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Name:	Smart system for the management and control of shift workers' circadian rhythms
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D2.1 Ethical roadmap

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Partners involved (leader in bold): FhP, BCB, KOHS, Ab.Acus, **GZE**, RKT
Authors: GZE

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

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

Partner list

Nr.	Partner name	Short name	Org. type	Country
1	Fraunhofer AICOS *(coordinator)*	FhP	R&D	Portugal
2	BCB Informática y Control SL	BCB	SME	Spain
3	KOHS PIMEX	KOHS	SME	Austria
4	Ab.Acus S.r.l.	ABACUS	SME	Italy
5	Grado Zero Espace S.r.l.	GZE	SME	Italy
6	RK Tech, Kft.	RKT	SME	Hungary

Revision history

Rev.	Date	Partner	Description	Name
1	01.02.2017	FhP	Created the template and added the sections	
2	27.02.2017	GZE	Added the sections' titles and filled the content of the deliverable	
3	28.02.2017	GZE	Finalized documents with the addition of the consent forms	Enrico Cozzoni
4	28.02.2017	FhP	Integrating RKT informed consent received from Domonkos Balazs	Maximiliano Romero
		Approved by (Partner)		

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Glossary

[Privacy]: **can mean different things in different contexts and cultures**. It can be the right to be left alone, but it can also be something positioned at the interface between private life and public life. It entails a dynamic relationship between private persons in different situations and different degrees of interaction.

[Data protection]: is meant to guarantee one's right to privacy. **Data protection refers to the technical framework and security measures designed to guarantee that all personal data are safe from unforeseen, unintended or malevolent use**. Data protection therefore includes measures concerning access to data, processing, communication and conservation of data. Also measures to assure the accuracy of the data can be included in a data protection strategy.

[In the context of research]: privacy issues arise whenever data relating to persons are collected and stored, in digital form or otherwise. **The main challenge for research is to use and share the data, and at the same time protect all identifiable information to guarantee personal privacy**.

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1. INTRODUCTION

Privacy and Data Protection are fundamental rights laid down as principles in the *Charter of Fundamental Rights* and the *Treaty on the Functioning of the European Union*. They need to be protected at all time.

The main objective of this deliverable D2.1 "*Ethical roadmap*" is to provide a brief guide with the aim to align the project implementation on ethical aspects related to **Data Protection and Privacy**. The information provided are assessed in the context of the EU's Data Protection Directive, so far as possible and applicable[3].

The information is intended to provide an overview of the major concepts about Data Protection and Privacy in research. It aims at raising awareness about these concepts, and help compliance with the most relevant ethical principles, during the implementation of the project actions.

[3] Current framework: Directive 95/46/EC (http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:31995L0046). The above-mentioned EU Data Protection Directive contains a number of key principles for the handling of personal data. The Directive provides the framework for the regulation of Data Protection and Privacy issues in the Member States of the European Union. When a research includes collection and processing of data carried out in such a Member State, applicants need to identify the applicable local or national legal requirements and the competent authorities to provide any necessary authorisations, if applicable. In 2018 the Data Protection Directive will be substituted by the General Data Protection Regulation, adopted by the Council and the Parliament in April 2016. Among other issues, the new legislative framework will imply matters such as: secondary processing of data, the right to be forgotten, big data, cloud computing, web and social media mining and monitoring tools, etc.

2. PERSONAL DATA

In legal terms, "***Personal data***" means:

1. **Any information** relating to an **identified or identifiable natural person** referred to as '*data subject*'; an identifiable person is one who can be
2. **identified directly or**
3. **indirectly**, in particular by reference to an identification number or to one or more factors specific to his or her physical, physiological, mental, economic, cultural or social identity.

The term "***any information***" clearly signals the willingness to design a broad concept of personal data. This wording calls for a wide interpretation. From the point of view of the nature of the information, the concept of personal data includes any sort of statements about a person. It covers "***objective***" information, such as the age of a data subject. It also includes "***subjective***" information, such as opinions or assessments.

Concerning "***directly***" identified or identifiable persons, **the name of the person is the most common identifier, and, in practice, the notion of "*identified person*" implies most often a reference to the person's name**.

As regards "***indirectly***" identified or identifiable persons, **this category typically relates to the phenomenon of "*unique combinations*"**, whether small or large in size. In cases where *prima facie* the extent of the identifiers available does not allow anyone to single out a particular person, that person might still be "*identifiable*" because that information combined with other pieces of information will allow the individual to be distinguished from others. To establish whether a person is identifiable, one needs to consider whether it could be singled out using all the means likely reasonably to be used either by the Data Controller or by any other person to identify the said person.

