Ecosystem infrastructure for smart and personalised inclusion and PROSPERITY for ALL stakeholders

D501.2-1 GPII Ethics Manual

as complement to the P4A Management Handbook

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Executive Summary

This document contains the Ethics Manual for Prosperity4All. Prosperity4All contributes to the Global Public Inclusive Infrastructure (GPII) – therefore, this Ethics Manual is not reduced to being an Ethics Manual just for Prosperity4All, but is at the same time the Ethics Manual for the all of the GPII.

Within Prosperity4All and GPII, the Ethics Manual will be used in the initial stages of Prosperity4All as a reference and guide. It is meant to be relevant for all researchers, who plan to run user studies or to develop software, which has user interfaces or stores user data. During Prosperity4All project, the Ethics Manual will be updated and further developed, where necessary, in order to be a living document, serving as Ethics Manual for GPII far beyond the duration of Prosperity4All.

1 Introduction to Ethics in Research

The inclusion of information and communication technology in public spaces, social spaces, homes and everyday life in general, has a number of ethical dilemmas concerning security, privacy, freedom of choice, dependency and consent which need to be considered very carefully. The objectives of Prosperity4All share this general concern in as much as it helps users accessing technology by activating their preferences.

There is a need for the inclusion of legal and normative frameworks and guidelines to be taken into account from the beginning of the project, even at its conception.

Therefore there are two main streams where ethical issues are considered during research:

1. Those related to the involvement of people in general in the project, such as prospective users, developers, stakeholders and any other kind of participants, e.g. experimenters, carers, volunteers and participants. This includes also the public who will potentially get in touch with Prosperity4All solutions. The matters treated in this part are of a pragmatic kind.
2. Those related to the consequences of the research itself. This angle has a more philosophical standpoint and its inferences are morally oriented.

To preserve the dignity, autonomy and values of the end-users and project participants, Prosperity4All continues the addressing of the ethical perspective from the very beginning in the same manner as the previous project Cloud4all did. The management of ethical issues within the project is the responsibility of different entities in the project management structure.

An Ethics Advisory Board is established within Prosperity4All (see chapter 3.1). Its head is the Ethics Supervisor, who oversees all relevant issues and trains all partners on how to abide with the recommendations of the Ethics Manual.

If ethical implications arise during the process they should be made understandable and manageable to users and developers. In order to achieve this goal there are different approaches to employ, depending on the specific situation:

- Strategies, with which it would be possible to avoid having to take ethical decisions. Starting with the implementation of a mechanism that informs stakeholders on ethical issues from the beginning of the project - and to its whole duration - and continuing with the implementation of consultation processes and decision mechanisms via ethical committees. Legal references and ethical guides preform the

instructive role, a body of information that usually should be sufficient to assure a correct ethical management of the project.

- In the case of unavoidable situations in which a decision would have to be taken, an efficient means to address any ethical issue that arises during the project will be the procedure previously established during the project: the review carried out by the different committees of any ethically concerning activity. Among these we can find the procedure to deal with emerging ethical issues. Local ethics committees will deal in the first instance with any ethical concern. On a second instance ethical issues will be dealt by the Ethics Advisory Board.
- Tools, development and gathering of efficient tools that serve to monitor, guide and control situations in which ethical issues have to be dealt with and solutions need to be offered. Among these, it is necessary to be aware of the legal requirements, norms and existing regulations. The establishment of ethics committees (local ethics committees and ethics advisory board) at various levels during the project also helps regulation of any possible anomaly.

On the other hand, the consortium has to be coherent with its ethical standpoint, and accessibility, therefore, has to be included in all the project areas: from recruitment of disabled people to assurance of accessibility of the working tools. This also includes accessibility of the media and products that are developed and used during the work done; this includes the recruitment strategies and policies.

These ethical guidelines are there to ensure researchers maintain these high ethical standards. The key principles of research ethics are:

- A duty to protect participants from harm, by not disclosing sensitive information
- A duty of confidentiality towards informants and participants
- A duty to treat participants as intelligent beings, able to make their own decisions on how the information they provide can be used, shared and made public (through informed consent)
- A duty to inform participants how information and data obtained will be used, processed, shared, disposed of, prior to obtaining consent
- A duty to wider society to make available resources produced by researchers with public funds (data sharing required by research funders)

The following section moves directly to the information developed for and to be used by our project. This will include the guidance to be provided to our teams and concrete examples to illustrate the dangers and illuminate the issues and traps.

1.1 About this Document

This Ethics Manual for Prosperity4All builds upon the Ethics Manual of the previous project Cloud4all and reuses parts of ethics manuals from other, similar targeted research projects, such as VUMS cluster (MyUI, Veritas, GUIDE) and di.me. It is thought to be not only an Ethics Manual for Prosperity4All, but for all elements of the Global Public Inclusive Infrastructure (GPII), which is developed within Properity4All and other research projects.

The first version of the Ethics Manual aims to address all work packages, where work on ethical aspects is necessary. Where possible, detailed information is given. Otherwise, the Ethics Manual will be continued in different work packages addressed within this document, so throughout the project, further versions of this Ethics Manual will be published.

2 Guidance

Translating ethical principles into ethical practice is a minefield (Swain et al., 1998). However, it is hoped that by doing so at least less harm can be done by the developer's ignorance. These guidelines can serve the purpose of ensuring the developers' awareness of their ethical responsibility as proposed by Gram-Hansen (2009).

Previous to the exposition of the guidelines it must be said that all four pilot sites (CERTH, KIT, LFTL and Technosite) involved in the testing and user´s involvement have extensive experience in performing user research, especially for the particular user group each test site is focused within Prosperity4All. This has been done e.g. by interviewing all kind of people with disabilities as well as elderly people in person and over the telephone. Contact through digital media is also used in their work activities. They also have a pool of researchers within their organisations who help them with research governance and ensuring that the organisation follows the appropriate user research techniques. The four organizations have been employing user centred design in their research and development programmes of assistive technology. They have also been responsible for gathering and collating information by interview for national and international research projects. Thus their ethical soundness is well established. However the guidelines exposed in this document will help to make sure usual good practices are applied and to guide other partners not so well versed in these issues. It will also help in developing awareness among partners and specially developers that might not have had contact with these issues previously. By doing that, the document will serve the purpose of ingraining ethical behaviour in the project development (Sainz, 2012).

One important part of the conceptual framework in ethical issues deals with the dilemma presented to researchers when carrying out the investigation, as they may perceive the outcomes of their studies to be more important than providing protections for individual participants in the research. Although it is understandable to focus on goals, our society values the rights and welfare of individuals and they should always be protected first.

The objectives of these ethical guidelines ensure that researchers maintain high ethical standards. The following issues are identified as core ethical issues: **privacy protection and confidentiality, personal safety, informed consent, data protection and management, and lastly compensation.** It is possible that in this highly innovative research field, additional ethical issues will be identified during the project. If so, the Ethics Manual will be updated.

The key principles of ethics in research are:

- Protect participants from harm, by not disclosing sensitive information
- Protect participants from any physical harm, by observing physical and electrical safety precautions.
- Protect informants' and participants' confidentiality
- Treat participants as intelligent beings, able to make their own decisions on how the information they provide can be used, shared and made public (through informed consent)
- Inform participants how information and data obtained will be used, processed, shared, disposed of, prior to obtaining consent

To comply with these objectives there should be an informed consent where researchers must explicitly state that participants:

1. Do not have to take part in the study
2. Do not have to give a reason for declining
3. Declining to participate will not affect or influence anything
4. Participants can withdraw from the research at any time, even after giving their consent, without further consequences.

It has to be understood that the informed consent is the central piece that deals with the ethical issues regarding research in the Project. It deals with all the aspects related to privacy protection and confidentiality, data protection and participants' dignity.

2.1 Privacy Protection and Confidentiality

As many end users in Prosperity4All will not have enough knowledge of legal or technical issues it is necessary to obtain sufficient information from the service provider to resolve concerns about information privacy and security, and to understand the inner workings of the particular service. The Global Public Inclusive Infrastructure (GPII) of Prosperity4All will store its information either locally at the user's device or within a cloud.

Within cloud computing, different implications of privacy protection and security apply, see Annex VII. Implications of cloud computing in terms of privacy protection and confidentiality for more information.

