Outcomes

Workshops

Interaction with stakeholders to assess their needs.

Publications

Production of scientific publications and contents for general public.

Guidelines

Develop, validate and publish comprehensive guidelines to improve the Informed Consent process.

Innovative Resources

Develop new resources to facilitate the understanding of Informed Consent using digital and non-digital tools.

Partners

The **i-CONSENT** 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 projects approach.

MRF Bristol, GSK Madrid, FISABIO Valencia, AND-CG Brussels, Bambino Gesù Rome, LUMSA, Rome, UNESCO Rome

Stakeholders

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

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

Contact

i-consentproject.eu

@ICONSENTEU

@iCONSENTProject

i-CONSENT Project

i-CONSENT

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.

i-consent.

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

i-CONSENT is a 3-year project funded by the European Union's H2020 Research and Innovation programme. Launched in 2017, the project aims to create a series of guidelines to improve the informed Consent process, 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 Informed Consent documents are complex, difficult to understand and are 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 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 "i" in i-CONSENT

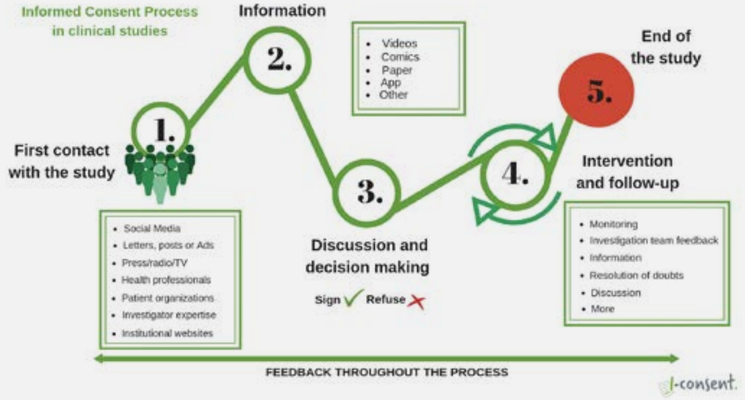
The meaning behind the letter "i" in **i-CONSENT** has various meanings.

· It refers to oneself and one's ability to give consent voluntarily and independently. It stands for the participant's autonomy, which is essential for the project.

· It connects, as well, with the fact that the process becomes personalised and participant tailored.

· **i-CONSENT** acronym also shows the i of innovation, and is also related to latest technologic products, which are synonym of quality, scientific advance and usefulness for society.

i-CONSENT proposal



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.

Once the potential participant has shown interest in the study, the investigation team will provide further information through different channels (videos, comic, app, website...). After processing the content, the potential participant will meet the investigator to solve any doubts about the study and his/her participation in order to ensure that he/she has enough knowledge and information to make an autonomous decision.

From the signature to the end of the study, the investigation team should be accessible and make a follow-up of the consent by monitoring its progress, resolving doubts, informing of any changes, etc. When the study finishes, all the information about the intervention must be noted in his/her medical records. It is advisable to give information about the results of the study to the participants.

During the whole study, feedback will be collected and analysed from patients and research team to assess the process, provide improvements and generate a new starting point for future research, turning informed consent into a dynamic process continually evolving.

Informed consent process principles

- Autonomy
- Health literacy
- Inclusion
- Innovation
- Personalisation
- Comprehension
- Ethics
- Flexibility
- Patient-oriented

Timeline

Project launch
i-CONSENT starts.

In depth understanding of the context
and workshop with patients to assess needs.

Report on age and gender
related issues regarding Informed Consent.

Digital technologies
systematic review of the use of digital technologies for Informed Consent.

Development
of innovative tools strategies for patient involvement in clinical trials.

Evaluation
of the draft guidelines and workshops with stakeholders.

Validation
of the guidelines.

Publication
and dissemination of i-CONSENT guidelines for informed consent.