DAPHNE

Data-as-a-service platform for healthy lifestyle and preventive medicine

DAPHNE

Data-as-a-service platform for healthy lifestyle and preventive medicine

610440

D10.2 Ethical monitoring report

Lead Author: Melania Manco (OPBG) & Giulia Cinelli (OPBG)

With contributions from: -

Reviewer: Tim Lobstein

Deliverable nature:	Report (R)
Dissemination level: (Confidentiality)	Public (PU)
Contractual delivery date:	31st Oct, 2014
Actual delivery date:	29th Oct, 2014
Version:	1.0
Total number of pages:	17
Keywords:	Data Protection Directive; Ethical issue management; Privacy; Security Regulation; Electronic Health Record.

Abstract

The D10.2 reports on the main ethical issues raised in the first year of the DAPHNE project and action taken to manage them. Issues concerned sensitive data protection and privacy regulation, ethical conducts for clinical research in humans. .

Executive summary

Deliverable D10.2 addresses the ethical issues specific to using the ICT (Information and Communication Technologies) developed in the DAPHNE project.

Safeguarding confidential patient/user information is one of the biggest challenges for the adoption of ICT in the healthcare system. The challenge is even bigger considering that patients/users will be minors too.

The DAPHNE system needs different type of input data; produces a variety of output data and it acts in different scenarios. Hence, different actions have to be thought and implemented to address and overcome ethical issues. Scenarios encompass the use of the DAPHNE system for clinical purposes with sharing of data limited between patient and doctor; for medical research or business intelligence use, with exchange of anonymous data and statistics.

The scope of the task is to identify the main ethical issues raised in the DAPHNE project in terms of data collection, privacy and protection, accessibility and disclosure, so that anonymity and confidentiality of patients/users can be ensured. It also takes into account the sensitive output data derived from psychological and nutritional assessment and the case in which children are involved.

Finally, this report explains the actions developed to manage ethical constraints, evaluating the ethical procedures followed in the UNIVLEEDS and UPM pilot tests for cycle 1.

Document Information

IST Project Number	610440	**Acronym**	DAPHNE
Full Title	Data-as-a-service platform for healthy lifestyle and preventive medicine		
Project URL	http://www.daphne-fp7.eu/		
Document URL			
EU Project Officer	Mr. Benoit Abeloos		

Deliverable	**Number**	D10.2	**Title**	Ethical monitoring report
Work Package	**Number**	WP10	**Title**	Project management

Date of Delivery	**Contractual**	M12	**Actual**	M12
Status	version 0.1		final ■	
Nature	prototype □ report ■ demonstrator □ other □			
Dissemination level	public ■ restricted □			

Authors (Partner)	Melania Manco (OPBG), Giulia Cinelli (OPBG)			
Responsible Author	**Name**	Melania Manco	**E-mail**	melania.manco@opbg.net
	Partner	OPBG	**Phone**	00390668592649

Abstract (for dissemination)	The present deliverable examines the main ethical issues raised in the project, concerning data protection, privacy regulation, sensitive output data and ethical procedures followed in the pilot tests. The deliverable further explains actions developed to manage them.
Keywords	Ethical Issues Management

Version Log			
Issue Date	**Rev. No.**	**Author**	**Change**

Table of Contents

List of figures

Abbreviations

DaaS: Data as a Service

EGE: European Group on Ethics in Science and New Technologies

EHR: Electronic Health Records

FFQs: Food Frequency Questionnaires

FP7: The 7th Framework Programme for Research and Technological Development

HCPs: Health Care Professionals

ICT: Information and Communication Technologies

MDR: Medical Device Records

OPBG: Ospedale Pediatrico Bambino Gesù

PHR: Personal Health Records

PHS: Personal Health Service

UNIVLEEDS: University of Leeds

UPM: Universidad Politécnica de Madrid

1 Introduction

1.1 Ethical principles for clinical research in humans

Fundamental ethical principles, included those reflected in the Charter of Fundamental Rights of the European Union1, must be respected in any kind of clinical research involving human beings.

To protect and guaranty people rights, every kind of study that involves human participants needs to go through a formal process of ethics review.

In particular, depending on the case, different ethical issues can come to light in a research project. Basic principles that must be ensured in doing research in humans are the following:

- Voluntary participation. It is important that people are not forced into participating, but voluntarily decide to do that.