Prosperity4All and GPII recognize that privacy is important. The user will always have full control of the stored data. Personal data will be kept confidentially and private. Services developed within Prosperity4All and GPII will be in accordance with the guidelines in this

document. Some of this information is treated in the section related to the informed consent. See chapter 2.4 for information about who stores the data and whom can be addressed to see / control them. A checklist can be found in: Annex IV. Work practices and environments in Personal data handling and privacy

2.2 Personal Safety

There are several aspects in relation to personal safety that will be taken into account in Prosperity4all:

- Personal safety for volunteers: there are no foreseen risks posed for volunteers: premises at all pilot sites comply with accessibility and safety regulations and are very well prepared to accommodate disabled people. Prosperity4all does not bring about any injury or other physical related risks, and Prosperity4all testing sites have extensive experience in dealing with volunteers. However it is strongly recommended to all test sites to obtain insurance or indemnity policy in order to be covered for risks.
- All test sites (all of them being very experienced in testing and interacting with persons with disabilities as previously stated) have accessible premises, adequate for testing with disabled users. Following the considerations of the Prosperity4all procedure, they will provide all documents needed for the trials (i.e. consent forms, questionnaires, etc.) in the suitable format (e.g. symbol supported text, TTS or audio supported documents, supplemented if needed by sign language interpreters, etc.). All pilot sites have video and sound recording facilities that can be deployed during performance testing of the Prosperity4all Pilot.
- Prosperity4all has been evaluated to present a low risk for side-effects in general. The major identified risk is the risk of invoking unrealistic hopes and expectations for personal benefits in terms of access to new and better assistive technology solutions, and the subsequent risk of disappointment. This is counteracted by very explicit and adequately communicated information about the limitations of such personal benefit and also established in the explanation on the informed consent.

2.3 Informed Consent

The consent forms and all ethical material has to be checked by all pilot sites ethics responsible board-person and approved prior to the test been carried out. The basis for achieving an adequate Informed Consent is to prepare a Project Information Sheet and to explain this to the potential user participant and then to confirm that they have understood

and agree to participation by signing a Consent Form. Further information and clear instructions about this are to be found in: Annex III. Considerations for Informed Consent.

Even though a general template has been provided, it needs to be adapted each time an activity would take place, and therefore further considerations are necessary:

The following general considerations regarding the consent forms should be taken into consideration by the test sites Local Ethics Committees.

1. Informed consent is a fundamental mechanism to ensure respect for people through provision of thoughtful consent for as a voluntary act. The procedures used in obtaining informed consent are designed to educate the participant population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "layman's language" (i.e. understandable by the people being asked to participate). The document is primarily thought of as a teaching tool, not as a legal instrument. Additionally, jargon should be avoided and gesture (signing), diagrams and pictures should be used if appropriate. The written presentation of information is used to document the basis for consent and for the participants' future reference. The consent document will be revised when deficiencies are noted or when additional information will improve the consent process.
2. The researcher should be aware of the fact that the use of the first person (e.g., "I understand that ...") can be interpreted as suggestive, may be, incorrectly, relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a participant.
3. Whenever possible, it should be arranged to obtain consent in good time before the beginning of the actual testing so that the person is not rushed at the last minute.
4. It should b e ensured that auxiliary aids or services to assist communication are available where necessary.
5. Participants should be encouraged to ask questions and the supervisors should ensure that they have understood the explanations/clarifications provided.
6. It should be ensured that participants have the option to change their mind and withdraw at any moment without giving any reason and without any impact on them.
7. It is preferable to see the person on his/her own (unless a carer/interpreter needs to be present) but if she/he wishes partners, carers or family to be present, it should be made sure that they do not put undue pressure on the person either to consent or to withhold consent.
8. Potential participants should not be overwhelmed with unnecessary information.

Also in the informed consent, a fundamental part in the management of ethical issues, the following information should be presented:

- What the research is about
- Who is carrying out the research
- Who is funding it
- Any benefits to individuals or groups
- Any possible adverse effects
- What the participants will have to do
- Length of the research
- Location of the research
- What the research findings will be used for
- What will happen to the results
- Whether they will receive a summary of the results
- Confidentiality agreements
- Entitlement to service statement

In addition to the above, please see also more elaborated information about the general Informed Consent template as well as further information related to the delivery of the information to different groups of users in Prosperity4All in Annex III. Considerations for Informed Consent Annex VI.

2.4 Data handling

There are three main areas where data handling, and therefore privacy and security, are categorized in relation to Prosperity4All: data handling of end user's preferences and needs, data handling in the developer's spaces and marketplace and data handling in the project environment (e.g. evaluation).

2.4.1 Personal data handling of end user's preferences and needs

End user's preferences and needs within GPII will be stored either locally on a device or within a cloud. It is clear that the benefits offered by cloud computing are numerous, however several outstanding questions exist regarding the relative security of cloud-based systems, and those that use it as compared to traditional, on-premises solutions. The use of cloud computing raises ethics issues around storing confidential user data on a system that might not be entirely controlled by developers and users.

One of the questions we can ask ourselves when facing data handling and privacy dealing on the cloud will be: how can the data in the cloud be used? This is important for the project, as users' needs and preferences may be stored in the cloud.

When it comes to confidential user information, the privacy policy generally outlines how the cloud computing provider can (or cannot) use the data the user enters into the application.

In general, all information the user enters into a cloud computing application should be treated as confidential, private information that cannot be used by the cloud computing provider (Newton, 2010). Furthermore, the cloud computing provider should only be permitted to view any of the user's private information with the user's explicit consent (for example, to troubleshoot a technical issue).

For storing user preferences and needs in the cloud, Prosperity4all will use mechanisms developed by the previous project Cloud4all (see D104.2 and D104.3 of Cloud4all). Since, Prosperity4all goes beyond Cloud4all in offering more elaborate services, it might have to expand existing mechanisms for protection of user data. If so, these issues will be handled within WP201 (security architecture) as well as within each relevant SP2 and/or SP3 deliverable.

2.4.2 Personal data handling within the developers' tools and marketplace

Developers within Prosperity4all will work together in a common developers' space, where they can share tools, as well as knowledge within the experts' network. A marketplace helps developers to market worldwide. Within these modules, participants will register personally. All information given will be shown transparently to the participant. Both modules build upon the GPII personalization infrastructure.

The information regarding data security and data handling as well as privacy within the GPII personalization infrastructure will be presented and updated in deliverables of WP 201. An updated version of this Ethics Manual will contain further information about how personal data of the developer is handled within GPII.

2.4.3 Personal data handling and privacy concerns in the project work environment

In (Annex IV. Work practices and environments in Personal data handling and privacy) a series of questions will serve as guide in order to make sure all processes performed during

the research activities carried out by people involved in Prosperity4All in their work environments are compliant with the norms. On top of this there will be assurance on secure handling of private data (data touching upon the identity and private life of the individual) and acknowledgement of the ethics policy regarding that. Evaluators should clearly explain to the volunteers that in line with the project ethics policy, the personal data that will be asked during the trials will not be permanently stored but it will be recorded only temporarily to allow scientific (statistical) analysis (also to provide feedback to them about the results of the studies).

Any personal information will be stored separately from data gathered during the pilots.

Trials will also take place online. In this case, the user will online get full information about who will get his information, which information is stored, how long it is stored and where it is stored. Also, he will have been given the details to contact in order to withdraw his data afterwards. When transferring information to further institutions, the user has to confirm this transfer in advance.

The data that will be asked during the trials from and about end users are namely: name, gender, age, specific type of impairment (if user with impairment) or expertise, address, e-mail and telephone number, familiarity with IT (extending in mobile and desktop applications) and which IT equipment in specific, main AT used and specific difficulties encountered while using them.

The data that will be asked during the trials from and about implementers are namely: name, gender, age, address, e-mail and telephone number, familiarity with AT (and which), expertise, professional background, years and domain of expertise.

This information might be updated within D401.1, D402.1 and D403.2, if necessary. An updated version of this Ethics Manual will then contain the updated information.

The approach to be followed within all evaluations should be acknowledged by participants:

- All participants will provide the information mentioned above to a single person in each pilot site. It will be stored in a protected local database (to allow contacting them further and arranging with them the sequence of the current or future tests). The contact person will issue a single Test ID for each of them. This person will not participate in the evaluation and will not know how each user behaved.
- Volunteers' names and contact details (address, telephone, e-mail) will be kept in the database only for the duration of the project. Such data will not be communicated to any other partner or even person in each pilot site. Once the project ends, they will be deleted.

- Since personal data will be deleted after the end of the project, no follow-up studies with the same people will be feasible.
- For the statistical analysis, the answers provided by the participants will be associated with their type of impairment(s) (if any) or expertise, age, gender as well as familiarity and use of IT and AT.
- The Local Ethics Committee in each pilot site will name a person responsible for monitoring and guaranteeing that the relevant procedures are strictly followed and that all recommendations and national relevant laws and regulations are being respected.
- Finally, the evaluators should ask the participants if they are taking any specific medication or other information that would be needed to be known in a medical emergency centre.

