Ethical Guide and Data Protection Plan

Deliverable D2.2

Work Package 2:End-User Input and Validation

DOCUMENT HISTORY

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EXECUTIVE SUMMARY

In this document Ethical Guideline and Data Protection Plan for 3rD LIFE project is presented. Relevant ethic aspects are highlighted and a guideline to ensure that all consortium partners respect them is described below.

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1. INTRODUCTION

1.1. ABOUT 3rD LIFE.

One of the project aims with 3rD LIFE is to create a 3D environment that allows users to communicate with other people. Communication between people leads to a situation where issues as privacy and sharing personal data need to be handled and secured. There are also some important differences between interacting with already known people or with unknown people as could be the case during the trials. 3rD LIFE has to allow users to set up their privacy level as they want for their personal data. For this reason, 3rD LIFE must be transparent and it has to accomplish the European Legislation, keeping the anonymity and privacy of the users and the other people who participate in the interaction intact..

3rD LIFE project follows a user centered design. This implies, in the first place, that users' needs and wishes are taken into account or in other words, that specifications that the solution must have for being useful to the final users must to be taken into account by the technological partners who are in charge of the development of the platform. In addition, a user centered design implies the testing of the system by real users who are already included in the design process. In the project, user trials are planned for assessing that the development of the system is adjusted to the users´ wishes and suggestions. All the data privacy and security issues that may arise in the trials must be specified and foreseen before they take place. Also, the principles of respect for autonomy, beneficence, non-maleficence and justice will be followed.

This deliverable addresses the way in which ethical issues are going to be considered along the 3rD LIFE project.

1.2. AIMS OF THIS DELIVERABLE

The core of D2.2. is to create an Ethical and Data Protection Plan. All the factors and considerations that should be taken into account before starting the research activities with humans are addressed, as well as the procedures for sharing information within the consortium and data analysis.

The main aim of this deliverable is to ensure compliance with the ethical issues in relation to users' privacy, confidentiality, consent and respects the common values of autonomy, beneficence, non-maleficence and justice during the whole project. It will also ensure the fulfilling of the current national and international laws regarding ethical and privacy issues and guarantee the safety of the users that will take part in the project, as well as the security of their personal data.

In addition, the Matia / INGEMA / Hurkoa Ethical Committee will give their feedback and approval of this project as a part of the requirements of the Spanish laws about scientific research involving human beings.

The impact of this deliverable will be in the area of the user involvement and actions.

This deliverable has a close relationship to others belonging to WP3 "Platform selection" especially with task 3.5. "Security and AAA support", and its deliverable 3.4. "Security and AAA mechanism specifications". The main aim is to deliver mechanisms necessary for the system's security and for delivering AAA (authentication, authorization and accounting) support. This mainly covers the issues of: data safety (backups), data encryption, user profiles (secured by a password), digital certificates, granting privileges to users based on their profile, logging, and possibly secure payment methods.

Deliverable 2.2. is structured as follows:

Section 2 provides a brief summary about the ethical issues in a general framework and in the countries involved in the project. Section 3 provides information regarding the ethical documents which are also shown in the annexes. The Data Protection Plan, which covers general issues, informed consent, the anonymization procedure, data storage and handling process, security measures, security enforcement and procedures of data destruction, appears in Section 4. Section 5 shows a guideline for judging the Data Protection Plan along the project and section 6 addresses the ethical concerns involved in the trials. Finally, some conclusions are drawn Section 7.

2. ETHICAL ISSUES MANAGEMENT IN EACH COUNTRY INVOLVED IN THE PROJECT

2.1. GENERAL ETHICAL FRAMEWORK

The goal of 3rD LIFE project is to develop a 3D platform that will facilitate interactions and other functionalities, with other users through Internet. The "primary target group" is the elderly people between 60 and 75 years old and their younger family members (called "secondary group"). Although the main group of users of the platform are expected to be familiarized with new technologies, there could also be included individuals with none or less previous experience. For that reason 3rD LIFE project will consider the ethical aspects of the project with the aim of ensure the adequate protection of the privacy and the personal rights of all the users.

Ethical aspects will not only affect the end-users participating in the project, but will also be considered relevant for the people and organisations participating in the project, and in general terms, will cover the limitations and regulations that must be applied to every project activity: research, development, testing, evaluation and dissemination.

General ethical framework. People and organisations participating in the project will guide their activities by means of the following four principles:

1. Non maleficence. The study and general operation of the device should not harm the participant, or put him or her under unacceptable risk (this includes risks to privacy).

2. Beneficence. The study and general operation of the device should benefit the participant according to his or her own conception of the good (this is a non-paternalistic interpretation of the principle, and includes ensuring that participants hold authentically those conceptions).

3. Justice. The study and general operation of the device should take into account the legitimate interests of third parties, and not incorporate or promote any bias based on gender, culture, nationality, or other sources of social prejudice (this includes fair selection of the subjects for the user trials). Benefits of the study will be shared with the involved communities (this includes publication of the results of the study).

4. Respect for autonomy. With the general aim of promoting the participants' cognitive and functional abilities, participation in the study and in the general operation of the device should be based upon a process of informed consent, and the participants right to control his or her personal information will be respected at all times (this includes issues of confidentiality and data security).

Because scientific research often consults human subjects directly and/or indirectly in its inquiries, it is of implicit necessity to pay special attention to this kind of scientific research.

Data privacy refers to the evolving relationship between technology and public expectation and legal right of privacy in the collection and sharing of data. Privacy problems exist wherever uniquely identifiable data related to a person or group are collected and stored, in digital form or otherwise. Improper or non-existent disclosure control can be the root cause for privacy issues. The most common sources of data that are affected by data privacy issues are:

- Health information.
- Criminal justice.
- Financial information.
- Genetic information.
- Location information.
- Cultural information.

The challenge in data privacy is to share data while protecting the personal identity from the information [1].

Directive 95/46/EC defines personal data as "all information on an identified or identifiable person", considering an identifiable person as anyone whose identity might be determined, directly or indirectly, in particular by means of an identification number or one or several specific elements, characteristics of his physical, physiological, mental, economic, cultural or social identity and attributes, with special protection to health data [2].

Privacy is important to participants since they expect to have the right to control and to inspect personal information, and they expect that their personal information maintained by colleges and centres will be accurate. Today's participants also expect information about their personal activities to be kept private.