While identification through the name is the most common occurrence in practice, a name may itself not be necessary in all cases to identify an individual. This may happen when other "*identifiers*" are used to single someone out.

Examples of potential identifiers: physical characteristics, pseudonyms, occupation, address etc. or any combination of these.

However, an individual is not regarded as '*identifiable*' if it involves excessive effort to identify them.

Considering the format or the medium on which that information is contained, the concept of personal data includes information available in whatever form, be it alphabetical, numerical, graphical, photographical or acoustic, for example. It includes **information kept on paper, as well as information stored in a computer memory by means of binary code, or on a videotape**, for instance. This is a logical consequence of covering automatic processing of personal data within its scope. In particular, **sound and image data qualify as personal data from this point of view, insofar as they may represent information on an individual**.

On the other hand, it is not necessary for the information to be considered as personal data that it is contained in a structured database or file. Also information contained in free text in an electronic document may qualify as personal data, provided the other criteria in the definition of personal data are fulfilled.

It is so important to **specify what kind of human participants/data are involved within the research**. Indicative categories of human participants are (as examples):

- Patients.
- Healthy volunteers (related to health research).
- **Volunteers** (for surveys, etc.).
- **Workers'** (e.g.: research lab personnel, etc.).
- Participating researchers' list.
- Children.
- Vulnerable adults
- Others … special population groups? Developing countries? etc.

Particular attention has to be used in identifying and assessing the categories of data used, their sources and usage history. The **content of the data set needs to be specified and copies of appropriate authorisations need to be provided according to the legal requirements of the area where the research is planned to take place**.

In legal terms, "***processing of personal data***" means: "*any operation ... which is performed upon personal data, whether or not by automatic means, such as collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction*".

In a nutshell: **anything you do with personal data is considered as processing**.

The rules and procedures governing the use and disclosure of personal data, are those outlined in the EU Data Protection Directive, complemented, when necessary, by local privacy and data protection laws that exist in the country of data collection.

When data are processed in more than one jurisdiction, the researcher must provide detailed information regarding the applicable legal framework in the countries where data collection or processing in general is going to take place. As a matter of law and principle, researchers shall comply with Data Protection legislation in the Member State where the research as a whole or parts of it will be carried out.

2.1 Basic principles of processing of personal data

Whenever personal data are being processed, you must keep in mind certain principles and conditions.

"***Data quality***" is the aim and this is achieved when the data processed are:

- *Adequate, relevant and non-excessive* (e.g., by minimising collected information/database fields).
- *Accurate and* where necessary, *kept up to date*.
- *Processed fairly and lawfully*.
- *Processed for limited and specified purposes* and not further processed in a way incompatible with these purposes.
- *Processed in line with data subjects' rights*.
- *Processed in a secure manner*.

- *Kept for no longer than necessary for the purposes for which the data was collected or for which it is further processed*.

The purpose for which the data were collected or for which they are further processed is what determines the length of time for which the data should be kept. Once the data are no longer needed they should either be deleted or kept in anonymous form if they serve historical, statistical or scientific uses.

In line with the latest trends to promote secondary processing of research and scientific data this provision should be interpreted as allowing the use of data obtained for research purposes to be used only for (non-incompatible) research purposes (though not necessarily for the same research).

Tips to help compliance with necessity and proportionality principles:

- Design proper data retention and deletion plans.
- Consider automated deletion of certain types of data during the carrying out of research, and introduce a data storage scheme for data kept after the project is completed.

Moreover, you need to take adequate precautions when personal data are transferred to third parties to fulfil "*data quality*".

2.2 Special categories of personal data (commonly called "Sensitive data")

Some categories of data are more sensitive than others and require special treatment. These are: **personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and data concerning health or sex life**.

Examples of Sensitive Personal Data:

- Religious beliefs.
- Sexual orientation.
- Ethnic identification records.
- *Health-related records (e.g., patient records, biographic data, medical photographs, diet information, hospital information records, biological traits and genetic material)*.
- Criminal records or legal justice investigations and proceedings.
- Circulation records such as visas; residence or various geographic recordings such as GPS satellite localization recordings.

As a general rule, the processing of such personal data is prohibited. However, the EU Data Protection Directive does allow it to be processed in specific circumstances. The most common in research is upon the **data subject's explicit consent**.

You will need to **explain the reasons behind the proposed data collection**: data from different sources should not be amalgamated without making sure that this action is legally possible, especially in cases where a data set might contain information that identifies individuals and information.