2.5 Compensation

Regarding compensation for participation in trials and other data gathering activities in Prosperity4All, there is a clear policy that volunteers can receive compensation for their time and effort during research and development activities. Once the schedule of the pilots is closed, it is necessary to estimate a compensation for users. This compensation can be of different type and value (i.e. cash, gift cards, tutorial attendances, etc.), and it will be fixed in advance depending on the budget available for this activity and the characteristics of the tasks to be performed by users (duration, difficulty, etc.). Details of the compensation plans for the pilots will be given in D402.1 and D403.1.

3 Structural and Procedural Establishment of Ethics Issues within Prosperity4All

Several institutions on different levels of the project have been set up in order to handle all ethical aspects, which may arise during the Prosperity4all. Figure 1 shows the structural organization of ethics-related institutions:

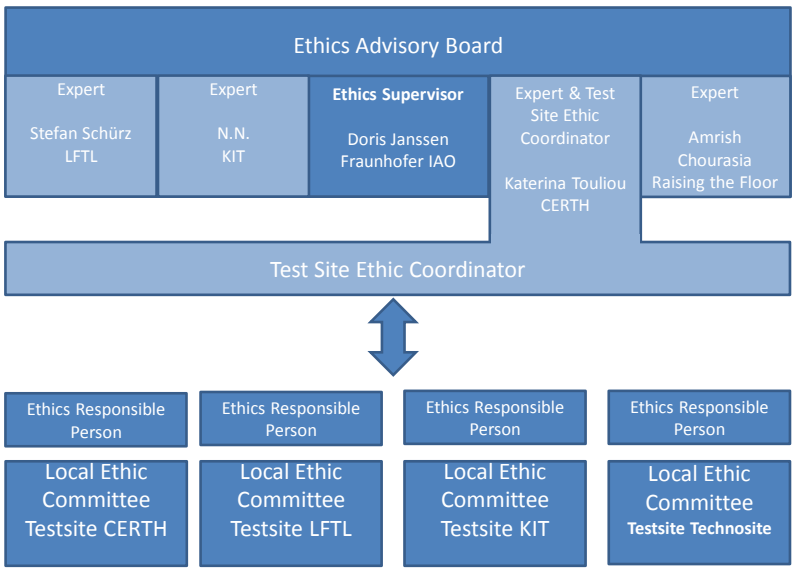

Figure 1: Institutions to handle ethical aspects during Prosperity4all

3.1 Local Ethics Committee and ethics responsible person

Each Pilot-Site names an Ethics Responsible Person, who is responsible for following the principles of Prosperity4All project's policy at the pilot site. This person will also report relevant ethics aspects to the Test Site Ethics Coordinator.

Pilot-Sites also have a local ethics committee, where ethical questions may be solved locally. These are:

- Local Ethics Committee Test site CERTH
- Local Ethics Committee Test site LFTL
- Local Ethics Committee Test site KIT

- Local Ethics Committee Test site Technosite

Persons within the committee should be experienced in solving ethical questions. The Committee usually already exists within the test site partners (e.g. called Ethics Review Board or similar) and is independent from Prosperity4All.

3.2 Test Site Ethics Coordinator

Prosperity4All has four different test sites, which will face similar questions regarding ethical aspects. In order to ease communication and to achieve a common understanding on ethical issues, the test site ethics coordinator is in place. The co-ordinator will coordinate relevant work (e.g. improvements on consent form) concerning all test sites as well as ensuring ethical aspects are sufficiently considered in work packages relevant for all test sites (WP 401, WP 402).

3.3 Ethics Advisory Board & Ethics Supervisor

The Ethics Advisory Board will ensure that all activities carried out in the project will comply with the presented guidelines and principles. The Ethics Advisory Board has five members:

- Expert:
  N.N., KIT
- Expert:
  Stefan Schürz, LIFEtool gGmbH, Stefan.schuerz.p4all@gmail.com
- Ethics Supervisor:
  Doris Janssen, Fraunhofer IAO, doris.janssen@iao.fraunhofer.de
- Expert & Test Site Ethics Coordinator:
  Katerina Touliou, CERTH, touliouk@certh.gr
- Expert:
  Amrish Chourasia, Raising the Floor, amrishc@gmail.com

An experienced ethics supervisor provided by FhG will lead the project Ethics Advisory Board, assisted by further experts. The role of the ethics supervisor is to oversee all relevant issues and to train partners on how to abide with the recommendations of the Ethics Manual. The Ethics Supervisor is first Member of the Ethics Advisory Board, as well as being highly committed to bring ethical thinking into the project reality of all project partners.

Among the objectives considered by the Ethics Supervisor there will be three main activities:

- Promotion of ethical standards: by means of specific informative actions. The development of a questionnaire for project members and its resulting analysis and result dissemination, as well as the establishment of communications to raise awareness among partners are an important part of this activity. The questionnaire intends to explore ethical awareness among project partners. See Annex V. Ethics questionnaire.
- Supporting process to defend ethical considerations by facilitating communication among stakeholders and dissemination of ethical issues that might arise during the research project.
- Technical Research Documentation: where all partners can get information on ethical issues. Establishment of a space where documentation regarding ethical issues can be consulted.

Regarding ethics in relation to the project the establishment of the Local Ethics Committees, the Test Site Ethics Coordinator, Ethics Advisory Board and the Ethics Supervisor will maximize the chances that the research carried out in Prosperity4all is of high standards.

3.4 Procedural organization: Controlling mechanisms

In order to track and control compliance with ethical guidelines and recommendations certain mechanisms have been put in place:

3.4.1 Process for Dissemination of Ethical Issues and Updating the Ethics Manual

The present document “Ethics Manual” has been circulated within the project. Different project partners have been working on it in order to achieve a common understanding of all relevant ethical issues within Prosperity4All and GPII. Once in a post-draft form, the document will be circulated once again, and every project member will be asked to complete the Ethics Questionnaire (see Annex V. Ethics questionnaire). This procedure shall assure a high level of commitment of all partners to the ethical conduct of the project.

The Ethics Supervisor is responsible for circulating the document and questionnaire as well as for the evaluation and communication of the results.

Any updates necessary to the Ethics Manual will be suggested to the Ethical Advisory Board. The Ethics Supervisor is responsible for keeping the Ethics Manual up-to-date and circulating it to all projects members.

Prior to any tests with users, test sites will have confirmed compliance for all the principles presented in this document, its annexes and 502.1. This compliance will be re-confirmed after each phase tests, via the LECs (Local Ethics Committees) established, to check if abidance to the following did take place indeed and, if not, the reason that it did not.

3.4.2 Process of controlling

Participants on the research, developers, evaluators, partners, must consider the possible implications that their work can have in terms of ethical issues. In order to assure this is carried out, communication will be established by the Ethics Supervisor. This person will have regular contact with such interested parties in order to make sure ethical considerations are reflected upon.

In Annex VII a table depicting specific ethical concerns will serve as a monitoring mechanism. The information gathered in the table will help with controlling ethical issues and compliance with the recommendations presented in this document.

Local Ethical Committees will be responsible for monitoring and reporting back to the Ethical Advisory Board as to their compliance (or not) with the Prosperity4All ethical policy and, as advance previously if any problems are encountered and how these had been dealt with.

It should be highlighted that, despite the confirmed intentions from the test sites before the first evaluation round, all of the issues above (as identified in the Ethics Questionnaire for Prosperity4All staff) will be cross-checked to assure that compliance to the ethics principles was followed as expected.

3.4.3 Ethical Conduct Controlling Report

Once a year, within the periodic progress report, an ethical conduct controlling report will summarize all work done on ethical issues within the projects, as well as showing which ethics-related problems arose and how the project has dealt with them. The Ethics Supervisor is responsible for writing the ethical conduct controlling report, which is part of the deliverables of Work package 501. All other project members, especially members of the Local Ethics Board, will contribute to that report. There will be four ethical conduct controlling reports:

Table 1: Deliverables linked to ethical aspects

Deliverable Number	Deliverable Title	Delivery Date (month)

D501.3	Periodic progress report 1 as requested by the EC, including risk assessment and ethical conduct controlling report updates	12
D501.4	Periodic progress report 2 as requested by the EC, including risk assessment and ethical conduct controlling report updates	24
D501.5	Periodic progress report 3 as requested by the EC, including risk assessment and ethical conduct controlling report updates	36
D501.6	Periodic progress report 4 as requested by the EC, including risk assessment and ethical conduct controlling report updates	48

3.4.4 Communication and escalation

During the project lifespan there will be open channels and flexible and quick procedures to communicate any relevant ethical issues and concerns that arise during the project execution. These channels can be used at any time by the concerned part to make their voice heard so emerging ethical issues can be dealt with. It will also try to assess which aspects of the combined mix of cloud computing and accessibility might give rise to ethical problems of a different nature, specific to the field. In turn, it will contribute significantly to a more adequate and proactive broadly applicable approach to the ethical aspects of the new technology.