The European Charter of Fundamental Rights [3] states:

Art 3: Right to the integrity of the person

1. Everyone has the right to respect for his or her physical and mental integrity.
2. In the fields of medicine and biology, the following must be respected in particular:
    1. The free and informed consent of the person concerned, according to the procedures laid down by law..
    2. The prohibition of eugenic practices, in particular those aiming at the selection of persons.
    3. The prohibition on making the human body and its parts as such a source of financial gain.
    4. The prohibition of the reproductive cloning of human beings.

Art. 8: Protection of personal data

1. Everyone has the right to the protection of personal data concerning him or her.
2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law.

Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.
3. Compliance with these rules shall be subject to control by an independent authority.

Art. 13: Freedom of the arts and sciences.

1. The arts and scientific research shall be free of constraint. Academic freedom shall be respected.

The European Directive on the protection of personal data contains a number of key principles which must be complied with. Anyone processing personal data must comply with the eight enforceable principles of good practice. They say that data must be:

1. Fairly and lawfully processed.
2. Processed for limited purposes.
3. Adequate, relevant and not excessive.
4. Accurate.
5. Not kept longer than necessary.
6. Processed in accordance with the data subject's rights.
7. Secure.
8. Not transferred to countries without adequate protection.

As stated in the previously mentioned European Charter of Fundamental Rights, this deliverable aims at providing concrete details on data protection and storage policy.

3rD LIFE consortium has through their profile great experience and relevant procedures for protecting and storing data of any kind. Two of the partners are conducting research involving testing with people and procedures for the protection and storage of data. The consortium as a whole will align to these procedures.

It has been clearly assumed within the project partners, that personal data may only be collected, processed, or used insofar as this is necessary for pre-determined, clear, and legitimate purposes. High standards must and will be ensured with regards to data quality and in technical protection against unauthorized access. The use of the data must be transparent for those concerned, and the rights of the latter must be safeguarded with regards to information and correction and, if applicable, to objection, blocking, and deletion.

2.2. NATIONAL LAWS

Research and development in the 3rD LIFE project will be conducted in Spain, Slovenia, Poland and Austria. In addition, field testing and evaluation will be performed in Donostia-San Sebastián (Spain) and in Vienna (Austria). The results are not planned to be transferred to non-European countries and for that reason all the national legislations of the involved countries will be considered.

2.2.1. SPANISH LAWS

INGEMA will fulfil all the requirements stated by the *Spanish Organic Law 15/1999 of 13th December on the Protection of Personal Data (LOPD 15/1999)* [4]that intends to guarantee and protect the public liberties and fundamental rights of natural persons, and in particular their personal and family privacy, with regard to the processing of personal data.

The Organic Law shall apply to personal data recorded on a physical support which makes them capable of processing and to any type of subsequent use of such data by the public and private sectors.

With personal data, the Organic Law means "any information concerning identified or identifiable natural persons". Some important information regarding the LOPD 15/1999 that applies to 3rD LIFE project:

Art. 4: Quality of the data

1. Personal data may be collected for processing, and undergo such processing, only if they are adequate, relevant and not excessive in relation to the scope and the specified, explicit and legitimate purposes for which they were obtained.
2. Personal data shall be erased when they have ceased to be necessary or relevant for the purpose for which they were obtained or recorded.
3. They shall not be kept in a form which permits identification of the data subject for longer than necessary for the purposes for which they were obtained or recorded.
4. Personal data shall be stored in a way which permits the right of access to be exercised, unless lawfully erased.

Art. 5: Right of information in the collection of data

1. Data subjects from who personal data are requested must previously be informed explicitly, precisely and unequivocally of the following:
    - The existence of a file of personal data processing operation, the purpose of collecting the data, and the recipients of the information.
    - The obligatory or voluntary nature of the reply to the questions put to them.
    - The consequences of obtaining the data or of refusing to provide them.
    - The possibility of exercising rights of access, rectification, erasure and objection
    - The identity and address of the controller or of his/her representative, if any.

Art. 9: Data security

1. The controller or, where applicable, the processor shall adopt the technical and organizational measures necessary to ensure the security of the personal data and prevent their alteration, loss, unauthorised processing or access, having regard to the state of the art, the nature of the data stored and the risks to which they are exposed by virtue of human action or the physical or natural environment.

2. No personal data shall be recorded in files which do not meet the conditions laid down by rules regarding their integrity and security, as well as the rules governing the processing centres, premises, equipment, systems and programs.

Art 10: Duty of secrecy

1. The controller and any persons involved in any stage of processing personal data shall be subject to professional secrecy as regards such data and to the duty to keep them. These obligations shall continue even after the end of the relations with the owner of the file, or, where applicable, the person responsible for it.

Art. 15: Right of access

1. The data subject shall have the right to request and obtain free of charge information on his personal data subjected to processing, on the origin of such data and on their communication or intended communication.

2. The information may be obtained by simply displaying the data for consultation or by indicating the data subjected to processing in writing, or in a copy, fax or photocopy, whether certified a true copy or not, in legible and intelligible form, and without using keys or codes which require the use of specific devices.

Art. 16: Right of rectification or cancellation

1. The controller shall be obliged to implement the right of rectification or cancellation of the data subject within a period of ten days.

INGEMA as a part of the MATIA group has, according to the Spanish law [223/2004] [5], a Research Ethics Committee that has to approve all research projects involving human participants. This Ethic Committee was accredited by Resolution 24th of the Basque Health Department published on the Basque Country Official Bulletin [6]. This Committee guarantees the best quality of social, psychological and public health attention to elderly people and the fundamental ethical principles that a Clinical Research on human beings has to have. This Committee respects the criteria of Good Clinical Practice in Investigation and Helsinki [7] and Oviedo Agreements [8]. Also the studies involving humans are supervised by Ethics Committee of Donostia Hospital.

INGEMA will follow the recommendations of the Organic Law on Protection of Personal Data (LOPD 15/1999). This means, among other, that data collected in the project, due to security issues, will not be accessible from the Internet and the people working with the data

will have to have a unique password to access the database. The database will of course be sealed from people not involved in the project but working at INGEMA. Before testing occurs the participants are clearly informed in that, they either are allowed in keeping the equipment or not and has to sign an Informed Consent. MATIA group and INGEMA have 10 years experience with projects including individuals participating in user trials.

