yes, every employee is required to follow written procedures. All information was included in D1.2.
3. Privacy guidelines
No, all information on national requirements was included in D1.2.
4. Confidentiality & Anonymity
Yes, this is a required procedure. Participants in the study shall read the terms and conditions of the study and sign a declaration accordingly.
5. Data Protection Officer
Yes, CIOP-PIB has a Data Protection Officer. This is Mr. Andrzej Biernacki.
6. HTTP cookies
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Ethics Checklist

No.	Question	Yes	No
1.	Does your research involve human participants?	✓	
2.	If yes, are they potentially vulnerable individuals or groups? (e.g. children, students, employees)	✓	
3.	Does your research involve the collection of confidential or sensitive information?	✓	
4.	Does your research involve controversial subject matter? (e.g. sensitive, embarrassing or intrusive topics)		✓
5.	May your research cause any harm to participants, researchers or others? (e.g. invasive techniques, physical interventions)		✓
	If all answers above are "No", then no formal ethics approval is required.		
6.	Has the research activity already approval from an ethics committee?		✓
7.	Is the research activity part of a larger study that has already received approval from an ethics committee?		✓
	If answer to question 6 or 7 is "Yes" then no further ethics approval is required.		
8.	Have health and safety risks due to the research been considered?	✓	
9.	Are data protection compliance measures taken for any personal data collected by the research?	✓	
	If one of the answers to question 1 – 5 is "Yes" and neither 6 nor 7 is "Yes", then a formal verification of the requirement of an ethics approval is advised under consideration of aspects 8 – 9.		

Risk assessment

No.	Question	Yes	No
1.	Does the activity involve the systematic monitoring of publicly accessible spaces?		✓
2.	Are the persons unaware of the collection and processing of their data?		✓
3.	Does the activity use automated data collection from open sources?		✓
4.	Does the activity involve the use of new technologies?		✓
5.	Is there a combination of a person's data from more than one source?		✓
6.	Is the personal data used for a purpose other than its original intention?		✓
7.	Would the processing of personal data be perceived as disruptive in this way?		✓
8.	Might data processing concern specific categories of personal data? (e.g. health)	✓	
9.	Does the data processing involve decisions or assumptions about individuals?		✓
10.	Would the data subject consider the processed information to be private?	✓	
	If any question is answered with "Yes", the need of a full risk assessment of data protection (DPIA) is indicated.		

Study description

1. Human participants & personal data
WP3, T3.1. We are planning to conduct questionnaire surveys and interviews with employees regarding workplace and individual factors related to their work ability and productivity. This data would be anonymous but employees' socio-demographic data (age, gender, job tenure, position in the organization, level of education) as well as lifestyle, self-rated health status etc. will be analysed.
2. Participants selection & recruitment
Participation in the study will be voluntary based on informed consent. Employees from the workplaces designated by industrial partners will be invited to participate. Inclusion criteria will be employee age. As far as employee sex is concerned, this criteria could be difficult to fulfil taking into account physical character of the job in ANEFA and Siemens.
3. (Sensitive) personal data
Personal data: age, gender, level of education, job tenure, position in the organization will be gathered only in the questionnaire survey in order to be included in the statistical analysis. However, the questionnaire will be pseudo anonymized by providing a user specific code. This code will serve to match the questionnaire with the signed consent form. Only the researchers from CIOP-PIB will have access to the consent forms and will be able to match them with the questionnaires in case the users decide to withdraw their data from the database. The consent forms will be locked with the key at CIOP-PIB and the database containing the user code will be available to other researchers from the consortium upon request.
4. Collection method & tools
We are planning to conduct questionnaires survey and individual interviews. Paper-and -pencil questionnaires will be implemented. The interviews will be based on prepared scenarios containing set of questions and issues to be addressed in the discussion and will be organized during the workshops conducted by UPM (Task 8.2). Employees will be informed about the aim of the study and their consent forms will be provided to be signed before the study. Questionnaire and interviews will be pseudo anonymised using specific user code invented by the participant and the individual answers will not be available to any of company representatives, managers, supervisors, nor analysed by CIOP-PIB They will serve only for collective statistical analysis.
5. Tracking or observation
No.
6. Purpose of data collection & processing
Data from the questionnaires and interviews answers will be statistically analysed in SPSS. The aim of the analysis will be to choose most relevant and significant factors related to employees work ability, productivity as well as other factors related to successful implementation of Ageing@Work system.
7. Secondary use
No.

8. Storage & backup
Data derived from questionnaires and interviews will be pseudo anonymised and stored in CIOP-PIB. Personal data derived from the consent form (signature) will be stored in CIOP-PIB and locked with a key
9. Data access
Only researchers participating in the Ageing@Work project will have access to the database.
10. Pooled data & transferring
Data will be collected in Spain and Germany but analysed in Poland in CIOP-PIB.
11. Company data & Confidentiality
Working conditions and work organization as perceived by the employees will be one of the main areas of interest in the questionnaire study in order to analyse their impact on employees; work ability and productivity
12. Picture, video or sound recordings
No.
13. Other ethical or legal issues
No.

Institution / Beneficiary:	Name:	Date:
HIT HYPERTECH INNOVATIONS LTD	Georgios Karagiannopoulos	08/05/2019

General Ethics

1. International/national legislation

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2. Ethics control body in the country

Data acquisition and evaluation in Cyprus are both subjected to scrutiny by the Cyprus National BioEthics Committee (CNBEC).
In accordance with article 3 (1) of the Law N. 150 (I) /2001 The Bioethics (Establishment and Function of the National Committee), the Committee`s mission is the constant monitoring, survey, systematic analysis and evaluation of the issues and problems that relate to the scientific research, progress and implementation of the sciences of biotechnology, biology, medicine, genetics and pharmaceutics as well as to the human intervention on the biological procedure and the human genotype and the investigation of their moral, deontological, social, humanistic and legal dimensions

3. Ethics control committee in the organisation

No.

4. Ethical control procedures

We are not performing tests on human subjects, so we haven't established any ethical control procedure.

5. Expertise in ethics and Member of Ethics Advisory Board

No.

Safety and hygiene

1. Written procedures for maintaining hygiene

Not needed.

2. Safety of employees

Not needed.

3. Safety of equipment

Not needed.

4. Formal hygiene and laboratory safety regulations

Not needed.

5. Risk assessment

Not needed.

6. Insurance against risks

Not needed.

Data Protection

1. Data Protection Authority

The Cypriot Data Protection Authority, named by the relevant law as the Commissioner Personal Data Protection, was set up in 2002 by the Processing of Personal Data (Protection of the Individual) Law of 2001 and amended in 2004 and 2018 (Law N. 125(I)/2018, Protection of Natural Persons with regard to the Processing of Personal Data (Data Protection Act)) and has operated since May 2002.
On 31 July 2018 the national law providing for the protection of natural persons with regard to the processing of personal data and for the free movement of such data (Law 125(I)/2018), was published in the official gazette of the Cyprus Republic. The law was adopted for the effective implementation of certain provisions of the Regulation (EE) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (GDPR), which applies as of 25 May 2018. Upon entry into force of the provisions of the law 125(I)/2018, the Processing of Personal Data (Protection of Individuals) Law of 2001 (Law 138(I)/2001) was repealed.
The Commissioner for personal data protection is an independent public authority responsible for monitoring the implementation of Regulation (EU) 2016/679 (GDPR) and other laws aiming at the protection of individuals with regards to the processing of their personal data. The Commissioner performs the duties and exercises the powers assigned by the GDPR or any other relevant law in complete independence.
The role of the Commissioner is to safeguard personal data by protecting personal information relating to an individual against its unauthorised and illegal collection, recording and further use and it also grants the individual certain rights, such as the right of information, the right of access and the right of objection and provides for the procedure of submitting complaints to the Commissioner for violations of the law. The Commissioner may impose on the controllers or their representatives a number of administrative sanctions and has on a number of occasions made use of this right.
The Commissioner represents the Republic of Cyprus in the relevant bodies and committees of the European Union, the Council of Europe, and other International Organisations. Among other things, the Commissioner participates in the European Data Protection Board, which is composed of all Supervisory Authorities of EU Member States and the European Data Protection Supervisor, as well as by the European Commission.

2. Privacy Policy

-

3. Privacy guidelines

No.

4. Confidentiality & Anonymity

Not applicable.

5. Data Protection Officer
HIT has established a clear data protection policy, but it hasn't appointed a DPO because none of the following requirements applies in its case. • the processing is carried out by a public authority or body, except for courts acting in their judicial capacity; • the core activities of the controller or the processor consist of processing operations which, by virtue of their nature, their scope and/or their purposes, require regular and systematic monitoring of data subjects on a large scale; or • the core activities of the controller or the processor consist of processing on a large scale of special categories of data pursuant to Article 9 or personal data relating to criminal convictions and offences referred to in Article 10'.
6. HTTP cookies
To be discussed at a later stage. As far we plan the tools do not require cookies.

Ethics Checklist

No.	Question	Yes	No
1.	Does your research involve human participants?		✓
2.	If yes, are they potentially vulnerable individuals or groups? (e.g. children, students, employees)		✓
3.	Does your research involve the collection of confidential or sensitive information?		✓
4.	Does your research involve controversial subject matter? (e.g. sensitive, embarrassing or intrusive topics)		✓
5.	May your research cause any harm to participants, researchers or others? (e.g. invasive techniques, physical interventions)		✓
If all answers above are "No", then no formal ethics approval is required.			
6.	Has the research activity already approval from an ethics committee?		✓
7.	Is the research activity part of a larger study that has already received approval from an ethics committee?		✓
If answer to question 6 or 7 is "Yes" then no further ethics approval is required.			
8.	Have health and safety risks due to the research been considered?		✓
9.	Are data protection compliance measures taken for any personal data collected by the research?		✓
If one of the answers to question 1 – 5 is "Yes" and neither 6 nor 7 is "Yes", then a formal verification of the requirement of an ethics approval is advised under consideration of aspects 8 – 9.			

Risk assessment

No.	Question	Yes	No
1.	Does the activity involve the systematic monitoring of publicly accessible spaces?		✓
2.	Are the persons unaware of the collection and processing of their data?		✓
3.	Does the activity use automated data collection from open sources?		✓
4.	Does the activity involve the use of new technologies?		✓
5.	Is there a combination of a person's data from more than one source?		✓
6.	Is the personal data used for a purpose other than its original intention?		✓
7.	Would the processing of personal data be perceived as disruptive in this way?		✓
8.	Might data processing concern specific categories of personal data? (e.g. health)		✓
9.	Does the data processing involve decisions or assumptions about individuals?		✓
10.	Would the data subject consider the processed information to be private?		✓

If any question is answered with "Yes", the need of a full risk assessment of data protection (DPIA) is indicated.

Study description

1. Human participants & personal data
No.
2. Participants selection & recruitment
Not applicable.
3. (Sensitive) personal data
Not applicable.
4. Collection method & tools
Not applicable.
5. Tracking or observation
No.
6. Purpose of data collection & processing
Not applicable.
7. Secondary use
No.
8. Storage & backup
Not applicable.
9. Data access
Not applicable.
10. Pooled data & transferring
No.
11. Company data & Confidentiality
No.