The procedure to make these concerns known would be to contact the Ethics Advisory Board through the relevant body, in most cases this will be done through the Test Site Ethics Coordinator as the closest and immediate contact. In exceptional cases this can be done by contacting the Ethics Advisory Board directly.

On the other hand, the Ethics Supervisor will proactively contact project members, when questions in terms of ethical issues are expected. This is to ensure, ethically important aspects are not to be forgotten while progressing in the project.

Also during the project, stakeholders' views will be solicited and will be taken into account. This will be done by contacting them and asking them to fill in a questionnaire and through it stakeholders can also report any issues they have. The project will try and provide a sound basis for EU ethical issues policy-making in the coming years related to user centred design in cloud computing. There is the intention of cooperation and using synergies with other EU-funded and international projects in this area of Ethical policies.

When problems and conflicts on ethical issues arise during the project, they will be dealt with first by the appropriate Local Ethics Committee in combination with the Test Site Ethics Coordinator. If solving of the problem is not possible on that stage, it will be delegated to the

Ethics Advisory Board, which then will reach a concordant decision or, if not possible, delegate the problem to the Projects Steering Committee (see Management Handbook, D501.2).

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Eyal, N. (2011): Informed Consent. In: Edward N. Zalta (Hrsg.): Stanford Encyclopedia of Philosophy. http://plato.stanford.edu/entries/informed-consent/

Normative references

Charter of Fundamental rights Charter of Fundamental Rights of the European Union 2000 http://www.europarl.europa.eu/charter/pdf/text_en.pdf

European Disability Strategy 2010-2020: A Renewed Commitment to a Barrier-Free Europe (and Implementation of the strategy: Objectives and Actions) http://ec.europa.eu/justice/discrimination/disabilities/disability-strategy/index_en.htm

European Directives

Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML

Directive 97/46/EC concerning the processing of personal data and the protection of privacy in the telecommunications sector: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31997L0066:EN:HTML

Directive 2000/78/EC on equal treatment in employment and occupation: http://europa.eu/legislation_summaries/employment_and_social_policy/employment_rights_and_work_organisation/c10823_en.htm

Directive 2001/29/EC on copyright:
http://europa.eu/legislation_summaries/internal_market/businesses/intellectual_property/l26053_en.htm

Directive 2002/21/EC on a common regulatory framework for electronic communications networks and services:
http://europa.eu/legislation_summaries/internal_market/single_market_services/l24216a_en.htm

Directive 2002/22/EC on universal service and users' rights relating to electronic communications networks and services (Universal Service Directive):
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:108:0051:0051:EN:PDF

Directive 2004/18/EC on awarding of public contracts
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0018:En:HTML

Directive 2007/65/EC on audiovisual media services:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:332:0027:0045:EN:PDF

Other sources

Getting Through Ethics Review: http://cordis.europa.eu/fp7/ethics_en.html

ICO (Information Commissioner Office) Guidance on the use of cloud computing Version 1.1.:
http://www.ico.gov.uk/for_organisations/data_protection/topic_guides/online/~/media/documents/library/Data_Protection/Practical_application/cloud_computing_guidance_for_organisations.ashx

http://www.criminallawlibraryblog.com/2010/04/intro_to_cloud_computing_and_i.html

https://www.privacyrights.org/fs/fs12-infohandling.htm

WMA Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects http://www.wma.net/en/30publications/10policies/b3/

Annexes

International and European regulations are presented in Annex I. In Annex II a checklist is presented regarding privacy and confidentiality. Annex III provides a checklist for the preparation of any informed consent necessary during the project. In Annex IV checklists dealing with personal data handling and privacy in the work environment and data handling in the cloud will help checking all aspects are covered. Annex V presents ethical questionnaire that will help in monitoring compliance with previously exposed normative, while also exploring participants' views on the project ethical approach. In Annex VI a controlling mechanism is set up for monitoring activities related to the implementation and correct handling of ethical issues in the project. Finally, Annex VII details implications that cloud computing may have in terms of privacy protection and confidentiality.

Further information especially to informed consent and ethics consideration in testing can also be found in the annex of D401.1.

Annex I. Ethical scenario and legislation

In January 2012, the European Commission published proposals for a new framework for data protection legislation. The proposals, in the form of the draft Data Protection Regulation is to replace the existing Data Protection Directive, are now being considered and amended by the European Parliament and Council before adoption. This process may take until 2015. The Regulation covers the use of personal data across a wide range of sectors and will affect how patient data are used in research. The original proposals set out a mechanism for protecting privacy, while enabling research and included a requirement for specific and explicit consent for the use and storage of personal data, while providing an exemption for research, subject to strong ethical and governance safeguards.

In October 2013, the Civil Liberties and Home Affairs (LIBE) committee of the European Parliament adopted amendments that would severely restrict the use of personal data for scientific research purposes without specific consent.

Changes in EU Directives affect the conduct of tests with human participants in all European countries but deviation for existing conditions might differ and be relevant to national legislations and code-of-practice.

Specific guidelines from the EFGCP (the European Forum for Good Clinical Practice) and the American Psychological Association (APA) Ethical Code of Conduct are considered, including reference to vulnerable users (disabled people).

The Council of Europe Convention for the protection of individuals with regard to automatic processing of personal data is the first European instrument in this field. It laid down the basic principles of a lawful data processing addressing the threats from the invasion of information systems, such as the data aggregation, at that time. In this respect, it concerns the automatic data processing, although the Member Countries could extend its applicability to non-automatic data processing. Art. 6 states that medical data may not be processed automatically unless domestic law provides appropriate safeguards. The Convention is of limited importance for EU countries after the enactment of the EC Directives on data protection.

The Charter of Fundamental Rights dedicates a separate article to the protection of personal data. Article 8 sets out the right to the protection of personal data of an individual and thus the protection of personal data has now its own 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 furthermore 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 which shall control the compliance with the data protection rules.

In 1999 the Council of Europe adopted the Recommendation on the Guidelines for the protection of privacy in the information highways. These Guidelines may be incorporated in or annexed to codes of conduct of Internet service provider to obtain legal validity. The Recommendation is in line with the EC Data Protection Directives regarding the principles of the lawful data processing, the duties of the Internet service providers and the rights of the data subject. The Recommendation encompasses a series of detailed information what the users and service providers shall do to reduce the risks arising from the Internet. It is worth mentioning that the users are required to use digital signature and encryption techniques. On the other hand, the service providers are required to use certified privacy enhancing technologies, to ensure data confidentiality and integrity as well as logical and physical security of the network and the services provided over the network. The service providers shall also incorporate detailed privacy statements on the web-sites. Finally, the communication of sensitive data, for instance medical data, for marketing purposes requires the previous, informed and explicit consent of the data subject.

The OECD (Organisation for Economic Co-operation and Development) is actively participating in the issues regarding the data protection, the data protection on the Internet as well as the protection of consumer rights with regard to e-commerce. First, OECD issued Guidelines governing the protection of privacy stipulating the fundamental principles (OECD, 1980).

In 1998, OECD issued a Recommendation with regard to the implementation of the aforementioned Guidelines on global networks. The Recommendation addresses mainly commercial sites offering various goods and services, such as tourism, air travel ticket sales, finance, etc. It is not legally binding, unless the Internet service providers stipulate this explicitly. Although the Recommendation does not address healthcare applications, its provisions might apply as following:

The Recommendation imposes the obligation to the web-site provider to refer with a hyperlink to the national legislation on data protection and the national Data Protection Authority. Moreover, every Data Protection Authority should be present on the Internet through relevant, well-documented and interactive sites. The web-sites shall also maintain on-line privacy statements giving details on the kind of data collected, the purpose of, the use of the clickstream data and processing to which they are subject, as well as the

opportunity to opt out. In case of on-line payments by cards they should configure their systems in such a way that they ask for the card details once, provided that they store this information in highly secure files on non-networked computers. Warning messages on the risks of the Internet shall be provided in case of processing of confidential data. For confidential data the highest degree of security shall be implemented. The implementation of privacy enhancing technologies is also required. Moreover, web-sites should formally state the acceptance of full responsibility for the security and confidentiality of the personal data collected and processed. With regard to data subjects rights the Recommendation highlights the right to access on-line the information collected and stored directly or indirectly, i.e. clickstreams or purchased profiles.

Data Protection Directive 95/46/EC

In 1995, the EC Directive on the protection of personal data was adopted by the Council. The Directive was the first attempt on EC level to recognise the right to privacy and harmonise the national laws. Some main characteristics of the Directive are that it applies equally to public and private bodies, to both automatic and non-automatic data processing, and that the protection is restricted to natural persons (as opposed to legal entities). Moreover, the data must form a part of a filing system, which is defined as any structured set of personal data accessible according to specific criteria.

