Deliverable 6.2

Informed consent procedures
Abstract

Deliverable 6.2 specifies in detail both general and specific considerations concerning the informed consent procedures to be followed for the participation of humans in the project pilots. The principles for informed consent include adequate information, voluntariness, and competence. Thus, explanations shall be given to prospective participants that participation is entirely voluntary, that no special benefits arise, that it can terminated for whatever reason with no consequence, etc. Informed consent should be asked by properly trained InLife personnel and should be given based on free will and not due to pressure. have ample time to consider their participation and to ask for clarifications. Finally, the deliverable also describes the handling rules for the consent forms.
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1. Introduction

InLife will provide an innovative gamification framework targeting both typical and special educational and social inclusion activities based on Serious Games. InLife’s core concept leverages on the potential of the Internet-of-Things (IoT) paradigm, to directly link actions, decisions and events happening in real-life with in-game educational progress and modern gaming technologies.

Informed consent [1] is “the decision, which must be written, dated and signed” to take part in a research study, “taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation”.

Valid consent is defined on the basis of three fundamental principles: adequate information, voluntariness, and competence [2]. Where competence is not apparent (i.e. cognitive fragilities, young children), direct consent from data subject cannot be valid, because the data subject belongs to vulnerable persons. InLife has both situations: normal consent and consent from vulnerable persons. Guidelines about ethics in research with children [3] will be applied with a specific attention in AKSION for the specific communication style in autism.

Deliverable 6.2 provides details on the informed consent procedures to be implemented for the participation of humans in the pilot activities of the InLife project. For InLife, informed consent is more than just a signature on a form; it is a process of information exchange. This is detailed in the next section.

2. Informed Consent Procedures

2.1. General considerations

Prospective participants in the pilots will be provided with written, and if desirable also verbal, information about:

- the purpose of the research project and pilots;
- the main gameplay of the Serious Game;
- the duration of the activities;
- the voluntary nature of participation;
- the right to drop out without explanation at any moment;
- possible risks, discomfort or disadvantages;
- benefits from participation;
- data protection, confidentiality and privacy policies;
- nature of data publicly available;
- where to get more information;
- what happens to data and results after the end of the project.

This information will be included in the information sheets and informed consent forms prepared by the project, the templates of which are documented in Deliverable D6.3. These shall:

- use simple language
- contain concise information, also allowing to easily find more detailed information
- be cross-checked by potential end-users prior to finalization
- be prepared in consideration of ethnical and other differences
Following the guidelines above, although it is often hard to establish whether someone is truly well informed, the probability of misinterpretation or of lack of key information will be minimized.

When involving minors, the information provided to them and their legally authorized representatives (parents or guardians) will use language that is comprehensible and suitable for each group. The information shall be clear and adequate in order for the minor and the legally authorized representative to make their decision about participation. Where children or adolescents have also a cognitive or intellectual deficit, explanation using symbols or facilitated communication will be developed to provide as much information as possible (see Deliverable 6.4 for the case of assent).

Moreover, in any case, InLife will ensure that consent is freely provided, without exercising any pressure to prospective participants. Specific measures and considerations are detailed in Section 2.2 that follows.

2.2. Specific considerations

As with the case of recruitment, InLife will ensure that, in the consent procedures, prospective participants are informed by someone who is:

- thoroughly knowledgeable about the pilot study
- able to answer questions
- trained in the voluntary nature of research participation
- competent in ethical matters

Moreover, prospective participants shall be informed that:

- they have ample time to consider their participation and to ask for clarifications
- participation is completely voluntary
- they are free to withdraw from participation at any point
- their personal data will remain confidential and anonymous, and that collected data will be analysed for the entire group of participants, rather than individually
- they can request for their data to be destroyed, without justification and without bearing any consequences
- no risk or discomfort is foreseen by participating in the pilot, and that, in any case, participation can be paused or completely stopped at any time
- there is no financial or other gain from participation (besides perhaps learning more about environmental protection or social inclusion)

2.3. Handling rules of the consent forms

When involved in the handling of consent forms, InLife project members must apply the following rules:

- use the consent form templates that are documented in Deliverable 6.3 and on the project website, when drafting the pilot consent form;
- release a new/updated consent form, when changing study procedures and/or identifying new risks to participants;
- obtaining the Project Coordination Committee (PCC) approval before using a revised consent form;
- keep all original signed consent forms with research study records in a secure place and manner;
- verify that each participant is given a signed and dated copy of the consent form at the time of initial consent;
- verify that participants answer all questions on the consent form;
- verify that the person obtaining consent (POC) has signed, when applicable;
- verify that signers complete all applicable lines on consent form;
- explain, if needed, that Legally Authorized Representative for a child is the parent or guardian;
- verify participant enters date of signing at the time of consent.
On the other hand, InLife project members must not:

- use expired consent forms;
- alter approved consent forms;
- leave consent form questions incomplete;
- confuse initials with checkmarks;
- share consent forms with non-authorized persons;
- include consent instructions that are not easy to follow, as they might be considered as noncompliance.

3. References

