



**Ambient Assisted Living  
AAL Joint Programme  
AAL-2011-4-040**

**ASSISTANT**

**Aiding SuSustainable Independent Senior TrAvellers to Navigate in Towns**

Orientation and Navigation

**D 5.2 Ethics Guideline Handbook**

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| RE | Restricted to a group specified by the consortium (including AAL) |    |
| CO | Confidential, only for members of the consortium (excluding AAL)  |    |



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# 1. Introduction

This document has been prepared by the ASSISTANT consortium, to be used as a guide with respect to ethical issues that may arise in the course of its research activities. These ethics will apply to all AAL partners undertaking research, and to guidance counsellors/participants enrolled on ASSISTANT programmes. This is not a document discussing the legal and theoretical aspects of ethics with respect to research and development. For this, there are many publications and books, some of which are listed in section two.

To promote ethical conduct in relation to its research activities, ASSISTANT's participants are required to consult and engage with this document throughout the research process. If an ethical issue arises during a trial, the trial investigator should initially consult this document and documents referenced in section 2, and contact the Technical Committee group if the issue remains unresolved.

Research ethics are fairly simple. In ASSISTANT, practical research ethics are basically concerned with:

- 1) Experimental protocol
- 2) Informed consent
- 3) Anonymous data

This deliverable will provide guidance on these three issues. First, there is a discussion of the source of the legal and procedural aspects of research ethics. Subsequent sections will discuss protocol generation and how to write and use informed consent documents. The deliverable finishes with a discussion of the concept of anonymous data, and its implementation.



## 2. Sources of Ethical Guidance

This section presents the sources that form the basis for the ethical approach to research that will be carried out during the ASSISTANT project. First, an overview of ASSISTANT will be provided, along with the general principles of ethical research. This will be followed by a table of references to the sources, drawn from the body of law and from European funding organizations. In considering these topics, it is worth noting that ASSISTANT, whilst not subject to the ethical obligations that medical experimentation requires because it cannot be considered as a "medical device" and therefore the ethical aspect of the tests should be limited to our internal guidelines. However it is not merely a technical system, so that the evaluation of system trials requires the same ethical considerations as a psychological experiment. A table of the five dimensions of ethics in research is presented as Annex A, at the end of the document.

There are four general ethical principles, which include a number of specific ethical standards.

1. Respect for the Rights and Dignity of the Person
2. Aptitude
3. Obligation
4. Veracity

The ASSISTANT project shall respect the rights of stakeholders and research participants to privacy, confidentiality, self-determination and autonomy, consistent with professional obligations, and within the law and according to the United Nations' Declaration of Human Rights [1].

The ASSISTANT project shall promote and honour the rights, dignity and worth of all its stakeholders, and those of research participants. Partners in the ASSISTANT project shall respect the rights of stakeholders and research participants to privacy, confidentiality, self-determination and autonomy, consistent with its professional obligations, and within the law. ASSISTANT will ensure that the research process is cognisant of diverse populations, and allow for the protection of certain groups, such as older people, people with physical or sensory disabilities, and those with mild cognitive disabilities.

