



### Project Identification

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Platform for Ergonomic and motivating,  
ICT-based Age-friendly woRkpLaces

### Document Identification

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## Abbreviations

| <i>Abbrev.</i> | <i>Description</i>                                     |
|----------------|--|
| AAL            | Ambient Assisted Living                                |
| AAL JP         | Ambient Assisted Living Joint Programme                |
| EU             | European Union   |
| NFC            | Near Field Communication                               |
| OECD           | Organisation for Economic Co-operation and Development |
| RFID           | Radio Frequency Identification                         |
| WMA            | World Medical Association                              |

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## Executive Summary

This document presents the ethical guidelines regulations including all ethical procedures of the project, roles and responsibilities of the Ethics Committee. The guidelines instruct the combination of partners' existing ethical test protocols, to result in a common PEARL Ethics framework which is used as an ethical background to all contact with end-users. Apart from the guidelines, this document includes a sample consent form that will be the basis for the participation of the users to the evaluation of the project.

# 1 About this Document

## 1.1 Role of the deliverable

The role of the deliverable is to define at the early stage of the project the framework of Ethical Guidelines. The document highlights the Ethics Committee instrument in PEARL project and the consent form template that will be used for the evaluation tasks of the project.

## 2 General Ethical Management Methodology

The deployment and use of PEARL solutions may entail several ethical issues (i.e. notably privacy issues) including: (a) monitoring human activity through (RFID/NFC) sensors, (b) data sharing and storage within corporate database, (c) study and tracking of social factors for humans (preferences, behaviors), (d) collecting and maintaining medical-related data (e.g. scores in assessment test) for the participating elderly. PEARL will thoroughly investigate all these ethical and privacy implications, especially in the scope of the user involving processes where these privacy issues will arise. In particular, the trial protocol (to be designed) will undergo ethical approval by the involved user sites. Therefore, the partners involved in the evaluation of PEARL will receive ethical approval from the Ethical Committee prior to the beginning of the evaluation phase. To guarantee that there is no delay in the evaluation phase the partners will submit the request with a large time in advance. As soon as the evaluation protocols are ready the partners will initiate ethical approval procedures. The ethical procedures to be established and applied in the project, will be reviewed and approved by an Ethical Committee to be established in the project with the participation of representatives from the end-user sites and user organization involved, as well as representatives of the technical/technological partners responsible for the pilots' technological setup (see D1.1 Project Handbook). This committee will include one external expert from AAU, with experience in ethical issues, in order to ensure objective participation out of the project's scope.

### 2.1 Handling of Informed Consent and Data Anonymization

During the project, but also during the productive deployment of the PEARL system informed consent processes will be mandatory. Older workers participating in the trial and/or the production phases of the project will be required to complete an informed consent form in order to participate in the usage of the projects solutions. Hence, PEARL will provide an informed consent form and related documentation will be provided to all older workers in their native language to ensure that there is no intimidation involved in their decision to participate. For all users participating in the trial, the informed consent form will describe the trial protocols, along with all ethical implications of the project. The form will be common across all pilot sites, and will be reviewed and approved by the Ethical Committee.

Data collected from the trials will be treated anonymously in the development of any reporting, and specific feedback from the users will not be identifiable with the originating individuals.

### 2.2 Relevant EU legislation and international contexts

The Consortium confirms that relevant EU legislation and international contexts will be observed. An initial survey has identified the following:

#### 2.2.1 The Charter of Fundamental Rights of the EU

The Charter of Fundamental Rights in the course of the respective legal trend dedicates a separate article to the protection of personal data. Article 8 sets out the right to the protection of personal data of an individual and thus the protection of personal data has now its own legal basis apart from the right to respect an individual's private life and the protection of human dignity. The article also defines the rules for the legitimate processing of personal data, notably that the processing shall be fair and for pre-specified purposes based on the consent of the data subject or other legitimate basis laid down by law. Furthermore, references are made to two rights of the data subject: the right of access to the data and the right to have it rectified. Finally, Article 8 sets out the need for an independent authority, which shall control the compliance with the data protection rules.

