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PREventive Care Infrastructure based on Ubiquitous Sensing

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1st annual ethical and privacy report for PRECIOUS development & implementation

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Abstract

The purpose of this deliverable is to highlight the ethical and privacy issues within the project, which have arisen during the first year of its development and implementation. Along with the identification of these issues, guidelines and measures to address such aspects are outlined. As part of the development of the PRECIOUS service, it is necessary to collect and store personal data from healthy and patient volunteers. Therefore, ethical approvals from appropriate ethics committees have been requested and current approvals are presented in this deliverable. The present document corresponds to an additional deliverable requested by ethical committee review during the grant negotiation. In order to address those requirements, the project added these annual reports to summarize the ethical and privacy measures deployed. Therefore, Two further releases are planned (November 2015 and November 2016), which will report on further ethical submissions and approvals, as well as arising ethical and privacy issues related to the development of the PRECIOUS service.

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List of acronyms

Dow: Description of Work packages
EC: European Commission
EU: European Union
FP7: Seventh Framework Programme
ICT: Information and communication technologies
PRECIOUS: PREventive Care Infrastructure based On Ubiquitous Sensing
T2D: Type 2 diabetes

1. Executive summary

The main objective of PRECIOUS is to provide a preventive health care system that will improve the health of the user and deliver cost savings in the public health sector. The project involves the deployment of ubiquitous sensing and diverse data collection, related to both physical and psychosocial attributes. Research within the project (e.g. testing the efficacy of the developed components) will be conducted with adult human participants, and will include both healthy and patient volunteers. A number of ethical issues have been identified with respect to this research and these are outlined below, along with measures that have been incorporated to ensure safeguarding, confidentiality and anonymity for participants taking part in the research. A brief overview of ethical and privacy issues associated with the PRECIOUS service is also included. However, these wider issues are considered in more detail in Deliverable 2.4 (Ethical and privacy guidelines for PRECIOUS system implementation).

The present deliverable describes the ethical issues that are associated with the concept, design, development and implementation of the PRECIOUS service during the first year of its execution.

The **target audience** for this deliverable is manifold and includes:

- The members of the consortium: Members of the project need to understand the ethical dimensions of PRECIOUS service, especially those involved in its development, deployment and implementation.
- Stakeholders involved in PRECIOUS service exploitation, sustainability and wider use: The present deliverable is relevant to all these stakeholders, since it will enhance their understanding of important ethical issues, whilst also providing insights about how these issues could be tackled (for further details, please see Deliverable 2.4 Ethical and privacy guidelines for PRECIOUS system implementation).
- Other projects dealing with similar topics (especially EC-funded projects): As the number of similar applications is proliferating in parallel with the increase of the number of sensors (including cameras, microphones, etc.), other related projects could benefit from the discussion and relevant guidelines presented in this deliverable, as well as Deliverable 2.4 (Ethical and privacy guidelines for PRECIOUS system implementation).

2. Background

2.1. Ethics for research studies

Within PRECIOUS a number of research studies will be conducted with adult human voluntary participants. In carrying out these studies, research ethics procedures that comply with EU and national legislation (e. g. The Charter of Fundamental Rights of the EU, Directive 95/46/EC of the European Parliament and the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and the free movement of such data[1,2]) will be followed.

Additionally, all PRECIOUS partners will respect the Helsinki Declaration in its latest version[3] and follow the ethical guidelines provided by their national scientific societies and their local research institutions (see section 4 of the present deliverable for further details). All field studies included in the PRECIOUS service development and implementation will have to be presented in advance to local research ethics committees for approval.

The participants will be either adult healthy volunteers or adult patients with a type 2 diabetes diagnosis (onwards, T2D) depending on the study. Informed written consent will be obtained in all cases. None of the methodologies and technologies that are intended to be used (specifically psycho-physiological recordings) is known to inflict any physiological or psychological damage on participants. The investigations included in the project are not medical examinations; rather they involve self-reported measures and data collection from sensors.

Table 1 summarizes the main ethical issues involved in the development and implementation of the PRECIOUS service (also described in the DoW).

Table 1. Ethical issues table checklist

	Yes	No
Informed consent		
1. Does the proposal involve children?		X
2. Does the proposal involve patients?	X (in some cases)	
3. Does the proposal involve persons not able to give consent?		X
4. Does the proposal involve adult healthy volunteers?	X (in some cases)	
Biological research		
1. Does the proposal involve human genetic material?		X
2. Does the proposal involve human biological samples?		X
3. Does the proposal involve human data collection?	X	
Research on human embryo/foetus		
1. Does the proposal involve human embryos?		X
2. Does the proposal involve human foetal tissue/cells?		X
3. Does the proposal involve human embryonic stem cells?		X
Privacy		
1. Does the proposal involve processing of genetic information or personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?	X	
2. Does the proposal involve tracking the location or observation of people?	X	