The directive regulates the processing of personal data, regardless if the processing is automated or not.

Scope

Personal data is defined as "any information relating to an identified or identifiable natural person ("data subject"); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his/her physical, physiological, mental, economic, cultural or social identity;" (art. 2 a).

This definition is meant to be very broad. Data is "personal data" when someone is able to link the information to a person, even if the person holding the data cannot make this link. Some examples of "personal data": address, credit card number, bank statements, criminal record, ...

The notion processing means "any operation or set of operations which is performed upon personal data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by

transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction;" (art. 2 b).

The responsibility for compliance rests on the shoulders of the "controller", meaning the natural or artificial person, public authority, agency or any other body which alone or jointly with others determines the purposes and means of the processing of personal data; (art. 2 d).

The data protection rules are applicable not only when the controller is established within the EU, but whenever the controller uses equipment situated within the EU in order to process data. (art. 4) Controllers from outside the EU, processing data in the EU, will have to follow data protection regulation. In principle, any online shop trading with EU citizens will process some personal data and is using equipment in the EU to process the data (the customer's computer). As a consequence, the website operator would have to comply with the European data protection rules. The directive was written before the breakthrough of the Internet, and to date there is little jurisprudence on this subject.

Principles

Personal data should not be processed at all, except when certain conditions are met. These conditions fall into three categories: transparency, legitimate purpose and proportionality.

Transparency

The data subject has the right to be informed when his/her personal data are being processed. The controller must provide his/her name and address, the purpose of processing, the recipients of the data and all other information required to ensure the processing is fair (art. 10 and 11).

- Data may be processed only under the following circumstances (art. 7):
- when the data subject has given his/her consent;
- when the processing is necessary for the performance of or the entering into a contract;
- when processing is necessary for compliance with a legal obligation;
- when processing is necessary in order to protect the vital interests of the data subject;
- processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller or in a third party to whom the data are disclosed;
- processing is necessary for the purposes of the legitimate interests pursued by the controller or by the third party or parties to whom the data are disclosed, except

where such interests are overridden by the interests for fundamental rights and freedoms of the data subject.

The data subject has the right to access all data processed about him/her. The data subject even has the right to demand the rectification, deletion or blocking of data that is incomplete, inaccurate or isn't being processed in compliance with the data protection rules (art. 12).

Legitimate Purpose

Personal data can only be processed for specified, explicit and legitimate purposes and may not be processed further in a way incompatible with those purposes (art. 6 b).

Proportionality

Personal data may be processed only insofar as it is adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed. The data must be accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that data which are inaccurate or incomplete, having regard to the purposes for which they were collected or for which they are further processed, are erased or rectified; The data shouldn't be kept in a form which permits identification of data subjects for longer than is necessary for the purposes for which the data were collected or for which they are further processed. Member States shall lay down appropriate safeguards for personal data stored for longer periods for historical, statistical or scientific use (art. 6).

When sensitive data is being processed, extra restrictions apply (art. 8). The data subject may object at any time to the processing of personal data for the purpose of direct marketing (art. 14).

A decision which produces legal effects or significantly affects the data subject may not be based solely on automated processing of data (art. 15). A form of appeal should be provided when automatic decision making processes are used.

Supervisory authority and the public register of processing operations

Each member state must set up a supervisory authority, an independent body that will monitor the data protection level in that member state, give advice to the government about administrative measures and regulations, and start legal proceedings when data protection regulation has been violated. (art. 28) Individuals may lodge complaints about violations to the supervisory authority or in a court of law.

- The controller must notify the supervisory authority before he/she starts to process data. The notification contains at least the following information (art. 19):

- the name and address of the controller and of his/her representative, if any;
- the purpose or purposes of the processing;
- a description of the category or categories of data subject and of the data or categories of data relating to them;
- the recipients or categories of recipient to whom the data might be disclosed;
- proposed transfers of data to third countries;
- a general description of the measures taken to ensure security of processing.
- This information is kept in a public register.

Art. 29-Data Protection Working Party: Working Document on Privacy on the Internet

The Data Protection Working Party has been established by art. 29 of Directive 95/46/EC and is the independent advisory body on data protection and privacy. Its tasks are laid down in art. 30 of Directive 95/46/EC and in art. 14 of Directive 97/66/EC. The opinions and recommendations of the Working Party are not legally binding, reflect, however, the current trends on European level and influence the decisions taken by the European Commission and the Committee established by art. 31 of Directive 95/46/EC.

This working document seeks to raise awareness and to promote the public debate on issues of on-line data protection. It therefore provides detailed information on technical aspects of how the Internet and the communications through the Internet are organised and what are the main privacy risks arising from the use of the Internet. In this context, it aims at the same time to provide an interpretation of the data protection Directives in that field. It follows a "holistic" approach by basing the analysis of privacy risks, the obligations and rights of the involved parties on both the general data protection Directive 95/46/EC and the privacy and telecommunications Directive 97/66/EC.

The risks to privacy arise from the activities of the various intermediaries. For instance, the use of routers, e.g. the telecommunications nodes in the Internet, which have the characteristic that the information may pass through a non-EU country which may or may not have adequate data protection, if this at the time of transmission is the "shortest" way of transmission.

According to the opinion of the Working Party, Directive 97/66/EC applies to telecommunication service providers who connect Internet users and ISPs and access service providers who provide the requested Internet service, transfer the request from the Internet user to proxy server and then to the requested website. It also applies to providers of routers and connecting lines. Moreover, the Directive 97/66/EC shall apply also to Internet Service Providers (ISPs) providing hosting services, such as portal services, who may log the

requests, the referring pages and post cookies on the hard disk of the user and make profiles. The latter is, however, arguable since the host service providers transmit content information and thus it should rather come under the general data protection Directive. The working document recognizes that the applicability of the Directive 97/66/EC to the activities of the host service providers is not always clear. When the provider hosts its own portal site comes under the general data protection directive whilst it comes under the specific when he plays the role of the access service provider.

The providers of Internet services, dependent on the aforementioned distinctions, are subject to the obligations to confidentiality and security laid down in both Directives (art. 4, 5 97/66/EC, art. 6 - 8, 16, 17 95/46/EC). Traffic data provided by providers of routers and connecting lines, ISPs and telecommunication providers shall be protected as content data according to art. 5 of Directive 97/66/EC as this is the case in the proposal for an amendment of 97/66/EC.

Interception of communication is unacceptable unless it fulfils three fundamental criteria in accordance with art. 8 (2) EHRC, and the European Court of Human Rights interpretation of this provision: a legal basis, the need for such a measure in a democratic society, and conformity with one of the legitimate aims listed in the Convention.

The Working party strongly recommends the use and offer of encryption tools by the providers of email services at no additional cost. The providers should also offer secure connection for the transmission of the emails. The need of integrity and authentication should be considered as well.

A means for ensuring encryption is the Secure Socket Layer (SSL) which is implemented in most popular browsers and establishes a secure channel between the client and server computers. This is achieved by means of encryption and digital certificates. SSL enables the authentication of the server to whom the information shall be sent and the integrity of the data. It does not ensure the authentication of the client. These difficulties shall be overcome by the protocol SET (Secure Electronic Transactions) that provides for confidential transmissions using encryption, authentication of the parties, integrity and non-revocation (through digital signatures). The Working Party seems to support the use of the SET protocol instead of SSL, especially when sensitive information, such as the credit cards data, will be transmitted. Moreover, if a higher level of security is needed, the digital certificates should be stored on smart cards.

It must be pointed out that concrete legal requirements on the data collection depend also on national legislation. All the above EC Directives and International Agreements will be fully

adopted within Prosperity4all. The conformance to them will be safeguarded by the Prosperity4all Ethics Advisory Board.

Annex II. Privacy and confidentiality

The following checklist can be used to ascertain appropriate dealings with privacy and confidentiality in Prosperity4All:

1. Is the user aware of the details set out in the terms of service for cloud providers or of the consequences of sharing information with a cloud provider?
2. Are there any procedural or substantive barriers that may prevent or limit the disclosure of some records to third parties, including cloud computing providers?
3. Are all parties aware of the fact that when a person or system stores information with a third party (including a cloud computing provider), the information may have fewer or weaker privacy protections than when the information remains only in the possession of the person?
4. As stored information may be subject to the laws of the country where the physical machine is located, are these relevant laws been checked and complied with? If the information is dispersed or moved around different countries this must also be evaluated.
5. Can a user freely examine the terms of service of a cloud provider? (Have you read the company's license agreement and Security policy, and do you understand the terms?)
6. In the solution developed are we putting everything in the cloud or are we only using a particular application in the cloud?
7. If you implement a hybrid system, that uses resources from the cloud and locally then it is necessary to make sure there is a tight integration between the two. Therefore, would there be any breach in the personal date due to the integration of a hybrid system?
8. Do you understand the technical facts in the application/solution and what are the backup procedures if one system fails?