12. Picture, video or sound recordings
No.
13. Other ethical or legal issues
No.

Institution / Beneficiary:	Name:	Date:
MultiMed Enegineers		

General Ethics

1. International/national legislation

The following elements inform ethics regulation in Italy:

- Declaration of Helsinki
- Recommendations issued by the Comitato nazionale per la bioetica (http://bioetica.governo.it/it)
- Approvals from specific Ethic Committees, regulated by Law "Decreto 8 febbraio 2013, Criteri per la composizione e il funzionamento dei comitati etici" (https://www.gazzettaufficiale.it/eli/id/2013/04/24/13A03474/sg)

2. Ethics control body in the country

A list of Italian Ethics Committees can be found here: https://retecomitatietici.apss.tn.it/comitati-etici-italiani/

3. Ethics control committee in the organisation

As an SME, MultiMed Engineers does not have an internal Ethics Committee

4. Ethical control procedures

As an SME the core business of which is not the conduction of clinical trials involving humans, MultiMed Engineers has no general internal ethics control procedures in place

5. Expertise in ethics and Member of Ethics Advisory Board

As an SME the core business of which is not the conduction of clinical trials involving humans, MultiMed Engineers has no general expertise in ethics

Safety and hygiene

1. Written procedures for maintaining hygiene

As any business in Italy, MultiMed Engineers complies to the norms on safety and hygiene on the workplace, as regulated by Law "Decreto legislativo 9 aprile 2008, n. 81, Testo unico in materia di salute e sicurezza nei luoghi di lavoro" (Law 81/2008). However, apart from obeying to these regulatory requirements, MultiMed Engineers core business/expertise is not related to safety and hygiene in the workplace, and the company's work in the Aging@Work project is not related to such topic.

2. Safety of employees

As per national Law 81/2008. See item (1) above

3. Safety of equipment

As per national Law 81/2008. See item (1) above

4. Formal hygiene and laboratory safety regulations

As per national Law 81/2008. See item (1) above

5. Risk assessment

As per national Law 81/2008. See item (1) above

6. Insurance against risks

As per national Law 81/2008. See item (1) above

Data Protection

1. Data Protection Authority
The data protection authority in Italy is the “Garante per la protezione dei dati personali”. It is an independent administrative authority established by the so-called privacy law (Law No. 675 of 31 December 1996) and regulated subsequently by the Personal Data Protection Code (Legislative Decree No. 196 of 30 June 2003) as amended by Legislative Decree No. 101 of 10 August 2018, which also established that the Italian DPA is the supervisory authority responsible for monitoring application of the General Data Protection Regulation (pursuant to Article 51 of Regulation No. 2016/679). (see https://www.garanteprivacy.it/web/guest/home_en)
2. Privacy Policy
Yes, we have a privacy policy document. It establishes: • The data controller reference information • The types of personal data managed by the Company • The reasons for data management • The way such data are managed • The methods used to manage data • A reminder of the rights of persons whose data the Company manages with reference to such management
3. Privacy guidelines
No.
4. Confidentiality & Anonymity
We will not act as data controller for personal data collected from participants in Aging@Work experiments, thus we will not directly contact such participants.
5. Data Protection Officer
According to the GDPR, for our Company the appointment of a DPO is not mandated.
6. HTTP cookies
We will not develop tools in the Aging@Work platform.

Ethics Checklist

No.	Question	Yes	No
1.	Does your research involve human participants?		✓
2.	If yes, are they potentially vulnerable individuals or groups? (e.g. children, students, employees)		✓
3.	Does your research involve the collection of confidential or sensitive information?		✓
4.	Does your research involve controversial subject matter? (e.g. sensitive, embarrassing or intrusive topics)		✓
5.	May your research cause any harm to participants, researchers or others? (e.g. invasive techniques, physical interventions)		✓
If all answers above are "No", then no formal ethics approval is required.			
6.	Has the research activity already approval from an ethics committee?		
7.	Is the research activity part of a larger study that has already received approval from an ethics committee?		
If answer to question 6 or 7 is "Yes" then no further ethics approval is required.			
8.	Have health and safety risks due to the research been considered?		
9.	Are data protection compliance measures taken for any personal data collected by the research?		
If one of the answers to question 1 – 5 is "Yes" and neither 6 nor 7 is "Yes", then a formal verification of the requirement of an ethics approval is advised under consideration of aspects 8 – 9.			

Risk assessment

No.	Question	Yes	No
1.	Does the activity involve the systematic monitoring of publicly accessible spaces?		✓
2.	Are the persons unaware of the collection and processing of their data?		✓
3.	Does the activity use automated data collection from open sources?		✓
4.	Does the activity involve the use of new technologies?		✓
5.	Is there a combination of a person's data from more than one source?		✓
6.	Is the personal data used for a purpose other than its original intention?		✓
7.	Would the processing of personal data be perceived as disruptive in this way?		✓
8.	Might data processing concern specific categories of personal data? (e.g. health)		✓
9.	Does the data processing involve decisions or assumptions about individuals?		✓
10.	Would the data subject consider the processed information to be private?		✓
If any question is answered with "Yes", the need of a full risk assessment of data protection (DPIA) is indicated.			

Study description

1. Human participants & personal data
MultiMed Engineers will not be involved in project activities directly addressing human participants and related personal data collection.
2. Participants selection & recruitment
Not applicable as per item (1)
3. (Sensitive) personal data
Not applicable as per item (1)
4. Collection method & tools
Not applicable as per item (1)
5. Tracking or observation
Not applicable as per item (1)
6. Purpose of data collection & processing
Not applicable as per item (1)
7. Secondary use
Not applicable as per item (1)
8. Storage & backup
Not applicable as per item (1)
9. Data access
Not applicable as per item (1)
10. Pooled data & transferring
Not applicable as per item (1)
11. Company data & Confidentiality
Not applicable as per item (1)
12. Picture, video or sound recordings
Not applicable as per item (1)
13. Other ethical or legal issues
Not applicable as per item (1)

Institution / Beneficiary:	Name:	Date:
MYSPHERA	Pilar Sala	9/5/2019

General Ethics

1. International/national legislation
No.
2. Ethics control body in the country
Depends on the type of research to be done. There is a network of accredited Research Ethics Committees of Universities and Public Research Organizations that can assess ethics aspects in research.
3. Ethics control committee in the organisation
No.
4. Ethical control procedures
If we perform directly tests on human subjects, we follow the guidelines provided by the EU Working Group on Science and Ethics.
5. Expertise in ethics and Member of Ethics Advisory Board
No.

Safety and hygiene

1. Written procedures for maintaining hygiene
No, it's not applicable, organization is an SME in the ICT development field.
2. Safety of employees
Yes, we follow the applicable regulation for prevention of occupational hazards for small companies and offices.
3. Safety of equipment
Not applicable.
4. Formal hygiene and laboratory safety regulations
Not applicable.
5. Risk assessment
Not applicable.
6. Insurance against risks
Not applicable.

Data Protection

1. Data Protection Authority
Yes, Spanish Data Protection Agency is the responsible entity with regard to data protection and privacy regulations.
2. Privacy Policy
The existing Privacy Policy refers to the interaction through digital channels with the company (web page, social networks). We are in the process to comply with GDPR and currently updating and adapting the company Privacy Policy to the new requirements.
3. Privacy guidelines
No.
4. Confidentiality & Anonymity
In the case that research with human subjects is performed under the direct supervision of Mysphera, we apply the standard guidelines of ethics in research, collecting informed consent prior to the involvement of participants in the activity and informing about the data that will be collected and how the privacy and anonymity will be preserved.
5. Data Protection Officer
Yes, we have a subcontractor, S2 group, that acts as our DPO.
6. HTTP cookies
No.

Ethics Checklist

No.	Question	Yes	No
1.	Does your research involve human participants?		
2.	If yes, are they potentially vulnerable individuals or groups? (e.g. children, students, employees)		
3.	Does your research involve the collection of confidential or sensitive information?		
4.	Does your research involve controversial subject matter? (e.g. sensitive, embarrassing or intrusive topics)		
5.	May your research cause any harm to participants, researchers or others? (e.g. invasive techniques, physical interventions)		
If all answers above are "No", then no formal ethics approval is required.			
6.	Has the research activity already approval from an ethics committee?		
7.	Is the research activity part of a larger study that has already received approval from an ethics committee?		
If answer to question 6 or 7 is "Yes" then no further ethics approval is required.			
8.	Have health and safety risks due to the research been considered?		
9.	Are data protection compliance measures taken for any personal data collected by the research?		
If one of the answers to question 1 – 5 is "Yes" and neither 6 nor 7 is "Yes", then a formal verification of the requirement of an ethics approval is advised under consideration of aspects 8 – 9.			

Risk assessment

No.	Question	Yes	No
1.	Does the activity involve the systematic monitoring of publicly accessible spaces?		✓
2.	Are the persons unaware of the collection and processing of their data?		✓
3.	Does the activity use automated data collection from open sources?		
4.	Does the activity involve the use of new technologies?		✓
5.	Is there a combination of a person's data from more than one source?	✓	
6.	Is the personal data used for a purpose other than its original intention?		✓
7.	Would the processing of personal data be perceived as disruptive in this way?		✓
8.	Might data processing concern specific categories of personal data? (e.g. health)	✓	
9.	Does the data processing involve decisions or assumptions about individuals?		
10.	Would the data subject consider the processed information to be private?	✓	

If any question is answered with "Yes", the need of a full risk assessment of data protection (DPIA) is indicated.

Study description

1. Human participants & personal data
Yes, WP4 deals with unobtrusive ambient activity and behaviour monitoring.
2. Participants selection & recruitment
This activity will be under the responsibility of other WP and partners.
3. (Sensitive) personal data
Not defined yet. For sure no genetic or biometric data, neither personal data revealing racial and ethnic origin, political opinions, religious or ideological convictions or trade union membership.
4. Collection method & tools
Not defined yet.
5. Tracking or observation
Yes, more likely.
6. Purpose of data collection & processing
To provide personalised models of workers for process optimization.
7. Secondary use
No.
8. Storage & backup
Not defined yet.
9. Data access
Not defined yet.
10. Pooled data & transferring
No.

11. Company data & Confidentiality
Not defined yet.
12. Picture, video or sound recordings
No.
13. Other ethical or legal issues
No.

Institution / Beneficiary:	Name:	Date:
Q-PLAN INTERNATIONAL ADVISORS	Evangelia Tsagaraki	9/5/2019

General Ethics

1. International/national legislation
Not applicable for our role at AGEING@WORK.
2. Ethics control body in the country
There is the National Bioethics Commission (www.bioethics.gr) with a consultation role.
3. Ethics control committee in the organisation
No.
4. Ethical control procedures
Not applicable.
5. Expertise in ethics and Member of Ethics Advisory Board
Not applicable.

Safety and hygiene

1. Written procedures for maintaining hygiene
The activities of the organisation do not entail any specific hygiene requirements. Nevertheless, there is a written procedure for maintaining hygiene in the organization workplace as part of the Quality Management System.
2. Safety of employees
Yes, there is a written procedure for occupational safety as part of the Quality Management System and the company has an appointed Safety Technician, in compliance with the Greek law about occupational health safety.
3. Safety of equipment
Not applicable.
4. Formal hygiene and laboratory safety regulations
Not applicable. The company does not have a laboratory.
5. Risk assessment
Not applicable.
6. Insurance against risks
No.

Data Protection

1. Data Protection Authority
Not applicable.
2. Privacy Policy
Yes, there is a company privacy policy in accordance to GDPR law.
3. Privacy guidelines
No.
4. Confidentiality & Anonymity
Not applicable.
5. Data Protection Officer
Yes. DPO: Petros Papadionisiou
6. HTTP cookies
Not applicable.

Ethics Checklist

No.	Question	Yes	No
1.	Does your research involve human participants?		✓
2.	If yes, are they potentially vulnerable individuals or groups? (e.g. children, students, employees)		✓
3.	Does your research involve the collection of confidential or sensitive information?		✓
4.	Does your research involve controversial subject matter? (e.g. sensitive, embarrassing or intrusive topics)		✓
5.	May your research cause any harm to participants, researchers or others? (e.g. invasive techniques, physical interventions)		✓
If all answers above are "No", then no formal ethics approval is required.			
6.	Has the research activity already approval from an ethics committee?		
7.	Is the research activity part of a larger study that has already received approval from an ethics committee?		
If answer to question 6 or 7 is "Yes" then no further ethics approval is required.			
8.	Have health and safety risks due to the research been considered?		
9.	Are data protection compliance measures taken for any personal data collected by the research?		
If one of the answers to question 1 – 5 is "Yes" and neither 6 nor 7 is "Yes", then a formal verification of the requirement of an ethics approval is advised under consideration of aspects 8 – 9.			