Research on animals		
1. Does the proposal involve research on animals?		X
2. Are those animals transgenic small laboratory animals?		X
3. Are those animals transgenic farm animals?		X
4. Are those animals cloned farm animals?		X
5. Are those animals non-human primates?		X
Research involving developing countries		
1. Use of local resources (genetic, animal, plant etc)?		X
2. Benefit to local community (capacity building i.e. access to healthcare, education etc)?		X
Dual use		
1. Research having direct military application		X
2. Research having the potential for terrorist abuse		X
ICT implants		
1. Does the proposal involve clinical trials of ICT implants?		X
(IF NONE) I CONFIRM THAT NONE OF THE ABOVE ISSUES APPLY TO MY PROPOSAL		

When conducted properly, the consent process ensures that individuals are voluntarily participating in the research with full knowledge of relevant risks and benefits. The standard is that the consenting individual must be presented with all of the information that might reasonably influence their willingness to participate in a form that they can comprehend.
American Psychological Association's Ethics Code[4] (and similar guidelines for research studies with adult human volunteers) mandates that researchers (psychologists in this case) should inform participants about:

1. The purpose of the research, expected duration and procedures.
2. Participants' rights to decline to participate and to withdraw from the research once it has started, as well as the anticipated consequences of doing so.
3. Reasonably foreseeable factors that may influence their willingness to participate, such as potential risks, discomfort or adverse effects.
4. Any prospective research benefits.
5. Limits of confidentiality, such as data coding, disposal, sharing and archiving, and when confidentiality must be broken.
6. Incentives for participation (if any).
7. Who participants can contact with questions.

Experts[3,4] also suggest covering the likelihood, magnitude and duration of harm or benefit of participation, emphasizing that their involvement is voluntary and discussing treatment alternatives, if relevant to the research.
The Ethics Code also includes specific mandates for researchers who conduct experimental treatment research. Specifically, they must inform individuals about the experimental nature of the treatment, services that will or will not be available to the control groups, how participants will be assigned to treatments and control groups, available treatment alternatives and compensation or monetary costs of participation.

Table 2 summarizes the main ethical principles and set of questions relevant when conducting research with adult human volunteers, referred to PRECIOUS service.

Table 2. Evaluation criteria regarding ethical issues with adult human healthy volunteers and adult patient volunteers

	Yes	No	Not applicable
Topic **Respect for autonomy (right to liberty)**			
• Dignity • Informed consent			
1. The product/application/service is not imposed (directly or indirectly) to people - Free choice versus enforced choice/decision.	X		
2. The decision for the product/application/service is free from coercion or undue pressure? This includes the decision of how to use the product/application/service.	X		
3. Use of the product/application/service can be interrupted by the user and then continued without loss of efficacy.	X		
4. During development/implementation phase use cases involving adult users have been conducted in order to test user acceptance of the system	X		
5. All actions in relation to the product /application/service are consented to and where consent is not able to be given other options were utilized to guarantee autonomy.	X		
Non-maleficence (avoiding harm), Beneficence & Justice			
• Safety • Social solidarity, inclusion and exclusion • Isolation and substitution of human contacts • Discrimination and social sorting • Universal service • Accessibility • Value sensitive design • Sustainability • Equality and fairness			
1. It is safe to use the product/application/service (does not put the user at risk, physically or psychologically).	X		
2. The product/application/service has been designed with the intention to prevent to harm people.	X		
3. The product/application/service has been implemented with the intention to prevent to harm people.			N.A. at this stage of the project
4. The usage of such product/application/service is possible for all/the majority of adult population.	X		
5. The product/application/service brings people “closer” to society, rather than isolates them.	X		
6. The product/application/service /has a user manual which is simple to be understood by the majority of people.			N.A. at this stage of the project
7. The usage of such product/application/service is possible for all genders.	X		
8. During development/implementation phase the product/application/service has been tested to assess usability.			N.A. at this stage of the project
Justice			
• Equality and fairness			
1. A dignified behaviour is maintained for people using the product/application/service.	X		
2. The design of the product/application/service has taken requirements related to dignity of users explicitly into account.	X		
3. The product/application/service does not impede the control of a person’s life.	X		
4. The product/application/service can be adapted to an individual user’s needs (not the opposite).	X		
Privacy and data protection			
• Collection limitation and retention • Data quality • Purpose specification • Use limitation			

• Confidentiality, security and protection of data • Transparency • Individual participation and access to data • Anonymity • Privacy of personal communications, monitoring and location tracking • Privacy of the person • Privacy of personal behaviour			
1. User privacy is respected while using the product/application/service.	X		
2. The product/application/service respects the data protection principles of purpose limitation, data minimization, access and correction of data by users.	X		
3. Informed consent is sought for the collected and processed data; in the case of health or other sensitive data explicit consent is sought.	X		
4. Data used and produced from the system are safely and properly stored and transmitted; data security is enforced.	X		
5. Data generated by the product/application/service are anonymised for all users.	X		
6. The design of the product/application/service has considered requirements related to privacy and data protection.	X		
7. The designers of the product/application/service are committed to monitor the latest developments on privacy and data protection to ensure enhanced protection of the privacy of users.	X		
8. During product/application/service implementation requirements related to privacy and data protection have been fulfilled.	X		

2.2. Ethical issues related to a service that collects and processes data from many sources

As a service, PRECIOUS will collect and process data from many sources, including sensors, mobile devices, users' inputs and social networks. A brief explanation of each collection method is offered below (further information is provided in Deliverable 2.4 Ethical and privacy guidelines for PRECIOUS system implementation).

