Grant Agreement No: 611366*

PREventive Care Infrastructure based on Ubiquitous Sensing

Instrument: Collaborative Project

Seventh Framework Programme (FP7) Call FP7-2013-10

3rd annual ethical and privacy report for PRECIOUS development & implementation

Due date of deliverable: 31/10/2016

Actual submission date: 31/10/2016

Start date of project:	November 1st 2013
Duration:	36 months
Project Manager:	Professor Jörg Ott
Revision:	V1.0

Abstract

The purpose of this deliverable is to highlight the ethical and privacy issues within the project, which have arisen during the third and last year of its development and implementation. As part of the development of the PRECIOUS service, it is necessary to collect and store personal data from users, and participants in studies within the PRECIOUS project. Therefore, ethical approvals and amendments from appropriate ethics committees have been requested during the third year and are presented in this deliverable.

* ***Funding:*** The PRECIOUS project (**PRE**ventive **C**are **I**nfrastructure based **O**n **U**biquitous **S**ensing (PRECIOUS): Grant Agreement No. 611366) is a project supported by the European Commission through the seventh Framework programme (FP7). PRECIOUS has eight beneficiaries from six countries (FI, UK, ES, AT, FR, BE) and is coordinated by AALTO-Korkeakoulusaatio (FI).

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WP number and title:	3rd annual ethical and privacy report for PRECIOUS development and implementation
Deliverable leader	Fundació Hospital Universitari Vall d'Hebron-Institut de Recerca (VHIR)
Authors & contributors	Charlotte Holmes (UK, Campdem BRI) Ari Haukkala (FIN, UH) Carmina Castellano (ES, VHIR)
Status:	Final report

Document History

Date	Version	Status	Change
15.09.2016	0.1	Draft	Draft version sent to consortium for comments
25.10.2016	0.2	Draft	Updates following consortium comments and updates
26.10.2016	0.3	Draft	Draft submitted to QEG
31.10.2016	0.4	Final	Final version submitted to EC

Peer Review History

Date	Version	Reviewed By
26.10.2016	0.3	PRECIOUS Quality Evaluation Group: Charlotte Holmes, Edward Mutafungwa

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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

MI: Motivational Interviewing

PRECIOUS: PREventive Care Infrastructure based On Ubiquitous Sensing

REC: Research Ethics Committee

T2D: Type 2 diabetes

1. Executive summary

The main objective of the PREventive Care Infrastructure based On Ubiquitous Sensing (PRECIOUS) project is to provide a preventive health care system that will foster healthier lifestyles and as a consequence, that will improve the health of the user. It is also expected that this solution will provide 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 (BodyGuard 2, PRECIOUS app, sensors).

Research within the project has been conducted with different types of participants, and a number of ethical issues have been identified with respect to the PRECIOUS system. All these issues along with the measures that have been incorporated to ensure safeguarding, confidentiality and anonymity for participants and users have been outlined in the *1st annual ethical and privacy report for PRECIOUS development & implementation* and the *2nd annual ethical and privacy report for PRECIOUS development & implementation*, as well as in Deliverable 2.4 (*Ethical and privacy guidelines for PRECIOUS system implementation*).

The **target audience** for this deliverable 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.
- Other projects dealing with similar topics (especially EC-funded projects) that could benefit from the discussion and relevant guidelines presented in this deliverable and the above mentioned previous related deliverables.

2. Background

2.1 Ethics for research studies with human participants

Full details of the ethics associated with research studies being conducted in year 3 are detailed in the *1st annual ethical and privacy report for PRECIOUS development & implementation*, however key aspects have been summarised below.

Within PRECIOUS a number of research studies have been conducted with voluntary participants and clinical samples with adult volunteers. 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]) have been followed in all cases.
Additionally, all PRECIOUS partners have always respected the Helsinki Declaration in its latest version[3] and have followed the ethical guidelines provided by their national scientific societies and their local research institutions (see section 4 of the present deliverable for further details concerning year 3 specific actions). All field studies included in the PRECIOUS service development and implementation have been presented in advance to local research ethics committees (REC) for approval.
American Psychological Association's Ethics Code[4] (and similar guidelines for research studies with adult human volunteers) mandates that researchers 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. All these actions have been performed within PRECIOUS field / pilot tests.

