beaconing

BREAKING EDUCATIONAL BARRIERS WITH CONTEXTUALISED PERVASIVE AND GAMEFUL LEARNING

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D1.7 Data Management & Ethics Process Plan

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Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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EXECUTIVE SUMMARY

The BEACONING project deals with minors and groups that are at risk. Therefore, both ethics and data management is of high importance for the quality assurance of the project and the project results. The BEACONING consortium pays specific attention to ethical issues and data management and has developed guidelines that will support the correct handling of data, as well as ensuring that national and EU laws and recommendations on privacy issues play an important role in the daily work within the BEACONING consortium.

The process and guidelines have been implemented, will be monitored through the quality management team and are documented in D1.7 Data management and Ethics Process plan: The BEACONING data management plan, in this first version, describes how we handle data. It is developed according to the guidelines on data management in the H2020 Online Manual and contains information on types of data, standards in use, data sharing (incl. how to deal with privacy and IPR issues) to the extent we, at the current time, know what we will collect and process. The deliverable also explains how to deal with the ethical issues raised by the involvement of end-users (especially minors and disabled) in the pilots. In particular, the critical aspects covered by the deliverable will be guidelines on the implementation of the informed consent procedures and on the way in which the voluntariness of consent will be guaranteed to participants in a position of dependence and vulnerability.

This document is the first of four that will be periodically delivered at month 6, 12, 24 and 36. Whereas this version comprises guidelines, templates and process descriptions, the following versions will focus on monitoring and reporting, the usage of data, as well as describing how ethical concerns are considered in the piloting. The first part of the deliverable is related to the ethical guidelines, whereas the last part deals with the data management.

1   INTRODUCTION

BEACONING is dealing with groups at risk and personalised learning. Therefore, the ethical and privacy issues are of great concern within the project. To ensure all partners and involved employees know how to deal with privacy, data and ethical issues, the BEACONING project provides key ethical guidelines. This section gives an overview of the most important regulations, laws and directives that the BEACONING project has to take into account regarding data management and ethics.

1.1   SCOPE OF ETHICAL AND DATA MANAGEMENT IN BEACONING

The objective of the ethical guidelines is to ensure that all BEACONING partners work in an ethically sound way with respect to involving participants in any of its pilots in the project, as well as creating ethically sound technology. The guidelines specify how the consortium will maintain security, privacy and confidentiality norms, as well as common values of autonomy, independence, beneficence, non-maleficence and justice will be respected. Furthermore, it will advise all partners in the consortium, both EU and non-EU, on how to work with participants, respecting the combined ethical standards of the consortium members, as well as the national regulations and pilot-specific guidelines.

- The guidelines are available in English. Each partner organisation is responsible for ensuring that all involved employees are aware and understand the guidelines (i.e. if required they will have to translate the content into national language);

- It is mandatory that each member organisation signs a declaration stating that ethical standards and guidelines of Horizon2020 will be rigorously applied, at the onset of BEACONING. Each partner is responsible for informing their own staff involved in the BEACONING project about these guidelines and this document (Template- see annex);

- The BEACONING project has, in addition to the quality manager, appointed Thusha Rajendran (HWU) as an Ethical Manager identified on the management committee, to oversee that an appropriate ethical approval process is implemented;

- All copies of ethical approvals for the collection of personal data by the competent University Data Protection Officer/National Data Protection authority, in the different EU countries, must be submitted to the management committee for ethical review;

- In order to ensure that no misinformation and manipulation can occur, only qualified personnel will conduct the studies – we will need to ascertain who the qualified personnel are with the assistance of the intermediary organisations;

- Approval of the local ethics committees will be sought prior the start of activities;

- Where needed (in the case of testing the BEACONING platform with learners) the consortium will need a specific ethical approval, or similar in their respective EU country, to ensure qualified personnel are cleared to work with:

  o children – Disclosure and Barring Service (DBS) checks will be required including a central means of ensuring these details are on file both for the BEACONING consortium and at each respective institutions' ethics committee

  o people who are considered vulnerable due to mental and/or physical ill-health, will be supported through an advocate, to support the person in being fully involved in the consent process, as well as to support and represent the person's wishes.

1.2 ROLE OF THIS DELIVERABLE IN THE PROJECT

This deliverable provides the Data Management and Ethics Process Plan for the BEACONING project. The document outlines how to handle data, developed according to the guidelines on data management in the H2020 Online Manual and how to deal with privacy and IPR issues. The deliverable will also explain how to deal with the ethical issues raised by the involvement of end-users (especially minors and disabled) to different stakeholders and target audiences, and it serves as a reference for all partners in their involvement in Data management and Ethics Process activities.

