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.

Pharmaceutical Industry

It will increase the European standards of clinical research ethics, specially the quality of informed consent and the comprehension by patients. Nowadays biomedical research is growing exponentially, and the ethics of informed consent tend to be defensive in terms of legal protection. Therefore, there is a huge need to concile these legal requirements and bioethics.

i-CONSENT will contribute in stimulating innovation for the individual benefit and public health. It will also help to build trust on the informed consent form and the information provided in clinical trials and in vaccines that will in the end improve the acceptance of vaccination within society.

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