3. INFORMED CONSENT

Informed consent: Declared one of the most pivotal principles in research ethics, a comprehensive informed consent is a crucial requirement in research.

Appropriate use of consent: Consent is sometimes a weak basis for justifying the processing of personal data and it loses its value when it is stretched or curtailed to make it fit to situations that it was never intended to be used in.

If it is used in circumstances where it is not appropriate, because the elements that constitute valid consent are unlikely to be present, this would lead to great vulnerability and, in practice, this would weaken the position of data subjects.

The **data subject's consent' shall mean** "*any freely given specific and informed indication of her/his wishes by which the data subject signifies her/his agreement to personal data relating to her/him being processed*".

Main aspects of Informed Consent:

1. "… ***freely given*** …" Consent can only be valid if the data subject is able to exercise a real choice, and there is no risk of deception, intimidation, coercion or significant negative consequences if he/she does not consent. In that regard, the potential participant must be given sufficient information in order to be able to make a choice of whether or not to participate that is based on an understanding of the risks and alternatives in an environment, which is free from any coercion.
2. "… ***specific*** …" To be specific, consent must be intelligible: it should refer clearly and precisely to the scope and the consequences of the data processing. It cannot apply to an open-ended set of processing activities. This means in other words that the context in which consent applies is limited and that blanket consent without specifying the exact purpose of the processing is not acceptable. Consent must be given in relation to the different aspects of the processing, clearly identified. It includes notably which data are processed and for which purposes. This understanding should be based on the reasonable expectations of the parties. Consent should refer to the processing that is reasonable and necessary in relation to the purpose. It should be sufficient in principle for data controllers to obtain consent only once for different operations if they fall within the reasonable expectations of the data subject.
3. "… ***informed*** …" There must always be information (appreciation and understanding of the facts and implications) of an action before there can be consent. The individual concerned must be given, in a clear and understandable manner, accurate and full information of all relevant issues such as:
    a. the nature of the data processed;
    b. purposes of the processing;
    c. the recipients of possible transfers;
    d. the rights of the data subject;
    e. consequences of not consenting to the processing in question
4. The decision of the potential participant on the consent issue must be evidenced. The participant needs to agree that her/his data will be used for a specific research scope and is aware of the meaning of such use.

When research consists of fieldwork, obtaining informed consent might not be a onetime event, but should rather be regarded as an ongoing process, which might evolve differently from what was anticipated before beginning research.

4. DATA SECURITY

Secure data storage so as for the data not to become accessible to unwanted third parties and to be protected against disaster and risk.

- **Data must be stored within a secured environment**. If stored electronically, this must be a machine, or set of machines located in a physically secured environment - with controlled access - as well as technically secured.
- Considering **hardware type in which data are stored** (paper, disk, removable device, etc.), **and the nature of the data used in the project**, it is necessary to clearly define what will be the adapted security processes to be followed, and how they guarantee the confidentiality of data.
- It is fundamental to define **who has access to the data** (also and especially third party).
- The **time the data will be stored and accessed, and what will happen to the data after the end of the study**. Duration of storage should be justified. Destruction at the convenience of the researcher would appear insufficient, unless clearly stated in the consent form and the approval of the local competent authority. Such deletion of data should be defined as irreversible, or reversible.
- If stored on a machine, has to be clearly defined if the **storage machine/server** is equipped with:
    - Wi-Fi.
    - Bluetooth.
    - USB drive.
    - On the whole, devices that might ease data duplication or circulation.
- The **data backup policies and processes** will be implemented.

Answering these questions will help you assess the data protection and privacy risks within the project, and therefore provide a "*state of the art*" risk management policy.

To process data in a secure manner you must:

- Take the appropriate technical and organisational measures to prevent any unauthorised act with regard to the data.
- Make sure that no one will access, read, copy, alter, use in any way or process the data unless he/she is authorised to do so according to clear access rules.
- Organise the processing in a way that gives you the complete control and tracking of the procedures followed.
- If someone is processing data on your behalf, you need to choose someone able to guarantee secure processing.

Secured access policy needs to be worked out and clearly specified. It needs to be proportional to the risks involved and the sensitivity of the data, and must clearly state the type of processes - such as

password protection, encryption, "*need to know basis*" principles (i.e.: only the users that need to access the data will be allowed to do so) - that will be implemented.

Data structures such as databases need to be specified - if applicable, it should be specified that identification data will be encrypted and strictly separated from sensitive data such as health data. It should also be specified how the unforeseen data added during the research such as incidental findings will be treated.