Annex III. Considerations for Informed Consent

Informed Consent is crucial in all aspects of social research and particular attention will be given, when disabled people are involved, that rights are protected and compliance is always freely entered into. Information that will affect the respondent's willingness to participate will always be provided in appropriate accessible formats and never be deliberately withheld. Potential participants will also not be overwhelmed with unnecessary information.

The following notes should be taken into account by the supervisors/investigators of the Prosperity4All trials. They refer to special issues that need to be known beforehand for testing with persons with several types of impairments. The notes below refer to the consent form itself and/or the treatment of the overall testing.

It has to be remembered that participants with cognitive impairments/ learning difficulties that are unable to understand the informed consent will not participate in the tests. Only participants with who can give informed consent will be offered to participate.

Considerations for speech and hearing impaired persons

1. If necessary, hire a sign language interpreter for deaf people who use Sign Language.
2. Remember that some deaf people will not be able to read the consent form since signs and not words may be their main means of communication. In such cases the sign language interpreter will need to interpret the form in sign language so that the person can understand it.
3. Make sure that a deaf communicator guide is reserved for people who are deaf.
4. Hire a lip speaker or note taker if necessary.
5. Provide written notes for hard of hearing people if they require it.
6. Make sure hearing aid users have hearing aids switched on with working batteries and have a neck loop if necessary. Provide loop induction output from computer sound output.
7. Make sure that people who are hard of hearing but do not use a hearing aid are provided with a head set if it helps them to hear better.
8. Follow the guidance on good practice in communicating with people who are hard of hearing and check that the person understands the procedure(s).

Considerations for partly sighted and blind persons

1. Provide a consent form transcribed into Braille for blind people who need it.

2. Produce a large print version of the consent form for partially sighted people who need it.
3. If people are unable to read the form, read it to them and talk through the questions ensuring that the person understands what is being asked of him/her.
4. Give them the opportunity to make clarifications and ask questions. Record in the notes that you have done so.
5. Make sure that a blind communicator guide is reserved for people who are blind.
6. Check that the person fully understands the procedure(s) and possible outcomes

Considerations for illiterate participants

1. Verbal consent is a valid form of consent provided that the principles of voluntarism, information and capacity are met. This should be witnessed and recorded in the researcher notes.
2. Make sure that the consent form is fully explained to the person and check that they understand the procedure(s).
3. The verbal consent should be recorded in the person's notes.
4. Some people may wish to make their mark on the form. This should be witnessed and recorded in the researcher notes.
5. A proxy is necessary in this case. The proxy will sign the initial form on behalf of the participant, whereas in addition the participant will sign the following short form (with a mark). The proxy will verify to the participant that the undersigned is in line with what they have orally consented to.
6. Another practice that could be followed is to audio record the consent process and give the participant a CD recording of the consent.

Considerations for persons with language impairments (i.e. dyslexic, print-disabled, etc.)

1. Some people with learning disabilities will be able to consent to participation especially if you take extra time is taken to help them to understand.
2. Family members or formal care-takers (if any) may express a view about what they think is best. However, they are not able to consent on behalf of an adult with learning disabilities and sign the consent form for them except as a witness.
3. Follow the good practice guidance on communicating with people with learning disabilities.

It is advised to seek oral consent as capacity to consent may be variable due to specificity of the learning disability. Thus, the initial participant consent form of Annex 1 should be used and consent should be recorded. However, in this case, the participant does not need to sign the additional short form of Annex 1; the original one is enough.

Considerations for persons with motor impairments (only persons with upper limb impairments will participate in Prosperity4All)

Prosperity4All participants include persons with limitations in motion or strength or coordination or anthropometric limitations of upper limbs. This includes people with tetraplegia, hemiplegia, one-handed users, co-ordination and balance disorders, and varying degrees of neuromuscular impediment.

These people are expected to completely understand the test procedures and therefore the same forms as for healthy and able bodied participants can be used. However, it may be the case that people with upper limb impairments may not be able to sign themselves the consent form, and as such, they will have to be witnessed or if applicable provided with the respective aid to do so themselves.

Example Wording for Informed Consent Form

The following consent form is to be pre-filled in by the investigator/supervisor of the Prosperity4All trials and then by each participant of the tests. Signatures are required from both sides. This form will be signed twice. The investigator/supervisor will keep one copy and the other copy will be given to the participant (or, if applicable, to the person representing the volunteer). The following form encompasses all cases (i.e. cases that do not require any special treatment, or cases that do so, like a verbal consent that is required by persons with cognitive impairments or illiterate participants). The supervisor of the trials should pre-review the following form (and its additional part) and remove all those parts that are not applicable in each participant.

The Informed Consent has two parts:

- **Information Sheet (to share information about the study with volunteer)**
- **Certificate of Consent (for signatures if volunteer choose to participate)**

Prosperity4All Informed Consent Form (General Template)

Information Sheet

This part will be pre-filled by the investigator for each user to participate in one or more trials and as follows it should contain all this information:

Introduction

Briefly state who you are and that you are inviting them to participate in research which you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions at any time.

(Example: I am X, working for the Y organization. I am doing research on accessibility through electronic devices. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

This consent form may contain words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me or of another researcher.)

Purpose of the research

Explain the research question **in lay terms** that will clarify rather than confuse. Use local and simplified words rather than scientific terms and professional jargon. In your explanation, consider local beliefs and knowledge when deciding how best to provide the information. Investigators however need to be careful not to mislead participants, by suggesting research interests that they do not have. For example, if the study wants to find out about treatments provided by local practitioners, wording should not suggest that they want to find out about how the practitioners are advertising themselves. Misleading participants may be essential and justified in certain circumstances, but that needs to be carefully argued, and approved by an ethics committee.

(Example: We want to find ways to make devices easy to access for people with disabilities through their preferences and needs. We believe that you can help us by telling us what you like and what are your needs when using digital devices. We want to learn about the way you use interactive technologies and the way you would like to use these technologies. We also

want to know more about your experiences using technology because this knowledge might help us to learn how to improve auto configuration methods.)

Type of Research Intervention

Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a questionnaire, or a series of finger pricks.

(Example: This research will involve your participation in a group discussion that will take about one and a half hour, and a one hour interview).

Participant Selection

Indicate why you have chosen this person to participate in this research. People wonder why they have been chosen and may be fearful, confused or concerned.

(Example: You are being invited to take part in this research because we feel that your experience as a disabled person (or as an expert, or as carer) can contribute much to our understanding and knowledge of users' interaction with digital devices.)

> ***Example of question to elucidate understanding:*** *Do you know why we are asking you to take part in this study? Do you know what the study is about?*

Voluntary Participation

Indicate clearly that they can choose to participate or not. State, **only if it is applicable**, that they will still receive all the services they usually do if they choose not to participate. Explanation: It may be more applicable to assure them that their choosing to participate or not will not have any bearing on their job or job-related evaluations. This can be repeated and expanded upon later in the form as well. It is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context. Although, if the interview or group discussion has already taken place, the person cannot 'stop participation' but request that the information provided by them not be used in the research study.

(Example: Your participation in this research is entirely voluntary. It is your choice whether to participate or not.

> ***Examples of question to elucidate understanding:*** *If you decide not to take part in this research study, do you know what your options are? Do you know that you*

do not have to take part in this research study, if you do not wish to? Do you have any questions?

Procedures

A. Provide a brief introduction to the format of the research study.

(Example: We are asking you to help us learn more about assistive technologies and their use among beneficiaries)

B. Explain the type of questions that the participants are likely to be asked in the focus group, the interviews, or the survey. If the research involves questions or discussion that may be sensitive or potentially cause embarrassment, inform the participant of this.

Example 1 (for focus group discussions)

Take part in a discussion with 7-8 other persons with similar experiences. This discussion will be guided by [name of moderator/guider] or myself.

The group discussion will start with me, or the focus group guide or moderator (use the local word for group discussion leader), making sure that you are comfortable. We can also answer questions about the research that you might have. Then we will ask you questions about the assistive technologies and give you time to share your knowledge. The questions will be about assistive technology, how is it used, what people used, and what happens when used it.

We will not ask you to share personal beliefs, practices or stories and you do not have to share any knowledge that you are not comfortable sharing.

The discussion will take place in [location], and no one else but the people who take part in the discussion and guide or myself will be present during this discussion. The entire discussion will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The tapes will be destroyed after _____number of days/weeks.

Example 2 (for interviews)

Participation in an interview with [name of interviewer] or myself.