1.3 APPROACH

There is a lot of knowledge on ethics and data management within the consortium. Thus, in addition to carrying out a desk top search on ethics and data management, a working group on ethics was established during the preparation of the description of action. This working group is still in operation and new members representing the pilots have been involved in the work.

Several brainstorming sessions, discussions about the topic and how this influences the work have been carried out. The main outcomes of the working group have been discussed during meetings in Coventry (kick off, January, 2016), WP 3 meeting (Barcelona, April 2016) and finally at the general assembly in Porto (June 2016). The feedback from consortium partners has been considered and integrated into the current updated guidelines. The desk top search was carried out to get an overview of regional, national and international (including EU) regulations, directives and laws on both topics and shall ensure that no major issues will occur during further activities of BEACONING.

1.4 STRUCTURE OF THE DOCUMENT

The document is structured as followed: Chapter 1 gives an overview of the topics and how the deliverable will influence the work carried out. It also describes the approach taken for developing the guidelines and the plan. Chapters 2 to 4 present the ethical guidelines, which are the result of the common development of internal experts on ethics and how to involve pilot participants and external researchers. Chapters 5 to 7 address the data aspects regarding BEACONING, with a specific in depth view on the Data Management Plan.

2   ETHICAL GUIDELINES

The main focus in this section of the document is ethical issues related to piloting and the usage of data from these for publications, pilot participants and pilot operation, whereas later sections deal more with data management and security issues. The advancement of new digital technologies being introduced in public communication networks in the Community, give rise to specific requirements concerning the protection of personal data and privacy of the user. Digital networks have large capacities and possibilities for processing personal data. The successful development of these services and networks is partly dependent on the confidence of users that their privacy will not be at risk.

2.1   OVERVIEW ETHICAL ISSUES

The design of activities within the BEACONING infrastructure will involve stakeholder's (learners, teachers, parents, and intermediary organisations) engagement, in deployment and testing within the test beds, which may raise concerns on data sharing and protection issues. BEACONING will follow all guidelines present in the most important pieces of European legislation and international conventions, as well as international declarations and codes of conduct relevant to research activities. All ethical and privacy regulations of participating countries will be respected. Furthermore, the project will conform to the following:
1) Current Legislation and Regulations in the country where the research will be carried out
2) European Legislation
3) International Conventions and Declarations.

Particularly relevant are:

- Article 19 "Ethical principles" of Regulation No. 1291/2013/EC of the European Parliament and of the Council which states the fundamental principles of the H2020 Ethics in research;

- 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;

- Ethical issues of healthcare in the information society. Opinion of the European Group on Ethics in Science and New Technologies No. 13, "Ethical issues of healthcare in the information society";

- The Charter of Fundamental Rights of the European Union (2000);

- Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications);

- Recommendation No. R (97) 18 of Committee of Ministers to Member States concerning the protection of personal data collected and processed for statistical purposes, adopted on 30 September 1997;

- Directive 96/9/EC of the European Parliament and the Council of 11 March 1996 on the legal protection of databases;

- The project will be carried out in accordance with the Helsinki declaration [1][2][3][4][5][6].

The consortium will take all measures to ensure that appropriate environmental safety provisions are fulfilled during the course of the project by all contractors. There will be no risks

of physical damage within the experiments/pilots taken in BEACONING. The behavioural measurements and materials used do not pose any risk or dangers to the participants. No specific ethical and legal aspects will have to be obeyed, as only non-invasive experimental examinations will be conducted and no medication will be applied. Due to expertise of all partners in their field and their acceptance of high ethical standards, accidental risks will be minimal. The local committees of each centre will be informed about the experiments and the approvals will be given before any experiment/pilot is conducted. The ethical committees will decide on the national ethical regulations for experiments in humans.

The following sections describe what to do in the case of new members joining the project team, how to manage the collected (partly personal) data and any further processing of these. This section will also describe how to involve pilot participants (to be carried out before piloting and data collection starts).

2.2   ETHICAL GUIDELINES FOR BEACONING PROJECT

In order to conform to national and international ethical guidelines, every researcher and employee involved in the project will receive an introduction and continued support from their ethical board. The employees shall receive this information before involvement in any BEACONING activities dealing with data related to piloting or data they will use for research. This is the responsibility of each partner organisation. For monitoring purposes, the employees of the project responsible in the partner organisation will sign a form. This form will be stored at the BEACONING internal working space (templates - see annex).