- Informed consent. It is necessary for participants to be fully informed about procedures, risks and benefits involved in the research. This should be made by signing a written informed consent.

- Autonomy. Participants must be made aware that they are free to withdraw from the study at any time, without giving a reason.

- Anonymity. Principle of anonymity means that the participant will remain anonymous throughout the study. This is possible removing participant's name from data, but it is not always easy to accomplish, especially in research studies requiring participant's multiple time-point evaluations.

- Confidentiality. Researchers must guarantee confidentiality in that participant's data must be collected anonymously and sensitive information (i.e. information that allow identifying the participant)not made available to anyone who is not directly involved in the study.

- Avoid causing harm. Researchers must reduce physical and psychological harm and risk for participants, optimizing on the other hand benefits derived from being involved in the study.

- Vulnerable groups. Particular care is needed when vulnerable groups (e.g. minors) are involved in the research.

  The application of ICT to clinical research in humans poses additional issues and concerns. To this regards, any research project dealing with ICT applied to research in humans must consider the recommendations of the European Group on Ethics in Science and New Technologies (EGE).

In particular, in the section dedicated to ICT and eHealth, from the Ethical Guidelines for undertaking ICT research in FP72, it has been stated:.

- "ICT implants should only be developed if the objective cannot be achieved by less-invasive methods such as wearable computing devices. To the extent that an individual, via an ICT implant or wearable computing device, becomes part of an ICT network, the operation of this whole network will need to respect privacy and data protection requirements.
- ICT implants in healthcare are, in general, acceptable when the objective is saving lives, restoring health, or improving the quality of life. They should be treated in the same way as drugs and medical devices.
- ICT implants to enhance human capabilities should only be developed: to bring individuals into the "normal" range for the population, if they so wish and give their informed consent; or to improve health prospects such as enhancing the immune system. Their use should be based on need, rather than economic resources or social position.
- ICT implants or wearable computing devices must not: allow individuals to be located on a permanent and/or occasional basis, without the individual's prior knowledge and consent; allow information to be changed remotely without the individual's prior knowledge and consent; be used

to support any kind of discrimination; be used to manipulate mental functions or change personal identity, memory, self-perception, perception of others; be used to enhance capabilities in order to dominate others, or enable remote control over the will of other people.

- ICT implants should not be developed to influence future generations, either biologically or culturally.
- ICT implants should be developed to be removed easily.
- The use of personal health data in ICT research for the purposes from which society as a whole benefits must be justified in the context of the personal rights.
- The security of ICT in healthcare is an ethical imperative to ensure the respect for human rights and freedoms of the individual, in particular the confidentiality of data and the reliability of ICT systems used in medical care".

1.2 Scope

The present deliverable's overall aim is to identify the main ethical issues raised in the DAPHNE project with regard to the data collection, privacy and protection, accessibility and disclosure, so that anonymity and confidentiality of patient/user data can be ensured. It also takes into account the cases in which children are involved and the sensitive output data derive from psychological and nutritional assessment.

Finally this report explains the actions developed to manage ethical constraints, evaluating the ethical procedures followed in the UNIVLEEDS and UPM pilot tests for cycle 1.

2 Ethical issues in the DAPHNE project

The main ethical issues, raised in the DAPHNE project concerned data protection and privacy regulation, sensitive output data derived from the scoring of psychological tests and nutritional analysis, and the involvement of children in the study.

2.1 Data protection and privacy regulation

Data and privacy protection is a fundamental right to be considered in ICT research and have been widely examined in D2.2 by ATOS. In particular, different European directives which regulates the protection and privacy of sensitive data within the European Union have been considered.

Concerning the directives' key principles and the different kind of data collected in the DAPHNE project, D2.2 highlights what is required in DAPHNE DaaS (Data as a Service) service to ensure data anonymity and confidentiality.

DAPHNE will handle personal health data, which are classified as sensitive data, so it is important that the service follows the EU directives but also it takes into account the specific national legislation.