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

Full details of the ethics related to the PRECIOUS service are detailed in the *first* and *second annual ethical and privacy report for PRECIOUS development & implementation* and in D2.4 (*Ethical and privacy guidelines for PRECIOUS system implementation*). Following the report of the issues highlighted in the 2nd annual review, no further ethical aspects were identified and no additional actions have been necessary.

4. Ethical approval for executed field / pilot tests within November 2015 – October 2016

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

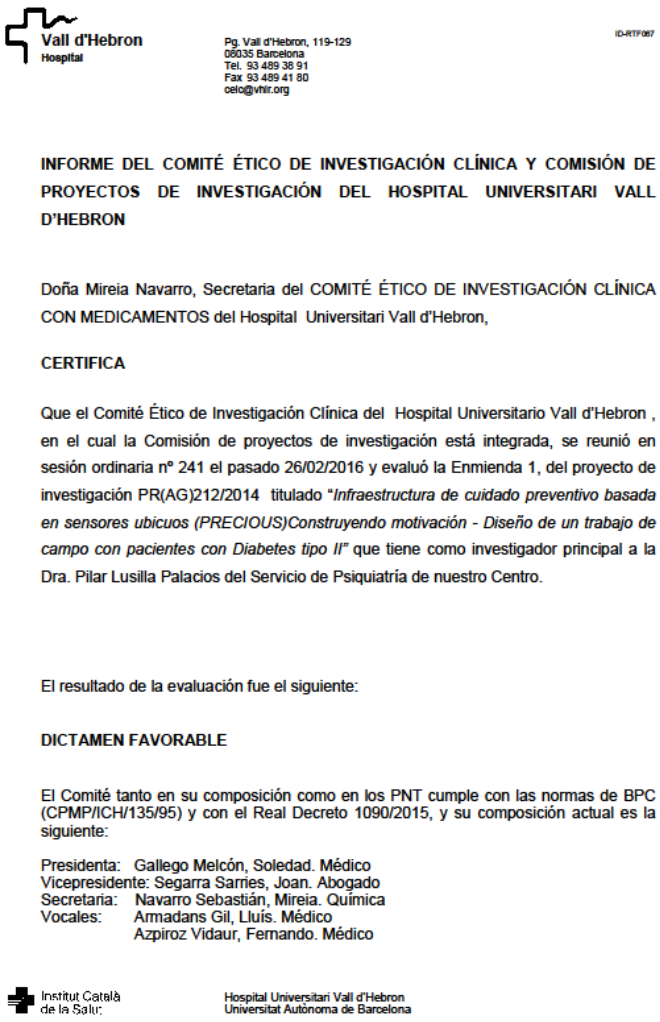
Procedures and general ethical guidelines relevant to each organisation and approximate approval timeframes have been detailed in the 1st and 2nd annual ethical report. In subsections below are detailed additional ethical actions performed during year 3.

4.1 Ethical amendment in VHIR (Spain) pilot test

As part of Task 5.3. (*Motivational system for behaviour change valuation plan*), VHIR has conducted a pilot test to assess users' overall satisfaction, usability and acceptability of the PRECIOUS system, and to explore if motivational interviewing (MI) in combination with gamification principles is a feasible solution to foster adherence to PRECIOUS system in a sample of end users. During the first year of the project the REC was sought presenting all relevant information to carry out this pilot test (first date of documentation presentation 1st July 2014 – approval 25th July 2014).

During the second year of PRECIOUS project, the PRECIOUS' consortium has continued to carry out all the tasks planned in the DoW in relation to the design and implementation of the system. As a result of these activities, parts of the system functionality have been defined and modified according to information obtained by different use case scenarios,

requirements, and focus groups carried out in different countries. These results have demonstrated that the design of the system, as it is defined to date, January 2016, is best suited to the needs and profile of morbidly obese pre-diabetic patients, rather than Type 2 diabetes (T2D) patients. This is mainly due to the approach of the system and the type of selected target behaviors (diet and physical activity) addressed within PRECIOUS. This situation has forced us, after careful study to reach consensus with the rest of the consortium, to change our initially planned target sample, already approved by the VHIR REC. Therefore, during January 2016 an amendment to VHIR ERC was presented to modify the inclusion and exclusion criteria of the sample and some measures. All other aspects, however, were not greatly affected. In this sense, the recruitment service of the sample has remained the same (Department of Endocrinology, University Hospital Vall d'Hebron – General Area, Dra. Andreea Ciudin & Gemma Parramón-Puig). The approval of such amendment was obtained in February 2016 (see Figure 1).