The consortium is furthermore applying the four principles of Pardo and Siemens (2014) in order to address numerous issues. The four principles are:

- **Transparency:** each and every stakeholder group, i.e. learners, teachers, educational administrators, should be provided with an overview of what data is collected, which purpose it serves and how it is processed and stored;

- **Student control over data:** every user shall possess the rights to access the data collected about them and, if necessary, to correct them;

- **Right to access:** in order to the insure security of the data, it has to be clearly defined, who possesses access rights for which data;

- **Accountability and assessment:** Definition of responsibility for what within the process;

- Any **equipment** used must be compliant with the respective legal and ethical requirements.

All reports and articles which have data of the BEACONING project as their foundation will be reviewed by different people with different social, academic or sexual background, before they are released, in order to ensure that these written pieces do not offend or discriminate single groups within the population.

2.2.1   Measures to minimize risk

Measures to minimise risks to research staff will detail:

- The process for conducting trials;

- The plan of participant recruitment and gaining informed consent;

- What data to collect, using what tools, and how it is securely stored;

- The process for research staff leaving the project;

- The handing over of any data;

- Such staff will sign a 'Declaration of confidentiality' regarding the intellectual property of the project.

Measures to minimise risks to participants will detail:

- Anonymity and privacy to research participants;

- Participants data and their names will be separated and stored on a specific server with higher security, separate from the 'web platform';

- Detailed information will be provided to all participants as part of the informed consent process about all potential risks;

- Who to contact in the event that something goes wrong;

- Who to contact in the event of wishing to make a formal complaint/access compensation.

2.2.2 Specific issues

BEACONING will follow the relevant recommendations contained in the EU Charter of Fundamental Rights of 7 December 2000, 2000/C364/01. The Charter of Fundamental Rights of the EU in the course of the respective legal trend dedicates a separate article to the protection of personal data.

Article 8 sets out the right to protect the personal data of an individual and therefore the protection of personal data now has a legal basis apart from the right to respect for an individual's private life and the protection of the human dignity. Art. 8 of the Charter sets out the rules for the legitimate processing of personal data, notably that the processing shall be fair and for pre-specified purposes based on the consent of the data subject or other legitimate basis laid down by law. Reference is also made to two rights of the data subject: the right of access to the data and the right to have it rectified. Finally, Art. 8 sets out the need for an independent authority, which shall control the compliance with the data protection rules.

BEACONING will adopt guidelines for data protection contained in the Privacy on the internet - an integrated EU approach on Data-line Data protection. Public-key technology will be applied.

2.2.3 Ethical management

Adherence to the principles of the Ethics Board review will be monitored by the Project Coordinator. With the support of the Project Manager and Ethics Advisor, the Project Coordinator will ensure that documentary evidence of ethical approval is obtained from all contracting organisations.

The following principles will be addressed:

- That informed consent is taken, i.e. it is properly explained to those that they are participating in research;

- The exact nature of the research procedures will be explained to the participants verbally and they will be given sufficient opportunity to read an information sheet in the appropriate language, describing the procedure;

- Participation in research will be entirely voluntary;

- Participants will be informed that they may withdraw from research at any time without providing reasons;

- Any risks will be explained. In practice, the present research is non-invasive and safe;

- All personal data will be stored and handled according to the principles of data protection. In practice this means written material will be stored in secured locations, data processed and stored digitally will be encrypted both at-rest and in-flight, and any publication derived from personal data will be presented in a way that makes it impossible to identify individuals;

- Any complaints or adverse incidents will be referred to the local ethical committee that approved the research, for independent review and appropriate disciplinary action if necessary.

2.2.4 Safety aspects

- The safety of the participants is a primary objective. The option of expert safety officers will be sought wherever appropriate;

- Staff involved in the project will comply with safety procedures. General safety procedures will be implemented for video display use, fire safety and other general issues such as the participation of pregnant women in research;

- All procedures involving devices such as electrical equipment (e.g. handheld computers) will be subject to standard safety review;

- Potential safety implications of developments within the BEACONING project will be clearly indicated;

- All participants will be strictly volunteers and are able to withdraw from the trials at any time without any restraints.

2.3 CONFIRMATION OF PARTICIPANTS

The project raises ethical questions as it uses personal information and takes investigative measures on persons. Every participant will receive a mandatory introduction and additional written information. Furthermore, each participant will have to give their written consent.