Risk assessment

No.	Question	Yes	No
1.	Does the activity involve the systematic monitoring of publicly accessible spaces?		✓
2.	Are the persons unaware of the collection and processing of their data?		✓
3.	Does the activity use automated data collection from open sources?		
4.	Does the activity involve the use of new technologies?		✓
5.	Is there a combination of a person's data from more than one source?		✓
6.	Is the personal data used for a purpose other than its original intention?		✓
7.	Would the processing of personal data be perceived as disruptive in this way?		✓
8.	Might data processing concern specific categories of personal data? (e.g. health)		✓
9.	Does the data processing involve decisions or assumptions about individuals?		✓
10.	Would the data subject consider the processed information to be private?		✓

If any question is answered with "Yes", the need of a full risk assessment of data protection (DPIA) is indicated.

Study description

1. Human participants & personal data
No.
2. Participants selection & recruitment
Not applicable.
3. (Sensitive) personal data
No sensitive/ personal data will be collected or processed.
4. Collection method & tools
Not applicable.
5. Tracking or observation
No.
6. Purpose of data collection & processing
Not applicable.
7. Secondary use
No.
8. Storage & backup
Not applicable.
9. Data access
Not applicable.
10. Pooled data & transferring
No.

11. Company data & Confidentiality
No.
12. Picture, video or sound recordings
In terms of reporting dissemination activities, for which Q-PLAN is work package leader, photos or video from project events may be taken. In such case, a consent form will be sought from persons appearing in photos/videos in a recognizable manner.
13. Other ethical or legal issues
No.

Institution / Beneficiary:	Name:	Date:
Siemens	Klaus-Peter Wegge	29. May 2019

General Ethics

1. International/national legislation
Yes.
2. Ethics control body in the country
No.
3. Ethics control committee in the organisation
Yes, not exactly an ethics control board but studies like the Ageing@Work one has to be reviewed and confirmed by the Siemens Workers Council.
4. Ethical control procedures
N/A for Ageing@Work.
5. Expertise in ethics and Member of Ethics Advisory Board
Yes we have data protection officer (Mr Achim Köhler) but we are currently not interested in joining the ethics board.

Safety and hygiene

1. Written procedures for maintaining hygiene
n/a for Ageing@Work.
2. Safety of employees
Yes: Safety officer and internal rules; Company agreement (Betriebsvereinbarung) and regular training courses Workplaces Ordinance and Rules of the GUV administrative professional association
3. Safety of equipment
Yes but n/a for Ageing@Work.
4. Formal hygiene and laboratory safety regulations
n/a for Ageing@Work.
5. Risk assessment
Risk ass about safety yes yearly workplace inspections; n/a ; n/a
6. Insurance against risks
For safety Deutsche Gesetzliche Unfallversicherung.

Data Protection

1. Data Protection Authority
1. Dataprotection Officer 2. Binding Corporate Rules https://assets.new.siemens.com/siemens/assets/public.1550663431.34016021-5967-4c51-bda0-c8a0368eebba.summary-of-third-party-rights-en.pdf/summary-of-third-party-rights-en.pdf 3. Business Conduct Guidelines https://w5.siemens.com/web/ua/ru/about/compliance/Documents/Siemens%20Business%20Conduct%20Guideline_ENG.pdf 4. Privacy Policy https://new.siemens.com/global/en/general/privacy-notice.html
2. Privacy Policy
Yes we use consent form.
3. Privacy guidelines
1. Binding Corporate Rules https://assets.new.siemens.com/siemens/assets/public.1550663431.34016021-5967-4c51-bda0-c8a0368eebba.summary-of-third-party-rights-en.pdf/summary-of-third-party-rights-en.pdf 2. Business Conduct Guidelines https://w5.siemens.com/web/ua/ru/about/compliance/Documents/Siemens%20Business%20Conduct%20Guideline_ENG.pdf 3. Privacy Policy https://new.siemens.com/global/en/general/privacy-notice.html
4. Confidentiality & Anonymity
Yes, see above (consent form).
5. Data Protection Officer
Yes, Mr Achim Köhler
6. HTTP cookies
Not applicable.

Ethics Checklist

No.	Question	Yes	No
1.	Does your research involve human participants?	✓	
2.	If yes, are they potentially vulnerable individuals or groups? (e.g. children, students, employees)	✓	
3.	Does your research involve the collection of confidential or sensitive information?	✓	
4.	Does your research involve controversial subject matter? (e.g. sensitive, embarrassing or intrusive topics)		✓
5.	May your research cause any harm to participants, researchers or others? (e.g. invasive techniques, physical interventions)		✓
If all answers above are "No", then no formal ethics approval is required.			
6.	Has the research activity already approval from an ethics committee?		✓
7.	Is the research activity part of a larger study that has already received approval from an ethics committee?		✓
If answer to question 6 or 7 is "Yes" then no further ethics approval is required.			
8.	Have health and safety risks due to the research been considered?	✓	
9.	Are data protection compliance measures taken for any personal data collected by the research?	✓	
If one of the answers to question 1 – 5 is "Yes" and neither 6 nor 7 is "Yes", then a formal verification of the requirement of an ethics approval is advised under consideration of aspects 8 – 9.			

Risk assessment

No.	Question	Yes	No
1.	Does the activity involve the systematic monitoring of publicly accessible spaces?		✓
2.	Are the persons unaware of the collection and processing of their data?		✓
3.	Does the activity use automated data collection from open sources?		✓
4.	Does the activity involve the use of new technologies?	✓	
5.	Is there a combination of a person's data from more than one source?		✓
6.	Is the personal data used for a purpose other than its original intention?		✓
7.	Would the processing of personal data be perceived as disruptive in this way?		✓
8.	Might data processing concern specific categories of personal data? (e.g. health)	✓	
9.	Does the data processing involve decisions or assumptions about individuals?		✓
10.	Would the data subject consider the processed information to be private?	✓	
If any question is answered with "Yes", the need of a full risk assessment of data protection (DPIA) is indicated.			

Study description

1. Human participants & personal data
YES WP7.
2. Participants selection & recruitment
Voluntary participation.
3. (Sensitive) personal data
Yes but no sensitive personal data.
4. Collection method & tools
Open interviews and questionnaires.
5. Tracking or observation
Yes.
6. Purpose of data collection & processing
For the projects objectives.
7. Secondary use
No.
8. Storage & backup
Digitally stored data only in an anonymized encrypted manner (access only to Ageing@Work project participants from Siemens). Questionnaires and Interview Notes, always taken in an anonymous manner, on paper will be scanned and stored like written above, originals will be destroyed according to industry standards.
9. Data access
Third parties will not have access to the data. Only the results of the analysis will be provided to the project partners. Data storage see above.
10. Pooled data & transferring
No.
11. Company data & Confidentiality
Yes, data on workplace design, work processes and other working conditions.
12. Picture, video or sound recordings
No.
13. Other ethical or legal issues
No.

Institution / Beneficiary:	Name:	Date:
UPAT	UNIVERSITY OF PATRAS	9/5/2019

General Ethics

1. International/national legislation

Apart from the Declaration of Helsinki which is a cornerstone on human research ethics, the Greek Laws 2472/1997 and 2472/1997, define a specific regulatory framework which is dedicated to privacy, data retention and data protection.

2. Ethics control body in the country

There is a Data Protection Control body in Greece which is the Personal Data Protection Authority (http://www.dpa.gr/). However there is not a unique control body regarding ethics. According to Law 4521/2018, there are Ethics Committees in each Research Center that evaluate all biomedical research involving human interventions or the use of their biological samples.

3. Ethics control committee in the organisation

Yes. Currently there is an ethics control body in University of Patras (The Bioethics committee).

4. Ethical control procedures

Within the Ageing @Work project, an Ethics Advisory Board (EAB) has been established to undertake ethics, legal and privacy issues that will probably emerge during the lifecycle of the project. The role of EAB is to assist the project partners in identifying and solving ethical concerns that might not be identified by the end users or the project group during the whole duration of the project and provide proper advice and solutions on ethics, privacy and socio-economic issues. Furthermore, the project's Ethics Protocol will be drafted and applied to address the ethical and legal issues that will potentially arise during the lifecycle of the project.
Ethical control procedures according to performing tests on human subjects have to be addressed mainly by the pilots of the project. In particular pilot sites should submit an application to the ethical committee in order to receive the approval for pilots' operation.

Ethical control refers also to proper certificates of devices. At Ageing@Work project, sensors and healthcare devices (medical devices) that will be used, will be properly certified. Moreover standards and regulations will be applied in Apps development.

Moreover a number of organizational and technical measures is provisioned to be adopted in order to address potential ethical and legal risks. Particularly, in alignment to the new regulation (GDPR), consent form is one of the seven legal grounds that have to be followed in terms of personal data processing in respect to the European Data Protection Directive (95/46/EC).

For this reason a detailed informed consent will be carefully prepared for each data collection process and pilot trial, at each pilot site, fully outlining the scope of the process/trial and its purposes along with the data collected and analysed.
Special emphasis will also be placed on user data privacy and security, taking concrete measures for worker data protection.

5. Expertise in ethics and Member of Ethics Advisory Board

UPAT has participated in a few European and national projects that had to cope with ethics. The persons selected to address these issues were appropriately informed in advance.
No, there is no interest from the side of UPAT to join the Ethics Advisory Board.

Safety and hygiene

1. Written procedures for maintaining hygiene
(If yes, please give a brief overview. If no, please explain why or what corrective actions you take.) The maintenance of hygiene is monitored by the Coordinating Committee on Health and Safety (http://osh.upatras.gr/). The national legislation for health and safety of the employees is the Law 3850/2010. According to the report of the panel appointed by the HQA to undertake the review of the Internal Quality Assurance System (IQAS) of the University of Patras (10/2018) "The Institution ensures that the working environment has a positive effect on the performance of the members of the academic community (students and staff) appropriately. The sanitary facilities, the lighting/heating/ventilation system, the cleanliness and the overall appearance of the premises, are in an acceptable condition."
2. Safety of employees
Similarly to health, safety of employees is monitored by Coordinating Committee on Health and Safety (see response to 1 section 5.4).
3. Safety of equipment
We follow general guidelines from the receipt of the equipment and during the usage of it. A quality control and validation of the equipment as well as the testing of its safety is conducted to maintain basic rules of safety. Furthermore, an appropriate managing and monitoring system managed by the facility management department (technical services) identify needs and promotes solutions for a favourable working environment.
4. Formal hygiene and laboratory safety regulations
Yes, the employees of the Wire Communications Laboratory at UPAT are familiar with the main hygiene and laboratory safety regulations.
5. Risk assessment
The main procedure for risk assessment in the context of research is carried out through a DPIA in order to apply the proper remedial measures.
6. Insurance against risks
Health insurance, valid at national level, is obligatory for the personnel of UPAT. The institution is not insured against risks due to invasion of privacy, safety and biocompatibility.

Data Protection

1. Data Protection Authority

Yes, the Hellenic Data Protection Authority (HDPA) (www.dpa.gr).

2. Privacy Policy

The UPAT team will follow strictly concrete ethical and legal strategies in respect to data analysis. Proper consent management, core principles as data minimization principle and anonymization transparency and other proper measures will be used according to the workplace models and productivity enhancement and learning tools that will be developed and used in terms of the Ageing@Work research.

3. Privacy guidelines

The UPAT partner should be compliant with the main regulations listed below:

- Law 2472/1997
- Law 3471/2006
- Law 3783/2009
- Law 3917/2011
- Law 4024/2011
- Law 4070/2012
- Law 4139/2013

4. Confidentiality & Anonymity

UPAT will receive anonymized data as part of the Ageing@Work project and therefore will not have to deal with issues in respect to data anonymity. All data will be kept strictly confidential.

5. Data Protection Officer

UPAT has assigned the role of DPO to Mr. Georgios Lekatsas who has a high level of expertise.

6. HTTP cookies

The tools to be developed by the WCL team of UPAT as part of the Ageing@Work project will not use HTTP cookies. If the external services of the University will use cookies, this will be handled with messages informing the user and asking for his/her permission.

