

# GUIDELINES FOR TAILORING THE INFORMED CONSENT PROCESS IN CLINICAL STUDIES



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



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[a] <https://i-consentproject.eu/workshop-a-step-closer-to-improving-informed-consent/>

[b] <https://i-consentproject.eu/project-recommendations-undergo-a-final-round-of-revision-with-experts/>



# TABLE OF CONTENTS

---

## 06 — GENERAL INFORMATION

- 06 — Introduction
- 07 — What do i-CONSENT guidelines add?
- 07 — Scope and purpose
- 07 — How to use these guidelines

## 10 — 1. CONSENT AS A PROCESS

- 10 — 1.1 The informed consent as a process
- 15 — 1.2 Designing consent WITH study participants
  - 16 — ◦ UNDERSTAND
  - 17 — ◦ CO-CREATE
  - 17 — ◦ OUTCOME
- 18 — 1.3 Tailoring the consent process to the target population
  - 18 — ◦1.3.1 The gender perspective during the consent process for clinical studies
  - 21 — ◦1.3.2 Adapting the informed consent process to fertility, pregnancy and breastfeeding
  - 22 — ◦1.3.3 The informed consent process in clinical studies involving minors
  - 23 — ◦1.3.4 The informed consent process in clinical research involving people from different cultural and religious backgrounds
  - 24 — ◦1.3.5 The informed consent process in clinical research involving low-income population

## 25 — 2. CHECKLIST: A STEP-BY-STEP GUIDE FOR CONDUCTING THE CONSENT PROCESS

- 25 — 2.1 Step 1: First contact with the potential participant
- 26 — 2.2 Step 2: Provision of information
- 26 — 2.3 Step 3: Discussion and decision making
- 27 — 2.4 Step 4: Intervention and follow up
- 28 — 2.5 Step 5: Completion of the study



## **29** ——— **3. FACT SHEETS AND TOOLS**

30 ——— FACT SHEET I. COMMUNICATING AT THE APPROPRIATE HEALTH LITERACY LEVEL FOR PARTICIPANTS

31 ——— FACT SHEET II. PRESENTING STUDY INFORMATION

32 ——— FACT SHEET III. ADVERTISING THE STUDY

33 ——— FACT SHEET IV. INFORMATION TO GIVE TO POTENTIAL PARTICIPANTS DURING THE INFORMATION PHASE

35 ——— FACT SHEET V. INVESTIGATOR-PARTICIPANT RELATIONSHIP DURING THE CONSENT PROCESS

36 ——— FACT SHEET VI. HOW TO ASSESS PARTICIPANT'S COMPREHENSION

37 ——— FACT SHEET VII. THE USE OF DECISION AID TOOLS

38 ——— FACT SHEET VIII. WHEN IS RE-CONSENT NEEDED?

39 ——— FACT SHEET IX. THE INFORMED CONSENT PROCESS IN CLINICAL RESEARCH INVOLVING HEALTHY PARTICIPANTS

40 ——— FACT SHEET X. INFORMED CONSENT AND THE USE AND STORAGE OF BIOLOGICAL SAMPLES AND DATA

42 ——— FACT SHEET XI. THE USE OF PLACEBO IN CLINICAL TRIALS

43 ——— FACT SHEET XII.

44 ——— TOOL I. HOW TO BECOME A GOOD COMMUNICATOR

46 ——— TOOL II. HOW TO GAIN PARTICIPANTS' FEEDBACK

47 ——— TOOL III. GUIDANCE ON CREATING "THANK YOU" LETTERS

48 ——— TOOL IV. CREATING A SUMMARY OF THE RESULTS FOR LAYPERSONS

49 ——— TOOL V. METHODOLOGIES AND TOOLS TO INCORPORATE THE PARTICIPANT'S PERSPECTIVE

50 ——— TOOL VI. FAKE NEWS AND THE RELIABILITY OF SOURCES

## **51** ——— **4. List of i-CONSENT's scientific deliverables & publications**

51 ——— Deliverables

52 ——— Papers

53 ——— Chapters in books & Books of Abstracts.



# GENERAL INFORMATION

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These guidelines have been designed to provide information and evidence to assist with the development, or review of the consent process for use in clinical studies with human participants. These guidelines do not deal with issues related to informed consent in clinical practice.

The guidelines were developed by the i-CONSENT consortium. i-CONSENT (H2020, Grant Agreement number 741856) is a European Union H2020 funded program that aims to improve the information that individuals receive when deciding whether or not to take part in clinical studies. The guidelines were developed based on a review of the scientific and ethical literature; policy documents and legal instruments, enlarging the perspective also on international normative documents; comparative analysis of the legislations of selected countries; declarations of international organisms/institutions; reports and guidance documents; stakeholder

consultation. The deliverables and articles produced during the project, which have been used for the elaboration of these guidelines, are available in [CORDIS](#) on [the project's website](#) and a list is provided at the end of this document (section 4).