2.2.2. SLOVENIAN LAWS

In the Republic of Slovenia, the right to the Access to Public Information [10] and the right to Personal Data Protection [11] are considered as Constitutional rights. They are defined in The Constitution of the Republic of Slovenia. Slovenian FOI (Freedom of Information) legislation is based on the guidelines of Article XIX and is harmonized with all European laws dealing with access to public information.

For 3rD-Life project we checked with the information officer about this in case the 3D servers are located at UL. They replied that no other requirements have to be met, except for those related to IT security of the servers (authorization, authentication).

2.2.3. POLISH LAWS

One2tribe will fulfil all the requirements stated by the Act of August 29, 1997 on the Protection of Personal Data [12]. Below, the most relevant articles and sections for 3rD LIFE are described.

Article 1

1. Any person has a right to have his/her personal data protected.
2. The processing of personal data can be carried out in the public interest, the interest of the data subject, or the interest of any third party, within the scope and subject to the procedure provided for by the Act.

Article 23

Paragraph 1. The processing of data is permitted only if:

> (1) the data subject has given his/her consent, unless the processing consists in erasure of personal data,
>
> (5) processing is necessary for the purpose of the legitimate interests pursued by the controllers or data recipients, provided that the processing does not violate the rights and freedoms of the data subject.

Paragraph 2. The consent referred to in paragraph 1, point 1 may also be applied to future data processing, on the condition that the purpose of the processing remains unchanged.

Article 24

Paragraph 1. In case where personal data are collected from the data subject, the controller is obliged to provide a data subject from whom the data are collected with the following information:

(1) the address of its seat and its full name, and in case the controller is a natural person about the address of his/her residence and his/her full name,

(2) the purpose of data collection, and, in particular, about the data recipients or categories of recipients, if known at the date of collecting,

(3) the existence of the data subject's right of access to his/her data and the right to rectify these data,

(4) whether the replies to the questions are obligatory or voluntary, and in case of existence of the obligation about its legal basis.

Article 26

Paragraph 1. The controller performing the processing of data should protect the interests of data subjects with due care, and in particular to ensure that:

(1) the data are processed lawfully,

(2) the data are collected for specified and legitimate purposes and no further processed in a way incompatible with the intended purposes, subject to the provisions of paragraph 2 below,

(3) the data are relevant and adequate to the purposes for which they are processed,

(4) the data are kept in a form which permits identification of the data subjects no longer than it is necessary for the purposes for which they are processed.

Article 47. Transfer of Personal Data to a Third Country

Paragraph 1. The transfer of personal data to a third country may take place only, if the country of destination ensures at least the same level of personal data protection in its territory as that in force in the territory of the Republic of Poland.

Paragraph 3. Nevertheless the controller may transfer the personal data to a third country provided that:

(1) the data subject has given his/her written consent,

(2) the transfer is necessary for the performance of a contract between the data subject and the controller or takes place in response to the data subject's request,

(3) the transfer is necessary for the performance of a contract concluded in the interests of the data subject between the controller and another subject.

2.2.4. AUSTRIAN LAWS

In Austria, the main legislation regarding privacy issues can be found in two laws, the Privacy law - Datenschutzgesetz 2000 or in short DSG 2000 (long name: Bundesgesetz über den Schutz personenbezogener Daten) [9].

- This law describes that Data should be protected against access from unauthorized persons, as well as protected against accidental and unlawful destruction and loss, according to paragraph 14, article 1.

- This also implies the declaration of those people that are allowed to access, update, analyse the data, the organisation of access control, the organisation of backups, the identification of users, etc.

- Anonymisation should be performed wherever possible and a relation to persons should only be available when it is absolutely necessary to a specific person. An ID is correct, as long as it cannot be indirectly connected to the specific person (e.g. through a combination of date-of-birth, city, employment).

- Distribution of data to other partners should be communicated to the Ethical committee with reason. Guidelines should be followed regarding encryption.

3. ETHICAL DOCUMENTS

The different documents needed before starting the user trials are explained in this chapter and attached in the annexes.

3.1. INFORMED CONSENT

Informed consent is the process by which a participant will be fully informed about the research in which he/she is going to participate. It originates from the legal and ethical right that the participant has to direct what happens to his / her personal data and from the ethical duty of the researcher to involve the participant in the research.

In order to involve a human being as a participant in research, the researcher will obtain the legally effective informed consent of the participant or the participant's legally authorized representative. In 3rD LIFE the target group have the cognitive capabilities preserved, so they will sign the consent by themselves.

The information given to the participant or the representative will be in understandable language to the participant or the representative person. No informed consent, whether oral or written, may include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the researcher, the sponsor, the institution or its agents from liability for negligence.

Also, appropriate and adequate information (e.g. the nature, duration, and purpose of the experiment; the method and means by which it will be conducted; any inconveniences and hazards reasonably to be expected; the effects upon his/her health, and that he/she may quit the testing at any point) shall be given in order to ensure informed consent. A model consent form in English has been appended to this document (Annex 9.1.). This was the consent used in one specific task with end users in the project. Each time the participants have to come for a new task the procedure part is adapted to this new task. This consent has been developed following the laws: Organic Law on Protection of Personal Data (LOPD 15/1999); Law 41-2002 of the Patient's Autonomy; Biomedical Law 14-2007. All test partners will use a translated version in order to ensure informed consent and integrity of the participants.

3.2. INFORMATION LETTER

The aim of this document is to provide the necessary information about the study in order to guarantee that the participant has enough information about the study and s/he can take

the adequate decision about her/his participation on it. The document summarizes the main information with regard to the project: objectives, methods, participants, etc. The information letter in English can be found in Annex 9.2., and also it will be translated by the test partners into their own languages.

Both the informed consent and the information letter were the ones developed for one concrete task in WP2. Of course, every time the user participates, s/he has to sign a new consent. The only difference between this consent and the one presented here is to be found in the "Procedure" part, which is updated with the actions, objectives, etc., required each time.

Participants will receive a copy of the Inform Consent and the Information letter.

3.3. ETHICS COMMITTEE APROVAL

As explained before, INGEMA has an official approval for the 3rD LIFE project by their local ethical committee (MATIA / INGEMA / Hurkoa ethical committee). For more information read section 2.2.1.