**Table 1 - Sources of ethical research**

| Topic   | Document  | Access  |
|---|---|---|
| Root of Helsinki declaration  | 1947 & 1948 (UNO) – Nuremberg Code  | <a href="http://libguides.library.dal.ca/aecontent.php?pid=313&amp;sid=26528">http://libguides.library.dal.ca/aecontent.php?pid=313&amp;sid=26528</a>   |
| Foundation of all research ethics   | WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects  | <a href="http://www.wma.net/en/30publications/10policies/b3/17c.pdf">http://www.wma.net/en/30publications/10policies/b3/17c.pdf</a>   |
| Psychological research ethics   | Ethical Principles of Psychologists and Code of Conduct   | <a href="http://www.apa.org/ethics/code/index.aspx">http://www.apa.org/ethics/code/index.aspx</a>   |
| Universal human rights in EU  | Universal Declaration on Bioethics and Human Rights   | <a href="http://unesdoc.unesco.org/images/0014/001461/146180e.pdf">http://unesdoc.unesco.org/images/0014/001461/146180e.pdf</a>   |
| Rights and fundamental freedoms, and the dignity and identity of human beings in this research.   | Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Council of Europe) | <a href="http://www.univie.ac.at/ierm/php/Dokumente/Oviedo-rap-E.pdf">http://www.univie.ac.at/ierm/php/Dokumente/Oviedo-rap-E.pdf</a>   |
| The European Commission's 7 <sup>th</sup> Framework Programme's guidance to researchers in identifying ethical issues in their ICT research       | Annex 5 - Ethical Guidelines for Undertaking ICT Research in FP7  | <a href="ftp://ftp.cordis.europa.eu/pub/fp7/docs/guidelines-annex5ict.pdf">ftp://ftp.cordis.europa.eu/pub/fp7/docs/guidelines-annex5ict.pdf</a>   |
| Basic human rights in EU  | Charter of Fundamental Rights of the European Union<br>The European Human Rights Convention   | <a href="http://www.europarl.europa.eu/charter/default_en.htm">http://www.europarl.europa.eu/charter/default_en.htm</a>   |
| Discussion of data protection issues in Europe, regarding protection of the privacy and processing of personal data and the movement of such data | The Data Protection Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995   | <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML</a>   |
| Research ethics in Austria  | "Datenschutzgesetz 2000" -<br>ber den Schutz personenbezogener Daten  | <a href="http://www.ris.bka.gv.at/Dokumente/Erv/ERV_1999_1_165/ERV_1999_1_165.pdf">http://www.ris.bka.gv.at/Dokumente/Erv/ERV_1999_1_165/ERV_1999_1_165.pdf</a>   |
| Finnish state law regarding research  | Occupational Safety and Health Act in Finland   | <a href="http://www.finlex.fi/en/laki/kaannokset/2002/en20020738.pdf">http://www.finlex.fi/en/laki/kaannokset/2002/en20020738.pdf</a>   |
|   | Act on the Status and Rights of Patients in Finland   | <a href="http://www.finlex.fi/en/laki/kaannokset/1992/en19920785.pdf">http://www.finlex.fi/en/laki/kaannokset/1992/en19920785.pdf</a>   |
|   | Medical Research Act in Finland   | <a href="http://www.finlex.fi/en/laki/kaannokset/1999/en19990488.pdf">http://www.finlex.fi/en/laki/kaannokset/1999/en19990488.pdf</a>   |
| Spanish research law  | Patient Rights in the EU - Spain  | <a href="http://www.eurogentest.org/web/files/public/unit4/spain.pdf">http://www.eurogentest.org/web/files/public/unit4/spain.pdf</a>   |
| French research law   | Law for protection of personal data   | <a href="http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000441676&amp;dateTexte=&amp;categorieLien=id">http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000441676&amp;dateTexte=&amp;categorieLien=id</a> |
| Texts on research ethics  | The Oxford Textbook of Clinical Research Ethics<br>The Student's Guide to Research Ethics<br>Research Ethics for Social Scientists                      | Available from Amazon   |



### 3. Experimental Protocol

This section provides a simple, annotated guide for creating a protocol, with minimal ‘theoretical’ information. Further information on ethics can be found in the references listed in section 2.

The guide has the form of a checklist, and each trial must have a written document containing the items listed below. Preparing this document will not only provide clarification to the various experimenters conducting the same trial, in the three trial cities (albeit with some local variations), but also provide the background for explaining the trial to potential participants for the purpose of obtaining informed consent.

1. Name and contact data (address, telephone number) of the partner who will carry out the experiments, project title, name of the project manager or other person responsible for the protocol and data policy.
2. A 200-word abstract of the project.
3. An abstract of the experiments, and a description of the methodology which will be applied, including information about:
  - a. Methods and materials
  - b. Descriptions of all instruments (tests, questionnaires, interview and observation schedules, scales, etc.) to be used, including:
    - Time and personnel requirements for time and personnel requirements for the administrative aspects of the experiment
    - Author(s)
    - Scoring procedures
    - Reliability
    - Validity
    - Copies of all instruments
  - c. Whether a video/audio/photo recording will be made, and why
  - d. Time requirements (how long it will take, how many times the user will participate...)
  - e. Tasks to be performed by the user
  - f. Methods of data analysis (statistical procedures, computer programs)
4. Benefits the study can provide to the participants and others like them, as well as the possible bibliometric impact (results publication).
5. Potential discomforts and risks and measures taken to minimize them. If the discomforts and risks are minimal, then it will be appropriate to state something like: “the risks for the participants are minimal, or the same as when they perform daily activities”.
6. Research questions (hypotheses) to be explored in the study. This issue is especially important, as without these boundaries a trial can turn into an unfocused narrative, rather than a controlled research process.