### **2.2.2 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 lays down a series of rights of the data subject.

### **2.2.3 Declaration of Helsinki**

The Declaration of Helsinki is a set of ethical principles regarding human experimentation developed for the medical community by the World Medical Association (WMA). It is widely regarded as the cornerstone document on human research ethics. [HelsWiki]

## 3 Ethical Guidelines

### 3.1 Overview

PEARL will be in line with the following guideline of the: *“Every art and every enquiry, and similar every action and pursuit, is thought to aim at some good; and for this reason the good has rightly been declared to be that at which all things aim”* –Aristotle, Nicomachean Ethics, Book I, Chapter I. Translation, J. Bywater, Oxford 1894- As stated in the Seventh Framework Programme (Decision n<sup>o</sup> 1982/2006/EC), Article 6: “All the research activities carried out under the Seventh Framework Programme shall be carried out in compliance with fundamental ethical principles”. PEARL, deals with a number of aspects that might impose ethical issues. Firstly, the ability to record conversations might raise privacy-related concerns. This risk is addressed through the technological design of the system, governed by the work on privacy. As part of the project management work package (administrative management), a formal ethical strategy will be created that describes how the consortium is going to deal with the PEARL ethical issues.

The project will also do user requirements analysis and evaluation involving senior workers. As older people can be considered to be a group that is vulnerable, specific attention is to be paid to involving these end-users in a way that maintains security, privacy and confidentiality of participants and respects the common values of autonomy, independence, beneficence, non-maleficence and justice.

There will be a continuous watch of new laws and legislations that may arise during the project development, regarding the ethical management of research with humans within national and EU levels, to ensure that if new legislations arise during the project, they will be immediately applied to the project’s research strategy. The strategy chosen to deal successfully with ethics in (i) the development and evaluation operations of PEARL and (ii) the involvement of potentially vulnerable end-users, as well as (iii) gender issues, is highlighted through the following mechanisms.

In preparing the user requirements analysis in WP2 and the evaluation operations, we will guarantee the comfort and safety of participants and/or professionals who take part in them, as well as the security of their personal data (on preferences, profile and localization), acquired during the evaluations. PEARL will follow the recommendations of the European group on ethics in science and new technologies to the European Commission. Furthermore, all consortium members agree to adhere to the Helsinki Declaration of 1964 (Recommendation for conduct of clinical research). All national legal and ethical requirements of the Member States where the research is performed will be fulfilled. There will be arrangements for protecting the confidentiality of personal data of participants at any time of the research, as also detailed in following paragraphs. Fundamental safety issues of good laboratory practices will be respected. Potential safety implications of PEARL will be clearly indicated.

This means in detail that:

- All the test subjects must give informed written consent to participate.
- All the subjects will be strictly volunteers and are able to withdraw from the trials at any time without any restraints.
- All personal data collected during the Pilots on the subjects’ preferences and habits will be strictly confidential.

In addition, all test volunteers, following detailed oral information, will receive in their own language:

- A commonly understandable written description of the project;
- The project objectives;
- The planned project progress;
- The related testing and examination procedures;



- Advice on unrestricted disclaimer rights on their agreement.
- Access to a complaints procedure

The written information as well as the sought informed consent corresponds to the revised version of the mentioned Declaration of Helsinki. Participants with legal guardian aids, as well as participants who cannot rationalize the expected end-user activities and goal based on any impairment of their cognitive abilities will be excluded from any project study.

At this point, we would like to stress the importance that the PEARL Consortium places on the close collaboration between the teams conducting the recruitment of senior persons for the evaluations, as well as those teams conducting the actual evaluations. The recruitment of test subjects in each evaluation will be made on the basis of concrete inclusion/exclusion criteria. These criteria will be related to the cognitive ability of the candidate test subjects, their ability or not to give informed consent, and, where it exists, related national legislation determining when a person is able to give informed consent or not. The Consortium will pay every effort possible to harmonize these inclusion/exclusion criteria for all pilot sites, however, we are aware that there will also be some pilot site-specific criteria, given the differentiation of national legislation on these issues.

At all cases, in addition to national legislation, which in many cases is generic and/or inadequate to cover the specific project needs, the PEARL Consortium will consult very closely with the experts of elderly people about their ability or not to give informed consent, since it is these experts who interact and follow the progress of each test subject on an everyday basis and this makes them to most appropriate persons to decide about the cognitive ability or not of a test subject.

Thus, the consortium shall implement the project in full respect of the legal and ethical national requirements and code of practice. Whenever authorizations have to be obtained from national bodies, those authorizations shall be considered as documents relevant to the project. Copies of all relevant authorizations shall be submitted to the Commission prior to commencement of the relevant part of the project.