Hence, some of the actions to be considered in managing health data are the following:

- Explicit consent of each user for the processing, storing and access to their data must be obtained (both for medical and non-medical data)
- Electronic Health Records (EHR) as well as Personal Health Records (PHR) and possibly Medical Device Records (MDR) is needed
- The different scenarios must been established, clarifying, for each one, data controller(s) and processor(s).
- Health data could be split into different categories depending upon their sensitivity so that the patient can determine by "opt-in" measures what type of sensitive data to include in the EHR and opt-out measures for less sensitive data such as wellbeing data.
- Any person acting under the authority of the controller or of the processor, including the processor himself, who has access to personal data must not process them except on instructions from the controller, unless he is required to do so by law.
- The data is only handled by authorised personnel and data subjects have access to health records to see his/her data and who was responsible for adding or accessing it.
- Patient has the right to withdraw from the service at any time

For a deep discussion and more detailed definitions about data protection and privacy regulation please refer to deliverable D2.2.

2.1.1 Informed consent

Informed consent is required for every kind of research in which participants are involved. It is a tool through which volunteers are fully informed about: the study purposes and procedures; the way they are involved in; the risks and the benefits derived from it; the data collection, privacy and protection, accessibility and disclosure. Participants has the right to decide what kind of data they want to share and to know they are free to take back their consent and opt-out of the trial at any time.

Informed consent must be written in a way that participants understand and must be obtained before the starting of the study.

"In the case of a legally incapacitated person who is incapable of free decision, and when domestic law does not permit the data subject to act on his/her own behalf, informed consent must be signed by the person recognised as legally entitled to act in the interest of the data subject or of an authority or any person or body provided for by law" (Deliverable D2.2 – ATOS).

In the case of children, instead, parents or caregiver must sign the informed consent, but the minor must provide his/her informed assent

For what concerns the DAPHNE project, informed consent must be obtained in all the three different cycle.

In cycle 1, volunteers are enrolled by UPM and UNILEEDS for pilot tests, while in cycle 2 there will be patients' involvement (adolescents for OPBG). In both cycles 1 and 2, it has been decided, as deeply described in deliverable D2.3 (ATOS), that:

- "Volunteers/patients will be informed in a face-to-face meeting with medical staff, about purposes of the trial;
- If he/she agrees with the informed consent, he/she will sign it. Adolescents will provide their written assent.
- Volunteers/patients have totally full control of their data being free to share them with the doctor/health care provider at all times.
- They are free to take back their consent and opt-out of the trial at any time.
- They are free to consent or not to use their data. The opt-in consent for the BIG Data service can be presented as a tick box to make sure the patient would be fully aware of this service and that it is optional. Moreover it is recommended that the patient is able to choose which data sub-categories they want to make available to the Big Data service and with what type of organisations (this is fully configurable to opt-in or opt-out at any time through the use of tick).

On the other hand, in cycle 3; we expect that any person from any European country may try the DAPHNE system and access its web platform. Hence:

- Data protection and security regulation must be in accordance with European Laws, for the different countries involved.
- Volunteers/participants must be fully informed about the purposes of the research.
- Volunteers/participants have full control sharing or not their data at any time. They are free to take back their consent and opt-out of the trial at any time.
- Two check boxes - possibility of not sharing for big data purposes
- Use of digital signature or postal registration"

In particular, in the PHS, at the moment of registration, privacy and security options are given to the user. He/she will read the informed consent and accept or not the terms and conditions of the service (Figure 1). The user can opt to share only some of his/her personal data.

Figure 1 Privacy and security in the PHS

2.2 Sensitive output data

2.2.1 Psychological wellbeing

As stated in D1.4 "For what concerns test used to evaluate psychological wellbeing, no compulsory input data are required. Questionnaires designed to assess dimensions of mood, depression, anxiety, stress, and quality of life, will be used and will vary between clinical/research partners." As explained in D1.4 "questionnaires will be completed electronically or on paper by the patient/research participant or the patient's guardian. It is likely the HCPs or researchers will input the data to the DAPHNE system. Responses will be uploaded automatically or manually to the Daphne system where they will be converted to their total scores and subscale scores. Questionnaires should be completed at a minimum of two time points – at the beginning and the end of an intervention or treatment and/or prior to consultation with their physician."