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

Doña Mireia Navarro, Secretaria del COMITÉ ÉTICO DE INVESTIGACIÓN CLÍNICA CON MEDICAMENTOS del Hospital Universitari Vall d'Hebron,

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 241 el pasado 26/02/2016 y evaluó la Enmienda 1, del proyecto de investigación PR(AG)212/2014 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 a la Dra. Pilar Lusilla Palacios del Servicio de Psiquiatría de nuestro Centro.

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 1090/2015, 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

Institut Català de la Salut

Hospital Universitari Vall d'Hebron
Universitat Autònoma de Barcelona

Figure 1. Approval of the VHIR pilot test amendment.

4.2 Ethical review in Campden BRI (UK) field study

This year as part of Task 5.4, Campden BRI has conducted a field study that will investigate whether the motivational aspects of the PRECIOUS food intake tool have an impact on user usage and perceived motivation. The study will also assess the usability of the mHealth tool. This study will assess two different elements of the overall food intake tool: 1) a food diary and 2) the diet challenges, with each aspect being assessed by sixty participants divided into four groups. All four groups (a minimum of 30 participants) will firstly complete an online attitudinal questionnaire. On completion of this questionnaire they will then download and use either the diary aspect (group 1 & 2) or fruit and vegetable challenge aspect (group 3 & 4) of the PRECIOUS food intake tool for 14 days. At day 7, the participants will be asked to complete a further attitudinal questionnaire and a usability questionnaire. After day 7, the experimental groups using each of the app elements (food diary and fruit and vegetable challenge) will have the motivational aspects of the PRECIOUS tool switched on. On Day 14 all participants will be required to complete a further attitudinal questionnaire and usability questionnaire. During the 14 day trial period usage data from the app will also be collected (downloaded directly from the PRECIOUS server).

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

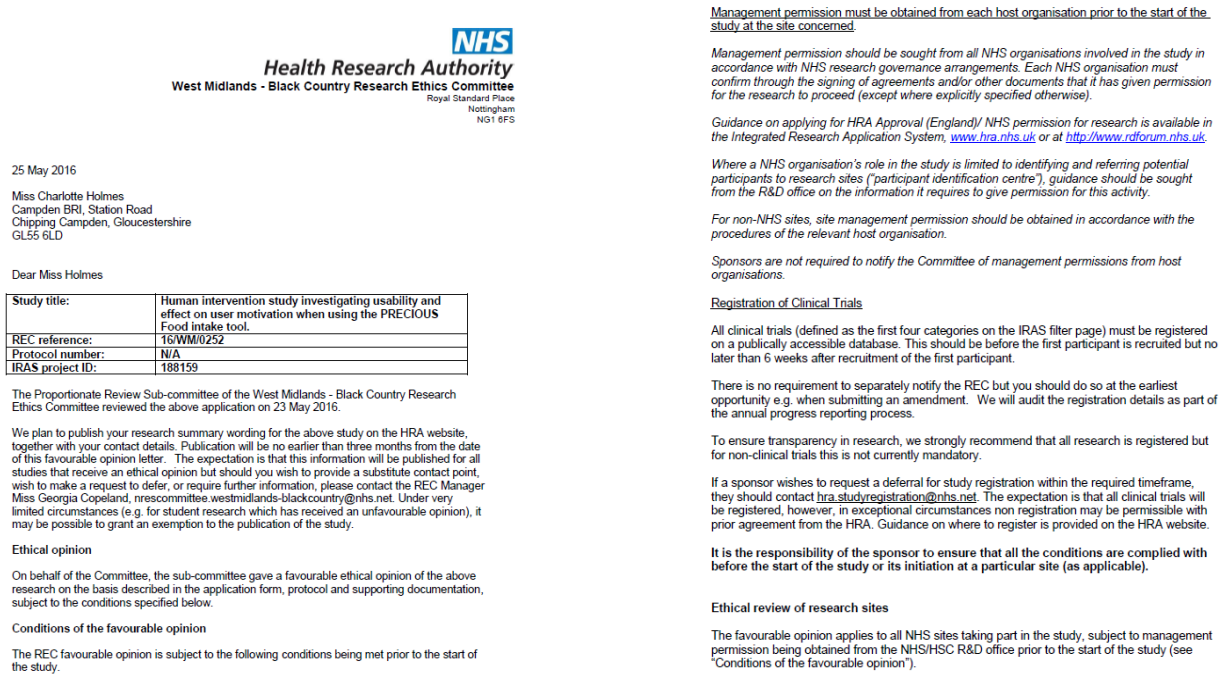
None of these RECs apply directly to Campden BRI, which is an independent research business (not a Higher Education Institute), or to the field study, as it does not involve NHS patients or NHS sites, is not a gene therapy trial, is not social care research and is not funded by the Ministry of Defense.

