



Improving the guidelines for informed consent, including vulnerable populations, under a gender perspective



Informed Consent is a key aspect in the decision process to participate in a study. During the Informed Consent process participants learn the most relevant aspects of the study and accept to participate in it or not. At present, most of Informed Consent documents are complex, difficult to understand and drafted without the participant's perspective. There is a need to improve the informed consent process through the implementation of innovative proposals tailored to participants' needs and exploring ICT tools, such as videos, comics and apps.

i-CONSENT understands informed consent as a bidirectional communication process that begins with the first contact with the potential participant and continues throughout the entire study until its end. The project is developing a series of strategies for the creation of an updated and inclusive informed consent process. This new perspective will empower the participant to voluntarily decide whether to participate in the study and facilitate and improve his/her autonomy in decision making and foster a personalised approach to researcher-participant communication.

The project consortium includes 7 partners from 4 countries including academia, research centres, industry, patient organizations and small and medium-sized enterprises. The nature of the consortium allows including the perspectives of all interested parties in the informed consent process in the project's perspective.

Stakeholders

i-CONSENT involves its stakeholders in the project's outcomes to ensure their participation and point of view in the process.

- ✓ Clinical Investigators
- ✓ Pharmaceutical Industry
- ✓ Ethical Advisory Boards
- ✓ Policy Makers
- ✓ Patient Organisations

Outcomes



Workshops

Meetings and interaction with stakeholders to assess their needs.



Guidelines

Develop, validate and publish guidelines to improve the ICP.



Publications

Production of scientific publications and contents for general public.



Innovative Resources

Develop resources to facilitate the understanding of IC using digital tools.

Policy Makers

Informed consent is a patient's right and a fundamental principle of medical ethics. **i-CONSENT** aims to complement the existing regulations on informed consent and increase the European standards of clinical trials.

The project proposes a departure from traditional notions of informed consent as a waiver of legal responsibility for researchers and sponsors. It promotes informed consent as a participant-tailored process adapted to the personal characteristics of the research subject, normally disregarded in this context, such as age, gender, and cultural background and vulnerability factors.



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