i-consent.

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.

Patient Organisations

Patient involvement in clinical trials is extremely important for the development of vaccines and new treatments but before anyone can decide to participate, he/she has to be fully informed and understand the implications of its participation. By improving the informed consent process, participants will understand clinical trials better and this will facilitate their involvement in clinical research based on a true understanding of what it entails.

The current system doesn't empower vulnerable populations to take part, many of whom will not be aware of such opportunities. Women, children and minorities should therefore be given a more equal chance to participate. In long term, this ultimately will contribute to the health of populations by enabling the development of new medicines.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 741856. More information on the Cordis portal.