Grant Agreement No: 611366

PREventive Care Infrastructure based on Ubiquitous Sensing

Instrument: Collaborative Project

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

2nd annual ethical and privacy report for PRECIOUS development & implementation

Due date of deliverable: 31/10/2014

Actual submission date: 04/01/2016

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 second 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 from appropriate ethics committees have been requested and current approvals are presented in this deliverable. A further ethical report will be produced in October 2016, to summaries the ethical and privacy considerations taken in the final year of the project.

Nature:	R (R: Report, P: Prototype, O: Other)
Dissemination Level:	PU (CO: Confidential, PU: Public)
Version:	1.0
Date:	04.01.2016
WP number and title:	2nd annual ethical and privacy report for PRECIOUS development and implementation
Deliverable leader	Fundació Hospital Universitari Vall d'Hebron-Institut de Recerca (VHIR) & Helsinki University (HU)
Authors	Charlotte Holmes (Campden BRI) Contributors: Carmina Castellano (VHIR), Pilar Lusilla (VHIR), Christophe Lohr (IMT), Mathieu Simonnet (IMT) and Phillppe Tanguy (IMT)
Status:	Final report

Document History

Date	Version	Status	Change
17.11..2015	0.1	Draft	Draft version sent to consortium for comments
30.11.15	0.2	Draft	Updates following consortium comments and updates
11.12.15	0.3	Draft	Draft submitted to QEG
01.04.16	1.0	Final	Final version submitted to EC

Peer Review History

Date	Version	Reviewed By
15.12.15	0.3	PRECIOUS Quality Evaluation Group

Table of Contents

List of acronyms

CNIL: National Commission for Data Protection and Liberties
Dow: Description of Work packages
EC: European Commission
EU: European Union
FP7: Seventh Framework Programme
HRA: Health Research Authority
IRAS: Integrated Research Application System
NHS: National Health Service
PRECIOUS: PREventive Care Infrastructure based On Ubiquitous Sensing
REC: Research Ethics Committee

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 will be conducted with participants, and in addition to this a number of ethical issues have been identified with respect to the PRECIOUS system. This research and the relevant issues are outlined below, along with the measures that have been incorporated to ensure safeguarding, confidentiality and anonymity for participants taking part in the research and potential users of the PRECIOUS system. 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) and the first annual ethical report.

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

Full details of the ethics associated with research studies being conducted in year 2 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 will be conducted with 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 healthy volunteers. Informed consent will be obtained in all cases.

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.

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

Following the review of the issues highlighted in the 1st annual ethical and privacy report for PRECIOUS development & implementation, no further issues were identified in year two.

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 IMT

The CNIL, a National Commission for Data Protection and Liberties, is in charge of French citizen data protection.

According to the law “Article 36 de la loi 78-17 modifiée” , it is not necessary to claim any data whether these data are anonymous, not sensible (no medical data) and will be only use for scientific objective.

Since IMT “sensors acceptability” experimentation does store any medical data and only poses questions about usability preference, no ethical approval is necessary and thus no specific claim to the CNIL is intended.

4.2 UK-Campden BRI

This year as part of Task 4.3b, Campden BRI has lead a field study that will investigate the usability of two freely available mobile health tools currently on the market, and one mobile health tools currently being developed through a EC-FP7 project. The study will look at the factors that affect the usability of each mobile health tool for different user groups.

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 organisation (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.

Following consultation with the HRA and a NHS REC panel member, 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. Emails to participants
6. Usability Questionnaire
7. Protocol
8. Confirmation of Insurance
9. 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 a sub-committee of the Wales REC 7, who 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;

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

1. The Information Sheet should outline that participants' direct quotes will be used in the findings report and that, although every effort would be made to anonymise what has been said, it may still be possible to be identified.
2. The online consent should also outline the above

Following discussion with the ethical board, the below procedure was agreed to mitigate the conditions of favourable approval raised;

Any quotes used, were to be generic in nature, and relate directly to the apps only. Campden BRI would screen any quotes potentially being used to ensure that the individual can not be identified from the extract being using, and any quotes where Campden BRI believed there is the slightest risk that the identity of an individual could be determined, would not be published.

Based on this a favourable opinion was awarded.

5. Summary

The present deliverable is aimed at providing insights and relevant ethical issues raised during the second year of PRECIOUS service development, in order to ensure that PRECIOUS meets the required ethical, legal and privacy requirements. 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.

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**

7. Annex I: Ethical approval of Human intervention study investigating the usability of mobile health tools to monitor food intake and physical activity for different user groups- Decision letter from Proportionate Review Sub-Committee of the Wales REC 7

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Gwasanaeth Moeseg Ymchwil
Research Ethics Service

Ariennir gan **Lywodraeth Cymru**
Funded by **Welsh Government**

WALES REC 7
PO Box 108
Building 1
St David's Park
Jobswell Road
Carmarthen
SA31 3WY

Tel: 01267 225045
Email: sue.byng@wales.nhs.uk

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

8 October 2015

Dear Miss Holmes

Study title:	**Human intervention study investigating the usability of mobile health tools to monitor food intake and physical activity for different user groups.**
REC reference:	**15/WA/0379**
Protocol number:	**N/A**
IRAS project ID:	**188160**

The Proportionate Review Sub-committee (PRSC) of the Wales REC 7 reviewed the above application on 07 October 2015.