During the interview, I or another interviewer will sit down with you in a comfortable place at XXXX. If it is better for you, the interview can take place in your home or a friend's home. If

you do not wish to answer any of the questions during the interview, you may say so and the interviewer will move on to the next question. No one else but the interviewer will be present unless you would like someone else to be there. The information recorded is confidential, and no one else except [name of person(s)] will access to the information documented during your interview. The entire interview will be tape-recorded, but no-one will be identified by name on the tape. The tape will be kept [explain how the tape will be stored]. The information recorded is confidential, and no one else except [name of person(s)] will have access to the tapes. The tapes will be destroyed after _____number of days/weeks.

Example 3 (for questionnaire surveys)

You fill out a survey, which will be provided by [name of distributor of blank surveys] and collected by [name of collector of completed surveys]. Or you may answer the questionnaire yourself, or it can be read to you and you can say out loud the answer you want me to write down.

If you do not wish to answer any of the questions included in the survey, you may skip them and move on to the next question. [Describe how the survey will be distributed and collected]. The information recorded is confidential, your name is not being included on the forms, only a number will identify you, and no one else except [name of person(s) with access to the information] will have access to your survey.)

Duration

Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

(Example: The research takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, we will visit you three times for interviewing you at one month interval and each interview will last for about one hour each. The group discussion will be held once and will take about one and a half hour.)

> ***Examples of question to elucidate understanding:*** *If you decide to take part in the study, do you know how much time will the interview take? Where will it take place? Do you know that we will be sending you transport to pick you up from your home? Do you know how much time will the discussion with other people take? If you agree to take part, do you know if you can stop participating? Do you know that you may not respond to the questions that you do not wish to respond to? Etc. Do you have any more questions?*

Risks

Although there is no foreseen risk in Prosperity4All research researchers should explain and describe any risks that you anticipate or that are possible. The risks depend upon the nature and type of qualitative intervention, and should be, as usual, tailored to the specific issue and situation.

Or if for example, the discussion is on opinions on government policies and community practices, and in general no personal information is sought, then the text under risks could read something like "There is a risk that you may share some personal or confidential information by chance, or that you may feel uncomfortable talking about some of the topics. However, we do not wish for this to happen. You do not have to answer any question or take part in the discussion/interview/survey if you feel the question(s) are too personal or if talking about them makes you uncomfortable.)

Benefits

Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question. Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation.

(Example: There will be no direct benefit to you, but your participation is likely to help us find out more about how to provide an easy way to personalize electronic devices and services).

Reimbursements

State clearly what you will provide the participants with as a result of their participation. These may include, for example, travel costs and reimbursement for time lost. The amount should be determined within the host country context.

Example: You will not be provided any incentive to take part in the research. However, we will give you [provide a figure, if money is involved] for your time, and travel expense (if applicable).

> ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be reimbursed? Do you have any other questions?*

Confidentiality

Explain how the research team will maintain the confidentiality of data with respect to both information about the participant and information that the participant shares. Outline any

limits to confidentiality. Inform the participant that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and therefore more likely to be stigmatized. If the research is sensitive and/or involves participants who are highly vulnerable - research concerning violence against women for example - explain to the participant any extra precautions you will take to ensure safety and anonymity.

(Example: The research being done in the community may draw attention and if you participate you may be asked questions by other people in the community. We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc.])

CERTIFICATE OF CONSENT

This section must be written in the first person. It should include a few brief statements about the research and be followed by a statement similar the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign (The witness has to be accepted by the Local Ethics Research Committee). A researcher or the person going over the informed consent must sign each consent. Because the certificate is an integral part of the informed consent and not a stand-alone document, the layout or design of the form should reflect this. The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

Example: I have been invited to participate in research about audiphones and hearing aids.

(This section is mandatory)

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to be a participant in this study

Print Name of Participant_____

Signature of Participant _____

Date _____

Day/month/year

Special Conditions

If the volunteer is illiterate then the consent certificate will present the following format:

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness_____

Signature of witness _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.

2.

3.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date _____

Day/month/year

Following the previous guidelines the Informed consent form used during the first users involvement was:

Consent Form for Participants in Prosperity4All Research and Evaluation Studies

Please complete this form after you have read the Information Sheet and/or listened to an explanation about the research.

Thank you for considering taking part in this research. The person organizing the research has explained the project to me and I agree to take part.

I understand that if I have any questions arising from the Information Sheet or explanation already given to me I can ask the researcher before I decide whether to join in. I will be given a copy of this Consent Form to keep and refer to at any time.

I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and withdraw from it immediately without giving any reason. Furthermore, I understand that I will be able to withdraw my data.

I consent to the processing of my personal information for the purposes explained to me. I understand that such information will be treated in accordance with the terms of Data Protection Laws.

Contact details of the participant:
[the following to be filled in by the participant or his/her proxy]:

- Name (in capitals):
- Gender:
- Age:
- Nationality:
- E-mail:
- Telephone:

- Type of impairment (if applicable; for users with impairments participating):
- Type and years of expertise (if applicable; for experts participating):
- Any medication taken or health condition that would be needed to be known by a medical emergency centre:
- Participant's reference number: [this is to be given and filled in by the supervisor]
- Contact details of the proxy (may be witness, carer, etc.): [the following to be filled in by the proxy of the participant, if any/applicable]:
- Name (in capitals):
- Relationship to participant:
- Expertise (if any; i.e. carer, ...):

Participant's Statement:

I _____ (Print Name) agree that the research project has been explained to me to my satisfaction and I agree to take part in the study. I have read both the notes written above and the Information Sheet about the project, and understand what the research study involves.

Signed: Date:

Venue (address):

Proxies/Witnesses Statement [only if applicable]:

I witness that the participant is unable to sign the consent form but has consented to participate in the project. They have read/been read both the notes written above and the Information Sheet about the project, and they understand what the research study involves.

Signed: Date:

Venue (address):

Relationship to participant: _____

Investigator's Statement:

I, _____, confirm that I have given this research participant information on the study, which in my opinion is accurate and sufficient for the participant to understand fully the nature, risks and benefits of the study, and the rights of a research participant.

There has been no coercion or undue influence. I have witnessed the signing of this document by the participant (and/or the proxy).

Signed Date:

Venue (address):

Additional form to be signed in addition to the above by the participant, the investigator and the proxy in cases of persons with cognitive impairments and illiterate persons

In these cases, the consent form should be verbally explained in a language that the participant can understand. His/her proxy should sign the above form on his/her behalf, whereas the participant needs to give oral consent that will be recorded and sign (with a mark if not possible in other way) the following short form (the proxy will verify that what the participant signs below is in compliance with what s/he has agreed orally).

Documentation of verbal presentation of English-language consent form

By signing below, I voluntarily agree to participate in this research study. The study and consent form have been verbally explained to me in a language I understand. I have had the opportunity to ask all my questions about this study. I have received answers to all my questions.

Date:

Venue (address):

Participant name (in capitals):

Participant signature:

Proxy name (in capitals):

Proxy signature:

Investigator/supervisor name (in capitals):

Investigator/supervisor signature

Annex IV. Work practices and environments in Personal data handling and privacy

The following questions can serve as a guide in order to make sure all process performed during the research activities carried out by people involved in Prosperity4all in their work environments are compliant with the norms.

Appropriate dealing with personal data handling and privacy concerns:

- Security of personally identifiable information—whether stored in electronic, paper or micro-graphic form— should be safe.
- Does the project have staff specifically assigned to data security?
- Do project staff members keep abreast of technical and legal issues concerning data security?
- Have you developed a security breach response plan in the event that the project experiences a data breach?
- Have you developed security guidelines for laptops and other portable computing devices when transported off-site?
- Is physical access restricted to computer operations and paper/micrographic (certain documents regarding questionnaires used in Prosperity4all that contains for example demographic data) files that contain personally identifiable information?
- Do you have procedures to prevent former employees engaged in Prosperity4all from gaining access to computers and paper files?
- Are sensitive files segregated in secure areas/computer systems and available only to authorized persons?
- Are filing cabinets containing sensitive information locked? Are computers, laptops, and networks password protected?
- Do all Prosperity4all project involved personnel follow strict password and virus protection procedures?
- Are employees engaged in Prosperity4all required to change passwords often, using "fool proof" methods?
- Is encryption used to protect sensitive information (a particularly important measure when transmitting personally-identifiable information over the Internet)?
- Do you regularly conduct systems-penetration tests to determine if your systems and Prosperity4all systems and solutions are hacker proof?

- If your organization is potentially susceptible to industrial espionage, have you taken extra precautions to guard against leakage of information?