The multi-stakeholder i-CONSENT Consortium includes representatives from academia: Ateneo Pontificio Regina Apostolorum (UNESCOBIOCHAIR) and Libera Università Maria SS. Assunta di Roma (LUMSA); an investigation and public health center: Fundación para el Fomento de la Investigación Sanitaria y Biomédica de la Comunitat Valenciana (FISABIO); the pharmaceutical industry: Glaxosmithkline S.A. (GSK); a small and medium enterprise: AND Consulting Group; a patient association: Meningitis Research Foundation (MRF); and a tertiary care academic hospital: Ospedale Pediatrico Bambino Gesù (OPBG).

## Introduction

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The consent process is an essential procedure that ensures the fundamental rights and freedoms of the participant, allowing them to voluntarily decide whether or not to take part in a study, with the option to withdraw at any time, without consequences.

The format of the consent process for clinical studies has remained relatively unchanged for decades. In its current format, typically a long and complex text document, there are still areas for improvement in order to promote clear communication between participants and investigators. Effective communication is essential to uphold the

fundamental ethical principle of respect for the participant's autonomy.

Several guidelines, legal documents and legal instruments about the consent process have already been implemented. These cover what informed consent is and should be; why it is important in clinical studies; the main procedures to follow during the informed consent process and the minimum content to be covered. The i-CONSENT guidelines have been written in accordance with these documents and they should be read in conjunction with them.



## What do i-CONSENT guidelines add?

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These guidelines provide ethical recommendations and practical tools that aim to make the consent process more comprehensive, tailored and inclusive.

They include a new and broader concept of the informed consent process, more focused on the participants, and incorporating their point of view in every step, starting from the design.

These guidelines represent a change in mentality that gives greater prominence to informed consent, turning it

into a process that provides added value and prevents it from becoming a bureaucratic act focused solely on the participant's signature on the informed consent form.

These guidelines provide a step-by-step description of the informed consent process, and a checklist to implement comprehensive and inclusive informed consent, as well as 12 fact sheets and 6 tools with recommendations and examples to put ethical considerations into practice.

## Scope and purpose

### Who are these guidelines for?

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These guidelines are relevant for all stakeholders involved in the design and implementation of the consent process. They can support the work of investigators and sponsors, but are also relevant for ethics committees involved in the evaluation and approval of consent materials.

### What is the purpose of the guidelines?

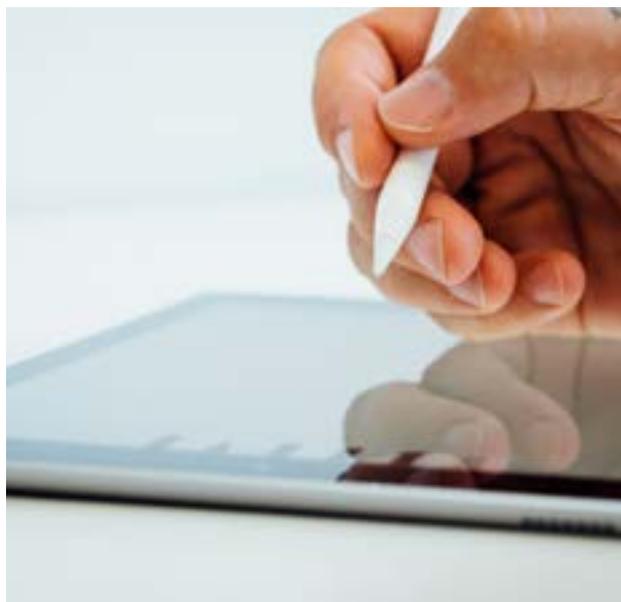
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Their purpose is to enhance the consent process in clinical studies, to make it more understandable, and where possible, tailored to the participants' needs, preferences and circumstances to ensure that individuals can make autonomous decisions about their participation in clinical research.

## How to use these guidelines

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The guidelines are divided into four parts. The first part describes the i-CONSENT perspective on the consent process and highlights the need to improve the traditional approach to obtaining informed consent. This includes specific recommendations in order to tailor the informed consent process to the target population. Parts two and three provide practical TOOLS and recommendations to implement a tailored and more understandable consent process. Part four lists the scientific deliverables and publications produced as part of the i-CONSENT project.



The contents of the four parts are:

### **1. CONSENT AS A PROCESS (Pp. 10-24)**

This part of the guidelines explains four key aspects of designing a consent process that meets participants' needs: (a) clear and concise information; (b) interdisciplinary mixed-methods (quantitative and qualitative research methodologies) to gain informed consent design insights; (c) co-design as a central concept; (d) the importance of providing inclusive information and of personalizing the consent process to the needs of individuals. In addition to providing recommendations for each of these aspects, this part aims to change the way consent is conceptualized.