- **Sensor-service interaction:**
  Body sensors track heartbeat, physical activity, stress levels, etc, and interact automatically with the PRECIOUS service (sensors collecting physiological data). Additionally, at home sensors collect data related to the user environment, such as humidity level, temperature, or light intensity (sensors collecting environmental data).
- **Mobile device-service interaction:**
  Mobile devices and personal computers interact with the central PRECIOUS service by transferring recorded data (via cloud services or home networks).
- **User-service interaction:**
  Users interact actively with PRECIOUS by entering personal data via their mobile devices or personal computers.
- **User-user interaction:**
  Following social psychological findings, the system will be designed so that the users can interact with other users for encouragement, goal setting, comparison or competition. The PRECIOUS service may be developed as a social network on its own or it may be used as part of existing social media (e.g. Facebook, Twitter, etc).

  In brief, numerous technologies, which involve collection, storage and processing of data from the users' surroundings (environment), and directly from the users

themselves (user input and sensors), are being developed in the PRECIOUS service. Depending on what is collected by these technologies, different ethical and privacy issues arise.

These issues are mostly focused on the protection of participants' privacy while using online data collection systems. The project will therefore adhere to a strict anonymisation policy. In this sense, during the project, all users will join the system voluntarily and after informed consent is obtained. Upon registration, users will have to accept the project data protection terms and conditions in order to be able to effectively use the system. The system will collect personal information to provide a thorough understanding of the user experience and progress, and better match the activities and feedback offered. A personal service tailoring requires access to in depth personal data and the user needs to be aware of. Ultimately, it is up to the user to decide how much data they are willing to submit to PRECIOUS.

In the scope of its proof-of-concept applications, PRECIOUS will also leverage sensors that will provide information about the environmental factors that influence the individual. This information has no ethical implications providing that the individual is aware of it and has given consent to measurements being taken.

The following recommendations for privacy are made for the PRECIOUS service:

1. A clear description of which data is collected and why will be given to the users.
2. Collected data will be stored securely and only made accessible to authorised persons.
3. Users will be allowed to use the service with pseudonyms (ID code) instead of their real name.
4. Users will be able to control which data is made public.
5. Users will be given the opportunity to correct/erase erroneous data and stop data sharing at any moment.
6. Users must accept data protection terms and conditions to use the service.

3. General ethical and privacy guidelines

In the design and ongoing development of PRECIOUS, the ICT research guidelines set out by the European Commission Seventh Framework Programme (FP7)[5] will be adhered to (http://cordis.europa.eu/fp7/ethics-ict_en.html), as well as the following international codes of practices:

- The Declaration of Helsinki in its latest version[3] (http://www.wma.net/en/30publications/10policies/b3/index.html)
- The European Human Rights Convention[6] (http://www.echr.coe.int/Documents/Convention_ENG.pdf)
- The Charter of Fundamental Rights of the European Union signed and proclaimed on 7 December 2000[1] (http://www.europarl.europa.eu/charter/default_en.htm)

- The Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data[2]
  (http://ec.europa.eu/justice/data-protection/index_en.htm)
- Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006[7]
  (http://cordis.europa.eu/documents/documentlibrary/90798681EN6.pdf)

As it can be observed, the ethical framework used in this project is comprised of a few main principles. The principles are themselves derived from recognized human rights that are defined in the above mentioned Charter of Fundamental Rights of the EU[1]. This became binding in December 2009 when the Lisbon Treaty came into force. It is the first formal EU document to combine and declare all values and fundamental rights to which EU citizens should be entitled. In Table 3, some articles of this Charter are summarized.

Table 3. Charter of Fundamental Rights of the EU[1]

Article 1. Human dignity	Human dignity is inviolable. It must be respected and protected.
Article 3. Integrity	Everyone has the right to respect for his or her physical and mental integrity.
Article 4. Prohibition of torture	No one shall be subjected to torture or to inhuman or degrading treatment or punishment.
Article 6. Liberty and security	Everyone has the right to liberty and security of person.
Article 7. Private life	Everyone has the right to respect for his or her private and family life, home and communications.
Article 8. Personal data	Everyone has the right to the protection of personal data concerning him or her.
Article 15. Engage in work	Everyone has the right to engage in work and pursue a freely chosen or accepted occupation.
Article 21. Non discrimination	Any discrimination based on any ground such as sex, race, colour, ethnic or social origin, genetic features, languages, religious or belief, political or any other opinion, property, birth, disability, age or sexual orientation, shall be prohibited.