7. <Optional – this is really only needed in publications about this experiment> Brief summary of related literature, and a statement explaining how this study differs from other research efforts.
8. Estimates of all costs, and the person or institution covering each cost.
9. Proposed timeline, beginning with the first involvement; this should indicate who will do what, to whom and on what dates.
10. A description of the place where the testing will be carried out.
11. Description of the design of the study, including:
  - a. Independent (treatment) and dependent (outcome) variables
  - b. Methods of selecting participants and assigning them to groups
    - Inclusion/exclusion criteria, including age, gender, number of participants, level of studies, relationship with new technologies, health related issues, life style, etc.
  - c. Benefits for the participants (e.g. trips, gifts, companionship, information that will be given in the future).
12. Researchers
  - a. CV of the researchers involved in the experiments
  - b. Explain each researcher's tasks
13. Author, and purpose, of the final report (dissertation, journal article, etc.)
14. Legal references (see also section 2). These should include general EU law and the laws, relevant to the experiment, of the country in which the trials are taking place. This does not need to be lengthy, but to merely cite the law and relevant sections that require compliance.
15. Methods of ensuring subject anonymity. Reference to privacy and the protection of the personal data of users (Directive 95/46/CE and the Law on Personal Data Protection in each country).
16. List of any other institutions or individuals sponsoring, or otherwise associated: with, this project (e.g. political or commercial organizations, religious groups, professional associations, etc.).
17. Bibliographic references.
18. Informed consent sheet, and sheet bearing information for the participant.
19. Providing: Information on whether any other services are intended to be given to the participant; Relevant information about the company doing the experiment given to the participant; a presentation of all additional tasks to be undertaken in this trial; and the budget (only if relevant for helping the participant understand the scale or scope of the project)

## 4. Informed Consent

Again, ASSISTANT's approach is simple and pragmatic. What is needed is knowledge of the elements that are required for informed consent, and of the requirements of different sub-groups of the populations, (in the case of ASSISTANT, these are seniors and seniors with some level of disability).

Informed consent is not just a document that is signed by the participant; it is a process in which the participant should be correctly informed about the methodology of the experiments, and the risks and benefits of taking part, in order to have sufficient information to be able to decide on his/her participation. At the end of this process, it is mandatory to have a written Identification: research organization/project, researcher responsible, participant.

Elements of informed consent:

1. Brief explanation of the procedure and duration of the experiments
2. Benefits, risks and possible discomforts
3. Alternative treatment, technique or procedure (if there is any)
4. Advantages and disadvantages of not participating
5. Contact information of experts/professionals able to deliver additional information and to clarify doubts
6. Freedom to decide on whether to participate, and/or to reconsider this decision
7. Confidentiality and privacy of personal data
8. Contact details of the researchers

A reference to the privacy of data should also be included.

According to the Ethical Committee for Clinical Research of the Basque Country [2], informed consent will have the following format:

|  |                             |            |
|--|-----------------------------|------------|
| <b>Research title</b>  |                             |            |
| I (name and surname) have read the information sheet that I have been given. |                             |            |
| I can ask questions about the research.                                      |                             |            |
| I have received enough information about the research.                       |                             |            |
| I have spoken with (name of the researcher).                                 |                             |            |
| I understand that my participation is voluntary.                             |                             |            |
| I understand that I can leave the research:                                  |                             |            |
| 1. When I wish   |                             |            |
| 2. Without giving any explanation  |                             |            |
| 3. With no impact on my medical condition                                    |                             |            |
| I freely give my consent to participate in the research.                     |                             |            |
| Date:  | Participant and researcher: | signatures |

## 5. Anonymity of User Data

The goal of experimentation using people, for the ASSISTANT project, is to produce data that will be used to inform design and evaluation of the ASSISTANT systems. These data need to be detailed and contextualized but there is a need to protect the identity and personal details of the participants.