4. DATA PROTECTION PLAN

For 3rD LIFE purposes, the way of collecting data to be carried out will be the collection of personal data (social demographic data, social relationships, cognitive status, leisure activities, and use of technologies). We have therefore analysed these aspects of data collection, studying the legislation in Europe as well as specifically in each involved country, and proposing a data protection plan that aims to cover all the cited aspects. This plan is presented below.

4.1. GENERAL ISSUES CONCERNING DATA PROTECTION PLAN

Purpose of the data protection plan: The data protection plan becomes part of the signed agreement between 3rD LIFE consortium and the investigator(s) participants in the project. If the agreement is executed, all members of the research team with access to the data are contractually obligated to follow all aspects of the data protection plan. The fundamental goal of the protections outlined in this plan is to prevent persons who are not signatories to the restricted data use agreement or the supplemental agreement with research staff from gaining access to the data.

What should be covered by the plan: The data protection plan applies to both the raw data file received from 3rD LIFE consortium as well as any copies made by the research team, and any new data derived solely or in part from the raw data file. The plan should also address how computer output derived from the data will be kept secure. This applies to all computer output, not only direct data listings of the file.

Components of the plan: 3rD LIFE data protection plan should contain the components listed from section 4.2. to section 4.7.

4.2. INFORMED CONSENT

We have already explained this aspect in the section 3.1.

4.3. DATA STORAGE AND HANDLING PROCESSES

Much research revolves around information about people –their age, lifestyle, health– drawn from records, scientific tests, surveys and interviews. Sometimes, the information also reveals facts about relatives and relationships. These types of information are sensitive and private for many people, although attitudes and expectations vary widely.

The protection of the privacy of participants is a responsibility of all people involved in research with human participants. Privacy means that the participant can control the access to personal information; he/she decides who has access to the collected data in the future.

Due to the principle of autonomy the participants have to be asked for their agreement (informed consent) before private information can be collected. It should be also ensured that all the persons involved in research work, understand and respect the requirement for confidentiality. The participants should be informed about the confidentiality policy that is used in the research.

The privacy plays a role at different levels:

- Hints to or specific personal information of any participant in publications.
- It should be prevented to reveal the identity of participants in research deliberately or inadvertently, without the expressed permission of the participants.
- Dissemination of data among partners.
- Access to data method of access, data formats, method of archiving (electronic and paper), including data handling, data analyses, and research communications. Offer restricted access to privacy sensitive information within the organization of the partner.
- Protection of the privacy within the organization of volunteers (employers, etc.) throughout the whole process like, communications, data exchange, presentation of findings, etc.
- Destruction of data once the purposes for which the data were obtained (and for which the consent form was signed) is over.

Furthermore, the participants have to be able to control the dissemination of the collected data. The investigator is not allowed to circulate information without anonymization. This means that only relevant attributes, i.e. gender, age, etc. are retained. Another possibility is to keep the identity of the participants, but only with prior consent of those.

As already mentioned, protection of confidentiality implies informing the participants about what may be done with their data (i.e. data sharing). As databases are developed, confidentiality will become increasingly hard to maintain. Simple stripping of the participants name and its replacement with a code is no guarantee of complete confidentiality.

4.4. PROCESS OF ENCODING AND ANONYMIZATION

Information should be anonymized so that individual identities cannot be revealed. Anonymization provides a safeguard against accidental or mischievous release of confidential information.

There are different ways in which personal data can be modified to conceal identities:

- Coded information contains information, which could readily identify people, but their identity is concealed by coding, the key to which is held by members of the research team using the information.
- Anonymized data with links to personal information is anonymized to the research team that holds it, but contains coded information, which could be used to identify people. The key to the code might be held by the custodians of a larger research database.
- Unlinked anonymized data contains nothing that has reasonable potential to be used by anyone to identify individuals.

As a minimum anonymized data must not contain any of the following, or codes for the following:

- Name, address, phone/fax. Number, e-mail address, full postcode.
- Any identifying reference numbers.
- Photograph or names of relatives.

Researcher and database developer should always consider – when designing studies, before passing information to others, and before publishing information- whether data contain combinations of such information that might lead to identification of individuals or very small groups. Within 3rD LIFE we will follow the unlinked anonymized data policy and any other identifiers, except age, gender and nationality. Once anonymized, the data will not allow tracing back the participant in any way.

Data will be encoded, and anonymized using numerical codes. During the experiments and the development stages, the correspondence with the users list will be saved into a local database, which will be encrypted.

Below you can find the computing environment in which the data will be used at each of the sites:

From INGEMA, specific measures will be developed and are recommended for the rest of the partners:

- Computing platform (PC, workstation, mainframe platform): PC
- Number of computers on which data will be stored or analysed: 2

- Whether personal computers used in the research project will be attached to a network or will operate independently (stand-alone): Stand-alone computers for the data collection, computers connected to a LAN for analysis.
- Physical environment in which computer is kept (e.g., in room with public access, in room locked when not in use by research staff): In a room locked when not in use by research staff.

4.5. SECURITY MEASURES FOR STORAGE AND HANDLING

All partners use state of the art technologies for secure storage, delivery and access of personal information as well as managing the rights of the users. In this way, there is complete guarantee that the accessed, delivered, stored and transmitted content will be managed by the right persons, with well-defined rights, at the right time.

State of the art firewalls, network security, encryption and authentication will be used to protect collected data. Firewalls prevents the connection to open network ports, and exchange of data will be through consortium known ports, protected via IP filtering and password. Where possible (depending on the facilities of each partner) the data will be stored in a locked server, and all identification data will be stored separately.

This will be combined with a controlled access mechanism and in the case of wireless data transmission with efficient encoding and encryption mechanisms.

At 3rD LIFE:

- At INGEMA on removable storage media such Zip(R) drive, with password access.
- At UL
- At O2t
- At I&IMS
- At CURE, 1) identifiable information will be stored in a Truecrypt encrypted volume on removable media, with password access for the principal investigators only. 2) Other anonymised data will be stored in a separate truecrypt encrypted volume, stored on CURE's intranet with password access to those CURE researchers directly involved in 3rD LIFE.

All sensible data will be encrypted and protected during storage and process so that user's identity and privacy will not be compromised as a result of the introduced sensors.

-Methods of data storage when data are not being used.