3.1. Information privacy principles: informed consent

The EU Directive on clinical trials (2001/20/EC)[8] provides good guidance on informed consent: ‘‘*A decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for national legislation*”.
By signing informed consent documents, research participants agree to a controlled breach of their privacy for a specific purpose and a specific period of time. In case an individual does not agree to such a temporary breach, he/she retains the right to withdraw from the study without consequence. Individuals should be made aware of the:

1. Methods used for handling personal data
2. Justification for requesting/obtaining their data
3. Duration of data use and storage
4. Guarantees concerning the rightful use of data

The main aspects of informed consent are as follows:

1. The potential participant must be given sufficient information in order to be able to make a choice of whether or not to participate, which is based on an understanding of the risks and alternatives, and is in an environment, which is free from any coercion.
2. The decision of the potential participant on the consent issue must be evidenced.
3. The participant must agree that her/his data will be used for a specific research scope and confirm that they are aware of the meaning of such use.

3.2. *Big data* management

The PRECIOUS service management of personal data will comply with Data Protection legislation (Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of the Council of Europe of 1 January 1981, Strasbourg http://conventions.coe.int/Treaty/EN/Treaties/Html/108.htm)[9].

3.2.1. Data retention, storage and exploitation

Researchers are ultimately responsible for ensuring appropriate security for confidential material. In order to protect the participants' privacy and anonymity, participants' data will be kept confidential, stored in anonymised form and be made inaccessible to third parties. All necessary precautions will be taken to protect the user's data from misuse. All questionnaires and assessment tools used in the field tests will use ID codes (rather than participant names) and will be stored in a dedicated locked room/secure file (specially, in field test cases).

PRECIOUS will provide a solution where data is collected in personal devices e.g. mobile phone and then transferred and stored in another user device at home e.g. home server. The data stored in the home device previous user consent can be uploaded to the server located in data centres (i.e. cloud) to be processed when additional computing power is required e.g. food analysis.

Usage time of data is not still fully stipulated at this stage of the project and will be specified in next ethical reports. For certain applications, it might be useful to store user-related data like medical data or images from different sources over a longer period of time for the purpose of later evaluation, which we refer to as *Big Data*.

Concerning *Big Data* in the overall security concept, privacy and security is ensured by the following concept:

- User-related *Big Data* is split into categories, e.g. location data is never stored together with related health data in order to make it impossible to find the identity of a user by analysing one category (like position data) and correlate it with another category (e.g. health related data).
- *Big Data* resides in a low (or even the lowest) security level because *Big Data* storage is assumed insecure in our security concept.

- The real identity of the user is hidden by removing any reference to the user from the data set and tagging the data set. The relation tag ⇔ user only is stored in a higher security layer than where the *Big Data* is located.
- 3rd party cloud providers should not be used.

3.2.2. Data encryption

The communications in PRECIOUS applications with the cloud processing components would use secure transport protocols such as HTTPS or SSL connections.
The PRECIOUS security concept is based on a number of *security layers*, which shall also be mapped to the hardware in order to eliminate e.g. data breach threats triggered by virtual environments. Security levels shall be separated from each other on an organizational and physical level. This separation of security layers is achieved by applying state-of-the-art data centre/cloud security mechanisms, like:

- On an *organizational level*, e.g. different people with their own access codes each shall be responsible for the different security layers and strict password rules shall be applied.
- On the *connectivity level*, established mechanisms like DMZ, Firewalls, Proxies, usage of encryption shall be applied.
- On the *physical level*, components of different security layers shall be physically separated and physical access shall be restricted.

In this security concept, the highest security level is called the *secure core*, which is also eligible for highly critical processes like payment, storage of critical user data, etc. Data of the secure core never leaves the core, but is always processed within the secure core as generally, data of a certain security layer shall never leak to a lower security layer unless it has been processed and is per definition allowed to leave the security layer. Access is only possible from one security layer to the next higher one and is protected by using *secure APIs*.

Please note that this high-level description of the security concept is only an incomplete list of utilised security and privacy mechanisms as the concept is still under development and is not at all subject of this deliverable.

3.2.3. Data transfer/monitoring

Encryption policies will be followed during transfer and limit transfer, especially outside organisations and by email.

3.3. Client-side data management

The underlying principle for data management in the PRECIOUS system is that the users' data should only be available in the physical locations where it is required by the algorithms and services. Further, the collected and synthesised data is owned and controlled exclusively by the user. This is in direct contrast with centralized data architectures that many existing systems employ, where all the data is stored and accessed in one central location and owned by an operator. This principle is derived from

the highly sensitive nature of the data collected and processed by the system, which calls for strong user controls of the data dissemination[10].

The following goals are set for the data management:

1. The user must have access to all data collected by the sensors.
2. The user must have access to all data synthesized by applications and services based on the collected sensor data.
3. The user must have the ability to delete any collected data, as well as data generated by the applications and services (e.g., health goals and personal programs).
4. The data must be stored by default only within devices owned and controlled by the user.
5. When data is required by external operators (e.g., sent to the "cloud" for further analysis), the user must be in full control of which data the operator is given access to, and must be able to provide the access anonymously or pseudonymously.
6. When data is required by local applications, the applications must get explicit permission from the user to access the data. The permission control must be fine-grained and partially revocable (i.e., the user should not have to either grant all permissions or not use the system at all).