Conservation methods need to be specified. A non-WAN connected computer server or HARD disk should be preferred. Data should not be stored on a memory stick or other easily lost/accessed media.

4.1 User authentication

The way to verify the identity of a user:

- One-factor: "*something a user knows*", e.g., a strong password[4].
- Two-factor: "*something a user has*", e.g., a signed digital certificate in a smart card.

4.2 Access control

A mechanism to allow or deny access to certain data:

- Based on predefined user lists and access rights, e.g.:
  - who can access what;
  - type of access (read, write, delete, etc.).
- Based on the functions of each user within the project.
- Role based - attribute based.

4.3 Storage security

Storing data in a way that no unauthorised party is able to access it:

- Operating system controls (authentication & access control).
- Use of passwords to access electronic files (e.g., use the text editor function to save a document password-protected).
- Local encrypted storage (enable the full disk encryption, enable the file system, enable the text editor encryption).
- Database encryption: turning data into a form that are unintelligible (for anyone not having access to the key).

[4] Key aspects of a strong password: length (the longer the better); a mix of letters (upper and lower case), numbers, and symbols; with no ties to your personal information, and no dictionary words).

- Consider that your storage concerns are equally important if your data are on your local PC, your portable storage device or in the cloud storage!

4.4 Communication security

Protecting data when transferred via communication means:

- Encrypted communication (SSL/TLS); (e.g. use web services whose URL starts with "*https://*" and not only "*http://*".
- Firewall systems and access control lists (e.g., make sure the firewall service is enabled on your PC).
- Anti-virus & anti-malware systems.

4.5 Other IT technical controls

- **Back-ups**: necessary for the availability of the systems and information.
- **PC configuration**: security-aware settings at user level (e.g., installing security updates, anti-virus protection, local back-ups, blocking of certain software installation, etc.).

5 DATA TRANSFER

"*Data transfer*" would normally imply at least the following elements:

- The communication, disclosure or otherwise making available of personal data from the researcher to a third party regardless of the medium, **including but not limited to movement across a network, physical transfers, transfers from one media or device to another, or by remote access to the data**,
- conducted with the knowledge or intention of the researcher that the third party – recipient will have access to it.

The concept includes: "***deliberate transfers***" and "***permitted access***" to data recipients.

Transborder flows of personal data means the movement of personal data across national borders by any means, including access of data from outside the country where collected and use of cloud technologies for data.

The EU Data Protection Directive disallows transfer of personal data to a third party (including country or territory outside the European Economic Area) **unless that third party ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data**.

For intra-EU transfers…

The recipients of the data shall have in place adequate safeguards for the protection of privacy compatible with the applicable EU Data Protection Directives or Regulations (e.g., the above-mentioned Directive 95/46/EC or any subsequent amending acts).

The following specific safeguards are also required:

- The data shall be necessary for the legitimate performance of tasks covered by the competence of the recipient or
- The recipient establishes that the data are necessary for the performance of a task carried out in the public interest or subject to the exercise of public authority or
- The recipient establishes the necessity of having the data transferred and if there is no reason to assume that the data subjects legitimate interests might be prejudicated.

Research participants must know what is happening with their personal data and this must be either explained verbally or provided in some written format or document that research participants have agreed to - i.e., via their consent which is recorded as evidence that they have agreed.

Tips upon data transfer:

- If data processing is outsourced, remove personal data where practicable and as far as **possible** so that only a pseudonymous ID number is used to link individual-level data with participants' identities.
- Assess the level of protection afforded by a third country or international organisation **in the light of all circumstances surrounding a data transfer operation or set of data transfer operations**.

Special precautions need to be taken when personal data is transferred to countries outside the EEA that do not provide EU-standard data protection. Transfer of data outside the EU needs to be identified and specified. The handling process should be specified. Data transfer (between whom and whom) within the project, especially with partners from non-EU countries (developed and/or developing countries) must be given special care due to the variety of legal and administrative standards. This is because EU legislation requires that the transfer of data outside Europe to be undertaken only to places where there is a local assurance that the level of data protection is compatible/ at least equivalent to that of the EU area. Researchers need to consider this aspect not only between institutions and companies and the like, but also within companies and the research partnership across geographical borders.

6 ANONYMISATION

Anonymisation is a technique applied to personal data in order to achieve irreversible deidentification. The anonymisation process, meaning the processing of such personal data to achieve their anonymisation, is an instance of "*further processing*".

One of the big advantages of anonymisation is to allow research that would otherwise not be possible due to privacy concerns.

A solution is to remove direct identifiers such as names, birth dates, and addresses, so that the data cannot be traced back to individuals.