To achieve this aim, the ASSISTANT project will:

- Seek and collect information that is germane to the purpose of the investigation or intervention.
- Take care not to infringe, in research or service activities, on the personally or culturally defined private space of stakeholders and research participants, unless clear and appropriate permission is granted to do so.
- Take care not to relay, except as required or justified by law, confidential information about others (i.e. stakeholders and research participants), to which it has become privy in the course of the research.
- Share confidential information with others only with the informed consent of those involved, or in such a way that the individuals involved cannot be identified, except as required or justified by law.
- Store, handle, transfer and dispose of all records, both written and unwritten (e.g. computer files, video tapes), in a way that in such a way that the need for privacy and security are fulfilled/respected, and which is in accordance with the law.
- Take all reasonable steps to ensure that records and data obtained through research remain personally identifiable only as long as is necessary in the interests of those to whom the records refer and/or to the purpose for which they were collected, or as required by law, and render anonymous or destroy any records that no longer need to be personally identifiable.
- Be acutely aware of the need for discretion in the collection, recording and communication of information (in the course of the research), so as to prevent it from being interpreted or used to the detriment of others. Appropriate action includes, but is not limited to: not collecting or recording information which could lead to misinterpretation and misuse; avoiding conjecture; clearly labelling opinion; and, communicating information in language that can be understood clearly by the particular recipient of the information.
- Inform participants about confidentiality, where it is appropriate to do so.
- Indicate the measures that will be taken to protect the confidentiality of research participants in group settings, including informing members of the risk of disclosure outside of the group by participants.

At the start of an experimental session, the participant's name and some personal information (such as specific contact details) are entered on informed consent forms, and at that time an anonymous identifier (in ASSISTANT these are sequential integers, i.e. 1,2,3....) is assigned and entered on the informed consent form. These forms will be kept in a separate, locked storage area, and any data obtained from the participant will be identified only with this "meaningless" number. A list matching subject names to numbers will be locked in a location separate from the data. The consent forms will indicate that all material gathered will be confidential, and that no individual will be identified in any reports, or in the presentation of any video or audiotaped



materials at seminars or conferences. Survey data, audio tapes, and video tapes will be identified by subject number.

After collecting data from participants, in the form of observations, interview responses or questionnaire replies, these will be used in an unidentifiable way, either by only identifying generic subject descriptions (e.g. “A 60-65 year old female who lived in a detached apartment said:.....”), or as aggregate data (typically in the form of statistics).

The participants’ experimental data, response forms and recording media will be kept in a secure place, (either physically, or on an appropriately password protected computer file system). Extra care must be taken when using lengthy transcriptions of participants’ responses, or location data, to maintain the anonymity of the participant.

Participants, consent forms and all experiment data will be destroyed within one year of the ASSISTANT project’s end (1<sup>st</sup> of June 2016).

Some personal data related to the trials will be stored in the ‘cloud’ (user name, preferences, created routes, ... ). Cloud storage is a model of data storage where the digital data is stored in logical pools, the physical storage spans across multiple servers (and often locations), and the physical environment is typically owned and managed by a hosting company. These cloud storage providers are responsible for keeping the data available and accessible, and the physical environment protected and running. ASSISTANT consortium will buy or lease storage capacity from the providers to store needed data for the trials. Participants will be informed about this and the information included in the ‘cloud’ by ASSISTANT application will be saved by special measures to ensure the privacy of the user. The consortium included a sentence in the informed consents to explain all this to the participants.



## 6. Supervision of Ethical Committee

The Ethical Committee is an external entity responsible of the supervision of testing with humans to guarantee that their treatment is according to standard ethical guidelines. In this case, in the ASSISTANT project, as explained above, interactions and instructions to the users during the trials will take into account all the ethical dimensions previously discussed.

As explained in this document the trials will be done according to the primary universal ethical rules and guidelines. The researchers also will define experimental protocols that will reflect all the relevant the ethical aspects. Participants will receive an appropriately phrased information sheet and informed consent about the trials. Because the tasks performed during the trials will not involve any special risk to the users, supervision from an external Ethical Committee will not be required.