In summary, PRECIOUS will deliver several mobile applications that collect user data from sensors. The client will store data locally and transfer to other personal devices at home where sensitive data will be stored. The mobile clients can send data to the cloud using secured transport protocols where data is encrypted during the communications.
The user decides the data to be sent to the cloud where it would be stored securely e.g. encrypted and access to third parties e.g. social networks would be granted based on user consent. Whenever a user shares data with another party, a trust relationship is required. In other words, the user must establish trust in the other party to handle the data according to the user's wishes and to not expose it to third parties. Most centralized systems require the user to fully trust one provider with all their data. In a distributed design, the user can have more fine-grained control over the trust relationships, and limit the amount of data each other party has access to. On the flip side, this does make maintaining the trust relationships more complex for the user (for further details, please consult Deliverable 2.4., Ethical and privacy guidelines for PRECIOUS system implementation)

4. Ethical approval

Ethical approval for individual studies within the project will be sought from appropriate ethical committees within the country where the research is taking place and by the organisation leading the research. An outline of planned research is provided in Deliverable 2.1 (List of usage scenarios and user requirements). Briefly, four main studies will be carried out, in addition to ad hoc gathering of user opinions, to inform next steps within the project.

Procedures relevant to each organisation and approximate approval timeframes are detailed below.

4.1. Finland-University of Helsinki review board in the humanities and social and behavioural sciences

A statement on the ethics of a proposed study, regardless of the discipline involved, must be requested from the University of Helsinki review board in the humanities and social and behavioural sciences if the study meets the requirements set out under items 1-6 below, as specified by the National Advisory Board on Research Ethics. University of Helsinki review board in the humanities and social and behavioural sciences reviews research designs that include the following types of interaction with the research subjects:

1. The study involves direct physical intervention with respect to the subjects.
2. The study deviates from the principle of informed consent.
3. The subjects are children under the age of 15, and the data are collected without parental consent and without providing the parents or guardians with an opportunity to prevent the child from taking part in the study, and the study is not part of the normal activities of a school or an institution of early childhood education and care.
4. The study exposes research subjects to exceptionally strong stimuli, and evaluating possible harm requires special expertise (e.g., studies involving violence or pornography).
5. The study may cause long-term mental harm (e.g., trauma, depression, insomnia) beyond the risks encountered in normal life.
6. The study can expose subjects to a security risk (e.g., studies involving domestic violence).

Additionally, researchers must specify the following aspects:

7. The funding agency or cooperation partner requires an ethical review.
8. The results are to be published in a scientific journal which requires ethical reviews.
9. The researchers wish to obtain a statement from the ethical committee to help their deliberations.
10. The study involves medical research under Section 2 of the Medical Research Act (No488/1999): Yes/No

Excerpt from Section 2 of the Act:
For the purposes of this Act:1) *medical research* means research involving intervention in the integrity of a person, human embryo or human foetus for the purpose of increasing knowledge of health, the causes, symptoms, diagnosis, treatment and prevention of diseases or the nature of diseases in general; (794/2919)
( ) Other reasons; please specify:
Has any other ethical committee reviewed this study or has review been applied?
( ) Yes, name of the committee:
( ) No

A researcher can also request an ethical review if the research subject, funding agency or cooperation partner so wishes or if the results are to be published in a scientific journal which requires ethical reviews. The ethical review of a study does not shift the researcher's

ethical responsibility for his or her work to the ethics board. In addition, the review process does not involve obtaining permission for the proposed study, which must typically be applied for from the unit in which the research material will be collected or the research carried out; rather, the review process involves the issuing of a statement on the ethics of the proposed study.

The ethical review process

Requests for ethical reviews addressed to the University of Helsinki review board in the humanities and social and behavioural sciences must be submitted to the committee secretary two weeks before the board meeting in which the request should be discussed.
Requests for statements must be accompanied by the following documents:

- ✓ A cover letter (0.5-1 page)
  - The cover letter presents the researcher's grounds for requesting a statement, and indicate the contact details of the principal investigator
- ✓ A statement of the grounds for the request

( ) The study involves direct physical intervention with respect to the subjects
( ) Research material will be collected without the consent of the subjects
( ) Research material with identifying or identifiable information will be handled without the consent of the subjects
( ) The subjects are children under the age of 15, and the data will be collected without parental consent and without providing the parents or guardians with an opportunity to prevent the child from taking part in the study, and the study is not part of the normal activities of a school or institution of early childhood education and care
( ) The study exposes research subjects to exceptionally strong stimuli, and evaluating possible harm requires special expertise
( ) The study may cause long-term mental harm (trauma, depression, sleeplessness) beyond the risks encountered in normal life
( ) The study can expose subjects to a security risk
( ) The funding agency or cooperation partner requires an ethical review
( ) The results are to be published in a scientific journal which requires ethical reviews
( ) The researchers wish to obtain a statement from the ethical committee to help their deliberations
( ) The study involves medical research under Section 2 of the Medical Research Act (No 488/1999): ( ) Yes / ( ) No

- ✓ A research proposal (max. 5 pages)

- The recommended length of research proposals is five pages, and proposals should be drawn up especially for an ethical review, focusing on the ethical principles guiding the committee's work and the consideration of research ethics. Research proposals must mention the interview framework as well as the journals, questionnaires and similar items used in the study.