All activities will conform to:

(1) the Charter of Fundamental Rights of the EU;

(2) Directive 95/46/EC of the European Parliament and of the Council (24.10.1995) on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

Furthermore, principles expressed in the Helsinki declaration in its latest version, convention on the Council of Europe on Human Rights and Biomedicine signed in Seoul on 22. October 2008 and The Universal Declaration of Human Rights adopted by the UN (10. December 1948) will be respected.

The BEACONING consortium confirms that, where it is required, the Commission will be informed that local, regional or national ethics approval has been obtained before the research to which it relates is carried out. In this respect, national regulations will be applied by respective partners active in those countries, and where approval is needed, it will be obtained from the responsible bodies in order to carry out BEACONING research according to national regulations. In all ethical issues which are under control of national law (e.g., privacy, data protection, etc.), the consortium members in their experimental work will strictly follow the law of the country in which the particular examination is performed.

In addition to the ethical issues of pilot operation, there are also issues related towards the research part of the project, i.e. publication of results, as well as access to data for external researchers. BEACONING partners will consequently apply research methodologies and have substantive knowledge accrued as researchers and members of their professional group have ethical obligations to their colleagues, research clients and to society in general. Here we will apply existing ethical guidelines related to the responsibilities of researchers to their profession and as professionals. Some of the basic principles are listed below:

- Ensure that an appropriate research method is selected based on informed professional expertise; i.e., to avoid physical danger, emotional danger, ethical danger, professional danger;

- Ensure research processes do not involve any unwarranted material gain or loss for any participants;

- Ensure factual accuracy and avoid falsification, fabrication, suppression or misinterpretation of data;

- Ensure methodology and findings are open for peer review and discussions;

- Ensure dissemination/reporting is carried out in a responsible manner and to acknowledge previous research, concepts, methodologies, etc. as a source of knowledge.

2.3.1 Informed consent

The BEACONING consortium guarantees that no research with human participants will be conducted without assuring and obtaining an informed consent. This will include the consent of all participating learners, teachers, parents, intermediary organisations, and as appropriate parents where this consent is on behalf of the minor.

Participants will be fully informed about the background, objectives, and possible risks of BEACONING in general and about the specific experiment, he or she will participate in. Participants will be informed that they can leave the study at any time without the need for explanation. It will be pointed out that no disadvantage will arise from leaving the study.

- Participants in any piloting/test/experiment will be fully informed in advance on the details of the procedure they will be part of, as well as on the basic content of the project;

- Clear explanations will be provided to all participants about all procedures both oral and written (e.g. face to face or telephone, consent will be recorded and sound files securely stored);

- Where individuals are under the age of consent, and considered a minor, the participants' parent/carer/responsible adult/advocate will be required to provide informed consent. Additionally, minors will also be asked for their verbal consent (this will be recorded);

- Consent statement: The consortium will not collect any data from persons unable to provide consent;

- As required, participants who may be classed/class themselves as vulnerable, may request the presence of an advocate when considering participation in the study.

Individuals may also request the presence of an advocate during the trial. In this instance a disclosure statement will be required for the advocate in their observer role;

● Participants always have the possibility to terminate the experiment without providing reasons and will be informed that this will not any way be detrimental to them. Withdrawing participation from a study is possible at any point in time. Verbal withdrawal is totally sufficient. Following withdrawal, the participant decides whether data collected so far will be used for research purposes. If not, all data will be destroyed (paper forms) or deleted (electronic data);

● No experiment will be conducted before the participant has been thoroughly informed about the experimental procedure and has given his or her written informed consent;

● No payment of incentives or rewards to participant will be made. This includes 'hard to reach' respondents (however this is defined) as this raises the issue of fairness in the treatment of respondents;

● All experimental protocols involving participants will have passed a reviewing process by a local ethics committee. A copy of each application to the local Ethics Committee and the informed consent applied in the study will be collected by the project manager to allow the project coordinator to have an overview that each study performed within BEACONING is approved;

● Participants will be made aware of who to contact should they wish to complain about any aspect of the study/to compensate for something which goes wrong;

● All personal data collected will be strictly confidential and anonymous (to include details on storage and passwords);

● The anonymising of data will occur at the point of collection;

● Data protection and secure communications will be applied according to CEN/TC 251 (WGIII) standards and recommendations; this will ensure data confidentiality, accountability and secure access;

● All studies performed with the stakeholders either for testing interactive virtual environments or for observational/ethnographic studies will be approved by the local ethics committee at the host university or associate partners – generic templates will be developed to ensure ethical consistency across all partners. The templates can then be adapted and developed as per the strict ethical guidelines of each partners' ethics board. The participants will then sign the agreement form. All consortium members will adhere to the following statement:

> Equality statement: There will be no discrimination in terms of gender, race, religion or sexual orientation. There will also be a balance of gender and ethnicity in the participating test subject cohort.