## References

1. United Nations, *Universal Declaration of Human Rights*, United Nations, Editor 1948: Paris, France.
2. (CEIC), C.É.d.I.C. *Farmacia: Comité Ético de Investigación Clínica (CEIC)*. 2012. [http://www.euskadi.net/r33-2732/es/contenidos/informacion/comite\\_etico/es\\_8123/presentacion\\_c.html](http://www.euskadi.net/r33-2732/es/contenidos/informacion/comite_etico/es_8123/presentacion_c.html)

## Annex A Ethical Issues Table

These are an overview of the ethical principles defined for eInclusion and ICT related projects.

**Table 1: Ethical principles**

|  |  |
|--|--|
| Respect for autonomy<br>(right to liberty) | <ul style="list-style-type: none"> <li>○ Dignity</li> <li>○ Informed consent</li> </ul>  |
| Non maleficence<br>(avoiding harm)         | <ul style="list-style-type: none"> <li>○ Safety</li> <li>○ Social solidarity, inclusion and exclusion</li> <li>○ Isolation and substitution of human contact</li> <li>○ Discrimination and social sorting</li> </ul>   |
| Beneficence                                | <ul style="list-style-type: none"> <li>○ Universal service</li> <li>○ Accessibility</li> <li>○ Value sensitive design</li> <li>○ Sustainability</li> </ul>   |
| Justice                                    | <ul style="list-style-type: none"> <li>○ Equality and fairness</li> </ul>  |
| Privacy and data protection                | <ul style="list-style-type: none"> <li>○ Collection limitation and retention</li> <li>○ Data quality</li> <li>○ Purpose specification</li> <li>○ Use limitation</li> <li>○ Confidentiality, security and protection of data</li> <li>○ Transparency</li> <li>○ Individual participation and access to data</li> <li>○ Anonymity</li> <li>○ Privacy of personal communications, monitoring and location tracking</li> <li>○ Privacy of the person</li> <li>○ Privacy of personal behaviour</li> </ul> |

## ANNEX A Informed Consent forms

**Austria:**

### EINVERSTÄNDNISERKLÄRUNG



|                           |  |            |             |
|---------------------------|--|------------|-------------|
| <b>Projektpartner</b>     | Universität Wien   |            |             |
| <b>Adresse</b>            | Universitätsring 1   |            |             |
| <b>Postleitzahl</b>       | 1010   | <b>Ort</b> | Wien        |
| <b>Tel..</b>              | 01/4277-0  | <b>Fax</b> | 01/42779486 |
| <b>Name des Projektes</b> | ASSISTANT (AAL-2011-4-040) / FFG Projekt 833604                            |            |             |
| <b>Institut</b>           | Institut für Geographie und Regionalforschung                              |            |             |
| <b>Projektleiter</b>      | Univ.-Prof. DI Dr. Wolfgang Kainz<br>(E-Mail: wolfgang.kainz@univie.ac.at) |            |             |

|                       |  |
|-----------------------|--|
| <b>Teilnehmercode</b> |  |
|-----------------------|--|

Ich

.....  
Vorname und Familienname

.....  
Adresse/E-Mail/Tel.

habe das Informationsblatt über das Projekt ASSISTANT erhalten und gelesen.

Ich bestätige von der Universität Wien über die Zielsetzungen des Projektes und über die Art und die Bedingungen meiner **Teilnahme an dem Systemtest** informiert worden zu sein.

Ich erkläre informiert worden zu sein, dass mir aus der Teilnahme keine Kosten, Risiken oder Nachteile erwachsen, die über normale tägliche Aktivitäten hinausgehen.

Ich bestätige, dass mir die Gelegenheit geben wurde, Fragen zum Projekt und zum Systemtest zu stellen und dass diese beantwortet wurden.

Ich verstehe, dass meine Teilnahme an dem Test freiwillig ist und ich jederzeit ohne Angabe von Gründen meine Teilnahme durch eine entsprechende schriftliche Mitteilung (Brief oder E-Mail) an den Projektpartner Universität Wien beenden kann. Wenn ich es wünsche, werden alle Daten, die während des Systemtests im Zusammenhang mit meiner Teilnahme gespeichert wurden, gelöscht. Andernfalls können die Daten anonymisiert für Zwecke des Projektes weiter verwendet werden.