✓ A research summary (0.5-1 pages)

- It must be written in Finnish even if the actual research proposal was submitted in English. The summaries of research proposals are not confidential under the Act on the Openness of Government Activities, and they are posted on the committee's intranet site to promote openness. The summaries can, however, be drawn up on a general level so as not to disclose the content of the study to third parties.

✓ Information for research subjects

1. Name and contact information of the principal investigator
2. Research organization(s) and funding agency
3. Purpose, objectives and significance of the study
4. Method of collecting material or conducting the research (concrete requirements for research subjects, including the time required for participation in the study)
5. The rights of subjects: voluntary participation and the right to ask for additional information about the study and to withdraw from the study without sanctions
6. The purpose of the research material, ensuring confidentiality (e.g., anonymity) and archiving the material for further research; the researcher's duty to maintain confidentiality and statutory exceptions to it should also be mentioned here
7. If information obtained from subjects is to be incorporated with information from official public registers, the subjects should be informed of the specific registers to be used in the study information geared to underage subjects should be tailored to their level of understanding

If the study involves direct physical intervention with respect to the subjects, the information provided to the subjects should adhere, where applicable, to the guidelines for medical research.

✓ A consent form

- Research subjects must be provided with a consent form if the research material includes identifying or sensitive information. The consent form should indicate at least the following:
- The study for which consent is requested
- Whether the subject has been offered sufficient information about the specific study and its purpose as well as the method of collecting information
- That the participation is voluntary
- The degree of confidentiality accorded to identifying or sensitive information
- How information will be retained and archived
- The subject's right to withdraw from the study at any point without reporting his or her reasons or facing penalties

- How information collected up until the time of withdrawing from the study is to be used
- The subject's signature, name in block letters and the date must also be given

✓ A plan for the management of research material
✓ A personal data file description for scientific research

The protection of identifying material must be carefully planned. Subjects' privacy must not be compromised by preserving material carelessly or transmitting material electronically over unsecured connections. If necessary, privacy can be protected by anonymising the material and regulating its further use. The purpose of anonymisation is to ensure that subsequent users of the material cannot immediately identify individual subjects. Identifying features include names, addresses, personal identity codes and student numbers; indirect identifiers include workplaces, schools, residences, professions and personal age. The plan for the management of research material must indicate at least the following:

- Where printed material with identifying information is to be kept
- At what point unnecessary information will be deleted or how it is to be preserved and archived for future studies.

When necessary, the scientific community is to be allowed to verify research results by accessing the material analysed in the study. Openness is essential for testing the validity of information, assessing the information critically and making scientific progress.
How electronic material with identifying information can be protected (backup copies, user IDs, processing on computers with no Internet connections if necessary) and which identifying features must be deleted or preserved in the material analysed.
Grounds for being permitted to handle material that contains identifying information, outlined for each researcher and other research staff. The project leader or principal investigator must ensure that the number of research staff with access to such information is restricted
How identifying information about subjects is to be protected and preserved separately from the material made available for subsequent communication. Information about criminal offences is sensitive and the researcher's duty to maintain confidentiality applies to and restricts the handling of such information in research. However, the duty to maintain confidentiality may be suspended in the case of preventing an aggravated crime.

If the statement indicates that the board would want additional material from the person who submitted the request, such information should be delivered to the secretary at least two weeks before the next board meeting to ensure the smooth processing of requests.
The researchers should first read the information on this website and familiarize themselves with the ethical principles of the Finnish Advisory Board on Research Integrity (http://www.tenk.fi/en/frontpage).

4.2. UK-Campden BRI

Within the project, Campden BRI will lead a field study that compares the use of different methods to collect information about the dietary habits of participants and asks participants to give opinions about the methods used.

- In the UK, Research Ethics Committees (RECs) review applications for research and give an opinion about the proposed participant involvement and whether the research is ethical. There are several different types of REC:NHS REC

- Gene Therapy Advisory Committee
- Social Care REC
- Ministry of Defence REC
- Higher Education Institution REC

None of these RECs apply directly to Campden BRI, which is an independent research association (not a Higher Education Institute), or to the field study, as it does not involve NHS patients or NHS sites, is not a gene therapy trial, is not social care research and is not funded by the Ministry of Defence. However, some types of research require NHS REC review by law whether or not they take place within the NHS or involve NHS patients or other service users. Campden BRI will consult the Health Research Authority to confirm whether the study is legally required to be reviewed by an NHS REC. Additionally, where a study presents no material ethical issues it may be eligible for NHS REC Proportionate Review (http://www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-proportionate-review-service/).