Ethics Checklist

No.	Question	Yes	No
1.	Does your research involve human participants?	✓	
2.	If yes, are they potentially vulnerable individuals or groups? (e.g. children, students, employees)	✓	
3.	Does your research involve the collection of confidential or sensitive information?	✓	
4.	Does your research involve controversial subject matter? (e.g. sensitive, embarrassing or intrusive topics)	✓	
5.	May your research cause any harm to participants, researchers or others? (e.g. invasive techniques, physical interventions)		✓
If all answers above are "No", then no formal ethics approval is required.			
6.	Has the research activity already approval from an ethics committee?		✓
7.	Is the research activity part of a larger study that has already received approval from an ethics committee?		✓
If answer to question 6 or 7 is "Yes" then no further ethics approval is required.			
8.	Have health and safety risks due to the research been considered?	✓	
9.	Are data protection compliance measures taken for any personal data collected by the research?	✓	
If one of the answers to question 1 – 5 is "Yes" and neither 6 nor 7 is "Yes", then a formal verification of the requirement of an ethics approval is advised under consideration of aspects 8 – 9.			

Risk assessment

No.	Question	Yes	No
1.	Does the activity involve the systematic monitoring of publicly accessible spaces?		✓
2.	Are the persons unaware of the collection and processing of their data?		✓
3.	Does the activity use automated data collection from open sources?	✓	
4.	Does the activity involve the use of new technologies?	✓	
5.	Is there a combination of a person's data from more than one source?	✓	
6.	Is the personal data used for a purpose other than its original intention?		✓
7.	Would the processing of personal data be perceived as disruptive in this way?		✓
8.	Might data processing concern specific categories of personal data? (e.g. health)	✓	
9.	Does the data processing involve decisions or assumptions about individuals?	✓	
10.	Would the data subject consider the processed information to be private?	✓	
If any question is answered with "Yes", the need of a full risk assessment of data protection (DPIA) is indicated.			

Study description

1. Human participants & personal data
UPAT as a technological provider will be involved only in pseudoanonymized data processing activities.
2. Participants selection & recruitment
UPAT does not participate in the pilot trials participants' recruitment process. In case of acquisition of data from volunteers in UPAT for the Ageing@Work project, proper ethical and legal guidelines according to the new regulation will be strictly followed.
3. (Sensitive) personal data
UPAT as a technological provider will be involved only in pseudoanonymized data processing activities. The R&D efforts of UPAT will involve collection and processing of personal, biometric and health data, and data of the working environment (e.g. a machine).
4. Collection method & tools
Data will be collected by approved equipment at the place of the pilot sites and part of it will be transferred anonymised to servers controlled by UPAT. In case that experiments are performed at UPAT for the project requirements, there is the possibility to collect human tracking data of affective traits, derived from wearable sensors (e.g. accelerometers, biosignals), from IoT sensors (e.g. environment state, temperature, humidity, lighting etc.) and also from RGB-D and acoustic sensors. All these data will be properly pseudoanonymized and be safely kept in dedicated PC units of the UPAT group. Besides human data part of the working environment will be scanned with depth cameras.
5. Tracking or observation
Yes. Wearable sensors will be used to collect basic biometric data (e.g health rate) and also cameras, IoT environment sensors and acoustic sensors will be used for observing employees while operating machines.
6. Purpose of data collection & processing
Data will be collected and processed in order to develop personal profiles of employees and offer personalised services in respect to health and well-being in workplaces in accordance to the project objectives and goals as described in the Ageing@Work DoA.
7. Secondary use
It is possible that previous collected data from HR departments of the pilot sites will be used.
8. Storage & backup
Data will be stored and backed up in a database (DB) in servers. The data of each individual will be associated with a numerical code, while only the PI (Principal Investigator) will have the information on the mapping between these codes and the names of participants; this information will be kept properly locked to ensure data safety and confidentiality.
9. Data access
Third parties will not have access. Access to the pseudoanonymized data will be given only to authorised personnel based on user authentication techniques and mechanisms to avoid unauthorised access.

10. Pooled data & transferring
The data will be gathered in the pilot sites' places (Spain and Germany). UPAT may also collect data within its premises during its R&D efforts. Data access is allowed only inside the EU and in consistency with the security and privacy measures defined by the consortium.
11. Company data & Confidentiality
Yes. Data in respect to workplace design, work processes and other working conditions will be collected within the project but with the consent of the company.
12. Picture, video or sound recordings
Yes, all of the above means will be used. For this reason a separate consent form is provisioned to be drafted and handed –out to participants in order to state their free choice to participate in the research.
13. Other ethical or legal issues
No, from UPAT's side there is no other ethical or legal issue that should be taken into consideration.

Institution / Beneficiary:	Name:	Date:
Universidad Politécnica de Madrid (UPM)		**06/05/2019**

General Ethics

1. International/national legislation

Yes, the publication of Law 14/2007, of July 3, of Biomedical Research (known in Spanish as LIB) established a specific regulatory framework in Spain, in order to guarantee the performance of biomedical research with full respect for the rights of people who participate in the investigation. The Royal Decree 1090/2015, of 4 December, regulating clinical trials with medicinal products, Ethics Committees for Investigation with medicinal products and the Spanish Clinical Studies Registry, was published to adapt the Spanish legislation to the Regulation (EU) No 536/2014 of the European Parliament and of the Council, of 16 April 2014, on clinical trials on medicinal products for human use.

2. Ethics control body in the country

There is not a unique control body. The LIB establishes that the Ethics Committees for Investigation (hereinafter CEI) corresponding to each center must evaluate all biomedical research involving human interventions or the use of their biological samples.

3. Ethics control committee in the organisation

Yes, there is an ethics committee in UPM, and before starting a research project the ethics committee has to approve the research to be carried, by answering a set of questions concerning ethics and data protection.

4. Ethical control procedures

Before performing the tests on humans, the UPM ethical committee must approve the procedures. These are required through a questionnaire on ethic issues. The ethical committee includes experts in different areas, and are not known (as there is no direct contact with the researchers and the experts of the ethical committee) by the researcher that asks for the approval.

5. Expertise in ethics and Member of Ethics Advisory Board

No.

Safety and hygiene

1. Written procedures for maintaining hygiene

The UPM Prevention Service Department has developed a brief guidelines with the basic norms and rules for health prevention. This includes recommendation to avoid infections and accidents at work, including both office and laboratories.

2. Safety of employees

The basic procedures are available online http://www.upm.es/Personal/PrevencionRiesgosLaborales/PlanPrevencionRiesgosLaborales and made known to the workers through the Intranet and other communications tools used by UPM.

3. Safety of equipment

There is a department in the organization leads with these activities. The Prevention representative in each centre is the training responsible of the new workers. Workers have the responsibility to know and apply the prevention rules.

4. Formal hygiene and laboratory safety regulations
In UPM LST group, we are familiar with the basic health and hygiene rules in office work. Information is available on line for each of the workers. Additionally, annually workers pass a medical recognition oriented to prevent health problems.
5. Risk assessment
In case of detected risks (when performing a risk analysis) we are able to conduct a DPIA and apply measures to mitigate the risk.
6. Insurance against risks
The University has an insurance that covers the civil liability of the entire group of people that constitute it (students, teachers and service personnel). This insurance is valid nationally and throughout the world except USA, Canada and Mexico.

Data Protection

1. Data Protection Authority
Yes, the Spanish Data Protection Agency (AEPD, Spanish: Agencia Española de Protección de Datos) is an agency of the government of Spain. The Spanish Data Protection Ageing is the independent public authority in charge of ensuring the privacy and protection of citizens' data.
2. Privacy Policy
Yes, UPM is an institution firmly committed to respecting freedoms and rights fundamentals of people, and follows the GDPR to protect the users' privacy.
3. Privacy guidelines
No, UPM follows the GDPR.
4. Confidentiality & Anonymity
Yes, we explain the participants how their data will be anonymised.
5. Data Protection Officer
Yes, the DPO in UPM is Luis Cancela de la Viuda.
6. HTTP cookies
No.

Ethics Checklist

No.	Question	Yes	No
1.	Does your research involve human participants?	✓	
2.	If yes, are they potentially vulnerable individuals or groups? (e.g. children, students, employees)	✓	
3.	Does your research involve the collection of confidential or sensitive information?	✓	
4.	Does your research involve controversial subject matter? (e.g. sensitive, embarrassing or intrusive topics)		✓
5.	May your research cause any harm to participants, researchers or others? (e.g. invasive techniques, physical interventions)		✓
	If all answers above are "No", then no formal ethics approval is required.		
6.	Has the research activity already approval from an ethics committee?	✓	
7.	Is the research activity part of a larger study that has already received approval from an ethics committee?		✓
	If answer to question 6 or 7 is "Yes" then no further ethics approval is required.		
8.	Have health and safety risks due to the research been considered?	✓	
9.	Are data protection compliance measures taken for any personal data collected by the research?	✓	
	If one of the answers to question 1 – 5 is "Yes" and neither 6 nor 7 is "Yes", then a formal verification of the requirement of an ethics approval is advised under consideration of aspects 8 – 9.		

Risk assessment

No.	Question	Yes	No
1.	Does the activity involve the systematic monitoring of publicly accessible spaces?		✓
2.	Are the persons unaware of the collection and processing of their data?		✓
3.	Does the activity use automated data collection from open sources?		✓
4.	Does the activity involve the use of new technologies?	✓	
5.	Is there a combination of a person's data from more than one source?	✓	
6.	Is the personal data used for a purpose other than its original intention?		✓
7.	Would the processing of personal data be perceived as disruptive in this way?		✓
8.	Might data processing concern specific categories of personal data? (e.g. health)	✓	
9.	Does the data processing involve decisions or assumptions about individuals?	✓	
10.	Would the data subject consider the processed information to be private?	✓	
	If any question is answered with "Yes", the need of a full risk assessment of data protection (DPIA) is indicated.		

Study description

1. Human participants & personal data
Yes, UPM leads the T5.2. Worker dashboard for personalized behaviour and workplace analysis. This task will have the essential role of providing the user with an easy-to-use, age-friendly, intuitive interface for understanding her/his own respective specificities, highlighting at the same time data and findings derived through the model assessment, in accordance to their possible significance.
2. Participants selection & recruitment
UPM does not recruit the participants.
3. (Sensitive) personal data
The data to be processed and presented in the dashboard, will be shared only with the employee source of the data, including behaviour and health data.
4. Collection method & tools
UPM is not in charge of collecting the data.
5. Tracking or observation
UPM is not involved in the tracking of participants, but different wearables or sensors such as a smart-band will be used to gather data.
6. Purpose of data collection & processing
The data that UPM will process, will be used only for research purposes in the framework of the project. The data will be presented to the user in a dashboard to explain to the important aspects of both the workplace ergonomics and the work schedule, and how these interact with the user specificities, from user physical and cognitive skills and needs through to personal and social needs.
7. Secondary use
No.
8. Storage & backup
The data to be used in the dashboard will be stored in secure servers in an anonymised way, by assigning to each user a unique id. This mapping will only be known by the person that recruits the user and the user himself. Anyone who access the database will not be able to identify the user which data will be presented in the dashboard.
9. Data access
Only authorised persons will have access to the data, by using a login with password access, and logs that will register who access the data.
10. Pooled data & transferring
The data will be gathered in Spain and Germany; and will be accessed only inside the EU, applying the same security and privacy measures.
11. Company data & Confidentiality
Yes, information on workplace and work processes will be collected always with the consent of the company involved.
12. Picture, video or sound recordings
This info is not for the presentation of the data in the dashboard.
13. Other ethical or legal issues
No from UPM's point of view, and role in the project.

Annex 4: Information on a research / study / experimental protocol

Under https://www.who.int/rpc/research_ethics/format_rp/en/ (Accessed 4 June 2019) recommendations of WHO for the preparation of research protocols can be found. Further guidance can be found below.

Preliminary remark: Some of the following points (e.g. those related to drug studies or clinical trials) are probably not relevant for Ageing@Work and can be neglected.