**DIE TEILNAHME WURDE BEENDET AM:** .....  
(Datum)

Ich verstehe, dass die Leiter des Systemtests angehalten sind, meine Daten strikt vertraulich zu behandeln.

Ich ermächtige die Universität Wien meine persönlichen Daten zu speichern und alleine für Zwecke dieses Projektes zu verwenden. Ich bin damit einverstanden, dass meine anonymisierten Daten (über den Teilnehmercode) von der Universität Wien an ASSISTANT Projektpartner allein für Zwecke der Forschung und Entwicklung des Projektes ASSISTANT weitergegeben werden dürfen.

Ich verpflichte mich, projekteinschlägige Informationen nicht an Dritte weiterzugeben und die mir zur Verfügung gestellte Gerätschaft für keine anderen Zwecke als die im Projekt vorgesehenen zu verwenden.

Ich erkläre informiert worden zu sein, dass nach Projektende keine Systemupdates mehr erfolgen, ich die Gerätschaft dem Projektteam zur Deaktivierung zu übergeben habe und mir auf Wunsch das deaktivierte Smartphone als normales Mobiltelefon ohne ASSISTANT Funktionen ausgehändigt werden kann.

Ich erlaube die Erstellung, Digitalisierung und Verwendung von Fotografien und audiovisuellen Aufzeichnungen, die während meiner Teilnahme am Projekt gemacht wurden.

**JA**

**NEIN**

Ich erlaube die Verwendung dieses digitalisierten Materials bei wissenschaftlichen Veranstaltungen und in wissenschaftlichen Publikation ausschließlich im Zusammenhang mit dem Projekt ASSISTANT.

**JA**

**NEIN**

Ich verstehe, dass ich jederzeit Einsicht in meine Person betreffende Daten, die Korrektur oder das Löschen derselben verlangen kann und dass ich mich ohne Angabe von Gründen gegen das Sammeln derselben aussprechen kann.

**DIE DATEN WURDEN GEÄNDERT AM**

.....  
(Datum)

**DIE DATEN WURDEN GELÖSCHT AM**

.....  
(Datum)

Mit meiner Unterschrift gebe ich daher mein Einverständnis zur Teilnahme an diesem Systemtest.

Universität Wien (Projektleiter)

Teilnehmer/in



Wien, am  
.....  
Datum / Unterschrift

Univ.-Prof. DI Dr. Wolfgang Kainz  
Name

Wien, am  
.....  
Datum / Unterschrift

.....  
Name

**Spain:**

## 1. INFORMACIÓN DEL PROYECTO

*Breve descripción del proyecto que se está realizando*

## 2. INFORMACIÓN DE LA ENTREVISTA

*Breve descripción de las pruebas que se van a realizar, si procede.*

### 2.1 OBJETIVOS

*Objetivos específicos de las pruebas*

### 2.2 METODOLOGÍA EMPLEADA

*Metodología que se va a emplear durante las pruebas para la recogida de datos e información que se espera recoger. Si se quiere realizar grabaciones o recoger datos gráficos se deberá explicar explícitamente en este apartado.*

*Se explicará cuáles son las actividades a realizar (de manera genérica), qué tipo de dispositivos se utilizarán para la recogida de datos, la duración de la prueba y las veces que tendrá que acudir.*

### 2.3 BENEFICIOS ESPERADOS

*Beneficios esperados para el participante, o la sociedad y para la investigación (posibles publicaciones, cursos, cambios en el diseño del sistema, etc.)*

## 3. DECLARACIÓN DE LOS INVESTIGADORES

La intención de esta hoja de información y la hoja de consentimiento informado es informarle sobre el proyecto en el que se engloban esta entrevista, para que Vd. decida participar en este estudio o no. Por favor, lea detenidamente estas hojas y pregunte cualquier cosa que no le haya quedado claro sobre sus derechos como voluntario o cualquier cosa sobre la que desee obtener más información. Cuando le haya quedado todo totalmente claro, puede decidir participar en este estudio o no. También le daremos una copia.

## 4. TRATAMIENTO DE DATOS

Todos los datos y la información que se recojan durante las pruebas se tratará tal y como se recoge en el documento de seguridad de Tecnalía y de acuerdo a las restricciones de la ley Orgánica 15/1999 de 13 de diciembre de Protección de Datos de Carácter Personal.