The data, not being used, will be stored in a locked server, and all identification data will be stored separately. In this way, there is complete guarantee that the stored content will be managed by the right persons, with well-defined rights, at the right time.

-Methods of transmitting the data between research team members

Researcher and database developer should always consider – when designing studies, before passing information to others, and before publishing information- whether data contain combinations of such information that might lead to identification of individuals or very small groups. Within 3rD LIFE we will follow the unlinked anonymized data policy and any other identifiers, except age, gender and nationality. Once anonymized, the data will not allow tracing back the participant in any way.

Data will be encoded, and anonymized using numerical codes. During the experiments and the development stages, the correspondence with the users list will be saved into a local database, which will be encrypted.

-Methods of storage of computer output (in electronic form as well as on paper).

- At INGEMA, the papers about evaluation of the participants will be kept with a code in a room locked and only the Principal Investigators would have access to the personal information and the information related with 3rD LIFE Project.

- At UL, O2t and IIMS it is not expected to storage personal information. If it is neccesary to do it, in future documents will be explicited the way in which this data is going to be storaged.

- At CURE, no paper based output will be kept or archived with respect to unanonymous data. The questionnaires that are filled out by the users will be only identifiable by a code. The relation between code and other data is kept only in computerized form stored in the Truecrypt volume described above. If paper output is used during the analysis phase, it is destroyed directly after usage whenever it relates back to individual participants. All computer outputs (such as statistical analyses, will be kept within the encrypted volume.

4.6. SECURITY ENFORCEMENT WITHIN THE PROJECT

Data will be collected at different research sites with surveys and experiments. The collected data will be stored in a secure server, only visible to the research site network, in a locked room at each of the research locations. Anonymous and identity data will be stored separately, and only the project leader will have access to all the users' identities. Anonymity will be granted by separating identifiable data from anonymous data. Each user will be granted a unique identifier that will link one to the other, but only anonymous data will be available to researchers. If any identifiable data is required, access to it will be granted only

after explicit user permission and after agreement of the responsible Data Protection Agency/Authority (Ethical Committee of Matia/Hurkoa/Gerozerlan).

Authentication will be required to access stored data on the research site. Authorized researchers will have access to the recorded anonymous data after authentication with a centralized server and on a need-to-know basis. Researchers performing the survey will have access rights to add data to the identity database, synchronized with the writing of the anonymous data. No editing or reading rights will be granted to them to prevent alteration/disclosure of private data.

Access to the different databases will be granted with an authentication server that will restrict access depending on the user identity, profile and the device he is currently using (identified through its IP address). If the device he is using is not from the local research site network, access will be banned. Access to each of the tables of the database will be also filtered on a user-based policy. A periodic change of password and minimum password quality policy will be enforced to grant the security of the system. Username, password and IP address will be checked before granting access to restricted data.

Those researchers working on 3rD LIFE abide by the contractual obligations of the consortium. If not included in this obligation, they will sign a statement that commits them to make sure project data are not provided to persons outside the project.

If an exchange of data among the different research sites is required, for example, due to the need of some researchers of data collected in another country, the data will be encrypted, prior to the transmission through a private virtual network from one site to the other, and the collected data will then be added to the database by authorized users (who will need the decryption password).

At 3rD LIFE:

-Types of protection expected

Although there are alternative ways to assure security for the data and applicants should prepare their plans in a manner that best meets their needs, some or all of the following features are typically found in successful data protection plans:

- Password protection for all files containing data (note that password protection is not regarded as sufficient protection by itself).
- Removable storage media holding the data (e.g., CDs, diskettes, zip disks, etc.) kept in a locked compartment/room when not in use.
- Printouts derived from data analysis stored in a locked compartment/room when not in use.
- No storage of the personal data any network, including LANs, Internet enabled, etc.
- No transmittal of data or analysis output derived from the data via e-mail, e-mail attachments, or FTP (either over the Internet, an Intranet system, or within a local area network).
- Use of the data on a dedicated computer kept in a secure room and not connected to a network.

- No backup copies of the data outside from the project to be made.
- Data stored in strongly encrypted form

-Disclosure Rules

The 3rD LIFE Data Protection Plan carefully describes how researchers and staff members will avoid inadvertent disclosure of respondents' geographic locations or identity in all working papers, publications, and presentations.

At minimum, researchers must agree to exclude from any type of publication or presentation, the following information:

- Listing of individual cases;
- Description of individual cases;
- Listing, description, or identification of a participants by number, by name, or by descriptive information;

As an international consortium between multiple partners that operate partly on the same data, the consortium will have to communicate data about the participants among each other. This data will only be communicated in an anonymous way. The data communicated will be sent in an encrypted, password-accessible form on a need-to-know basis, with access only to the staff directly related to the project. The data is subsequently stored at the individual partner locations in the manner described above.

4.7. PROCESS OF DATA DESTRUCTION

During the data collection, it needs to be clear that any personal data gathered from the persons participating in the project are relevant and as less as necessary for the successful development of the relevant purposes of the project. However, in this process of data collection, special needs may rise up that require collection of sensitive information when it comes to train or improve a technological device relevant for the project.

From INGEMA, specific measures will be developed and are recommended for the rest of the partners:

- Dissociation of personal identifiable data as it was specified in section 3.1.3.
- Destruction of paper/documents with a paper destroyer after 5 years the project ends.
- Erasing of electronic documents containing personal data after 5 years the project ends.

5. EVALUATION CRITERIA OF THIS DATA PROTECTION PLAN

These data protection plan evaluation criteria will be followed as guidelines throughout the project and its fulfilment will be supervised, deviations from it will be minimized and appropriately justified.

The proposed criteria that will be observed to measure the fulfilment of this evaluation plan will be the following:

Table 1. Evaluation criteria of this Data Protection Plan

Criteria	*YES*	*NO*	*N/A*
The users have been informed about the goals of the project.			
The users have given their consent to their participation.			
All the data collected in the user requirements questionnaire are necessary (but also are the minimum as possible, in order to avoid asking for non relevant, but sensitive, information) for the subsequent development of the 3rD LIFE.			
For any data not initially expected or specified in the consent form, a justification for its needs has been reported to the respective ethical committees (if required). This may include: -Video information about the users. -Audio information about the users.			
For any data not initially expected or specified in the consent form, additional consent forms have been provided to the users.			
Socio demographic identifiable data have been dissociated from the rest of information about the users.			
Socio demographic identifiable data have been encrypted on a separate database.			
Risk of identifying users in profiles or scenarios have been minimized.			
Any file exchanging personal information from the users have been encrypted.			
The site where the SPSS matrix of 3rD LIFE users' information is stored is password protected.			
Scenarios show conflict with legislations about privacy and security.			
For those scenarios showing conflict with legislations about privacy and security, necessary adaptations to fulfil these legislations have been carried out.			
Dissemination activities performed do not allow identification of the users.			