If NHS REC approval is not required Campden BRI will follow all ethical and privacy guidelines as outlined within this document. In particular, written informed consent will be sought and all data will be securely stored in anonymised form. Finally, approval time frame is detailed below:

- NHS REC – opinion provided within 60 calendar days of receipt of a valid application.
- NHS REC Proportionate Review – opinion provided within 14 calendar days of receipt of a valid application.

4.3. Spain-The Ethics Committee of the University Hospital Vall d'Hebron – *Institut de Recerca* (part of the *Institut Català de la Salut)*

The Clinical Research Ethics Committee (CREC) of Hospital Universitari Vall d'Hebron was established on the 26th of October 1992 (Order of *Departament de Sanitat i Seguretat Social* 26.10.1992) to obey the Law 25/1990 of 20th of December, which establishes the need that all clinical trials projects, study protocols and reserahc projects in general must have the approval of *Comitè Ètic d'Investigació Clínica*, which must be accredited by a relevant authority. In Catalunya this authority is the *Departament de Sanitat i Seguretat Social de la Generalitat de Catalunya*. The main objective of CREC of Hospital Universitari Vall d'Hebron is to contribute to improve quality, management and relevance of clinical trials that aim to develop our environment. This position is a clear desire to strengthen the position of the Hospital and its CREC, not only to be more competitive in market of research but to develop and to exert leadership in promoting clinically-oriented research.

The CREC of the Hospital Universitari Vall d'Hebron is also qualified by The Office for Human Research Protection (OHRP) - US Department of Health & Human Services Office of the Secretary Office of Public Health & Science Office for Human Research Protections (HHS):

• Institutional Review Board (IRB)-IRB00002850
• IRB Organizations (IORGs)-IORG0002313
• Federal wide Assurance (FWA) for the protection of the human subjects for international (Non-US Institutions-FWA Number 00003437)

Committee's meetings are scheduled four-weekly throughout the year. The deadline for submission of documentation will be between days 1 to 5 of each month in accordance with the provisions of the RD223/2004. This term must submit the necessary documents (form on the rules, protocol and/or project report, patient information sheet and informed consent, the sheet researcher or manual, signature sheet) to ensure inclusion on the agenda. All documents must be submitted via email and signatures' sheet physically. Approximate approval timeframe ranges from five to twelve weeks depending on the amendments requested. First notice will convey either "approval" of the project or "conditional approval" subject to listed conditions. An approval means that data collection may proceed immediately. Notice of conditional approval need to satisfy the requirements listed prior to commencing data collection. Once the researchers' amendments are received and after reviewing if all requirements are met, an approval letter is sent.
In some instances, where significant questions about methodology or other major issues arise, researchers are advised that consideration has been deferred pending clarifications and resolution of listed matters.

5. Executed field tests within November 2013 – October 2014

In the first year of the project Campden BRI led qualitative research (face to face interviews) to determine the user requirements of the PRECIOUS service (the results of this research are presented in Deliverable 2.1 List of usage scenarios and user requirements).

In designing the study protocol and carrying out recruitment and interviews Campden BRI and EuroFIR AISBL followed the Market Research Society (MRS) Guidelines, which include guidelines for carrying out qualitative research. Campden BRI and EuroFIR AISBL carried out interviews in a face-to-face setting in the UK and Finland respectively. Additionally, EuroFIR AISBL carried out interviews by telephone (in order to reach their membership base across Europe). Prior to the beginning of the telephone interviews, EuroFIR AISBL consulted an independent ethical advisor in order to assure that any eventual gaps related to ethical questions were not present during the interviews.

Data collected during recruitment, interview audio recordings and interview transcripts, were anonymised (records could not be traced back to individual participants). Data were stored in secure files/folders, to which only researchers working on PRECIOUS had access. All interview transcripts were sent to Campden BRI for coding and analysis.

Prior to beginning the interview, the interviewer explained the general purpose of the interview and it was explained to the participant that they had the right to end the discussion at any time. Verbal consent was obtained from each participant to record the interview for transcription at a later date. Written consent was also obtained from all participants taking part in the study.

Due to the participation of employees and members of the organisations undertaking the interviews, it was explained to employees that the study was not related to work and that responses would have no bearing on their employment, and to members that their

involvement/withdrawal would not result in penalty or loss of benefits to which they might otherwise be entitled.

6. Summary

The present deliverable is aimed at providing insights and relevant ethical issues raised during the first year of PRECIOUS service development, in order to ensure that PRECIOUS progresses are ethical, legal and privacy friendly. Each of these issues has been addressed by both the psychological and technological project partners to ensure the maximum safeguarding of the participants and their minimum risk.

Ethical approval for the planned field tests has been obtained for all partners involved in such activity and presented here in this deliverable.

The Consortium will continually refer to the ethical guidelines and recommendations set out in the DoW in the development and evaluation of the PRECIOUS system.