### **3.2 Ethics Committee**

PEARL will make a significant effort to fully analyze and take in to consideration all ethical issues mentioned above. To ensure the validity of the ethical approach taken in the project, an Ethics Advisor is appointed within the project, to manage and guide the ethical content and procedures as part of the ethical strategy and the ethics framework for the involvement of end-users. This person is the first point of contact within the consortium for any questions regarding ethical issues, such as privacy, security, freedom of choice, dependency and consent, and is also the responsible for the communication to the EC regarding ethical reports and approval where required.

An Ethics Committee will be also established, to guarantee the best quality of social, psychological and public health attention to elderly people and the fundamental ethical principles that research on human beings has to have. This Ethics Committee will include at least one representative per evaluation site who is well acquainted with national ethical legislation and procedures. The Committee will be responsible for establishing and implementing all ethical procedures that are relevant to each pilot site (request of permissions from relevant authorities, drafting of material necessary for obtaining permissions, drafting of informed consent forms, etc.). This Committee will also approve all research activities involving human participants. Its responsibility is to guarantee the best quality of social, psychological and public health attention to elderly people and the fundamental ethical principles that research involving potentially vulnerable human beings has to have.

### 3.3 National Rules for Ethical Management

PEARL will pay special attention to any ethical rules and regulations, stemming from national laws and directives. Such national directives may require additional targeted ethical interventions for specific pilot sites. PEARL will ensure compliance with both EU directives and national directives (at the countries where evaluations will be performed).

### 3.4 Compliance to Relevant EU Legislation and Privacy Texts

With respect to security and privacy associated with citizens' data and participation in the PEARL platform the project will comply with relevant EU legislation and international texts on privacy. In particular:

#### 3.4.1 The Charter of Fundamental Rights of the EU

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

#### 3.4.2 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. The Directive lays down a series of rights of the data subject, for instance the patient: These are:

- The right of access to his / her personal data
- The right of erasure, blocking or rectification of the data, which do not comply, with the provisions of the Directive, are incomplete or inaccurate.
- The right to be informed of all relevant details relating to the data processing and the rights granted to him/her
- The right to a judicial remedy for any breach of the above mentioned rights.
- All these are applicable to PEARL. The first three aforementioned rights may be restricted if this is necessary for reasons relating to the protection of the data subject or the rights and freedoms of others or to prevent a criminal offence or for reasons relating to public security.

Regarding regulation at international level, starting from the OECD guidelines including the "Guidelines on the protection of privacy and transborder flow of personal data" (1981) and "Guidelines for the security of information systems" (1991/92), the PEARL consortium in particular acknowledges heterogeneity in international data protection jurisdiction.

## 4 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 the participant has to direct what happens to his/her body and personal data and from the ethical duty of the investigator to involve the participant in research. Seeking the consent of an individual to participate in research reflects the right of an individual to self-determination and also his/her fundamental right to be free from bodily interference whether physical or psychological and to protect his/her personal data. These are ethical principles recognized by Law as legal rights. A distinction between three informed consent elements is possible: the information given, the capacity to understand it and the voluntariness of any decision taken.

Respect for persons requires that participants, to the degree they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided, when adequate standards for informed consent are satisfied.

The written information as well as the sought informed consent corresponds to information gathered from the revised version of the Helsinki Declaration of 1964, as lastly amended in Tokyo, 2004, and the Convention of the Council of Europe on Human Rights and Biomedicine (1997).

### 4.1 Basic elements of informed consent

In order to involve a human being as a participant in research, the investigator will obtain the legally effective informed consent of the participant or the participant's legally authorized representative.

All investigators within PEARL will seek such consent only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

The information given to the participant or the representative will be in language understandable to the participant or the representative.

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 investigator, the sponsor, the institution or its agents from liability for negligence.

The informed consent will contain a description of the procedures for protecting the confidentiality of personal data.

Much research revolves around information about people – their age, lifestyle, health and work – 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 the 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.

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.

While common law establishes some core principles, it does not specify when confidential information may be disclosed to others, in research. Individuals and organizations using confidential information have to take responsibility for deciding what is justified and acceptable on a case-by-case basis (Medical Research Council, 2000).

In the behavioral sciences, respect for privacy and confidentiality is a central concept in the conduct of ethical research with human participants. Difficulties with privacy issues can lead to difficulties in properly conducting research. If a participant perceives that his or her privacy is threatened this can lead to biased sampling, evasive and/or false responses, and many other impediments that can affect the validity of the results.

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.