6. ETHICS IN PRACTICE

User centered design procedures included in the 3rD LIFE evaluation protect user rights from the start of the project until its end, 1) by including usability, ease to learn, acceptability and friendliness of the technologies developed, and 2) also by including evaluation procedures with the users involved. User-system interaction will be evaluated in order to ensure the most usable system to respond to real user needs, ensuring adequate privacy and safety of the participants.

3rD LIFE system uses very personal data; these data are intended for use in the private domain and, as such, we strive to carry out tests with personal information. Usability evaluations of usage contexts imply a higher level of user privacy. Nevertheless, as has been pointed out before in this document, the personal data collected will always be relevant and not excessive in accordance with the scope and purposes of the project. Privacy will be ensured through the procedures described in this deliverable.

Users in these phases (first and second prototype) will be recruited from the pool of users of each partner. The processing of the data subjects will be carried out with appropriate safeguards for the rights and freedoms of the participants, including the explanation of the project's procedures and the signature of a consent form.

All the ethical aspects involved in the different trials will be explained in detail when the trial scenarios will be developed. For that reason this deliverable will have additional amendments including the specific ethical issues that will derive from the designed trial scenarios.
By now, we can only say that each time the participants carry out a test, evaluation or another kind of participation, they must give their informed consent, which means that the proposed procedure and its implications will be discussed, and only afterwards will the participant sign the relevant form. As explained before, in the informed consent process the following parts are to be discussed:

- Aim of the study.
- Voluntary nature.
- Risks/ Benefits.
- How the information is stored?
- How the information is encoded?

During the trials, the partners of the project have to share participants' personal and private information. For this reason, they have to follow these principles:

- Before starting the trials it is necessary to prepare the users for the situation. That means, to explain the general objective of the evaluation, the methodology to be carried out, and the participation requested of them. Also, all the doubts should be clarified before starting.
- During the test, people are not obliged to give details about their own lives
- The data will be encrypted or protected with a code during the storage and process

- Anonymized, as the last year, when people came for the audio and video recordings, with the day, number of session… without names, photographs, identifying numbers.
- The same codes as the ones given last year (e.g. of a code: 3D001//11).

- Each partner should store the information in a secure way. The database will be sealed from people not involved in the project but working in the organization
- The correspondence between the numerical codes and the user list will be saved into a local encrypted database.
- The data will be stored in a locked server and the identification data will be stored separately

In the same way, it must take into account that after the trial:

- It is not allowed to circulate information between partners without anonymization.
- Regarding dissemination (paper, publications, presentations…) it is not allowed:
  -Listing of individual cases
  -Description of individual cases
  -Listing, description or identification of the participants by number, by name, or by descriptive information.

The data will be saved for five years after the end of the project. After this time, each partner will be responsible for destroying the personal data in his organization.

Whenever a question arises from any partner in the project related with themes about how safeguard the information, share it, or so on, they can ask directly to any partner of INGEMA.

7. CONCLUSION

Up to now, in the actions carried out with end users, interviews and focus groups, no ethical problems have been identified. Obviously, issues regarding privacy and protection of personal data arise in the interviews and focus groups. 3RD LIFE consortium is already applying the Data Protection Plan exposed here.

Finally, some of the actions that have been mentioned before are summarize in the following points. Besides, some recommendations when the tester will be interacting with the user are provided. The aim is to help the tester to know if he is acting with the user in an ethical way.

- Each partner has to carefully read their country laws.
- The user has to sign the consent before starting the trial. It is not possible to carry out the trial without signing the consent. Besides all the parts of the study must be clear to the user.
- The informed consent and all the documents will use an equal language, without discriminating people for their gender.
- The data will be encrypted and protected with a code.
- The user's personal data has to be safeguard from other people not involved in the project
- In the publications, no personal data will be provided.
- At the end of the trials specific analysis will be made in order to assess if gender and cultural differences (between Vienna and San Sebastian) are found.
- The personal information will be saved for five years after the end of the project. After that, each partner has to destroy it.
- For any question which gives rise during the trials, the partners can consult INGEMA about it.

8. REFERENCES

[1]	European Commission: Ethics for researchers, Facilitating research excellence in FP7.
[2]	Directive 95/46/EC. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
[3]	Charter of Fundamental Rights of The European Union. 2000/C364/01. Official Journal of the European Communities 18 December 2000.
[4]	Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de CarácterPersonal (BOE núm. 298, 14-12-1999, pp. 43088-43099) [Organic Law, 15/1999, for Protection of Data of Personal Nature, Text in Spanish].
[5]	Decreto 143/1995, de 7 de febrero, sobre creación y acreditación de Comités de Ética Asistencial. (BOPV núm. 1995043, 02-03-1995, pp. 2060-2064).
[6]	Resolución nº 3831 de 24 de junio de 1997 del Departameno de Sanidad del Gobierno Vasco (BOPV núm. 1997137, 18-07-1997, pp. 12480).
[7]	World Medical Association (1964) Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects.
[8]	Instrumento de Ratificación del Convenio para la protección de los derechos humanos y la dignidad del ser humano con respecto a las aplicaciones de la Biología y la Medicina (Convenio relativo a los derechos humanos y la biomedicina), hecho en Oviedo el 4 de abril de 1997. (BOE núm. 251, 04-04-1997, pp. 36825-36830). [Instrument for the ratification of the Agreement for the protection of the human rights and human being dignity with respect to the Biology and Medicine applications, Text in Spanish].
[9]	Privacy law - Datenschutzgesetz 2000 or in short DSG 2000 (long name: Bundesgesetz über den Schutz personenbezogener Daten).
[10]	Access to Public Information Act. Available at https://www.ip-rs.si/index.php?id=324 Consulted on 14-02-2012.
[11]	Personal Data Protection Act is in Slovene language: Zakon o varstvu osebnih podatkov. ZVOP. (ZVOP-1-UPB1) is published in: Official Gazette of the Republic of Slovenia, No. 94/2007.
[12]	Act of August 29, 1997 on the Protection of Personal Data. Available at: http://www.dataprotection.eu/pmwiki/pmwiki.php?n=Main.PL