## 5. ACLARACIONES

- Su decisión de participar en esta entrevista es completamente voluntaria y no habrá ninguna consecuencia desfavorable para usted, en caso de no aceptar la invitación, o desear abandonar la entrevista en cualquier momento y sin necesidad de dar explicaciones para ello.
- Si decide participar en la entrevista puede retirarse en el momento que lo desee, aún cuando el investigador responsable no se lo solicite.
- En el transcurso de la entrevista usted podrá solicitar información actualizada sobre el mismo, al investigador responsable.
- Los promotores del estudio están obligados a guardar una estricta confidencialidad de sus datos y a que los datos que permiten identificarle se guarden bajo llave y no serán digitalizados.

## 6. INFORMACIÓN DE CONTACTO

En todo momento, podrá ampliar la información referente a este estudio contactando con (nombres de los investigadores a contactar) investigadores de TECNALIA.

(Nombre, Como mínimo se dará el nombre de una persona de contacto)

Paseo Mikeletegi, 1 – Parque tecnológico  
E-20009 Donostia – San Sebastián  
Telf.: (+34) 946 430 850  
e-mail:

Fax: (+34) 946 460 900  
web: [www.tecnalia.com](http://www.tecnalia.com)



## Consentimiento informado

|                             |                                |                  |              |               |
|-----------------------------|--------------------------------|------------------|--------------|---------------|
| <b>NOMBRE DE LA EMPRESA</b> | TECNALIA RESEARCH & INNOVATION |                  | <b>CIF</b>   | G4897576<br>7 |
| <b>DIRECCIÓN</b>            |                                |                  | <b>C.P.</b>  |               |
| <b>LOCALIDAD</b>            |                                | <b>PROVINCIA</b> |              |               |
| <b>TLFNO.</b>               | 902 760 000                    | <b>FAX</b>       | 901 760 009  |               |
| <b>NOMBRE DEL PROYECTO</b>  |                                |                  |              |               |
| <b>UNIDAD DE NEGOCIO</b>    |                                |                  |              |               |
| <b>DIRECTOR PROY.</b>       |                                |                  | <b>FECHA</b> |               |

|                                 |  |
|---------------------------------|--|
| <b>CÓDIGO DEL PARTICIPANTE:</b> |  |
|---------------------------------|--|

**YO**

.....  
 (NOMBRE Y APELLIDOS DEL PARTICIPANTE) he leído la hoja de información que se me ha entregado.

**YO**

.....  
 (NOMBRE Y APELLIDOS DEL PARTICIPANTE) en representación de  
 .....  
 (NOMBRE Y APELLIDOS DEL PARTICIPANTE) he leído la hoja de información que se me ha entregado.

**AUTORIZO** participar en el proyecto descrito en el documento adjunto / la entrevista / sesión de trabajo.

**DECLARO** haber sido informado por parte de TECNALIA de los procedimientos, compromisos y objetivos del estudio y haber recibido la información al respecto por parte del investigador principal del proyecto .....  
 (NOMBRE DEL INVESTIGADOR PRINCIPAL)

**DECLARO** conocer la naturaleza y condiciones de mi participación.

**DECLARO** haber sido informado de que no existen riesgos e inconvenientes derivados de mi participación, más allá que lo que implica la realización de actividades diarias (riesgo mínimo).

**DECLARO** haber podido hacer preguntas relacionadas con el estudio, y que estas han sido atendidas.

**COMPRENDO** que mi participación en el estudio es voluntaria, pudiendo abandonar el estudio en cualquier momento sin necesidad de dar explicaciones para ello y sin que esto repercuta en mis cuidados médicos. Este abandono podrá implicar si es mi deseo la destrucción de todos los datos capturados durante mi participación.

**LA PRUEBA HA SIDO  
ABANDONADA CON FECHA  
DE:**

**ENTIENDO** que los promotores del estudio están obligados a guardar una estricta confidencialidad de mis datos, que los datos que permiten identificarme están restringidos a esta hoja y será guardada bajo llave.