A question currently under debate among behavioral scientists is whether a consent form stating that personal data will not be shared precludes sharing of data even if identifying characteristics are removed. The removal of identifying information from data gathered on an individual may not be enough since identities can be reconstructed from disparate data sources.

There are solutions to the challenge of maintaining confidentiality including substituting numerical identifiers for names, aggregating data so that the performance of individuals is not obtainable, encryption or layering data so that researchers who need identifying information can obtain it only after signing a legal document that requires honoring the confidentiality of individuals. Researchers who do not need identifying information can have free access to aggregated data.

Visual information will be used as provided (no facial and other features altered) and all accompanying information will be clearly indicated as example/fictional. The possibility of intentionally modifying this accompanying information will be considered for minimizing the chance of user identification by external-to-the-project subjects. This way, legislation restrictions will not pose any obstacle to the project's implementation. In addition, all stored information will be made available only to authorized users through special secure access management mechanisms, therefore, avoiding jeopardizing personal privacy when the project's results will be commercially exploited.

The personal data will be shared by the consortium members in an anonymous form and the participants will need to be informed about why this has to be done. This information needs to be secured to prevent this information from being available outside the consortium.

The questionnaires will be handled in the strictest confidence – the results will be entered immediately into a database from where each set of results will be given an automatic number and the personal details omitted. The questionnaires themselves will be kept in a folder, which is kept in a lockable drawer. The questionnaires will be destroyed at the end of the project.

The server, which will collect data on use of the system, will be kept in a locked server room with electronic access only to those analyzing the results of the PEARL project from the consortium. Additionally, all personal data can be modified and even erased on request from the person via an easy to use interface. Also the user should be able to inquire about his/her stored data via an easy to use interface.

Anonymization will be used to protect the user's identity. The name of the persons and any kind of identification data will appear on the consent forms, of which one copy is kept by the project leader and the other one by the person participating to the experiment. All recordings will then be anonymized by assigning a numerical code to each user (local database), and stored accordingly (e.g. Subject 1, Subject 2, etc.). More details are provided in the following Sections. All data will also be anonymized in internal reports, internal communications and external publications.

### **4.2 Description of the process of encoding or anonymization used**

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. How much of this potentially identifying information can be safely included in data that is assumed to be unidentifiable can only be judged on a case-by-case basis taking into account the sample size, the ways in which results will be published and used (Medical Research Council, 2000).

Within PEARL we will follow the unlinked anonymized data policy, excluding users having rare diseases 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 pilot stages, the correspondence with the users list will be saved into a local database, which will be encrypted.

### **4.3 Ethics Documents Needed**

As illustrated in the previous paragraph, the PEARL partners have a sound understanding of the ethical processes needed at national and EU level, as well as of the structure and content of the relevant

documents (notably the description of the study and the informed consent forms). As already outlined the partners will adapt these documents according to the requirements of their respective countries, while they will also provide localized versions of the documents. As an example, we provide in Annex A a sample consent form, which will be finalized/completed as part of the WP1 of the project.

## References

[DoW], PEARL Description of Work

[HelsWiki], Declaration of Helsinki, [http://en.wikipedia.org/wiki/Declaration\\_of\\_Helsinki](http://en.wikipedia.org/wiki/Declaration_of_Helsinki)

## Appendix A Informed Consent Form

The following document is an indicative Informed Consent (IC) Form. Before the start of the pilots, the IC forms of the countries involved will be prepared and will comply with the country specific legislation.

### Informed Consent Form

**Project Coordinator:**

**Site Address:**

**Site Phone Number:**

**Subject Identifier**

**Project acronym: PEARL**

**Project full title:**

**Version Number #**

**Date:**

#### What does giving consent mean?

You are being invited to take part in a research project. Before you, and the person who comes to the clinic with you, decide whether you take part, it is important for you to know why the project is being done and what it will involve. Please take time to read the following information carefully and discuss it if you wish with relatives. Ask us if there is anything that is not clear or if you would like more information.

#### What are the objectives of this project?

PEARL will facilitate the development and deployment of the next generation of ICT-based age-aware working spaces. These working spaces will primarily target older workers aged 55+, notably aged individuals that work in the creative industries. Note that such industries could greatly benefit from prolonging the working life of aged individuals, given the experience and proven expertise of older adults in several creative tasks (such as design tasks). For the purpose of the project's validation and evaluation the target group of workers aged 55+ will be segmented into the following subgroups: (A) Individuals aged 55-65, i.e. workers (currently) at the latest stages of their working life, which would be willing and interested in essentially prolonging their working life rather than retiring and (B) Individuals aged 65+ (including retired workers), notably



individuals willing to return to work under proper working conditions (including proper working environment). The PEARL platform will be able to produce different deployment configurations for different user groups and task requirements. On the basis of this capability, it is likely that more fine-grained subgroupings of the above groups will be studied during the project. For the two groups mentioned above, the project will specify more detailed inclusion and exclusion criteria, which will drive the recruitment processes during validation.