2.3.2 Ethical Procedures for BEACONING RELATED to PILOTING

BEACONING will carry out several pilots involving teachers, students, parents etc. Some of these participants are minors, or persons at risks as described above. Based upon the previous elements, the ethical manager has suggested a procedure for gaining informed consent from children and adults with (and without) mental impairment/mental illness disabilities and/or communication difficulties. All members of the consortium are aware of the specific situation of conducting experiments/trials with human participants.

All participants or their legal representative included in the study will be able to give informed consent prior to the actual study.

The management team will monitor the procedures to ensure they will be carried out according to the ethical standards.

All partners of BEACONING have experience in working with human participants and Ethical Committees of the Universities are paying specific attention to make sure that all ethical concerns are addressed before applications are approved.

Fig. 1 illustrates the process flow (need some local adaption) to be applied in order to get approval. Each pilot partner will follow the procedure before starting the pilot and report to WPL, WP5 & 6, PM, QM and EM:
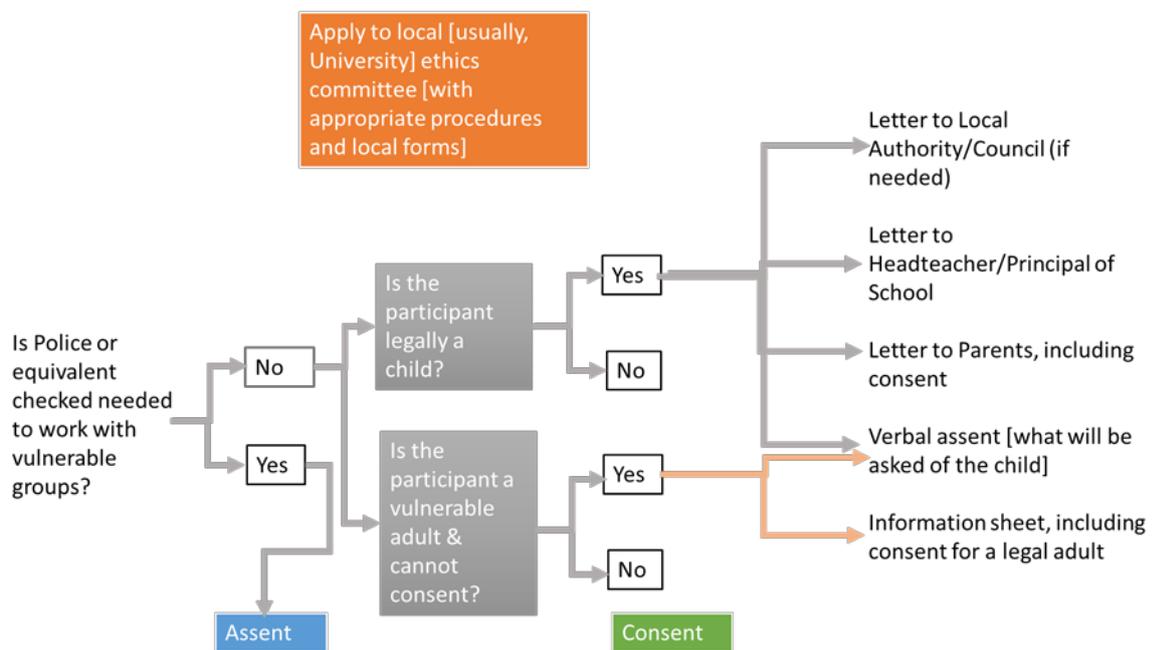

Figure 1: Procedure of approval

The same procedures will be applied by any other partner organisation (including all associate partners or external researchers) if they deal with any piloting issue.

All studies will first be performed after approval by the local Ethics Board (if required according to local law) respecting international ethical guidelines (e.g. World Medical Association, Declaration of Helsinki; see section "Legal guidelines for ethical decisions"). Furthermore, the organisation carrying out the study will inform the BEACONING ethical board in advance and ensure that all guidelines are followed.

Any equipment connected to a participant will be evaluated for personal safety. Any electric equipment will conform to European and international standards for medical electric equipment (EN60601-1). Any psychophysiological devices built or adapted in part or integrated in whole as a monitoring system must comply with EU directive 93/42/EEC Annex II and ISO 13485:2003 medical class IIa.