"Items to be included in a protocol (or associated documents) for health-related research involving humans [16]

(Include the items relevant to the study/project in question)

1. *Title of the study;*
2. *A summary of the proposed research in lay/non-technical language;*
3. *A clear statement of the justification for the study, its significance in development and in meeting the needs of the country /population in which the research is carried out;*
4. *The investigators` views of the ethical issues and considerations raised by the study and, if appropriate, how it is proposed to deal with them;*
5. *Summary of all previous studies on the topic, including unpublished studies known to the investigators and sponsors, and information on previously published research on the topic, including the nature, extent and relevance of animal studies and other preclinical and clinical studies (Guideline 4);*
6. *A statement that the principles set out in these Guidelines will be implemented;*
7. *An account of previous submissions of the protocol for ethical review and their outcome;*
8. *A brief description of the site(s) where the research is to be conducted, including information about the adequacy of facilities for the safe and appropriate conduct of the research, and relevant demographic and epidemiological information about the country or region concerned;*
9. *Name and address of the sponsor;*
10. *Names, addresses, institutional affiliations, qualifications and experience of the principal investigator and other investigators (Guideline 1);*
11. *The objectives of the trial or study, its hypotheses or research questions, its assumptions, and its variables (Guideline 1);*

[16] Recommendations taken from CIOMS: International Ethical Guidelines for Health-related Research Involving Humans [26] https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf (Accessed 23 April 2019).
The references to guidelines contained herein refer to the same document.

12. *A detailed description of the design of the trial or study. In the case of controlled clinical trials the description should include, but not be limited to, whether assignment to treatment groups will be randomized (including the method of randomization), and whether the study will be blinded (single blind, double blind), or open (Guideline 5);*
13. *The number of research participants needed to achieve the study objective, and how this was statistically determined;*
14. *The criteria for inclusion or exclusion of potential participants, and justification for the exclusion of any groups on the basis of age, sex, social or economic factors, or for other reasons (Guideline 3);*
15. *The justification for involving as research participants children or adolescents, persons who are unable to give informed consent or vulnerable persons or groups, and a description of special measures to minimize risks to such persons (Guidelines 15, 16 and 17);*
16. *The process of recruitment, e.g. advertisements, and the steps to be taken to protect privacy and confidentiality during recruitment (Guideline 3);*
17. *Description and explanation of all interventions (the method of treatment administration, including route of administration, dose, dose interval and treatment period for investigational and comparator products used);*
18. *Plans and justification for withdrawing or withholding standard therapies in the course of the research, including any resulting risks to persons (Guidelines 4 and 5);*
19. *Any other treatment that may be given or permitted, or contraindicated, during the study (Guideline 6);*
20. *Clinical and laboratory tests and other tests that are to be carried out;*
21. *Samples of the standardized case-report forms to be used, the methods of recording therapeutic response (description and evaluation of methods and frequency of measurement), the follow-up procedures, and, if applicable, the measures proposed to determine the extent of compliance of persons with the treatment;*
22. *Rules or criteria according to which participants may be removed from the study or clinical trial, or (in a multi-centre study) a centre may be discontinued, or the study may be terminated;*
23. *Methods of recording and reporting adverse events or reactions, and provisions for dealing with complications (Guidelines 4 and 23);*
24. *The known or foreseen risks of adverse reactions, including the risks attached to each proposed intervention and to any drug, vaccine or procedure to be tested (Guideline 4);*
25. *The potential individual benefits of the research to participants and to others (Guideline 4);*
26. *The expected benefits of the research to the population, including new knowledge that the study might generate (Guidelines 1 and 4);*
27. *For research carrying more than minimal risk of physical injury, details of plans, including insurance coverage, to provide treatment for such injury, including the funding of treatment, and to provide compensation for research-related disability or death (Guideline 14);*
28. *Provision for continued access to study interventions that have demonstrated significant benefit, indicating its modalities, the parties involved in continued care and the organization responsible for paying for it, and for how long it will continue (Guideline 6);*

29. *For research on pregnant women, a plan, if appropriate, for monitoring the outcome of the pregnancy with regard to both the health of the woman and the short-term and long-term health of the child (Guideline 19);*
30. *The means proposed to obtain individual informed consent and the procedure planned to communicate information to prospective participants, including the name and position of the person responsible for obtaining consent (Guideline 9);*
31. *When a prospective subject is not capable of informed consent, satisfactory assurance that permission will be obtained from a duly authorized person, or, in the case of a child who is sufficiently mature to understand the implications of informed consent but has not reached the legal age of consent, that knowing agreement, or assent, will be obtained, as well as the permission of a parent, or a legal guardian or other duly authorized representative (Guidelines 16 and 17);*
32. *An account of any economic or other inducements or incentives to prospective participants to participate, such as offers of cash payments, gifts, or free services or facilities, and of any financial obligations assumed by the participants, such as payment for medical services;*
33. *Plans and procedures, and the persons responsible, for communicating to participants information arising from the study (on harm or benefit, for example), or from other research on the same topic, that could affect participants' willingness to continue in the study (Guideline 9);*
34. *Plans to inform participants about the results of the study;*
35. *The provisions for protecting the confidentiality of personal data, and respecting the privacy of persons, including the precautions that are in place to prevent disclosure of the results of a subject's genetic tests to immediate family relatives without the consent of the subject (Guidelines 4, 11, 12 and 24);*
36. *Information about how the code, if any, for the persons' identity is established, where it will be kept and when, how and by whom it can be broken in the event of an emergency (Guidelines 11 and 12);*
37. *Any foreseen further uses of personal data or biological materials (Guidelines 11 and 12);*
38. *A description of the plans for statistical analysis of the study, including plans for interim analyses, if any, and criteria for prematurely terminating the study as a whole if necessary (Guideline 4);*
39. *Plans for monitoring the continuing safety of drugs or other interventions administered for purposes of the study or trial and, if appropriate, the appointment for this purpose of an independent data-monitoring (data and safety monitoring) committee (Guideline 4);*
40. *A list of the references cited in the protocol;*
41. *The source and amount of funding of the research: the organization that is sponsoring the research and a detailed account of the sponsor's financial commitments to the research institution, the investigators, the research participants, and, when relevant, the community (Guideline 25);*
42. *The arrangements for dealing with financial or other conflicts of interest that might affect the judgement of investigators or other research personnel: informing the institutional conflict-of-interest committee of such conflicts of interest; the communication by that committee of the pertinent details of the information to the ethical review committee; and the transmission by that committee to the research participants of the parts of the information that it decides should be passed on to them (Guideline 25);*

43. *For research that is to be carried out in a low-resource setting, the contribution that the sponsor will make to capacity-building for scientific and ethical review and for health-related research in the host country, and an assurance that the capacity-building objectives are in keeping with the values and expectations of the participants and their communities (Guideline 8);*
44. *The research protocol or documents send to the research ethics committee should include a description of the plan for (continued) community engagement, and present resources allocated for the community engagement activities. This documentation must clarify what has been and will be done, when and by whom to ensure that the community is clearly mapped and defined and can be proactively engaged throughout the research to ensure that the research is relevant to the community and is accepted. The community should participate, when feasible, in the actual discussion and preparation of the research protocol and documents (Guideline 7);*
45. *Particularly in the case of an industrial sponsor, a contract stipulating who possesses the right to publish the results of the study, and a mandatory obligation to prepare with, and submit to, the principal investigators the draft of the text reporting the results (Guideline 24);*
46. *In the case of a negative outcome, an assurance that the results will be made available, as appropriate, through publication or by reporting to the drug registration authority (Guideline 24);*
47. *Plans for publication of research results in certain fields (for example, epidemiology, genetics, sociology) that may present risks to the interests of communities, societies, families, or racially or ethnically defined groups and for minimizing risks to these groups, notably by maintaining confidentiality during and after the study and publishing the resulting data in a manner that is respectful of the interests of all concerned (Guideline 4); and*
48. *A statement that any proven evidence of falsification of data will be dealt with in accordance with the policy of the sponsor to take appropriate action against such unacceptable procedures."*

Annex 5: Informed Consent Form (ICF) Template from D1.1

Consent Form

The Ageing@Work project and consortium attach a high priority to the ethical conduct of research. We therefore ask you to consider the following points before signing this form which will act as a written record of your consent.

This Informed Consent Form has three parts:

1. *Information Sheet (this side used to share information about the research with you)*
2. *Demographics and Device Profile Questionnaire (the upper part of the other side used for collecting basic demographics of the participants)*
3. *Certificate of Consent (the lower part of the other side used for signatures if you agree to take part)*

Part I: INFORMATION SHEET

Project Purpose

***AgeingAtWork** (Smart, Personalized and Adaptive ICT Solutions for Active, Healthy and Productive Ageing with enhanced Workability (2019: H2020-SC1-DTH-2018-1, RIA) is a EU project aimed to develop a novel ICT-based, personalized system to support ageing workers (aged 50+) into designing fit-for-purpose work environments and managing flexibly their evolving needs. Advanced dynamically adapted virtual models of workers will incorporate specificities in respect to skills, physical, cognitive and behavioural factors, being extended from the work context to personal life aspects interacting with workability, health and well-being. The worker models will be populated by highly unobtrusive worker sensing, both at work, at home and on the move. To foster workability and productivity, highly personalized, intuitive, age-friendly productivity, co-design enhancement tools will be developed, including ones for AR/VR-based context-awareness and telepresence, lifelong learning and knowledge-sharing. Recommendations will then be provided both to the worker and company (under strict privacy restrictions), on how the working conditions must adapt.*

The integrated system will be developed by user-centered design and will be evaluated at two pilot sites, related to core Industry 4.0 processes of mining and machines production.

Rationale

*The title of our study is 'TITLE OF THE PILOT STUDY' and it is related to the **AgeingAtWork** project. All the information participants are needed to be aware of will be shared by this note. The reason we are doing this research is to test the validity and performance of the proposed **AgeingAtWork** solution. Moreover, you should feel free to ask any question related to the data collection process and the kind of data to be collected. For further queries in relation to your participation you can contact the person responsible for organizing the respective pilot or data collection process: XXX.*

Methods

The instrument used to collect information is [Questionnaire, wearable device, online survey, other]. The data to be collected include your [GPS location, physiological measurements, blood pressure, other]. The data collection will be automated and there will be no interruption of the user. The data will be [collected locally, or be transmitted to cloud services]. Anonymized personal data will be analyzed by statistical methods and will be used to evaluate the project's results.

Confidentiality

*The information that will be collected from this research project will be kept confidential [in CERTH servers, site manager files, other] and will be destroyed XXX months after the termination of the project. Information about you that will be collected during the research will be put away and no-one but the researchers and HR managers will be able to see it. Only the researchers will know what your real name is and we will lock that information up with a lock and key. It will not be shared with or given to anyone else except researchers of the consortium -if asked. In such a case, any information about you will have a number on it (**user id**) instead of your name.*

Based on the above you are invited to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. Your participation in this research is entirely voluntary. It is your choice whether to participate or not.

You can ask to have access to all your data being collected. Also, you may change your mind later and stop participating even if you agreed earlier.