An **effective anonymisation solution** prevents all parties from:

- Singling out an individual in a dataset.
- Linking two records within a dataset (or between two separate datasets) and from
- Inferring any information in such dataset.

Removing directly identifying elements in itself is not enough to ensure that identification of the data subject is no longer possible. Additional measures are usually necessary to prevent identification, depending on the context and purposes of the processing for which the anonymised data are intended.

Common anonymisation techniques

1. **Randomisation as…**

A family of techniques that alters the veracity of the data in order to remove the strong link between the data and the individual. If the data are sufficiently uncertain then they can no longer be referred to a specific individual.

2. **Generalisation as…**

An approach consisting of generalizing, or diluting, the attributes of data subjects by modifying the respective scale or order of magnitude (i.e., a region rather than a city, a month rather than a week). Generalisation can be effective to prevent singling out but does not allow effective anonymisation in all cases. Make sure you devise specific and sophisticated quantitative approaches to prevent linkability and inference.

3. **Pseudonymisation as…**

A hybrid technique referring to the process of disguising identities by replacing one attribute (typically a unique attribute) in a record by another.

Useful tips:

- Natural person still likely to be identified indirectly but only under pre-defined circumstances.
- When used alone it does not result in an anonymous dataset.
- It reduces the linkability of a dataset with the original identity of a data subject.
- It is a useful security measure but not a method of anonymisation.
- Use random and unpredictable pseudonyms.
- Make sure the number of pseudonyms possible is so large that the same pseudonym is never randomly selected twice.
- If the codes used are unique for each specific person, the risk of identification occurs whenever it is possible to get access to the key used for the encryption.
- If, the codes are not unique, but the same code number (e.g., "*123*") is used to designate individuals in different towns, and for data from different years (only distinguishing a particular individual within a year and within the sample in the same city), the controller or a third party could only identify a specific individual if they knew to what year and to what town the data refer.

Anonymous data as…

Any information relating to a natural person where the person cannot be identified, whether by the data controller or by any other person, taking account of all the means likely reasonably to be used either by the controller or by any other person to identify that individual.

Anonymised data as…

Anonymous data that previously referred to an identifiable person, but where that identification is no longer possible.

Carry out a case-by-case analysis to assess:

- Whether the data allow identification of an individual, and
- Whether the information can be considered as anonymous or not,
- The extent to which the means are likely reasonably to be used for identification.

This is particularly relevant in the case of statistical information, where despite the fact that the information may be presented as aggregated data, the original sample is not sufficiently large and other pieces of information may enable the identification of individuals.

- **Clarify whether the data will be anonymised** (link to the data will be destroyed) **or coded** (the data will be reversible).
- **Explain how you will ensure data protection and how any link to the research participants will be handled if not fully anonymised**.
- **Insist that participants in surveys/experiments use their initials** (not ID session numbers or full signatures) when they sign their consent forms, and not simply suggest that they do so.
- **If the data will not be anonymised, explain why you cannot anonymise the data** (e.g., you need to recontact the participants or do follow-up in case of long-term study). **If the data will be coded, describe the coding system, and who will have access to the code**. Confirm that it cannot be tracked back to individuals unless essential for the study.
- **Use data for statistics only after anonymisation techniques have been applied**.

ANNEXES

Consent forms to the processing of personal data

The forms relating to the informed consent to the processing of personal data as used for collecting information through a survey on the users' needs are reported below, divided by country in which the data were collected.

Italy

CONSENSO AL TRATTAMENTO DEI DATI PERSONALI

Il sottoscritto _____ nato a _____ Il _____ CF _____ Residente a _____ Via _____ n._____ Tel. _____ Cell. _____

ACCONSENTE ai sensi e per gli effetti degli artt. 13 e 23 del D. L.gs. n. 196/2003, con la sottoscrizione del presente modulo, al trattamento dei dati personali secondo le modalità e nei limiti di cui all'informativa allegata.

Letto, confermato e sottoscritto

_____, Li _____

INFORMATIVA EX ART. 13 DEL D.LGS. N. 196/2003

Gentile Signore/a,

Desideriamo informarLa che il D.lgs. n. 196 del 30 giugno 2003 ("*Codice in materia di protezione dei dati personali*") prevede la tutela delle persone e di altri soggetti rispetto al trattamento dei dati personali. Secondo la normativa indicata, tale trattamento sarà improntato ai principi di correttezza, liceità e trasparenza e di tutela della Sua riservatezza e dei Suoi diritti.