With respect to, and for awareness of gender differences, BEACONING ethical guide takes into consideration language used and guidelines recommended for non-sexist research methods. A useful checklist is provided by Margrit Eichler (1991, ISBN: 9780415906050) which lists extensive types of problems that can emerge during a research project that researchers need to be aware

of. The British Sociological Association (http://www.britsoc.co.uk/) further provides guidelines on non-sexist language. These will be particularly useful in the preparation of survey forms through to training of research associates conducting experimentations.

2.4   MEDIA COVERAGE

We consider media presence very important for the dissemination of our results and products and for keeping the people up-to-date about our developments. All members of the consortium are (1) constantly approached by media, (2) highly experienced in dealing with media, and (3) well aware of the necessity to protect privacy of people involved in the project. Members of the consortium will provide general information about the background and objectives of BEACONING. The media related informed consent will be written with the support of the legal administration of each of the Universities.

The next section will cover the data management plan aspects. Since there are still some uncertainties in exactly what data we will need to collect, this part will be updated in month 12, 18 and 24.

3   DATA PROTECTION ISSUES

3.1   PARTICIPANTS

Background data of participants collected will include age and gender. The participants will be informed that the signed informed consent will at no time be stored together with the collected data to ensure anonymity (see chapter 2). Each participant will receive a code number. Only the person in charge of the study will have a list with names and codes to allow participants to withdraw the data at any point in time during the study. These lists will be in hard copy, (as malware cannot read), and stored in a locked filing cabinet for all members of the consortium. These are routine procedures for privacy and data protection.

3.2   DATA STORAGE DURATION

The British Psychological Society on Good Practice Guideline[1] outlines within its Data Storage Section, that if the research is to be published, most scientific journals require original data (including videos and transcripts) to be kept for 5 years. If it is not to be published then the data should be kept for 1 year, but this can lead to difficulties if publication is subsequently required as original data cannot be checked or examined if necessary (p. 11 on Data Storage). In relation to data retention, and where the aforementioned guideline is insufficient, all academic and industrial partners are to consult the appointed Data Protection Officer to provide specific guidance. Personal background-related data will be stored separately from research relevant data. All data will be pseudo-anonymized such that nowhere within the data a direct connection to the individual can be drawn.

4 DETAILED PROCEDURES ENSURING EFFICIENT DATA PRIVACY PROTECTION

4.1 PRIVACY PROTECTION PROCESS

Each participant will be assigned a code to identify his/her respective data. To enable participants to withdraw their data at any state of the project, each code and the participants' name have to be linked.

4.2 ENCRYPTION OF THE KEY-FILE CONTAINING IDENTITY INFORMATION

The key-file containing identity information will be kept separate from the rest of the data. The data containing information about the participants' identity will be stored in a secure file to which only the project leaders of the participating institutions will have the keys. Participants will be informed about this process and sign an agreement before data acquisition. For all members of the consortium these are routine procedures for privacy and data protection. The encryption use the AES 256 algorithm. To ensure forward secrecy, any data acquisition or communication will be performed using asymmetric algorithms using keys of at least 2048 bits.

4.3 APPROPRIATE DISCIPLINARY ACTION IF NECESSARY

In the unlikely event that staff hired on the project disclose private information from anyone working on the project or complains about such a behaviour, the local ethics committee will handle and necessary action will be taken. This will also be reported to the project coordinator, project manager and the ethical board. These will analyse the complaint and suggest actions to be taken. These will be discussed by the consortium board. In the case it should be necessary to ask for withdrawal of staff from the project due to professional misconduct, the partner employing the staff will accept this decision and act accordingly.

5   DATA MANAGEMENT PLAN (DMP)

5.1   DATA SUMMERY

The purpose of the collected and generated data is to use them for carrying out the tasks as described in DoA, as well as to be able to validated and assess the BEACONING platform and component. Thus the data is crucial for the project.

The data can be divided into personal and anonymised data. At this stage of the project, it is not yet known which formats the data will have, but it will at least contain .docx, .pdf, .jpeg and geopostiona data. Furthermore, the participants will have to fill out surveys and the answers will be another data source for the researcher within the project.

Data from the pilots are being reused in order to optimize the final version accordingly.

The data will be generated and/or provided by the participants, consortium and from the teachers.

The researcher, the consortium and teacher will find the collected data useful.

5.2   FAIR DATA

Due to the early stage of the project and the insecurity about the data formats, its quality and quantity, it is not possible to plan how to make the data findable, accessible, interoperable and reusable (FAIR). The consortium is striving to make the project data FAIR as described in the guidelines, provided by the European Commission and their directorate-general for Research & Innovation, for H2020 programs but an exact plan will not be made before a later stage of the data management plan. This is due in month 12, 24 and 36 of the project.