Following consultation with the HRA and a NHS REC, it was deemed that the study should undergo ethical review. To apply for review by an NHS REC committee, an application form on the Integrated Research Application System (IRAS) has to be completed. This is a single system for applying for the permissions and approvals for health and social care / community care research in the UK. As part of this application form, a summary of the study and the

ethical, legal and management issues that may arise in the study and how they will be managed. It also requires submission of the following documents:

1. Recruitment Questionnaire
2. Invite Questionnaire
3. Participant Information sheet
4. Consent Questionnaire
5. Attitudinal and usability questionnaires
6. Protocol
7. Confirmation of Insurance
8. Covering Letter from Chief Investigator

Following initial review of the application it was deemed that the study presented no material ethical issues and was eligible for NHS REC Proportionate Review (http://www.hra.nhs.uk/resources/applying-to-recs/nhs-rec-proportionate-review-service/).
The study was then allocated for Proportionate Review by Proportionate Review Sub-committee of the West Midlands - Black Country Research Ethics Committee, who gave a favorable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation.



NHS
Health Research Authority
West Midlands - Black Country Research Ethics Committee
Royal Standard Place
Nottingham
NG1 6FS

25 May 2016

Miss Charlotte Holmes
Campden BRI, Station Road
Chipping Campden, Gloucestershire
GL55 6LD

Dear Miss Holmes

Study title:	**Human intervention study investigating usability and effect on user motivation when using the PRECIOUS Food intake tool.**
REC reference:	**16/WM/0252**
Protocol number:	**N/A**
IRAS project ID:	**188159**

The Proportionate Review Sub-committee of the West Midlands - Black Country Research Ethics Committee reviewed the above application on 23 May 2016.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Miss Georgia Copeland, nrescommittee.westmidlands-blackcountry@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Figure 2. Approval of the Campdem trial (I).

Summary of discussion at the meeting

The PR Sub-Committee agreed that this was a well presented study with no material ethical issues.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Covering letter on headed paper [Letter from Chief Investigator-Signed V1]	1	03 May 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [2016 summary of Insurance cover]	1	03 May 2016
IRAS Checklist XML [Checklist_17052016]		17 May 2016
Letter from sponsor [Letter from Sponsor- Signed V1]	1	04 May 2016
Letters of invitation to participant [Annex 1 Recruitment Invite Screener V10]	10	03 May 2016
Non-validated questionnaire [Annex 5 Questionnaire Day 0 V6]	6	03 May 2016
Other [Annex 7 Questionnaire Day 7 V5]	5	03 May 2016
Other [Annex 8 Questionnaire Day 14 V6]	6	03 May 2016
Other [Annex 6 Invite to participate and download app V8]	8	03 May 2016
Other [Principle Investigator CV 2015]	1	03 May 2016
Other [Annex 2 Invite to Participate V9]	9	03 May 2016
Other [pre validation correspondence - e-mail]		17 May 2016
Other [PRECIOUS Food intake Tool Desginer's desgins]	1	17 May 2016
Participant consent form [Annex 4 Consent form V10]	10	03 May 2016
Participant information sheet (PIS) [Annex 3 Participant information V10]	10	03 May 2016
REC Application Form [REC_Form_16052016]		16 May 2016
Research protocol or project proposal [Protocol V15]	15	03 May 2016
Summary CV for Chief Investigator (CI) [Chief Investigators CV]	1	03 May 2016