Institution: NAME OF RESPONSIBLE PARTNER

Logo of the responsible Partner

Study: TITLE OF THE STUDY, PILOT, OR DATA COLLECTION PERIOD

Name of Principal Investigator: NAME OF RESPONSIBLE RESEARCHER

User Identification Number for this trial: USER_YY_ZZ_XXX [YY: partner short name, ZZ: data collection period number, XXX: user auto increment number]

Part II: DEMOGRAPHICS

Gender:		Age (in years):	
Education (in years):		City of Residentship:	
Var 5		Var 6	

Part III: CONSENT FORM

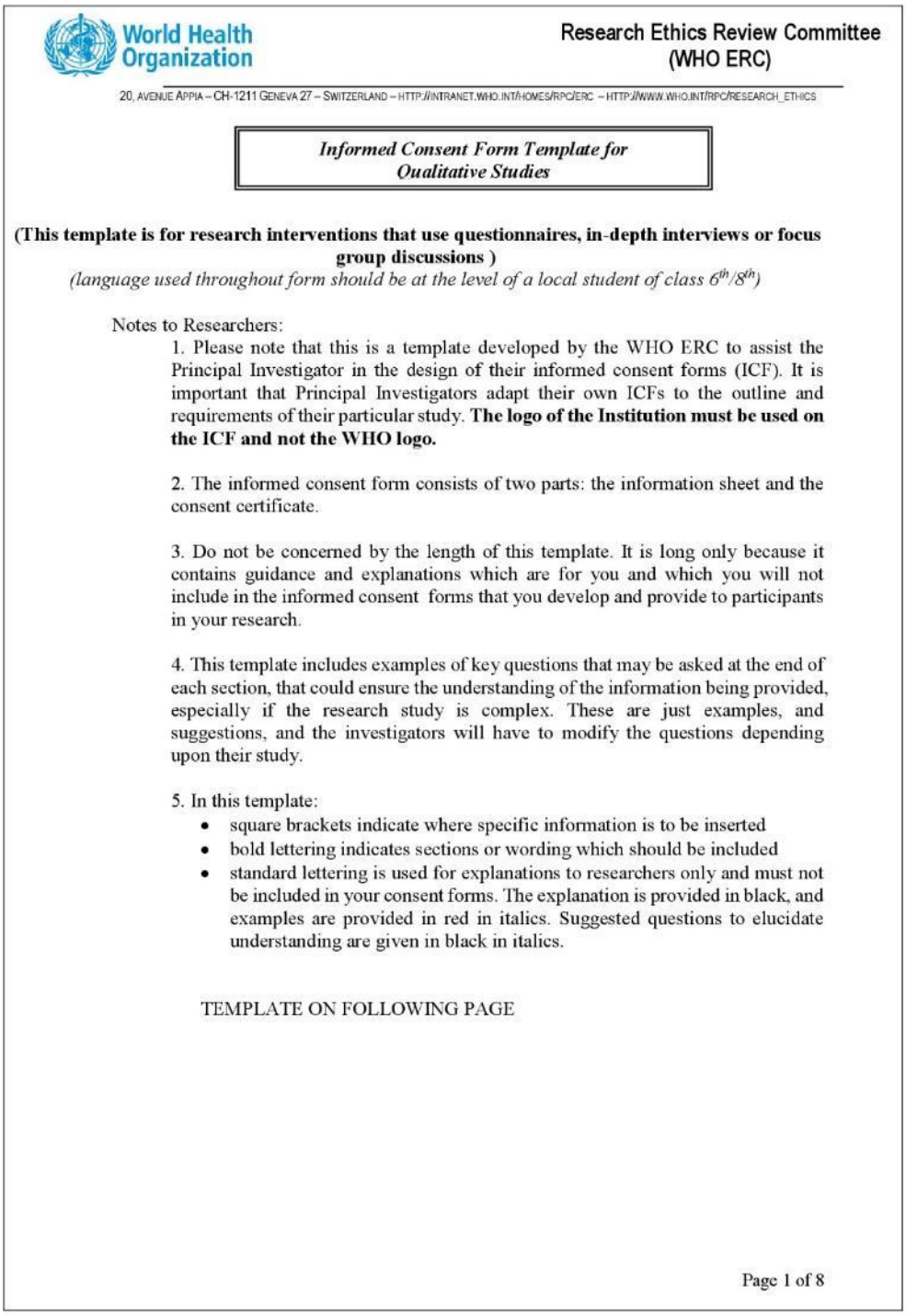
Please initial all boxes

1. I confirm that I have read and understand the information sheet dated [XX/XX/2019] for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. ☐
3. I understand that relevant sections of my personal notes and data collected during the study, may be looked at by individuals from the RESPONSIBLE PARTNER and possibly other members of the Ageing@Work consortium who will be authorized by the Project Coordinator and the Data Protection Officer to use them only for research purposes. I give permission for these individuals to have access to my records. ☐
4. I agree to take part in the above study. ☐

_____ _____ _____

Name of Participant Date Signature

Annex 6: WHO Templates for ICFs [17]



World Health Organization

Research Ethics Review Committee (WHO ERC)

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – HTTP://INTRANET.WHO.INT/HOMES/RPC/ERC – HTTP://WWW.WHO.INT/RPC/RESEARCH_ETHICS

Informed Consent Form Template for Qualitative Studies

(This template is for research interventions that use questionnaires, in-depth interviews or focus group discussions)

(language used throughout form should be at the level of a local student of class 6th/8th)

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study. **The logo of the Institution must be used on the ICF and not the WHO logo.**

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.

4. This template includes examples of key questions that may be asked at the end of each section, that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.

5. In this template:
   - square brackets indicate where specific information is to be inserted
   - bold lettering indicates sections or wording which should be included
   - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

TEMPLATE ON FOLLOWING PAGE

Page 1 of 8

[17] Taken from https://www.who.int/rpc/research_ethics/informed_consent/en/ (Accessed 4 June 2019) An editable version of the ICFs is also available here.

[YOUR INSTITUTIONAL LETTER HEAD]
Please do not submit consent forms on the WHO letter head

[Informed Consent Form for _____]

Name the group of individuals for whom this consent is written. Because research for a single project is often carried out with a number of different groups of individuals - for example counselors, community members, clients of services - it is important that you identify which group this particular consent is for.

(Example: This informed consent form is for social service providers in the community X and who we are inviting to participate in research Y, titled "The Community Response to Malaria Project".)

You may provide the following information either as a running paragraph or under headings as shown below.

[Name of Principle Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Project and Version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

You will be given a copy of the full Informed Consent Form

Part I: Information Sheet

Introduction
Briefly state who you are and that you are inviting them to participate in research which you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions at anytime.

(Example: I am X, working for the Y organization. I am doing research on the disease malaria which is very common in this country and in this region. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.
This consent form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.)

Purpose of the research
Explain the research question in lay terms which will clarify rather than confuse. Use local and simplified words rather than scientific terms and professional jargon. In your explanation, consider local beliefs and knowledge when deciding how best to provide the information. Investigators however need to be careful not to mislead participants, by suggesting research interests that they do not have. For example, if the study wants to find out about treatments provided by local practitioners, wording should not suggest that they want to find out about how the practitioners are advertising themselves. Misleading participants may be essential and justified in certain circumstances, but that needs to be carefully argued, and approved by an ethics committee.

(Example: Malaria is making many people sick in your community. We want to find ways to stop this from happening. We believe that you can help us by telling us what you know both about malaria and about local health practices in general . We want to learn what people who live or work here know about the causes of malaria and why some people get it. We want to learn about the different ways that people

try to stop malaria before someone gets it or before it comes to the community, and how people know when someone has it. We also want to know more about local health practices because this knowledge might help us to learn how to better control malaria in this community.)

Type of Research Intervention
Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a questionnaire, or a series of finger pricks.

(Example: This research will involve your participation in a group discussion that will take about one and a half hour, and a one hour interview).

Participant Selection
Indicate why you have chosen this person to participate in this research. People wonder why they have been chosen and may be fearful, confused or concerned.

(Example: You are being invited to take part in this research because we feel that your experience as a social worker (or as a mother, or as a responsible citizen) can contribute much to our understanding and knowledge of local health practices.)

- ***Example of question to elucidate understanding:*** *Do you know why we are asking you to take part in this study? Do you know what the study is about?*

Voluntary Participation
Indicate clearly that they can choose to participate or not. State, only if it is applicable, that they will still receive all the services they usually do if they choose not to participate. Explanation: It may be more applicable to assure them that their choosing to participate or not will not have any bearing on their job or job-related evaluations. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context. Although, if the interview or group discussion has already taken place, the person cannot 'stop participation' but request that the information provided by them not be used in the research study.

(Example: Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate all the services you receive at this Centre will continue and nothing will change.
OR
The choice that you make will have no bearing on your job or on any work-related evaluations or reports. You may change your mind later and stop participating even if you agreed earlier.)

- ***Examples of question to elucidate understanding:*** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

Procedures
A. Provide a brief introduction to the format of the research study.

(Example: We are asking you to help us learn more about malaria in your community. We are inviting you to take part in this research project. If you accept, you will be asked to….:)

B. Explain the type of questions that the participants are likely to be asked in the focus group, the interviews, or the survey. If the research involves questions or discussion which may be sensitive or potentially cause embarrassment, inform the participant of this.

(Example 1 (for focus group discussions)
take part in a discussion with 7-8 other persons with similar experiences. This discussion will be guided by [name of moderator/guider] or myself.

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The group discussion will start with me, or the focus group guide or moderator (use the local word for group discussion leader), making sure that you are comfortable. We can also answer questions about the research that you might have. Then we will ask you questions about the malaria and give you time to share your knowledge. The questions will be about malaria in your community, how is it recognized, what people do to stop it from spreading to other people, who people go to for help and what happens when people become sick with it.
We will also talk about community practices more generally because this will give us a chance to understand more about malaria but in a different way. These are the types of questions we will ask…..
We will not ask you to share personal beliefs, practices or stories and you do not have to share any knowledge that you are not comfortable sharing.
The discussion will take place in [location of the FGD], and no one else but the people who take part in the discussion and guide or myself will be present during this discussion. The entire discussion will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The tapes will be destroyed after _____number of days/weeks.

Example 2 (for interviews)
participate in an interview with [name of interviewer] or myself.
During the interview, I or another interviewer will sit down with you in a comfortable place at the Centre. If it is better for you, the interview can take place in your home or a friend's home. If you do not wish to answer any of the questions during the interview, you may say so and the interviewer will move on to the next question. No one else but the interviewer will be present unless you would like someone else to be there. The information recorded is confidential, and no one else except [name of person(s)] will access to the information documented during your interview. The entire interview will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The tapes will be destroyed after _____number of days/weeks.

Example 3 (for questionnaire surveys)
fill out a survey which will be provided by [name of distributor of blank surveys] and collected by [name of collector of completed surveys].OR You may answer the questionnaire yourself, or it can be read to you and you can say out loud the answer you want me to write down.
If you do not wish to answer any of the questions included in the survey, you may skip them and move on to the next question. [Describe how the survey will be distributed and collected]. The information recorded is confidential, your name is not being included on the forms, only a number will identify you, and no one else except [name of person(s) with access to the information] will have access to your survey.)

Duration
Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

(Example: The research takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, we will visit you three times for interviewing you at one month interval and each interview will last for about one hour each. The group discussion will be held once and will take about one and a half hour.)

- ***Examples of question to elucidate understanding:*** *If you decide to take part in the study, do you know how much time will the interview take? Where will it take place? Do you know that we will be sending you transport to pick you up from your home? Do you know how much time will the discussion with other people take? If you agree to take part, do you know if you can stop participating? Do you know that you may not respond to the questions that you do not wish to respond to? Etc. Do you have any more questions?*

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Risks
Explain and describe any risks that you anticipate or that are possible. The risks depend upon the nature and type of qualitative intervention, and should be, as usual, tailored to the specific issue and situation.

(If the discussion is on sensitive and personal issues e.g. reproductive and sexual health, personal habits etc. then an example of text could be something like "We are asking you to share with us some very personal and confidential information, and you may feel uncomfortable talking about some of the topics. You do not have to answer any question or take part in the discussion/interview/survey if you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question, or for refusing to take part in the interview"
OR If for example, the discussion is on opinions on government policies and community beliefs, and in general no personal information is sought, then the text under risks could read something like "There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You do not have to answer any question or take part in the discussion/interview/survey if you feel the question(s) are too personal or if talking about them makes you uncomfortable.)

Benefits
Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

(Example: There will be no direct benefit to you, but your participation is likely to help us find out more about how to prevent and treat malaria in your community).

Reimbursements
State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives beyond reimbursements for expenses incurred as a result of participation in the research. These may include, for example, travel costs and reimbursement for time lost. The amount should be determined within the host country context.

Example: You will not be provided any incentive to take part in the research. However, we will give you [provide a figure, if money is involved] for your time, and travel expense (if applicable).

- ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be re-imbursed? Do you have any other questions?*

Confidentiality
Explain how the research team will maintain the confidentiality of data with respect to both information about the participant and information that the participant shares. Outline any limits to confidentiality. Inform the participant that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and therefore more likely to be stigmatized. If the research is sensitive and/or involves participants who are highly vulnerable - research concerning violence against women for example - explain to the participant any extra precautions you will take to ensure safety and anonymity.

(Example: The research being done in the community may draw attention and if you participate you may be asked questions by other people in the community. We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc])

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The following applies to focus groups:
Focus groups provide a particular challenge to confidentiality because once something is said in the group it becomes common knowledge. Explain to the participant that you will encourage group participants to respect confidentiality, but that you cannot guarantee it.

(Example: We will ask you and others in the group not to talk to people outside the group about what was said in the group. We will, in other words, ask each of you to keep what was said in the group confidential. You should know, however, that we cannot stop or prevent participants who were in the group from sharing things that should be confidential.)

- ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you understand that the we cannot guarantee complete confidentiality of information that you share with us in a group discussion Do you have any more questions?*

Sharing the Results
Your plan for sharing the findings with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You may also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.

(Example: Nothing that you tell us today will be shared with anybody outside the research team, and nothing will be attributed to you by name. The knowledge that we get from this research will be shared with you and your community before it is made widely available to the public. Each participant will receive a summary of the results. There will also be small meetings in the community and these will be announced. Following the meetings, we will publish the results so that other interested people may learn from the research.)

Right to Refuse or Withdraw
This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom you are seeking consent. The example used here is for a community social worker. Participants should have an opportunity to review their remarks in individual interviews and erase part or all of the recording or note.

(Example: You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect your job or job-related evaluations in any way. You may stop participating in the [discussion/interview] at any time that you wish without your job being affected. I will give you an opportunity at the end of the interview/discussion to review your remarks, and you can ask to modify or remove portions of those, if you do not agree with my notes or if I did not understand you correctly.)

Who to Contact
Provide the name and contact information of someone who is involved, informed and accessible - a local person who can actually be contacted. State also the name (and contact details) of the local IRB that has approved the proposal. State also that the proposal has also been approved by the WHO ERC.

(Example: If you have any questions, you can ask them now or later. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail]
This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact _____ .)

This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number.]). It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is funding/sponsoring/supporting the study.

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- ***Example of question to elucidate understanding:*** *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.*

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

Part II: Certificate of Consent

This section must be written in the first person. It should include a few brief statements about the research and be followed by a statement similar the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. Because the certificate is an integral part of the informed consent and not a stand-alone document, the layout or design of the form should reflect this. The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

Example: I have been invited to participate in research about malaria and local health practices.

(This section is mandatory)
I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study

Print Name of Participant_____
Signature of Participant _____
Date _____
Day/month/year

If illiterate [1]

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **Thumb print of participant** ☐

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

_____

[1] A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb print as well.

1.
2.
3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.
Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

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World Health Organization

Research Ethics Review Committee
(WHO ERC)

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – HTTP://INTRANET.WHO.INT/HOMES/RPC/ERC – HTTP://WWW.WHO.INT/RPC/RESEARCH_ETHICS

Informed Consent Form Template for Clinical Studies

(This template is for either clinical trials or clinical research)
(language used throughout form should be at the level of a local student of class 6th/8th)

Notes to Researchers:

1. Please note that this is a template developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study. **The logo of the Institution must be used on the ICF and not the WHO logo.**

2. The informed consent form consists of two parts: the information sheet and the consent certificate.

3. Do not be concerned by the length of this template. It is long only because it contains guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.

4. This template includes examples of key questions that may be asked at the end of each section, that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.

5. In this template:
   - square brackets indicate where specific information is to be inserted
   - bold lettering indicates sections or wording which should be included
   - standard lettering is used for explanations to researchers only and must not be included in your consent forms. The explanation is provided in black, and examples are provided in red in italics. Suggested questions to elucidate understanding are given in black in italics.

TEMPLATE ON FOLLOWING PAGE

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[YOUR INSTITUTIONAL LETTERHEAD]
Please do not submit consent forms on the WHO letter head

[Informed Consent form for _____________ _______]

Name the group of individuals for whom this informed consent form is written.Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

(Example: This Informed Consent Form is for men and women who attend clinic Z, and who we are inviting to participate in research on X. The title of our research project is "............................")

You may provide the following information either as a running paragraph or under headings as shown below.

[Name of Principal Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Proposal and version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

Briefly state who you are and explain that you are inviting them to participate in the research you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions now or later.

(Example: I am X, working for the Y Research Institute. We are doing research on Z disease, which is very common in this country. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.)

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Purpose of the research

Explain in lay terms why you are doing the research. The language used should clarify rather than confuse. Use local and simplified terms for a disease, e.g. local name of disease instead of malaria, mosquito instead of anopheles, "mosquitoes help in spreading the disease" rather than "mosquitoes are the vectors". Avoid using terms like pathogenesis, indicators, determinants, equitable etc. There are guides on the internet to help you find substitutes for words which are overly scientific or are professional jargon.

(Example: Malaria is one of the most common and dangerous diseases in this region. The drugs that are currently used to help people with malaria are not as good as we would like them to be. In fact, only 40 out of every 100 people given the malaria drug XYZ are completely cured. There is a new drug which may work better. The reason we are doing this research is to find out if the new drug ABX is better than drug XYZ which is currently being used.)

Type of Research Intervention

Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a biopsy or a series of finger pricks.

(Example: This research will involve a single injection in your arm as well as four follow-up visits to the clinic.)

Participant selection

State why this participant has been chosen for this research. People often wonder why they have been chosen to participate and may be fearful, confused or concerned.

(Example: We are inviting all adults with malaria who attend clinic Z to participate in the research on the new malaria drug.)

- ***Example of question to elucidate understanding:*** *Do you know why we are asking you to take part in this study? Do you know what the study is about?*

Voluntary Participation

Indicate clearly that they can choose to participate or not. State, what the alternative - in terms of the treatment offered by the clinic - will be, if they decide not to participate. State, only if it is applicable, that they will still receive all the services they usually do whether they choose to participate or not. This can be repeated and expanded upon later in the form as well, but it is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context.

(Example: Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will offered the treatment that is routinely offered in this clinic/hospital for disease Z, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.)

- ***Examples of question to elucidate understanding:*** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

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Include the following section only if the protocol is for a clinical trial:

Information on the Trial Drug [Name of Drug]

1) give the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.
2) provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.
3) explain the known experience with this drug
4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

(Example: The drug we are testing in this research is called ABX. It has been tested before with people who do not have malaria but who live in areas where malaria is common. We now want to test the drug on people who have malaria. This second research is called a "phase 2" trial.

The drug ABX is made by Company C. You should know that it has a few side effects. One of the side effects, or problems, is that you may feel tired for the first day after being given the drug. Also, 20% of the people who tried the drug in previous research experienced temporary swelling where the injection entered the skin. We know of no other problem or risks.

Some participants in the research will not be given the drug which we are testing. Instead, they will be given the drug XYZ, the drug which is most commonly used in this region to treat malaria. There is no risk associated with that drug and no known problems. It does not, however, cure malaria as often as we would like.)

Procedures and Protocol

Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and any drugs that will be given. Explain from the outset what some of the more unfamiliar procedures involve (placebo, randomization, biopsy, etc.) Indicate which procedure is routine and which is experimental or research.Participants should know what to expect and what is expected of them. Use active, rather than conditional, language. Write "we will ask you to...." instead of "we would like to ask you to....".

In this template, this section has been divided into two: firstly, an explanation of unfamiliar procedures and, secondly, a description of process.

A. Unfamiliar Procedures

This section should be included if there may be procedures which are not familiar to the participant.

If the protocol is for a clinical trial:
1) involving randomization or blinding, the participants should be told what that means and what chance they have of getting which drug (i.e. one in four chances of getting the test drug).

(Example:. Because we do not know if the new malaria drug is better than the currently available drug for treating malaria, we need to compare the two. To do this, we will put people taking part in this research into two groups. The groups are selected by chance, as if by tossing a coin.

Participants in one group will be given the test drug while participants in the other group will be given the drug that is currently being used for malaria. It is important that neither you nor we know which of the two drugs you are given. This information will be in our files, but we will not look at these files until

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after the research is finished. This is the best way we have for testing without being influenced by what we think or hope might happen. We will then compare which of the two has the best results.

The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the drug is doing, we will find out which drug you are getting and make changes. If there is anything you are concerned about or that is bothering you about the research please talk to me or one of the other researchers)

2) involving an inactive drug or placebo, it is important to ensure that the participants understand what is meant by a placebo or inactive drug.

(Example: A placebo or inactive medicine looks like real medicine but it is not. It is a dummy or pretend medicine. It has no effect on a person because it has no real medicine in it. Sometimes when we want to know whether a new medicine is good, we give some people the new medicine and some people the pretend or dummy medicine. For the research to be good, it is important that you do not know whether you have been given the real medicine or the pretend or dummy medicine. This is one of the best ways we have for knowing what the medicine we are testing really does.)

3) which may necessitate a rescue medicine, then provide information about the rescue medicine or treatment such as what it is and the criterion for its use. For example, in pain trials, if the test drug does not control pain, then intravenous morphine may be used as a rescue medicine.

(Example:. If we find that the medicine that is being used does not have the desired effect, or not to the extent that we wish it to have, we will use what is called a "rescue medicine." The medicine that we will use is called QRS and it has been proven to control pain. If you find that the drug we are testing does not stop your pain and it is very uncomfortable for you, we can use the rescue medicine to make you more comfortable.)

If the protocol is for clinical research:
Firstly, explain that there are standards/guidelines that will be followed for the treatment of their condition. Secondly, if as part of the research a biopsy will be taken, then explain whether it will be under local anesthesia, sedation or general anesthesia, and what sort of symptoms and side effects the participant should expect under each category.

(Example: You will receive the treatment of your condition according to national guidelines. This means that you will be (explain the treatment). To confirm the cause of your swelling, a small sample of your skin will be taken. The guidelines say that the sample must be taken using a local anesthesia which means that we will give you an injection close to the area where we will take the sample from. This will make the area numb so that you will not feel any pain when we take the sample.)

For any clinical study (if relevant):
If blood samples are to be taken explain how many times and how much in a language that the person understands. It may, for example, be inappropriate to tell a tribal villager that blood equal to a wine-glass full will be taken but it may be very appropriate to use pictures or other props to illustrate the procedure if it is unfamiliar.

If the samples are to be used only for this research, then explicitly mention here that the biological samples obtained during this research procedure will be used only for this research, and will be destroyed after ____ years, when the research is completed. If the tissues/blood samples or any other human biological material will be stored for a duration longer than the research purpose, or is likely to be used for a purpose other than mentioned in the research proposal, then provide information about this and

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obtain consent specifically for such storage and use in addition to consent for participation in the study - (see last section)

(Example: We will take blood from your arm using a syringe and needle. Each time we will take about this much blood (show a spoon, vial or other small container with a small amount of water in it. In total, we will take about ... ...this much blood in x number of weeks/months. At the end of the research, in 1 year, any left over blood sample will be destroyed.)

B. Description of the Process

Describe to the participant what will happen on a step-by-step basis. It may be helpful to the participant if you use drawings or props to better illustrate the procedures. A small vial or container with a little water in it is one way of showing how much blood will be withdrawn.

(Example: During the research you make five visits to the clinic.

- *In the first visit, a small amount of blood, equal to about a teaspoon, will be taken from your arm with a syringe. This blood will be tested for the presence of substances that help your body to fight infections. We will also ask you a few questions about your general health and measure how tall you are and how much you weigh.*
- *At the next visit, which will be two weeks later, you will again be asked some questions about your health and then you will be given either the test drug or the drug that is currently used for malaria. As explained before, neither you nor we will know whether you have received the test or the dummy/pretend drug.*
- *After one week, you will come back to the clinic for a blood test. This will involve....)*

Duration

Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

(Example: The research takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, it will be necessary for you to come to the clinic/hospital/health facility _____(number of) days , for ____ (number of) hours each day. We would like to meet with you three months after your last clinic visit for a final check-up.