9. ANNEXES

9.1. INFORM CONSENT

Consortium	Name	Acronym	Country
1 (Project leader)	Fundación Insituto Gerontológico Matía	INGEMA	Spain
2	University of Lubjana	UL	Slovenia
3	One 2 Tribe	O2T	Poland
4	Information & Image Management Systems	IIMS	Spain
5	Centre for Usability Research and Engineering	CURE	Austria

Title of the project:	3rD-LIFE: 3D VIRTUAL ENVIRONMENT FOR SOCIAL INTERACTION OF ELDERLY PEOPLE
Coordinator:	Cristina Buiza (INGEMA)
Principal investigator at local level:	
Institution	
Financed by	EU, bmvit
Programme & Call	AAL Joint Programme - Call 2
Project Number	AAL-2009-2-XXX
Project Duration	18 Months
Project Start & End	Juli 2011 – December 2012

The study described in this text is a part of the research project 3rD-LIFE: 3D VIRTUAL ENVIRONMENT FOR SOCIAL INTERACTION OF ELDERLY PEOPLE, funded by European Union (EU) and National funding Organization under the AAL Joint Programme.

I. INTRODUCTION:

You have been invited to participate in a research study. Before you decide to participate, please read this consent report carefully. Please ask all the questions that may come to your mind. In this way, we will be sure that you understand all procedures of the study, including the risks and the benefits.

This consent sheet may include words that you do not understand. If so, please ask the contact researcher or any person included in the study to explain to you any word or information you do not clearly understand. You can take a copy of this consent to think about it or to discuss it with your family before making any decision.

II. AIM OF THE STUDY:

The main aim of the 3rD-LIFE project is to develop a 3D virtual desktop environment providing a tool for entertainment, education, communication and other functionalities to improve the quality of life of ageing people (aged 60-75 years) without specific cognitive impairments exceeding the expected level due to the healthy ageing process. With only a computer and an internet connection, it will be possible for the ageing target group to

communicate, make audio and video calls to external telecommunication devices from their own homes and through their own voices, and live a more joyful and active life through the 3D environment (based on existing 3D platforms). The 3D environment will help the users to communicate in the "natural way" (the project will concentrate on user interface usability), through the well designed virtual world and spacial navigation. This will differentiate the solution from the typical, portal like 2D, text-based tools.

III. PARTICIPANTS AND POSSIBLE PARTICIPATION IN THE STUDY:
You are being kindly asked to volunteer in this research study. This consent/information form includes information about this study. We want to make sure that you are informed on the purpose of this study and what it means for you to participate in this study.

Please ask us for clarification on any point in the following information sheet. If you do not understand certain contents, please do not sign this form before you feel confident that you are aware of the study and its goals.

The participation in the study is totally voluntary. You can quit at any moment without being penalized or losing your benefits. However, we kindly ask you to participate in all of the requirements analysis and end-user input studies throughout the project.

The primary participants will be elderly people aged between 60-75 with no cognitive impairment or age associated memory impairment. None of the participants in this study, primary participants as well as other participants, like family members, friends or health professionals should have strong symptoms of cognitive diseases (e.g. Dementia, Alzheimer) or visual impairments resulting problems in depth perception.

Only in Austria: At the end of the study you will receive a financial compensation for your time spent and your valuable input in the amount of [To Be Defined] €.

IV. PROCEDURES:
In the initial phase, your participation will consist of an interview/ questionnaire. The goal will be to gather information about: demographic data, quality of life, social activities, communication habits (friends & family), physical, psychological and social health, skills and interests about new technologies.

As a next step, a focus group will be organized to gather preferences, needs and requirements of the participants regarding the 3D environment (design, functionalities, controls, etc.).

After this step, trials will be carried out using low- & high-fidelity prototypes with participation of the target users.

V. RISK OR INCONVENIENCES:
No risks or damages are foreseen during the assessment.

VI. BENEFITS:
It is likely that you will receive any personal benefit for your participation in this study. In any case, the data collected in this study might result in a better knowledge of elderly people's needs.

VII. PRIVACY AND CONFIDENTIALITY:
We will record your responses, however no personal identification will be included. In other words, when you agree to participate in the research, your results will receive a code-number, and the data will be saved under that code anonymously. The information will be processed during the analysis of the data obtained and will appear in the project deliverables but only in the way that it will not be possible to identify from whom we received the information observing at all times:

> **in Spain** the Spanish Data Protection Organic Law 15/1999, at December the 13th:
> "In that law performance we inform you that all personal data that you will provide us by the filling out of the present questionnaire or by the documentation that you will give us to INGEMA Foundation will be part of an automated file property of the Foundation, and they will only be used for the management steps and the turnover of the provision of services. Likewise you expressly give us your consent of the data use for the research aims"
>
> **in Austria** the Federal Act concerning the Protection of Personal Data (DSG 2000):
> "According to the law aforementioned, we inform you that all provided personal data that will be scientifically analyzed will be coded from CURE so that it will not be possible to identify your name or other personal information about you in the results of the scientific analysis. All provided personal data will be stored in a file store that can only be accessed by researchers from CURE that are involved in the 3rD-LIFE project. None of the provided personal data will be handled out to third parties."

The results of this research can be published in scientific magazines or be presented in clinical sessions, always guaranteeing the complete anonymity.

The authorization for the use and access of the information for the aim of research is totally voluntary. This authorization will apply to the end of the study unless you cancel it before. In this case we will stop the use of your data.

If you decide to withdraw your consent later on, we ask you contact principal investigator of this study and let him know that you are withdrawing from the study.

The Principal Investigator can be contacted under the following address:

Dr. Cristina Buiza Bueno
Fundación INGEMA
Parque Tecnológico de San Sebastián. Paseo Mikeletegi 1-3
20009 San Sebastián
Telf. 943 224643

Since the moment of your withdrawal, your data will not be processed again in any further phases of the research project. However, it will not be possible to alter already existing published documents or completed project deliverables.