Ai sensi dell'articolo 13 del D.lgs. n. 196/2003, pertanto, Le forniamo le seguenti informazioni:

1. I dati da Lei forniti verranno trattati per le seguenti finalità: STUDIO DEI (BIO-) RITMI CIRCADIANI E VALUTAZIONE DI EVENTUALI DISFUNZIONI CRONOBIOLOGICHE DERIVANTI DAL LAVORO A TURNI E NOTTURNO (DISTURBI DEL SONNO, DELL'UMORE, ECC.) - PROGETTO DI RICERCA "*CLOCKWORK*".
2. Lo studio prevede l'utilizzo dei seguenti dispositivi:
    a. SISTEMA INDOSSABILE PER IL MONITORAGGIO DEI DATI FISIOLOGICI/PARAMETRI VITALI (FREQUENZA CARDIACA, FREQUENZA RESPIRATORIA, PRESSIONE ARTERIOSA, SATURAZIONE DI OSSIGENO, TEMPERATURA, LIVELLO DI MELATONINA (OPZIONALE), DIARIE DEI PASTI E DEL SONNO).

   b. SISTEMA AMBIENTALE PER IL MONITORAGGIO DEGLI SPAZI DI LAVORO (LUCE, RUMORE, TEMPERATURA).
   c. SISTEMA LUMINOSO AUTOREGOLABILE SULLA BASE DEI PARAMETRI RACCOLTI DAL SISTEMA INDOSSABILE E DAL SISTEMA AMBIENTALE DEI PRECEDENTI PUNTI a E b.
3. Il trattamento sarà effettuato mediante sistema informatizzato.
4. Il conferimento dei dati è facoltativo, e l'eventuale rifiuto di fornire tali dati non ha alcuna conseguenza, se non per le finalità dello studio.
5. I dati non saranno comunicati ad altri soggetti, né saranno oggetto di diffusione.
6. Il trattamento riguarderà anche dati personali rientranti nel novero dei dati "sensibili", vale a dire dati idonei a rivelare il genere e l'origine razziale e/o etnica, nonché i dati personali idonei a rivelare lo stato di salute. I dati sanitari potranno essere trattati da centri specializzati e da esperti nel valutare il miglioramento delle condizioni lavorative, in riferimento alla finalità dello studio di cui al punto 1.
7. Il trattamento che sarà effettuato su tali dati sensibili dal sistema informatizzato avverrà in via del tutto anonima in riferimento al titolare dei dati di cui sopra, e mediante processamento algoritmico-deduttivo, con le finalità di monitoraggio, al fine di consentire la progettazione del dispositivo luminoso autoregolante del punto 2.c, e per fornire una base di comparazione per le finalità dello studio, come espresse al precedente punto 1.
8. Tale trattamento sarà effettuato mediante processi di elaborazione della serie di dati acquisiti, al fine di trarre conclusioni circa le informazioni che contengono, e migliorare le condizioni dei lavoratori oggetto di studio.
9. I dati in questione non saranno comunicati ad altri soggetti né saranno oggetto di diffusione.

Il titolare e responsabile del trattamento è il Coordinatore del progetto CLOCKWORK, Fraunhofer Portogallo: info@clockworkproject.eu

In ogni momento potrà esercitare i Suoi diritti nei confronti del titolare del trattamento, ai sensi dell'art. 7 del D.lgs. n. 196/2003.

Portugal

CONSENTIMENTO PARA PARTICIPAÇÃO EM INVESTIGAÇÃO

O projecto ClockWork – dos parceiros Associação Fraunhofer Portugal Research (Portugal), Grado Zero e AbAcus (Italia), BCB (Espanha), RKTech (Hungria) e KOHS (Austria) – tem como objectivo estudar os (BIO) ritmos circadianos e avaliar falhas crono biológicas decorrentes da trabalho por turnos e noite (sono, humor, ETC.). O estudo envolve a utilização dos dispositivos seguintes:

a- um sistema de vestível para o controlo dos dados fisiológicos/sinais vitais (frequência cardíaca, frequência respiratória, pressão arterial, saturação de oxigênio, temperatura, nível de melatonina (opcional), subsídio diário de refeições e sono).

b. um sistema ambiental pelo monitoramento de espaços de trabalho (luz, ruído, temperatura).

c. um sistema de iluminação com regulação automática com base nos parâmetros recolhidos pelo sistema vestível e o sistema ambiental dos pontos anteriores a e b.

O projecto é apoiado pelo programa Europeu AAL JP, que promove a melhoria da qualidade de vida dos trabalhadores à rotação. O projecto começou em Júnio de 2014 e termina em Dezembro de 2018.