What it is important in this project's section is the management of these measurements' feedback to participants, considering the fact that questionnaires regard depression/anxiety state and suicidal ideation/intent. Some suggestions concerning how to handle this part are shown below:

- Response came out from questionnaires should be used exclusively for research purposes, so that participants should not have a score back.
- In case of negative results (state of anxiety/depression/suicidal ideation or intent) some practise actions are needed.
    a) If questionnaires are completed in hospital HCPs can handle the situation by informing patients about results and giving recommendations for further examinations.
    b) If questionnaires are filled up electronically simple phrases could be delivered to users to invite them to ask for help (e.g. "I/WE are also concerned that your current situation may be causing you some anxiety and I/WE think you should talk to someone about it"). More over researchers should contact participants for further examinations.

Hence, it is necessary for participants to be informed that questionnaire's results will not be given to them and that it could be possible to be contacted for further examinations. This section should be included in the informed consent (both on paper and electronically) and should be remarked, in the PHS, in the first screen before the user starts to fill up questionnaires.

2.2.2 Nutritional assessment

Nutritional assessment is provided through the use of tools such as FFQ and food diary.
In the PHS, data derived from food diary are processed and feedback is given about daily calories intake (and expenditure in case of physical activity assessment) (figure 3). In children /adolescents it is not a good practice to talk explicitly about calories, because of the risk of incurring in obsessive behaviour and raising of eating disorders, most of all if we are dealing with overweight/obese people.

Hence, some suggestions concerning how to handle this part for children/adolescent are shown below:

- This section should be managed without expressing calories intake and expenditure.
- It is good to use of % of carbohydrates, fat and proteins from total energy intake, as a measurement of how much adequate eating behaviour is, compared to Mediterranean Diet recommendations.
- Energy intake and expenditure could be shown using coloured graphic in which users can clearly see if they are over/under/into the regular range for age/height/weight.
- Recommendations should be expressed in term of adequate eating habits (not health risks). E.g.: "You have reached your energy intake today!!" - "You have done all the 5 meals today..well done!!!" - "Remember that fruit is the best you can choose for morning and afternoon snacks!".