7. Annex I: Ethical approval of University of Helsinki review board in the humanities and social and behavioural sciences

Helsingin yliopiston
ihmistieteiden eettisen
ennakkoarvioinnin toimikunta

University of Helsinki Ethical review
board in humanities and social
and behavioral sciences

Lausunto/Statement
15/2014

EETTINEN ENNAKKOARVIOINTILAUSUNTO

Helsingin yliopiston ihmistieteiden eettisen ennakkoarvioinnin toimikunta on kokouksessaan 27.5.2014 käsitellyt Niklas Ravajan ja hänen tutkimusryhmänsä tutkimusta "Computer game-induced changes in approach/avoidance motivation and learning related to healthy eating". Toimikunta toteaa sille toimitetun aineiston perusteella, että suunniteltu tutkimus on Tutkimuseettisen neuvottelukunnan antamien ohjeiden mukainen ja eettisesti hyväksyttävä.

ETHICAL REVIEW STATEMENT

University of Helsinki Ethical review board in humanities and social and behavioral sciences has reviewed Niklas Ravaja's and his research groups study "Computer game-induced changes in approach/avoidance motivation and learning related to healthy eating" in the board meeting on the 27th of May 2014. The review board finds that based on the received material the planned study follows the Ethical principles of research in the humanities and social and behavioral sciences issued by the Finnish Advisory Board on Research Integrity. Thus the review board states that the mentioned study is ethically acceptable.

Helsinki 27.5.2014

Anna-Kaisa Tuovinen
sihteeri/secretary

HELSINGIN YLIOPISTO
HELSINGFORS UNIVERSITET
UNIVERSITY OF HELSINKI

8. Annex II: Ethical approval of VHIR

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Hospital

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ID-ATP080

INFORME DEL COMITÉ ÉTICO DE INVESTIGACIÓN CLÍNICA Y COMISIÓN DE PROYECTOS DE INVESTIGACIÓN DEL HOSPITAL UNIVERSITARI VALL D'HEBRON

Doña Inmaculada Fuentes Camps, Secretaria en funciones del Comité Ético de Investigación Clínica de l'Hospital Universitari Vall d'Hebron de Barcelona,

CERTIFICA

Que el Comité Ético de Investigación Clínica del Hospital Universitario Vall d'Hebron, en el cual la Comisión de proyectos de investigación está integrada, se reunió en sesión ordinaria nº 223 el pasado 25 de julio de 2014 y evaluó el proyecto de investigación PR(AG)212/2014 presentado con fecha 01/07/2014, titulado "*Infraestructura de cuidado preventivo basada en sensores ubicuos (PRECIOUS)Construyendo motivación - Diseño de un trabajo de campo con pacientes con Diabetes tipo II*" que tiene como investigador principal al a la Dra. Pilar Lusilla Palacios del Servicio de Psiquiatría de nuestro Centro.

Y que tras emitir un informe aprobado condicionado en dicha reunión y evaluar la documentación recibida posteriormente en respuesta a este informe

El resultado de la evaluación fue el siguiente:

DICTAMEN FAVORABLE

El Comité tanto en su composición como en los PNT cumple con las normas de BPC (CPMP/ICH/135/95) y con el Real Decreto 223/2004, y su composición actual es la siguiente:

Presidenta: Gallego Melcón, Soledad. Médico
Vicepresidente: Segarra Sarries, Joan. Abogado
Secretaria: Navarro Sebastián, Mireia. Química

Vocales: Armadans Gil, Lluís. Médico
Azpiroz Vidaur, Fernando. Médico
Corona Pérez-Cardona, Pablo. Médico
Cucurull Folguera, Esther. Médico Farmacóloga
Latorre Arteche, Francisco. Médico
De Torres Ramírez, Inés M. Médico
Fernández Liz, Eladio. Farmacéutico de Atención Primaria
Ferreira González, Ignacio. Médico
Fuentelsaz Gallego, Carmen. Diplomada Enfermería
Fuentes Camps, Inmaculada. Médico Farmacóloga
Guardia Massó, Jaume. Médico
Hortal Ibarra, Juan Carlos. Profesor de Universidad de Derecho
Montoro Ronsano, J. Bruno. Farmacéutico Hospital
Rodríguez Gallego, Alexis. Médico Farmacólogo
Sánchez Raya, Judith. Médico
Solé Orsola, Marta. Diplomada Enfermería
Suñé Martín, Pilar. Farmacéutica Hospital
Vargas Blasco, Víctor, Médico
Vilca Yengle, Luz Mª. Médico

En dicha reunión del Comité Ético de Investigación Clínica se cumplió el quórum preceptivo legalmente.

En el caso de que se evalúe algún proyecto del que un miembro sea investigador/colaborador, éste se ausentará de la reunión durante la discusión del proyecto.

Lo que firmo en Barcelona a 04 de agosto de 2014

NOMBRE FUENTES CAMPS INMACULADA - NIF 46228895E

Dra. Inmaculada Fuentes Camps

Secretaria en funciones

2

9. Annex III: Ethical approval of Campden BRI

(Nothing to attach for Year 20013-2014)

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