Riscos em Participar

Na parte inicial deste projecto, o grupo de parceiros está interessado em perceber o contexto actual dos trabalhadores seniors e em particular os trabalhadores a rotação. Com este questionário recolheremos alguma informação pessoal. De forma a salvaguardar e proteger a sua informação, os dados recolhidos vai ser tratados de forma anónima e não serão acedidos por terceiros não autorizados. Seis meses depois do fim do projecto, a informação recolhida nestes questionários vai ser destruída permanentemente. O projecto vai seguir a nova Lei Geral de Protecção de Dados da União Europeia, a Carta dos Direitos Fundamentais da União Europeia e a Declaração de Helsínquia. A participação no estudo não apresenta nenhum risco para a integridade física e mental dos participantes, não envolve qualquer dano material e não envolve qualquer forma de pagamento.

Benefícios em participar

A informação recolhida será usada para criar uma solução tecnológica de nutrição, eficiente, que responda às necessidades da população sénior e que possa, assim, melhorar aspectos da sua qualidade de vida. Ao participar, pode ajudar-nos a perceber as necessidades actuais e contribuir para o desenvolvimento do projecto de forma activa. Além disso, a sua participação poderá contribuir para a independência da população sénior no futuro.

Informação

A informação recolhida é confidencial, será apenas usada pelos investigadores para os fins estabelecidos e não pode ser associada ao participante. Os parceiros do projecto tomarão todas as medidas necessárias à salvaguarda e protecção dos dados recolhidos por forma a evitar que venham a ser acedidos por terceiros não autorizados.

Participação

Se tem 45 anos ou mais, gostávamos de contar com a sua participação. A sua participação no questionário vai demorar cerca de 30 minutos. A participação é voluntária, podendo em qualquer altura cessá-la sem qualquer tipo de consequência.

Agradecemos muito o seu contributo, fundamental para a nossa investigação!

O/A participante:

Declaro ter lido e compreendido este documento, bem como as informações verbais fornecidas e aceito participar nesta investigação. Permito a utilização dos dados que forneço de forma voluntária, confiando em que apenas serão utilizados para investigação e com as garantias de confidencialidade e anonimato que me são dadas pela/o investigador/a. Autorizo a comunicação de dados de forma anónima a outras entidades que estabeleçam parceria com o projecto ClockWork para fins académicos e de investigação científica. A minha informação pessoal será tratada de forma anónima e destruída seis meses após o fim do projecto.

Por favor marque uma das caixas abaixo de forma a registar a sua disponibilidade para continuar a participar no estudo:

☐ ***Sim, autorizo*** *que me contactem para outras actividades no projecto ClockWork*

Email: _____ ou Endereço: _____

_____ ou Telefone: _____

☐ ***Não, não autorizo*** *que me contactem para outras actividades no projecto ClockWork*

Nome: _____

Assinatura: _____ Data ___ / ___ / _____

Coordenador do projeto: Fraunhofer Portugal

Contacto: info@clockworkproject.eu

ESTE DOCUMENTO É FEITO EM DUPLICADO: UM PARA A/O PARTICIPANTE E UM PARA A/O INVESTIGADOR/A

Hungary

ADATVÉDELMI TÁJÉKOZTATÓ ÉS HOZZÁJÁRULÓ NYILATKOZAT
a CLOCKWORK Kutatásban történő részvételhez

Az információs önrendelkezési jogról és az információszabadságról szóló 2011. évi CXII. törvény 20. §-ában rögzített kötelezettségünknek eleget téve, ezúton tájékoztatjuk a CLOCKWORK Kutatásban történő részvétellel

(a továbbiakban: Kutatás) való jelentkezéssel kapcsolatban Önt, mint Kutatásra jelentkezőt (a továbbiakban: Vizsgált személy) személyes adatainak kezeléséről:

1.
Az adatkezelők neve és székhelye
Név:
Székhely:

2. A kezelt személyes adatok fajtái, forrása és jogalapja

2.1. A kezelt adatok fajtái:
a Vizsgált személy neve, állandó lakóhelye, levelezési címe, anyja neve, születési helye és ideje; telefonszáma, email címe, mért élettani értékei

2.2. A kezelt személyes forrása: A Vizsgált személyre vonatkozó személyes adatok közvetlenül a Vizsgált személy általi önkéntes adatszolgáltatás útján kerülnek felvételre a Kutatásba való jelentkezés benyújtásával egyidejűleg.