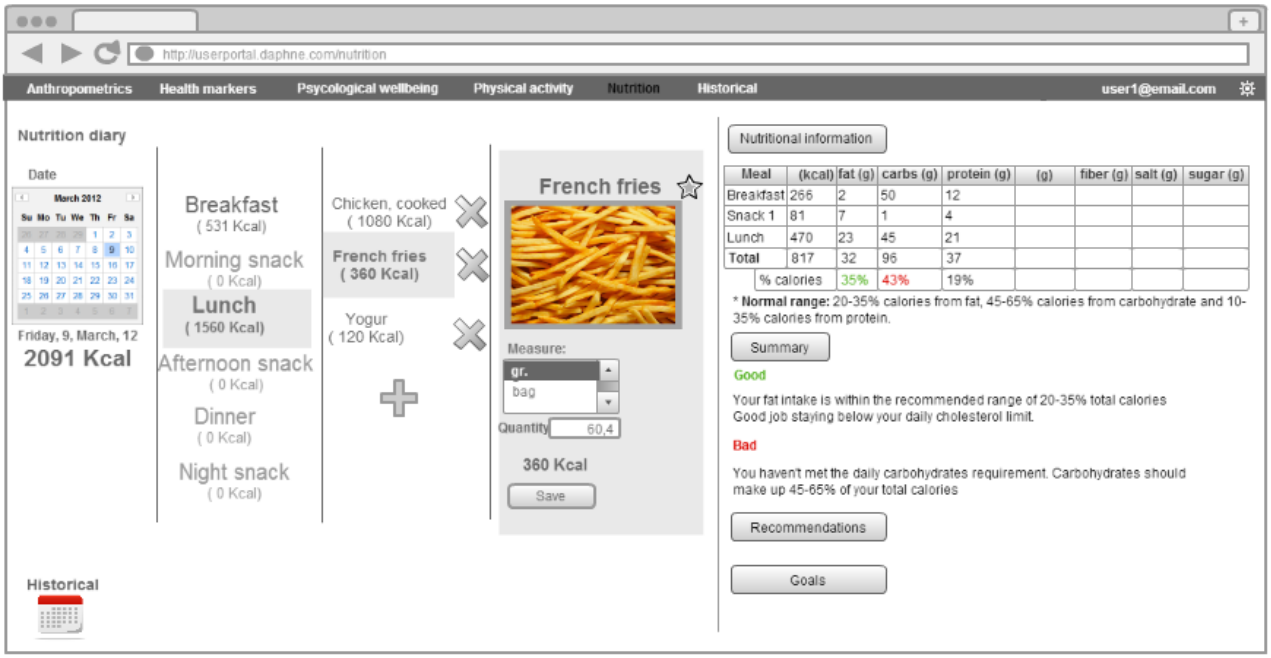


Figure 2 Nutritional assessment in the PHS

3 What if the participant is a minor?

Adolescents will be involved in the second cycle of the research project to test efficacy of the DAPHNE system. Minors belong to a vulnerable group since they lack mature decisional capacity, they are subject to parents' authority, they can act in a way that can mask underlying dissent, their rights, desires, needs and interests may be undervalued[3].

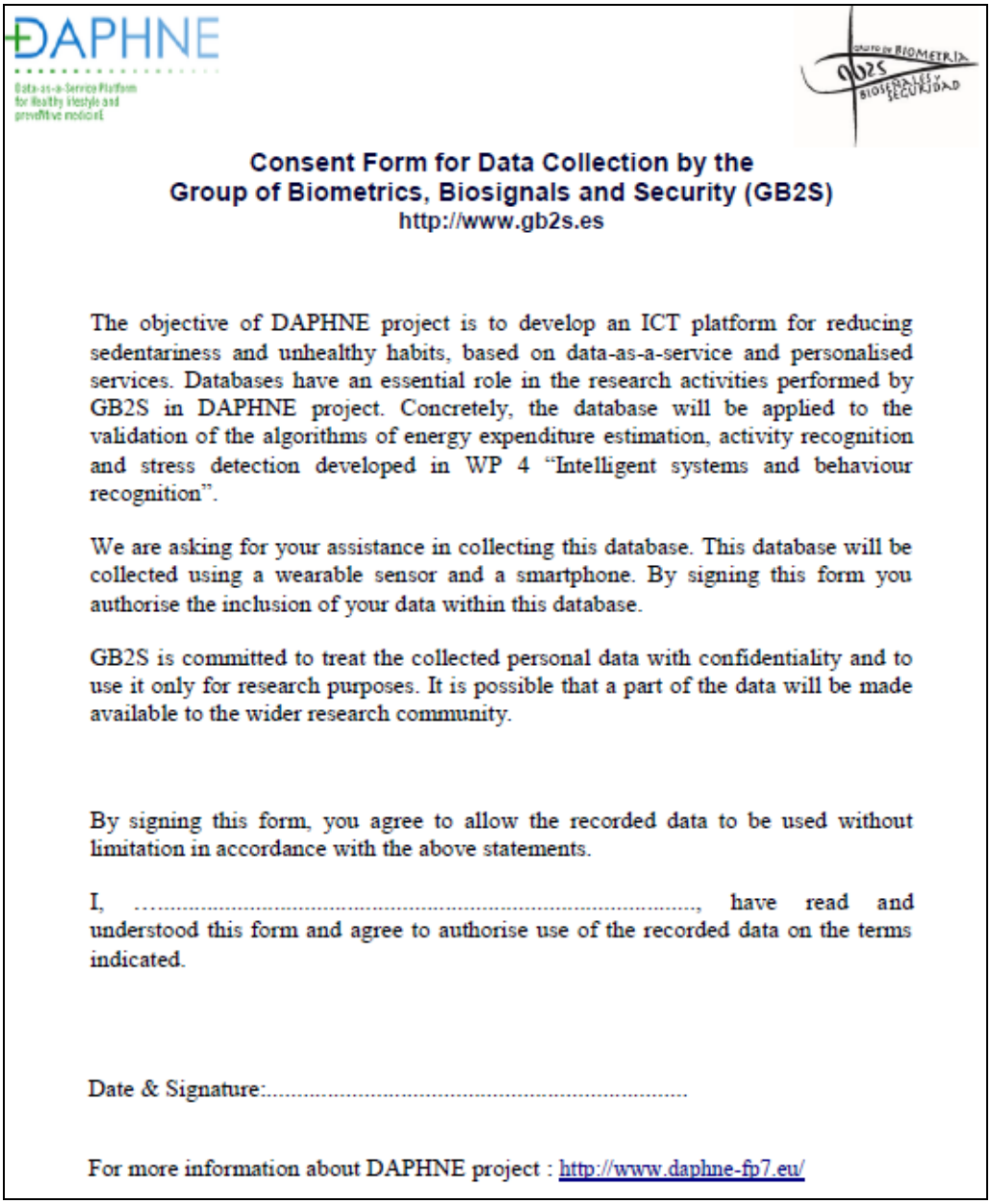
Hence, in case of minor's involvement, it is important to ensure the full respect of all the ethical principles and guidelines. First, it is necessary to guarantee non-maleficence and, conversely, beneficence of treatment, secured data management to ensure the user's anonymity and data confidentiality as stated in the informed consent. The minor should provide assent as well as the valid parents' consent should be obtained (or by any authorized representative) .

