DATA PROTECTION AND CONFIDENTIALITY

All consortium partners aim to ensure that the legal provisions on the processing of medical data will be respected during the entire course of the project. For instance:

The European Directive 95/46/EC and proposed Regulation Directive 2002/58/EC for data protection in EU, that aims to protect individuals regarding the processing of personal data and the free movement of such data. It is important to note that a new European Directive is expected to enter into effect in 2018, adopting the General Data Protection Regulation (GDPR), and therefore any IoT-related technology deployed within vINCI will be in compliance with the GDPR; 2. The European Convention for the Protection of Individuals regarding Automatic Processing of Personal Data signed in Strasbourg on 28 January 1981; Regulation (EC) No 45/2001 on the protection of individuals regarding the processing of personal data by the Community institutions and bodies and on the free movement of such data; ABNT NBR IEC 60601-1-6 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

vINCI will be handling personal data collected from human patients using sensors (full medical-clinical trial); hence the legislation and regulation specifically set out for this type of trial activity will be directly applicable to this Project. The necessary measures will be taken to ensure data protection of the highest grade. No data will be disclosed to third parties under any circumstance unless express consent is obtained, as suggested by the DICOM standard PS 3-2001.

The application of the legal framework is twofold. The functioning of the envisaged technology will be legally compliant and privacy enhancing, from the design phase. The choices of the consortium will be inspired by privacy and data protection requirements from the early stages in the project, and the project solution will not only visually embrace privacy in its system design but also throughout the development. Legal compliance will also be enforced in the formal project development. On the road to the end-product privacy principles will shape the decisions of the consortium. vINCI aims to meet the requirements resulting from the proposed Data Protection Regulation which formally introduces the concept of privacy-by-design in the European Union. By a close collaboration between technical partners and their legal departments, and using proven security technology, the vINCI consortium will provide a privacy-by-

design solution for the vINCI platform in the its application scenarios.

Ethical Issues (with respect to research involving human subjects and medical devices): The Helsinki declaration of Ethical Principles for Medical Research Involving Human Subjects; EU regulation on Clinical Trials will be followed, in particular regarding the following issues: 1) obtaining informed consent and 2) ethics committee approval; The European Consultation on the Rights of Patients will be used to establish grounds in terms of patients' rights; EU directive 2007/47/EC Medical Devices. We will adhere to the principles for clinical investigations of medical devices as set out in the Standard BS EN ISO 14155-1; 2002, "Clinical Investigation of Medical Devices for Human Subjects-part 1: General Requirements", and BS EN ISO 14155-2:2002, "Clinical Investigation of Medical Devices for Human Subjects- part 2: Clinical Investigation Plans".

No research will be carried out without the approval of the ICI's Ethics Committee. Informed consent from older adults will be obtained before any information is used (including in the open call study group). They will be informed that they can withdraw that permission at any time during the project. The informed consent explains the nature of the diseases (where appropriate).

Before informed consent may be obtained, the older adult is given ample time and opportunity to inquire about details of the study and decide whether to participate. Participation is therefore fully voluntary. Refusal to participate will have no consequences. The subject may discontinue participation at any time. Prior to adult participation, the written informed consent form should be signed and personally dated by the individual and by the person who conducted the informed consent discussion (the investigator) who could be contacted at any time for further questions and/or clarifications.

General Considerations The consortium is fully aware of the cultural and legal diversity of its envisaged end-users and its members. In addition, the consortium is aware of the many ethical pitfalls rising during its research. The consortium will respect the ethical standards laid down in the EU Charter of Fundamental Rights of the European Union and the opinions of the European Group on Ethics in Science. As such, the consortium will ensure to uphold scientific standards, to comply with applicable legislation and to avoid social and personal harm.

The science must be of high quality and clinical support well-structured and efficient. Our work will be carried out in accordance with the relevant guidelines and legislations. However, both the science and the clinical care support must be founded on high ethical standards and consider the good empirical evidence of the psychosocial aspects of clinical interventions. For these reasons, the vINCI government will include an ethical manager Dr. Costas Constantinou during the lifetime of the project.