**What does the project involve?**

The PEARL project involves \_\_\_\_\_

If you meet all the conditions and can participate in this project, you will be asked to participate in the project for about \_\_\_\_ months. During this time, you will need to visit the site \_\_\_\_ times. These visits will include \_\_\_\_\_.

**Are there any benefits for taking part in the project?**

Your participation will help us to learn more about impact of ergonomic and motivating, ICT-based age-friendly workplaces.

**Do you have to stay in the project?**

Participation in this project is completely voluntary, and you can choose to stop participating at any time. If you decides to withdraw from the project, contact your project coordinator and they will explain the best way for you to stop taking part. Information and data, which has been collected up until the time that you withdraw, will continue to be used by the PEARL Consortium.

In addition, you should know that you may be withdrawn from the project for any of the following reasons:

- If you don't follow the project instructions
- If you don't attended the scheduled visits
- If the project coordinator decides that it is in the best interest of your health and welfare to withdraw
- If the whole project is stopped, for reasons not known now.

**Who will have access to personal information about you that is collected in this project?**

If you decide to take part in the project, the project coordinator and staff will collect information about you as part of the project. The PEARL Consortium members and other like the independent ethics committee or the institutional review board for the project or regulatory authorities will have access to this information at the site in order to check that the project is done properly. The PEARL Consortium members who see this information at the site will keep it confidential.

Your project coordinator will also transfer to the PEARL Consortium members some of the information collected in a coded form. The information transferred will not include your name, initials, address, or other direct identifiers. It will be assigned a code number that only your project coordinator can connect back to your name.

From time-to-time, coded information will also be transferred to an independent Data Monitoring Committee made up of statistical experts. Their job will be to monitor the safety of the intervention during the project and to make recommendations about whether the project should continue and/or whether only certain treatment groups should continue.

Your permission to the project coordinator and staff to use this information or share it with the PEARL Consortium members and others as described below for the project does not automatically end at a particular time.

Information about you may be produced as part of the research or project procedures. While you are in the project, the project site will not share certain new information about you that is created as part of the project (such as the results of certain tests) unless the project coordinator decides it is important to do so. This is done to stop the project results from being distorted. Once the project is over, you will be given access to information about you that you are entitled to see. You will be told if any of this information requires confirmation.

**What will the PEARL Consortium do with the information it gets?**

The PEARL Consortium may use the information that the project doctor gives it (i.e. the coded information):

- By storing and analyzing it electronically to find out what this project is telling us
- By sharing it with regulatory authorities or groups that check that research is done properly
- By publishing the results of the project (this will not include any information that directly identifies you)
- By sharing it as part of research with companies or universities for the purpose of further understanding or developing this intervention. If the information is sent to another country, the PEARL Consortium will apply the same level of protection to your information, to the extent permitted by local law.
- By using it to plan new studies or other types of research purposes related to the development of the intervention.

**What payments will be made for the project?**

You will not be paid for taking part in the project.

**Who should you contact to answer any questions on the project?**

You can ask ..... at ..... any questions at any time.

If you have questions about your rights as a subject in a research project, you should contact ..... at .....

**Consent and Assent Instructions**

**Consent:** Subjects able to provide consent must sign on the subject line below. Consent is provided by the Legally Authorized Representative for subjects unable to consent.

**Assent:** Is required for subjects able to express agreement.

**Consent Form**

**Subject's Signature** \_\_\_\_\_ **Date:** \_\_\_\_\_  
DD/MM/YY

**Printed name of Subject** \_\_\_\_\_

\* **Signature of Legally** \_\_\_\_\_ **Date:** \_\_\_\_\_  
**Acceptable Representative** DD/MM/YY

\* **Printed name of Legally**  
**Acceptable Representative** \_\_\_\_\_

**Signature of Person** \_\_\_\_\_ **Date:** \_\_\_\_\_  
**conducting Consent** DD/MM/YY

**Printed name of Person** \_\_\_\_\_  
**conduction Consent**