For the aforementioned reasons, the following actions should be considered:
- specific informed assent/consent should be obtained in a written form both by the minor and parents/caregivers;
- the document should be exhaustive in order to fully and deeply inform participants and parents covering all the aspects related to the research and in a language which easily intelligible and appropriate to the age of participants;
- once the minor registers in the PHS, the tutor/responsible guardian must provide consent as "informal caregiver";
- in the PHS, nutritional and psychological wellbeing assessment in minors should be differ from that of adults (as explained in D 2.2) in order to minimize risks.

4 Pilot tests ethical management

First cycle of validation is about testing designed concepts, ideas and user profiles through field trials. Clinical partners involved are university groups of UNIVLEEDS and UPM.

Informed consent document, that UPM will request to their volunteers in cycle 1 of testing, in shown in figure 2.



DAPHNE
Data-as-a-Service Platform for Healthy Lifestyle and preventive medicine

Consent Form for Data Collection by the Group of Biometrics, Biosignals and Security (GB2S)
http://www.gb2s.es

The objective of DAPHNE project is to develop an ICT platform for reducing sedentariness and unhealthy habits, based on data-as-a-service and personalised services. Databases have an essential role in the research activities performed by GB2S in DAPHNE project. Concretely, the database will be applied to the validation of the algorithms of energy expenditure estimation, activity recognition and stress detection developed in WP 4 "Intelligent systems and behaviour recognition".

We are asking for your assistance in collecting this database. This database will be collected using a wearable sensor and a smartphone. By signing this form you authorise the inclusion of your data within this database.

GB2S is committed to treat the collected personal data with confidentiality and to use it only for research purposes. It is possible that a part of the data will be made available to the wider research community.

By signing this form, you agree to allow the recorded data to be used without limitation in accordance with the above statements.

I, ..., have read and understood this form and agree to authorise use of the recorded data on the terms indicated.

Date & Signature:.....

For more information about DAPHNE project : http://www.daphne-fp7.eu/

Figure 3 UPM trials' informed consent

It is necessary, for what concern, patients' involvement, in next phases of the project, to:

- Implement the informed consent with a more completed explanation of purposes and procedures of the study
- Use an adequate language
- Add a section in which is clearly specified that volunteers/user are free to withdraw at anytime
- Add the tick boxes so that patients can chose what kind of data they want to share.

5 Conclusions

The present deliverable has produced a complete assessment of the ethical issues involved in the DAPHNE project. Basic principles for an ethical research and the European Law have been reviewed to apply to the research requirements of the DAPHNE project and practical actions established in keeping with them.

Despite different scenarios involved in the three cycles of validation are yet to be fully established, some fundamental rules concerning ethical management have been put forward. In particular, the involvement of minors and the remark that some sensitive feedback, i.e. those concerning the psychological wellbeing and nutritional assessment, have been carefully evaluated to minimize psychological and physical hurt for users.

Further minor changes to the informed consent and PHS will be done to fit more closely research ethical principles in phases two and three of the project.

References

[1] http://www.europarl.europa.eu/charter/default_en.htm

[2] ftp://ftp.cordis.europa.eu/pub/fp7/docs/guidelines-annex5ict.pdf

[3] Royal College of Paediatrics and Child Health: Ethics Advisory Committee. Guidelines for the ethical conduct of medical research involving children. (2000). Arch Dis Child; 82:177-82.