5.3   DATA SECURITY

Considering that BEACONING deals with sensitive data, to ensure data confidentiality updates on standards concerning encryption systems are analysed (ISO/IEC 18033-2:2006 Information technology -- Security techniques – Encryption algorithms -- Part 2: Asymmetric ciphers, reviewed in 2013). Both data at rest and data in flight will be encrypted using the AES symmetric cipher while secure key exchanges will be performed using an asymmetrical cipher of at least 2048 bits in length.

BEACONING has an explicit plan on how the consortium will handle data generated or provided by the participants (Fig. 2). The figure also illustrates how different data types are handled and stored with a special emphasis on the different approaches between anonymised and pseudo-anonymised data samples. These differences are especially important due to the different ethical problems these respective datatypes uphold, as described in chapter 2.
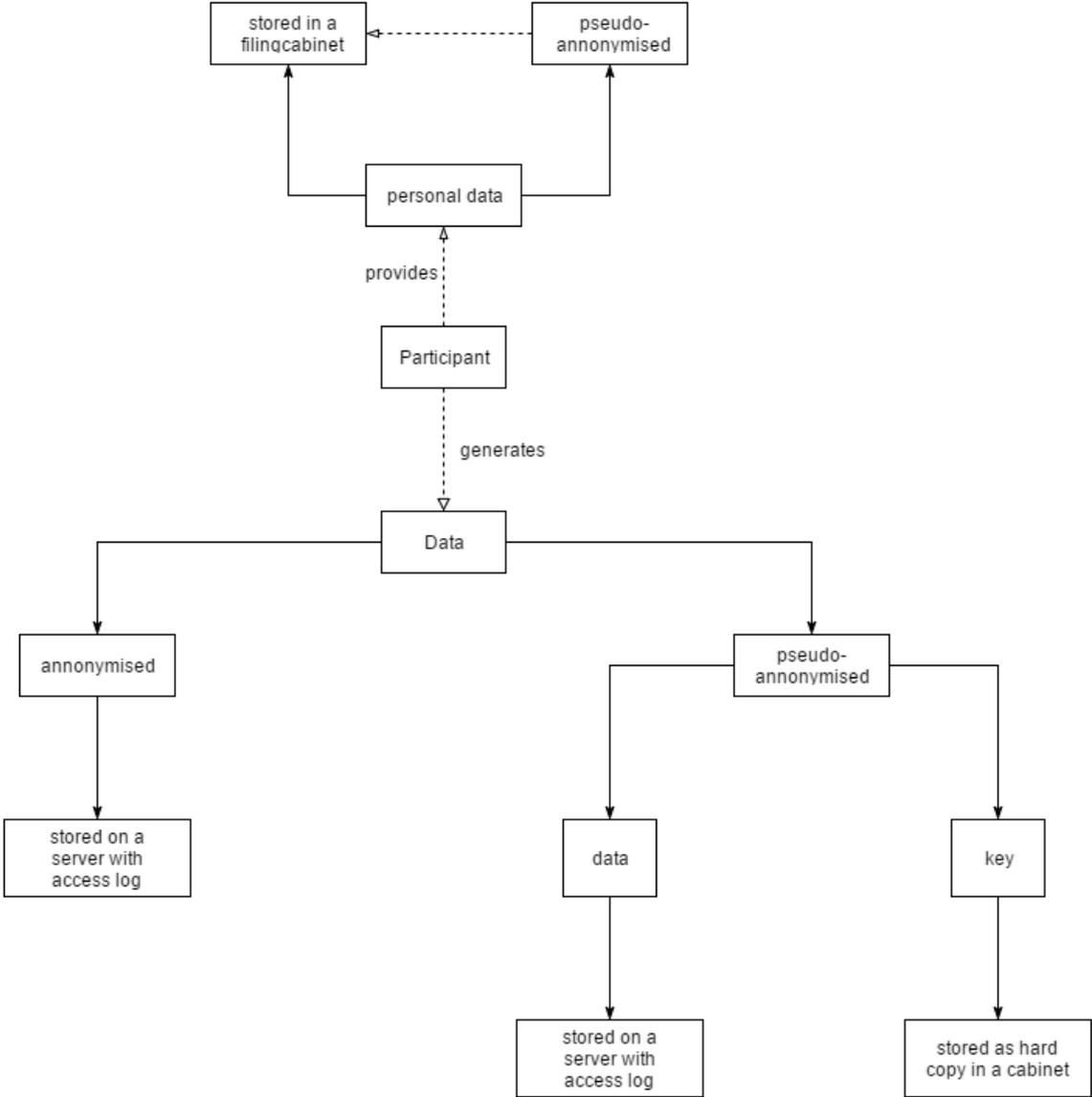
Figure 2: Data storage plan

6 CONCLUSION

This deliverable plays a key role for ensuring that all partners involved in the project pay attention to ethical issues and data management. It provides an overview of different legal, technical and ethical problems a project like BEACONING may face and how important it is to generate a baseline within the consortium in order to ensure a smooth progress.