**AUTORIZO** a que mis datos personales sean tratados por TECNALIA e incorporados a sus ficheros (Según Ley Orgánica 15/1999 de 13 de Diciembre de Protección de Datos de Carácter Personal) con la exclusiva finalidad de realizar estudios de investigación.  
**AUTORIZO** a que mis datos puedan ser cedidos a terceros que colaboren con TECNALIA exclusivamente en el ámbito y con las finalidades de los estudios de investigación.

**AUTORIZO** al uso de *equipos fotográficos y/o de grabación de audio y/o video* durante mi participación y a la consiguiente digitalización de las fotografías y/o las grabaciones con el fin de complementar los datos adquiridos durante mi participación.

**SI**  **NO**

**AUTORIZO** a que este material digitalizado sea presentado en eventos científicos (congresos o jornadas), artículos científicos, y/o eventos pedagógicos (seminarios o cursos), relacionados exclusivamente con el Proyecto actual.

**SI**  **NO**

**ENTIENDO** que podré acceder, rectificar, cancelar u oponerme a la recogida de mis datos personales en cualquier momento en que yo lo solicite sin necesidad de dar explicaciones para ello.

**LOS DATOS HAN SIDO  
MODIFICADOS CON FECHA  
DE:**

**LOS DATOS HAN SIDO  
ELIMINADOS CON FECHA DE:**



Por tanto, **PRESTO LIBREMENTE** mi conformidad para participar en este estudio.

|  |   |
|--|---|
| <p>Firma en delegación de TECNALIA (Firma del Responsable del Proyecto)</p><br><br><br><br><br><br><br><br><br><br><p>NOMBRE Y APELLIDOS</p> <hr/> | <p>Firma</p><br><br><br><br><br><br><br><br><br><br><p>NOMBRE Y APELLIDOS</p> <hr/><br><p>En calidad de:</p> <ul style="list-style-type: none"><li><input type="checkbox"/> Participante</li><li><input type="checkbox"/> Tutor legal</li></ul> |
|--|---|





<

**France:**

## FORMULAIRE DE CONSENTEMENT

|                       |                            |              |       |
|-----------------------|----------------------------|--------------|-------|
| <b>Partenaire</b>     | Association e-Seniors      |              |       |
| <b>Adresse</b>        | 19, cité de Phalsbourg     |              |       |
| <b>Code Postal</b>    | 75011                      | <b>Ville</b> | Paris |
| <b>Tel..</b>          | 06 24 39 64 34             |              |       |
| <b>Nom du projet</b>  | ASSISTANT (AAL-2011-4-040) |              |       |
| <b>Responsable du</b> | Monique EPSTEIN            |              |       |

Je soussigné(e),

.....  
(NOM, PRENOM) demeurant

.....  
(ADRESSE)

accepte librement et volontairement de participer, de manière gratuite, au test du prototype ASSISTANT. Je certifie avoir été informé du projet ASSISTANT et avoir reçu toutes les renseignements nécessaires à ma participation au test. Je confirme avoir pu poser des questions à l'association e-Seniors sur le test du prototype.

Je comprends que ma participation est volontaire et que je peux arrêter le test à tout moment et sans préavis. Si je le désire, toutes les données me concernant qui ont été stockées pendant les essais du système dans le cadre de ma participation, seront supprimées sur demande de ma part à l'issue du projet.

J'autorise l'association e-Seniors à stocker mes données personnelles pour seules fins du projet. J'autorise la divulgation de ces renseignements par e-Seniors aux autres partenaires du projet pour seules fins de recherche et de développement du projet ASSISTANT.

J'autorise la prise, la numérisation et l'utilisation de photographies et enregistrements audiovisuels faits au cours de ma participation au projet :

OUI  NON

J'autorise l'utilisation de ce matériel lors de conférences et publications scientifiques exclusivement en relation avec le projet ASSISTANT :

OUI  NON

Conformément à la loi Informatique et Libertés du 6 janvier 1978, je comprends que j'ai toujours un droit de regard, de correction et de suppression concernant mes données personnelles.

En signant ci-dessous, je donne donc mon consentement à la participation de la phase test du projet ASSISTANT.



Association e-Seniors (Responsable du projet)

A Paris, le  
.....  
Date et Signature

Monique EPSTEIN  
Directrice de l'association

<

Participant

A Paris, le  
.....  
Date et Signature

.....  
Nom