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

16/WM/0252 **Please quote this number on all correspondence**

Yours sincerely

PP

Reverend Keith Lackenby
Acting Chair

Email: nrescommittee.westmidlands-blackcountry@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

"After ethical review – guidance for researchers"

West Midlands - Black Country Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting on 23 May 2016

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Chris Bell	Lay Member	Yes	
Reverend Keith Lackenby (Acting Chair)		Yes	
Mr Nanak Singh Sarhadi	Consultant Plastic Surgeon	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Lindsey Wallace	REC Assistant

Figure 3. Approval of the Campdem trial (II).

4.3 Ethical review in University of Helsinki (Finland) field study

University of Helsinki has leaded field trial 5.2 "Effects of motivational and self-regulation components on physical activity and diet". In this trial we are examining how certain components of the PRECIOUS application combine to foster motivation for behavior change, engagement with self-regulation components (e.g., goal setting) and behavior change itself,

with a particular focus on physical activity. The trial examines the effects of motivational interviewing components and Firstbeat biofeedback, and the effects of notifications to prompt goal setting and action planning on behavioral performance.

University of Helsinki consulted the Hospital District of Helsinki and Uusimaa (HUS) regional ethical committee if the study belonged to the medical research review board (Medical Research Act No488/1999) to clarify if heart rate variability measures from Firstbeat biofeedback (BodyGuard2) create a situation that required special ethical consideration. The medical review board from HUS directed this issue to University of Helsinki Ethics review board in the humanities and social and behavioural sciences. The grounds for request ethical review board were based on two reasons a) The funding agency or cooperation partner requires an ethical review and b) The results are to be published in a scientific journal which requires ethical reviews. Applications include: research proposal, assessment of the ethics of the study, information letter to the research subjects, consent form to be signed by the research subjects, questionnaires and data management plan. Based on this board, Helsinki University obtained favorable statement in January 2016 (see Figure 4).

Helsingin yliopiston
ihmistieteiden eettisen
ennakkoarvioinnin toimikunta

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

Lausunto/Statement
3/2016

EETTINEN ENNAKKOARVIOINTILAUSUNTO

Helsingin yliopiston ihmistieteiden eettisen ennakkoarvioinnin toimikunta on kokouksessaan 8.12.2015 arvioinut Ari Haukkalan ja hänen tutkimusryhmänsä tutkimusta "PREventive Care Infrastructure based On Ubiquitous Sensing (PRECIOUS)": 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 Ari Haukkalas and his research group's study "PREventive Care Infrastructure based On Ubiquitous Sensing (PRECIOUS)" in the board meeting on the 8th of December 2015. 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 27.1.2016

Johanna Väyrynen
Sihteeri / secretary

HELSINGIN YLIOPISTO
HELSINGFORS UNIVERSITET
UNIVERSITY OF HELSINKI

Figure 4. Ethical approval of the HU pilot.

5. Summary

The present deliverable is aimed at providing insights and relevant ethical issues raised during the third and last year of PRECIOUS service development and implementation, 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 all the field and pilot tests has been obtained for all partners involved in such activity and all of them have been presented in the first and second ethical and privacy reports, as well as, 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.

6. References

1. The Charter of Fundamental Rights of the European Union signed and proclaimed on 7 December 2000. Retrieved in October 2014, from: http://www.europarl.europa.eu/charter/default_en.htm

2. 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 (http://ec.europa.eu/justice/data-protection/index_en.htm)

3. The Declaration of Helsinki in its latest version. Retrieved in October 2014, from: http://www.wma.net/en/30publications/10policies/b3/index.html

4. Ethical Principles of Psychologists and Code of Conduct, including 201 amendments. Retrieved in October 2014, from: http://www.apa.org/ethics/code/index.aspx