2.3. Az adatkezelés jogalapja: Az adatkezelés a Vizsgált személy hozzájárulásán alapul.

3. Az adatkezelés célja Adatkezelő a Vizsgált személytől a fenti. 2. pontban gyűjtött személyes adatokat az alábbi célból kezeli:

3.1. Általános cél: Adatok gyűjtése kutatási-fejlesztési feladatok megvalósításához

3.2. Konkrét célok: A Clockwork Kutatás kitűzött céljainak megvalósítása
Adatkezelőt terhelő, Kutatással és támogatással kapcsolatos pénzügyi elszámolás, ellenőrzés;
Kutatással kapcsolatos anonimizált adatokat tartalmazó statisztikai kimutatások elkészítése céljára

4.
Az adatkezelés és adatfeldolgozás helye:
Az adatkezelés helye:

Az adatok feldolgozását az Adatkezelő végzi:
A Vizsgált személy személyes adatai a Konzorciumi tagok részére továbbításra kerülhetnek.
A fent megnevezett Adatkezelő mindvégig az alkalmazandó adatkezelési szabályokat betartva jár el, annak érdekében, hogy biztosítsa a Vizsgált személy személyes adatainak és magánszférájának védelmét, gondoskodik a Vizsgált személy adatainak biztonságáról és minden intézkedést megtesz jogosulatlan hozzáférés ellen.

5.
Az adatkezelés (tárolás) időtartama A Vizsgált személy személyes adatait az adatkezelés céljainak megvalósítása érdekében szükséges ésszerű időtartamig, a Kutatás záró időpontjáig, illetve Adatkezelő jogszabályban előírt kötelezettségének teljesítéséhez szükséges időtartamig kezeli az Adatkezelő.
A Vizsgált személy kérése esetén haladéktalanul, de legkésőbb 15 munkanapon belül a Vizsgált személyre vonatkozó személyes adatokat töröljük.

6.
Jogorvoslatok
Felhívjuk a figyelmét, hogy Önt az alábbi jogok illetik meg kezelt személyes adatai tekintetében:

6.1. Tájékoztatást kérhet személyes adatai kezeléséről;

6.2. Tiltakozhat személyes adatainak kezelése ellen;

6.3. Kérheti személyes adatainak helyesbítését;

6.4. Kérheti személyes adatainak törlését vagy zárolását;

6.5. Adatkezeléssel kapcsolatos jogainak megsértése esetén bírósághoz fordulhat;

6.6. Jogorvoslatért fordulhat a Nemzeti Adatvédelmi és Információszabadság Hatósághoz (1125 Budapest Szilágyi Erzsébet fasor 22/c.) fordulhat;

6.7. Az Ön adatainak jogellenes kezelésével, vagy az adatbiztonság követelményének megszegésével az adatkezelő által, vagy az adatfeldolgozó által Önnek okozott kárt az adatkezelő köteles megtéríteni.

Az információs önrendelkezési jogról és az információszabadságról szóló törvény
5. § (1) bekezdésének a) pontja értelmében személyes adatainak fentiek szerinti kezeléséhez az Ön, mint érintett önkéntes hozzájárulása szükséges. Ennek megfelelően, amennyiben a fentiekkel egyetért, kérjük, szíveskedjen az alábbi hozzájáruló nyilatkozatot kitölteni és aláírni

HOZZÁJÁRULÓ NYILATKOZAT
személyes adatok megismeréséhez és kezeléséhez

Név: ……..
Anyja neve: ……..
Születési hely, idő: ……..

az információs önrendelkezési jogról és az információszabadságról szóló 2011. évi CXII. törvény 5. § (1) bekezdés a) pontja alapján nyilatkozom, hogy az ……. által meghirdetett

részvétel CLOCKWORK kutatásban

kapcsolatban hozzájárulásomat adom személyes adataim megismeréséhez és kezeléséhez a Kutatásban résztvevők számára.

Az adatkezelés célja és feltételei: a Kutatás során a mért élettani értékek feldolgozásához, használatához szükséges információk megismerése és ezen okokból való felhasználása.
Az adatok megismerhetősége: a Vizsgált személyek adatait kizárólag a Kutatás időszakában és kizárólag a Kutatásban résztvevő személyek ismerhetik meg.
Az adatkezelők személye: a Kutatásban a Konzorciumi tagok vesznek részt.
Az adatkezelés időtartama: adatkezelés kizárólag a Kutatás záró időpontjáig történik. Az adatok további felhasználáshoz, a kutatási adatbankba történő bekerüléshez újabb hozzájáruló nyilatkozat szükséges.
Dátum: .....

……
aláírás

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