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 Ms Sue Byng. 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.
The Committee has considered and reviewed the project as research and given the ethical opinion detailed below. However, we note that NHS ethical review was not required as participants are voluntary members of a consumer panel for a commercial food science and technology company.

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

1) The Information Sheet should outline that participants' direct quotes will be used in the findings report and that, although every effort would be made to anonymise what has been said, it may still be possible to be identified.
2) The online consent should also outline the above.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

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

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System 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 approvals 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").

Summary of discussion at the meeting (if applicable)

Social or scientific value; scientific design and conduct of the study

The PRSC queried if this application needed ethical review as the participants appeared to be voluntary members of a consumer panel for a commercial food science and technology company. They are not NHS patients and this study does not use NHS facilities. The participants are not being recruited because of any illness and are not having any treatment. *Miss Charlotte Holmes responded that the only reason they were seeking NHS ethical review was because the new app is funded by European money and ethical review was a requirement of the process.*

Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity

The PRSC noted the application stated that direct quotes would be used but there was no mention of this in the Participant Information Sheet (PIS) or online consent. Therefore, the PIS should outline that participants' direct quotes would be used in the findings report and that, although every effort would be made to anonymise what has been said, it may still be possible to be identified.

Informed consent process and the adequacy and completeness of participant information

The PRSC noted the PIS was not prepared in the standard NHS format although the CI had apparently referred to the HRA standard template. It was decided the content was satisfactory.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Covering letter on headed paper		28 September 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		02 January 2015
IRAS Checklist XML [Checklist_01102015]		01 October 2015
Letter from sponsor		28 September 2015
Letters of invitation to participant [Recruitment Questionnaire] Annex 1	5	28 September 2015
Questionnaire (invitation to complete Annex 6	5	28 September 2015
Invite Questionnaire (having completed the recruitment survey) Annex 2	5	28 September 2015
Participant information sheet – (Participant background information) - Annex 3	5	28 September 2015
App download instructions	2	28 September 2015
CV – Dr Sarah Thomas		Undated
Participant consent form	3	28 September 2015
REC Application Form [REC_Form_01102015]		01 October 2015
Research protocol or project proposal	5	28 September 2015
Summary CV for Chief Investigator (CI) Charlotte Holmes		28 September 2015

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.

15/WA/0379	**Please quote this number on all correspondence**

Yours sincerely

pp. Dr Gareth Davies
Chair

Email: sue.byng@wales.nhs.uk

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

"After ethical review – guidance for researchers"

Copy to: *Mrs Claire Cairns*

Wales REC 7

Attendance at PRS Sub-Committee of the REC meeting on 07 October 2015

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Gareth Davies	Principal Public Health Intelligence Analyst / Chair	Yes	
Mr Dennis Evans	Lay member	Yes	
Mr Derek Lassetter	Lay member / Vice-Chair	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Sue Byng	REC Manager

8. Annex 2: Ethical approval of Human intervention study investigating the usability of mobile health tools to monitor food intake and physical activity for different user groups- Acknowledgement of additional conditions' letter from Proportionate Review Sub-Committee of the Wales REC 7

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Gwasanaeth Moeseg Ymchwil
Research Ethics Service

Ariennir gan Lywodraeth Cymru
Funded by Welsh Government

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Tel: 01267 225045
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Miss Charlotte Holmes
Campden BRI
Station Road
Chipping Camden
Gloucestershire
GL55 6LD

15 October 2015

Dear Miss Holmes

Study title: **Human intervention study investigating the usability of mobile health tools to monitor food intake and physical activity for different user groups**
REC reference: **15/WA/0379**
IRAS project ID: **188160**

I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 8 October 2015.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant Background Information	6	15 October 2015
Online Consent	6	15 October 2015

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Covering letter on headed paper		28 September 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		02 January 2015
IRAS Checklist XML [Checklist_01102015]		01 October 2015
Letter from sponsor		28 September 2015
Letters of invitation to participant [Recruitment Questionnaire] Annex 1	5	28 September 2015
Questionnaire (invitation to complete Annex 6)	5	28 September 2015
Invite Questionnaire (having completed the recruitment survey) Annex 2	5	28 September 2015
Participant information sheet – (Participant background information) - Annex 3	6	15 October 2015

App download instructions	2	28 September 2015
CV – Dr Sarah Thomas		Undated
Online consent	6	15 October 2015
REC Application Form [REC_Form_01102015]		01 October 2015
Research protocol or project proposal	5	28 September 2015
Summary CV for Chief Investigator (CI) Charlotte Holmes		28 September 2015

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

15/WA/0379	**Please quote this number on all correspondence**

Yours sincerely

Ms Sue Byng
REC Manager

Copy to: *Mrs Claire Cairns*