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.

Clinical Investigators

A physician's primary obligation is to act as a fiduciary towards its patients, whereas a researcher's duty is to benefit society at large by producing generalizable knowledge. In health related studies, physicians serve both roles simultaneously and this might be cause for concern due to potential conflicts of interest.

i-CONSENT will develop strategies to guide investigators in the elaboration of an informed consent process where the potential participant is fully autonomous and literate in health. The project will help the professionals identify appropriate means to request informed consent taking into account language and cultural group delimitation, for example.

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