Additional Security Practices

- When providing copies of information for others, do employees make sure that nonessential information is removed and that personally identifiable information that has no relevance to the transaction is either removed or masked?
- Are employees engaged in Prosperity4all trained never to leave computer terminals unattended when personally identifiable information is on the screen? Do you use password-activated screen-saver programs?
- Are all employees engaged in Prosperity4all who handle personal information—including temporary, back-up and contract staff—trained to detect when they are being "pumped" for personal information by unauthorized and unscrupulous persons? For example pretext interviews are more common than might be expected and are the stock in trade of persons bent on finding out confidential personal information to which they are not entitled. Equally, information registered on forms (experimental tasks as well as questionnaires from all user involvement activities) has data that must be safeguarded.
- Do you perform background checks on prospective employees who will have access to personal information of customers, clients, or employees?
- Have employees been instructed on what might constitute inappropriate use of social networking sites? Employees must be made aware of the privacy pitfalls inherent in social media. "Tweeting" or "Facebooking" about sensitive work issues can have adverse consequences far beyond a simple conversation. This point is relevant in Prosperity4all in the use of dissemination and recruitment activities.
- Have you inventoried the various types of data being stored and classified it according to how important it is and how costly it would be to the organization if it were lost or stolen?

Records Retention and Disposal

- Does your organization have a records retention/disposal schedule for personally identifiable information, whether stored in paper, micrographic or electronic (computer) media?
- Volunteers' records stored electronically or in paper files are company assets, just like the furniture or the computers. Not only is that, but volunteers' personal

information, subject to a myriad of laws that dictate privacy protections, safeguarding measures, and proper disposal. Even in hard times, when a company has to close its doors, customer data should never be abandoned or left at the curb for the trash collector. Such actions could subject owners, even of a defunct business, to unwanted lawsuits by customers and government regulators.

- When disposing of computers, diskettes, magnetic tapes, CD-ROMs, hard drives, memory sticks, mother boards, and any other electronic media which contain personally identifiable information, are all data rendered unrecoverable by either physically destroying the device or by over-writing the data sufficiently to ensure destruction?
- If you use third-party services for computer recycling or destruction, have you selected a service that provides a certificate of destruction?
- When disposing of waste and recycling paper, are all documents that contain personally identifiable information placed in secure padlocked containers or shredded? (Shredding should be cross-cut, diamond-cut, or confetti-cut shredding, not simply continuous [single-strip] shredding, which can be reconstructed.) Does your recycling company certify its disposal/destruction methods? Is it bonded?
- When engaging an external business to destroy records or electronic media, do you check references? Do you insist on a signed contract spelling out the terms of the relationship? Do you visit the destruction site and require that a certificate of destruction be issued upon completion?
- When dealing with another company or government agency, do you ask about its security protocol regarding personal information? Do you inquire whether it shares that information with anyone? Do you find out if it does background checks on employees with access to your personal information.
- Contracts with outside service providers as well as employee agreements should specify that customer data is the company's exclusive property and should only be used as necessary to carry out contractor or employment duties. Such contracts and agreements should also incorporate the company's privacy and data security policies. Contracts should also delineate the service provider's specific obligations, rather than simply stating that the contractor will comply with all applicable laws. Is staff specifically assigned to data security?
- Do staff members participate in regular training programs to keep abreast of technical and legal issues?
- Have you developed a security breach response plan in the event that your company or organization experiences a data breach?

- Have you developed security guidelines for laptops and other portable computing devices when transported off-site?
- Is physical access restricted to computer operations and paper/micrographic files that contain personally identifiable information?
- Do you have procedures to prevent former employees from gaining access to computers and paper files?
- Are sensitive files segregated in secure areas/computer systems and available only to qualified persons?
- Are filing cabinets containing sensitive information locked? Are computers, laptops, and networks password protected?
- Do you have audit procedures and strict penalties in place to prevent telephone fraud and theft of equipment and information?
- Do all employees follow strict password and virus protection procedures? Are employees required to change passwords often, using "fool proof" methods?
- Is encryption used to protect sensitive information (a particularly important measure when transmitting personally-identifiable information over the Internet)?
- Do you regularly conduct systems-penetration tests to determine if your systems are hacker proof?
- If your organization is potentially susceptible to industrial espionage, have you taken extra precautions to guard against leakage of information?

Wireless Communications

- Are employees properly trained to make sure that all data is properly encrypted and that encryption is not either accidentally or intentionally disabled?
- While organization policies should emphasize the importance of encryption, these policies may be ignored by careless users, particularly if non-compliance does not result in adverse consequences.
- Many organizations remain overly dependent upon encryption solutions to protect sensitive data on their laptops. Companies relying solely on encryption cannot be sure whether stored data has actually been encrypted, if it has been compromised, or even which files have been accessed. Corporations should take a layered approach to security, making encryption but one layer of their approach to data security.
- Are employees trained in techniques to spot suspicious activity, including signs that a computer has been infected with malware?

- Does the organization have policies, procedures and training programs that emphasize responsible information-handling practices?
- Is the network connection between home and work secure?
- Do laptops containing sensitive information have a "kill-switch," that is, remotely-enabled software that can disable lost or stolen laptops? The loss or theft of laptops is one of the most common ways that the security of corporate data is compromised.

Annex V. Ethics questionnaire

Questionnaire for Prosperity4All staff

Introduction

As a way to extend the knowledge we have on ethical issues regarding people with disabilities and senior citizens participating in this research processes is important to receive your feedback on the Ethics Manual (D501.2 ff.) document.

Researchers input

Please let us know of any comments, concerns, observations and opinions that you have on the issues reflected on the specific document.

It would also be interesting to know about the following issues:

Q1. Do you think the document is relevant to the project? Yes / No

Q2. The contents of the document fit the project…

Very well 1 2 3 4 5 6 7 Very poorly

Q3. The document objectives were established at the beginning of the document... Very clearly 1 2 3 4 5 6 7 Very poorly

Q4. Relating to the content was…

Very easy 1 2 3 4 5 6 7 Very difficult

Q5. Understanding the document was…

Very easy 1 2 3 4 5 6 7 Very difficult

Q6. Indicate on the following scale, the level to which you feel the objectives have been achieved (where 1 = 10% and 10 = 100%)

1 2 3 4 5 6 7 8 9 10

Q7. What could have been done, or what do you feel you needed that could have facilitated information acquisition on the ethical area?

Q8. Is it inconvenient to follow the ethical procedures? If you found some obstacles to follow ethical guidelines, what are they?

Q9. Making colleagues aware of the ethical issues compliance need is

Very Easy 1 2 3 4 5 6 7 Very Difficult

Annex VI. Ethics indicators

In order to track assurance of ethical guidance in the project the following information can be registered.

The informed consent that should be presented to all volunteers in testing and other participatory activities can be evaluated for its clarity and ethical appropriateness. Prosperity4all evaluators will register whether volunteers understood the information presented in the informed consent, whether this was adequate and whether users signed the document. Discrepancies between these three parameters (Comprehension, truth and freedom) would show inconsistencies in the procedure and an investigation must be carried out in order to correct it.

The information procured by the Ethics Questionnaire will also serve to understand any possible concern that participants have and to check that open channels are presented to them.

Registration of approaches to the Local Ethics Committee will also provide information about the openness and willingness in the project to take into account ethical issues. Its outcomes, if such approaches are taken, will also be monitored.

Tools	Description	Information	Value
Informed Consent	Evaluation of Informed Consent	Understood Signed	
Ethics	Information Provided Informed Consent	Adequate	
Questionnaire feedback	Information relevant to the project	Comments, observations, etc.	
Local Ethics Committee	Request to the Local Ethics Committee	Nature of request	

Annex VII. Implications of cloud computing in terms of privacy protection and confidentiality

According to Gellman (Gellman, 2009) there are several implications from cloud computing in terms of privacy protection and confidentiality:

- Cloud computing has significant implications for the privacy of personal information as well as for the confidentiality of business and governmental information.
- A user's privacy and confidentiality risks vary significantly with the terms of service and privacy policy established by the cloud provider.
- For some types of information and some categories of cloud computing users, privacy and confidentiality rights, obligations, and status may change when a user discloses information to a cloud provider.
- Disclosure and remote storage may have adverse consequences for the legal status of or protections for personal or business information.
- The location of information in the cloud may have significant effects on the privacy and confidentiality protections of information and on the privacy obligations of those who process or store the information.
- Information in the cloud may have more than one legal location at the same time, with differing legal consequences.
- Laws could oblige a cloud provider to examine user records for evidence of criminal activity and other matters.
- Legal uncertainties make it difficult to assess the status of information in the cloud as well as the privacy and confidentiality protections available to users.
- Responses to the privacy and confidentiality risks of cloud computing include better policies and practices by cloud providers, changes to laws, and more vigilance by users.