VIII. CONTACT PERSON

For further information about your rights as a research participant, or if you are not satisfied with the manner in which this study is being conducted or if you have any questions or suffer any injury during the course of the research or experience any adverse reaction to a study drug or procedure, please contact the principal Investigator:

Dr. Cristina Buiza Bueno
Fundación INGEMA
Parque Tecnológico de San Sebastián. Paseo Mikeletegi 1-3
20009 San Sebastián
Telf. 943 224643

IX. CONFIRMATION:

Your participation in the study is possible only if you sign a stand-alone consent form that will authorize us to use your personal and health information and the information on your health status. If you do not wish to do so, please do not take part in this study.

I have read the information written in this consent report or has been adequately read to me. All my questions about this study and about my participation on it have been met.

Tick one of the following:
O I read all the information in this form.
O The information in this form was read to me by:_____

All questions I had were answered by:_____

I authorize the use and dissemination of my answers to the aforementioned entities and for the above mentioned purposes. The signing of this consent report does not imply the renunciation to any legal right. I voluntarily agree to participate in this research study carried out by INGEMA Foundation and other members of the 3rD-LIFE project.

I understand that all information will be kept confidential and will be reported in an anonymous way.

Name and surname of participant:_____
Date:_____
Signature of participant_____

Name and surname of the researcher_____
Date:_____
Signature of the researcher_____

X. PHOTO, VIDEO AND AUDIO RECORDING
The study is lead by:

Dr. Cristina Buiza Bueno
Fundación INGEMA
Parque Tecnológico de San Sebastián. Paseo Mikeletegi 1-3
20009 San Sebastián
Telf. 943 224643

As part of this research project, photograph, videotape (Austria) and audiotape (Spain) recording during the participation in the study will take place.

I have received a thorough description of the purpose and procedures for these recordings and I give my consent to allow [**Name of the Local Institution]** record during my participation; process, use the recordings or parts of the recordings in analysis, related studies and project results and presentations, as well as for marketing and PR purposes of the research project 3rD-LIFE*:* 3D VIRTUAL ENVIRONMENT FOR SOCIAL INTERACTION OF ELDERLY PEOPLE.

I understand that all information will be kept confidential and will be reported in an anonymous way.

Name and surname of participant:_____
Date:_____
Signature of participant_____

Name and surname of the researcher_____
Date:_____
Signature of the researcher_____

9.2. INFORMATION LETTER

Title: 3D VIRTUAL ENVIRONMENT FOR SOCIAL INTERACTIONOF ELDERLY PEOPLE

Proposal acronym: 3rD-LIFE

AAL-2009-2

Consortium	Name	Acronym	Country
1 (Project leader)	Fundación Insituto Gerontológico Matía	INGEMA	Spain
2	University of Lubjana	UL	Slovenia
3	One 2 Tribe	O2T	Poland
4	Information & Image Management Systems	IIMS	Spain
5	Centre for Usability Research and Engineering	CURE	Austria

I. PROJECT GOALS

3rD-LIFE is a Project funded by the AAL Programme (The Ambient Assisted Living Joint Programme) with an expected duration of 18 months, starting in July of 2011 and ending in December 2012.

The general objective of the project is to improve the quality of life of ageing people providing them with a virtual tool, to be able to interact with other users and use other functionalities. It will be achieved through the development of a 3D virtual environment (based on existing 3D platforms) especially adapted to the use of ageing people. With only a computer and an Internet connection, users will be able to, from their own homes and through their own voices, communicate with other users, make audio and video calls to real world terminals and have a more joyful and active live thanks to the e-learning tools, cognitive games and other applications that will be implemented. 3rD-LIFE might establish the basis for developing a wide number of applications that may improve the quality of life of the elderly people including: organization of social activities such as going to the movies, exchanging books or organizing social gatherings, soliciting peer help on housekeeping and other daily activities, allowing support organizations to place relevant content to interested elderly users, allowing caregivers, facilitators and family members to receive alerts if certain expected home activities of the elderly people are interrupted or responding to emergency or unexpected situations that may need immediate action.

The users will be represented as avatars, which mean that accessibility, usability and navigation will be central points in the project.

II. WHO IS THIS PROJECT AIMED AT?

The end users' group at which this Project aims is: adults (between 60 to 75 years old) without any special characteristics: no specific physical or cognitive characteristics will be required or look for. It is directed towards people with some previous Internet experience. The trials, both the initial trials and the final trials, will be conducted in San Sebastian, Spain and in Vienna, Austria.

III. Study participants

Requirements, needs and wishes of primary users, this is people between 60 and 75 years old, will constitute the back bone of 3rD LIFE project. The aim is to have the focus of the elders since the very beginning of the project. Participants will be demanded tor participate in three different phases during the whole project:

- Initial designing phases (ideas generation and data recollection for the design of 3rD LIFE).
- First trials of 3rD LIFE.
- Final trials of 3rD LIFE.

In both countries, there will be a total of 50 participants divided in different groups. Due to the risk of fall outs, a bigger number of participants will be recruited at the beginning. INGEMA (Spain) will recruit 4-5 groups and CURE (Austria) 2-3 groups with 7-10 people each. Since the first contact, participants will be asked for continue with their collaboration during the whole project; although they are no forced to compromised theirselves.

The main aim of the first phases is to gain knowledge about users needs and interests. Sociodemographic data, life style, social networks, capabilities, interests and interaction with the new technologies will be asked in a semi-structured interview that will carry out for reach the aims of this initial phase. In addition a cognitive assessment will carry out in order to explore the functions of the elders (only in Spain).

Based on the information recollected in the initial interviews a first low-fi prototype will be design. Then, in the second phase of the project, different trials of this prototype will carry out. The aim of these trials is to obtain data that allow us to improve and to continue with the development of 3rD Life.

In the final evaluation of 3rD LIFE, the interaction of the users with the final prototype will be observed. Additionally, the acceptance of the technological solution will be studied and the opinion of the users regarding future development of 3rD LIFE will be collected.

Method and detailed planification for the users assessment will be setted up specifically for each phase of the project.

For further information about this project, please contact with the Coordinator and Main Researcher:

Dr. Cristina Buiza Bueno
Fundación INGEMA
Parque Tecnológico de San Sebastián. Paseo Mikeletegi 1-3
20009 San Sebastián
Telf. 943 224643