In total, you will be asked to come 5 times to the clinic in 6 months. At the end of six months, the research will be finished.)

- ***Examples of question to elucidate understanding:*** *Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? The research project? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?*

Side Effects

Potential participants should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

(Example: As already mentioned, this drug can have some unwanted effects. It can make you tired and it can cause some temporary swelling around the place where the injection goes into your arm. It is possible that it may also cause some problems that we are not aware of. However, we will follow you

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closely and keep track of any unwanted effects or any problems. We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may stop the use of one or more drugs. If this is necessary we will discuss it together with you and you will always be consulted before we move to the next step.)

Risks

Explain and describe any possible or anticipated risks. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it. A risk can be thought of as being the possibility that harm may occur. Provide enough information about the risks that the participant can make an informed decision.

(Example: By participating in this research it is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that your disease will not get better and that the new medicine doesn't work even as well as the old one. If, however, the medicine is not working and your fever does not go down in 48 hours we will give you quinine injections which will bring your fever down and make you more comfortable.

While the possibility of this happening is very low, you should still be aware of the possibility. We will try to decrease the chances of this event occurring, but if something unexpected happens, we will provide you with_____.)

- ***Examples of question to elucidate understanding:*** *Do you understand that, while the research study is on-going, no-one may know which medicine you re receiving? Do you know that the medicine that we are testing is a new medicine, and we do not know everything about it? Do you understand that you may have some unwanted side-effects from the medicines? Do you understand that these side-effects can happen whether or not you are in the research study? Etc. Do you have any other questions?*

Benefits

Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation. Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question.

(Example: If you participate in this research, you will have the following benefits: any interim illnesses will be treated at no charge to you. If your child falls sick during this period he/she will be treated free of charge. There may not be any benefit for you but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.)

Reimbursements

State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives. However, it recommends that reimbursements for expenses incurred as a result of participation in the research be provided. These may include, for example, travel costs and money for wages lost due to visits to health facilities. The amount should be determined within the host country context.

(Example:. We will give you [amount of money] to pay for your travel to the clinic/parking and we will give you [amount] for lost work time. You will not be given any other money or gifts to take part in this research.)

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- ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be re-imbursed? Do you have any other questions?*

Confidentiality

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant which would otherwise be known only to the physician but would now be available to the entire research team. Note that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and is therefore more likely to be stigmatized.

(Example: With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].)

- ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?*

Sharing the Results

Where it is relevant, your plan for sharing the information with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You should also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.

(Example: The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.)

Right to Refuse or Withdraw

This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom you are seeking consent. The example used here is for a patient at a clinic.

(Example: You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way.)
OR

(Example: You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.)

Alternatives to Participating

Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.

(Example: If you do not wish to take part in the research, you will be provided with the established standard treatment available at the centre/institute/hospital. People who have malaria are given….)

Who to Contact

Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted. State also that the proposal has been approved and how.

(Example: If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail])

This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number.]). It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is funding/sponsoring/supporting the study.

- ***Example of question to elucidate understanding:*** *Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to? Do you know that you can ask me questions later, if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.*

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

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Date _____
Day/month/year

If illiterate
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____ **AND** **Thumb print of participant**

Signature of witness _____

Date _____
Day/month/year

Statement by the researcher/person taking consent
I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:
1.
2.
3.
I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____
Day/month/year

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Annex 7: List of national Data Protection Authorities [18]

National Data Protection Authorities

(updated on 19 April 2018)

Belgium

Commission de la protection de la vie privée
Commissie voor de bescherming van de persoonlijke levenssfeer
Rue de la Presse 35 / Drukpersstraat 35
1000 Bruxelles / 1000 Brussel
Tel. +32 2 274 48 00
Fax +32 2 274 48 35
e-mail: commission@privacycommission.be
Website: http://www.privacycommission.be/

Art 29 WP Vice-President: **Willem DEBEUCKELAERE**, President of the Belgian Privacycommission

Cyprus

Commissioner for Personal Data Protection
1 Iasonos Street,
1082 Nicosia
P.O. Box 23378, CY-1682 Nicosia
Tel. +357 22 818 456
Fax +357 22 304 565
e-mail: commissioner@dataprotection.gov.cy
Website: http://www.dataprotection.gov.cy/

Art 29 WP Member: **Ms Irene LOIZIDOU NIKOLAIDOU**
Curriculum vitae (230 kB)

Art 29 WP Alternate Member: **Mr Constantinos GEORGIADES**

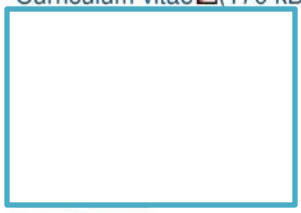
[18] Taken from https://edpb.europa.eu/about-edpb/board/members_en (Accessed 27 April 2019)

Germany

Die Bundesbeauftragte für den Datenschutz und die Informationsfreiheit
Husarenstraße 30
53117 Bonn
Tel. +49 228 997799 0; +49 228 81995 0
Fax +49 228 997799 550; +49 228 81995 550
e-mail: poststelle@bfdi.bund.de
Website: http://www.bfdi.bund.de/

The competence for complaints is split among different data protection supervisory authorities in Germany.
Competent authorities can be identified according to the list provided under https://www.bfdi.bund.de/bfdi_wiki/index.php/Aufsichtsbeh%C3%B6rden_und_Landesdatenschutzbeauftragte

Art 29 WP Member: **Ms Andrea VOSSHOFF**, Federal Commissioner for Freedom of Information
Curriculum vitae (170 kB)



Art 29 WP Alternate Member: **Prof. Dr. Johannes CASPAR**, representative of the federal states

Greece

Hellenic Data Protection Authority
Kifisias Av. 1-3, PC 11523
Ampelokipi Athens
Tel. +30 210 6475 600
Fax +30 210 6475 628
e-mail: contact@dpa.gr
Website: http://www.dpa.gr/

Art 29 WP Member: **Mr Konstantinos Menoudakos,** President of the Hellenic DPA
Curriculum vitae

Art 29 WP Alternate Member: **Dr.Vasilios ZORKADIS**, Director

Italy

Garante per la protezione dei dati personali
Piazza di Monte Citorio, 121
00186 Roma
Tel. +39 06 69677 1
Fax +39 06 69677 785
e-mail: garante@garanteprivacy.it
Website: http://www.garanteprivacy.it/

Art 29 WP Member: **Mr Antonello SORO**, President of Garante per la protezione dei dati personali
Curriculum Vitae (173 kB)

Art 29 WP Alternate Member: **Ms Giuseppe BUSIA**, Secretary General of Garante per la protezione dei dati personali

Poland

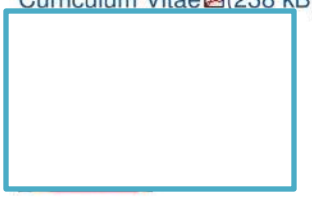
The Bureau of the Inspector General for the Protection of Personal Data - GIODO
ul. Stawki 2
00-193 Warsaw
Tel. +48 22 53 10 440
Fax +48 22 53 10 441
e-mail: kancelaria@giodo.gov.pl; desiwm@giodo.gov.pl
Website: http://www.giodo.gov.pl/

Art 29 WP Member: **Ms Edyta BIELAK-JOMAA**, Inspector General for the Protection of Personal Data
Curriculum Vitae (235 kB)

Spain

Agencia de Protección de Datos
C/Jorge Juan, 6
28001 Madrid
Tel. +34 91399 6200
Fax +34 91455 5699
e-mail: internacional@agpd.es
Website: https://www.agpd.es/

Art 29 WP Member: **Ms María del Mar España Martí**, Director of the Spanish Data Protection Agency
Curriculum Vitae (238 kB)



Art 29 WP Alternate Member: **Mr Rafael GARCIA GOZALO**

United Kingdom

The Information Commissioner's Office
Water Lane, Wycliffe House
Wilmslow - Cheshire SK9 5AF
Tel. +44 1625 545 745
e-mail: international.team@ico.org.uk
Website: https://ico.org.uk

Art 29 WP Member: **Ms Elizabeth DENHAM**, Information Commissioner
Curriculum Vitae (5 kB)

Art 29 WP Alternate Member: **Mr Steve WOOD**, Deputy Commissioner

Annex 8: DPIA Template [19]

Sample DPIA template

This template is an example of how you can record your DPIA process and outcome. It follows the process set out in our DPIA guidance, and you should read it alongside that guidance and the Criteria for an acceptable DPIA set out in European guidelines on DPIAs.

Start to fill out the template at the beginning of any major project involving the use of personal data, or if you are making a significant change to an existing process. Integrate the final outcomes back into your project plan.

Step 1: Identify the need for a DPIA

Explain broadly what the project aims to achieve and what type of processing it involves. You may find it helpful to refer or link to other documents, such as a project proposal. Summarise why you identified the need for a DPIA.

DPIA template
20180209
v0.3

1

[19] Taken from https://gdpr.eu/wp-content/uploads/2019/03/dpia-template-v1.pdf (Accessed 24 June 2019)

Step 2: Describe the processing

Describe the nature of the processing: how will you collect, use, store and delete data? What is the source of the data? Will you be sharing data with anyone? You might find it useful to refer to a flow diagram or another way of describing data flows. What types of processing identified as likely high risk are involved?

Describe the scope of the processing: what is the nature of the data, and does it include special category or criminal offence data? How much data will you be collecting and using? How often? How long will you keep it? How many individuals are affected? What geographical area does it cover?

DPIA template
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v0.3

2

Describe the context of the processing: what is the nature of your relationship with the individuals? How much control will they have? Would they expect you to use their data in this way? Do they include children or other vulnerable groups? Are there prior concerns over this type of processing or security flaws? Is it novel in any way? What is the current state of technology in this area? Are there any current issues of public concern that you should factor in? Are you signed up to any approved code of conduct or certification scheme (once any have been approved)?

Describe the purposes of the processing: what do you want to achieve? What is the intended effect on individuals? What are the benefits of the processing for you, and more broadly?

Step 3: Consultation process

Consider how to consult with relevant stakeholders: describe when and how you will seek individuals' views – or justify why it's not appropriate to do so. Who else do you need to involve within your organisation? Do you need to ask your processors to assist? Do you plan to consult information security experts, or any other experts?

Step 4: Assess necessity and proportionality

Describe compliance and proportionality measures, in particular: what is your lawful basis for processing? Does the processing actually achieve your purpose? Is there another way to achieve the same outcome? How will you prevent function creep? How will you ensure data quality and data minimisation? What information will you give individuals? How will you help to support their rights? What measures do you take to ensure processors comply? How do you safeguard any international transfers?

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4

Step 5: Identify and assess risks

Describe the source of risk and nature of potential impact on individuals. Include associated compliance and corporate risks as necessary.	**Likelihood of harm**	**Severity of harm**	**Overall risk**
	Remote, possible or probable	Minimal, significant or severe	Low, medium or high

DPIA template
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v0.3

5

Step 6: Identify measures to reduce risk

Identify additional measures you could take to reduce or eliminate risks identified as medium or high risk in step 5				
Risk	**Options to reduce or eliminate risk**	**Effect on risk**	**Residual risk**	**Measure approved**
		Eliminated, reduced or accepted	Low, medium or high	Yes/no

DPIA template
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v0.3

6

Step 7: Sign off and record outcomes

Item	Name/date	Notes
Measures approved by:		Integrate actions back into project plan, with date and responsibility for completion
Residual risks approved by:		If accepting any residual high risk, consult the ICO before going ahead
DPO advice provided:		DPO should advise on compliance, step 6 measures and whether processing can proceed
Summary of DPO advice:		
DPO advice accepted or overruled by:		If overruled, you must explain your reasons
Comments:		
Consultation responses reviewed by:		If your decision departs from individuals' views, you must explain your reasons
Comments:		
This DPIA will be kept under review by:		The DPO should also review ongoing compliance with DPIA

DPIA template
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v0.3

7