The ethical guideline developed will reduce the risk of misunderstandings within the consortium.

Furthermore, technical aspects of data security have been addressed which results in mandatory rules for safekeeping of sensitive or personal data.

The results of this deliverable are the ethical guidelines regarding BEACONING and procedures in order to ensure the safety of the data included in the project.

This deliverable is essential in order to create a mutual understanding about the ethical and technical questions this project may have and how the consortium should proceed with them. This deliverable is the basis of future development of BEACONING regarding data security, how everyone within BEACONING should act in order to ensure maximum anonymity of the participants and to exclude unauthorized access to the data generated or provided by any stakeholder group taking part in the project.

Next update will be provided in month 12.

7   REFERENCES

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1. http://ec.europa.eu/research/participants/data/ref/fp7/90448/fp7ec_en.pdf
2. http://eur-http://www.coe.int/t/dghl/standardsetting/dataprotection/EM/EM_R(97)18_EN.pdf
3. http://www.coe.int/t/dghl/standardsetting/dataprotection/dataprotcompil_en.pdf 6.
4. http://www.coe.int/t/dghl/standardsetting/dataprotection/EM/EM_R(97)18_EN.pdf
5. http://www.wipo.int/wipolex/en/details.jsp?id=1409
   http://eur-lex.europa.eu/legalcontent/EN/TXT/HTML/?uri=CELEX:32002L0058&from=EN
7. http://ec.europa.eu/justice_home/fsj/privacy/docs/wpdocs/2000/wp37en.pdf
8. http://www.psy.ed.ac.uk/psy_research/documents/BPS%20Guidelines%20for%20the%20Conduct%20of%20Research%20within%20the%20NHS.pdf

ANNEX: TEMPLATES

Ethical introduction – project leader

I hereby confirm, that I gave an introduction regarding the ethical guidelines and standards for the BEACONING project as defined in D1.7 of the BEACONING project to the people listed in the table below. I am also aware, that I have to ensure that these standards and guidelines are upheld as long as I or any project members are working with any part of the BEACONING project (including its data).

Name	Organization	Signature

Place, date   *(Signature and printed name)*

Ethical Agreement - employee

I hereby confirm, that I have received an introduction to the ethical guidelines and standards for the BEACONING project by a project leader.

I hereby confirm that I have understood to the ethical standards and guidelines as defined in D1.7 for the BEACONING project. I furthermore assure, that I will act accordingly for all tasks (including publications written after project finishes) I carry out relating to the BEACONING-project, its participants and other stakeholder groups within the project. The BEACONING guidelines are based on the following directives and pillars, and I confirm that I have knowledge of its content:

- **Article 19 "Ethical principles" of Regulation No. 1291/2013 /EC** of the European Parliament and of the Council;
- **Directive 95/46/EC** of the European Parliament and of the Council of 24 October 1995;
- **Opinion of the European Group on Ethics in Science and New Technologies No. 13**, "Ethical issues of healthcare in the information society";
- The **Charter of Fundamental Rights** of the European Union (2000);
- **Directive 2002/58/EC** of the European Parliament and of the Council of 12 July 2002;
- **Recommendation No. R (97) 18** of Committee of Ministers to Member States, adopted on 30 September 1997;
- **Directive 96/9/EC** of the European Parliament and the Council of 11 March 1996;
- The project will be carried out in accordance with the **Helsinki declaration**;
- Any legal guidelines regarding ethical conducts within my country that is not listed above.

I also declare, that I will not conduct any experiments before I have the explicit agreement from my local or national ethics committee, if that is required according to national laws or directives.

I am also aware that my signature commits me to ensure that any data I am handling or generating is protected against unauthorized access attempts and that I am not allowed to store anonymised or pseudo-anonymised data and their respective key at the same place. Any data that could be linked directly to a participant will be stored securely and handled with the utmost care be me.

I have been made aware of the consequences any misconduct may have for me personally.

Place, date   _(Signature and printed name)_