This part also describes the consent process step-by-step. It highlights the importance of understanding the process as a whole, rather than only focusing on the participants' signature on the form. It also provides specific recommendations for the informed consent (a) to apply a gender perspective; (b) when the studies involve minors; fertile, pregnant or breast-feeding women; participants coming from different cultural and religious backgrounds; or/and low-income populations.

### **2. CHECKLIST: STEP BY STEP GUIDE FOR INVESTIGATORS DESIGNING A CONSENT PROCESS (Pp. 25-28)**

This checklist is a practical tool that aims to help investigators and organizations in fulfilling the requirements of regulatory, funding and other bodies. It also helps with identifying and reviewing all the key aspects that should be covered in the consent process.

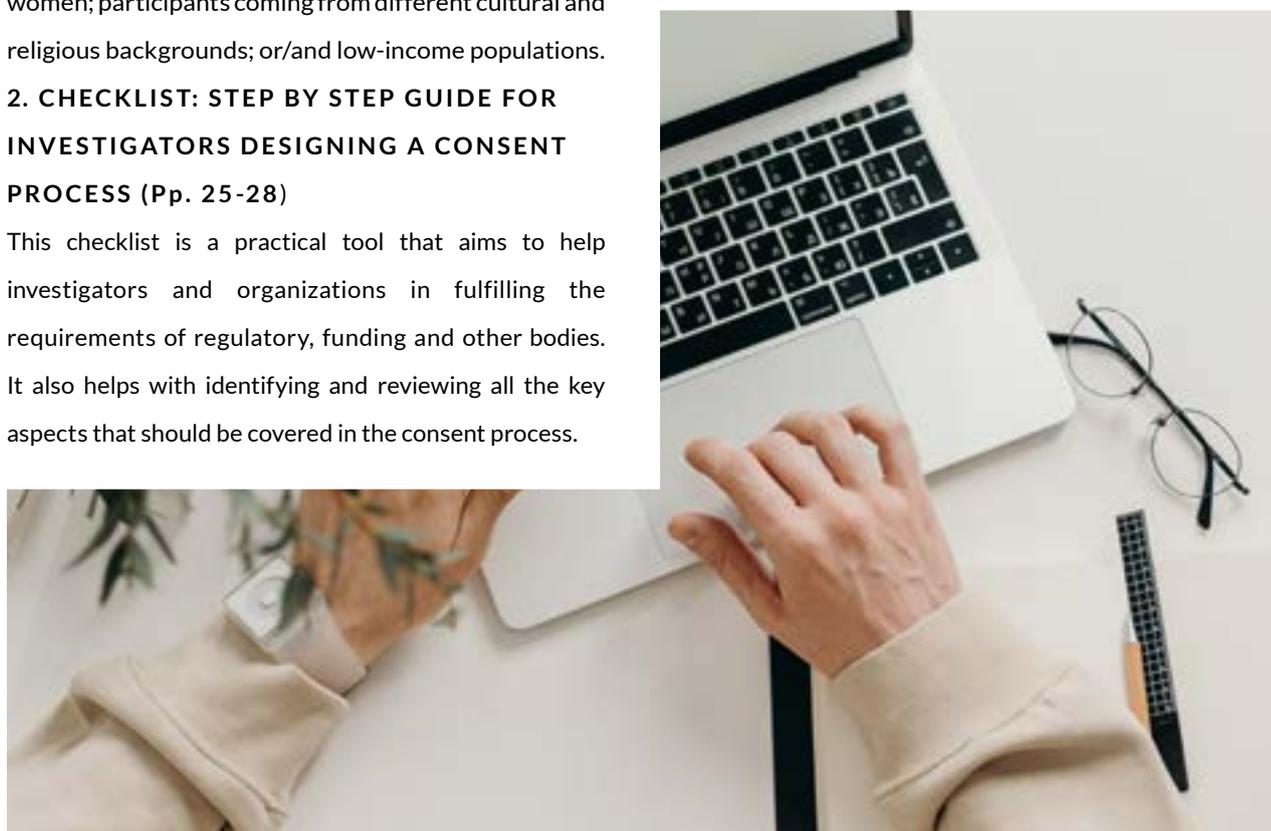
### **3. FACT SHEETS AND TOOLS (Pp. 29-50)**

The third part of the guidelines provides a series of easy-to-read fact sheets and tools which complement the core document, highlight the importance of several aspects of the informed consent process, and provide recommendations on how to implement best practice. The fact sheets and tools also emphasize the different factors involved in the informed consent process. The fact sheets deal with aspects directly related to the informed consent process, while the tools include aspects that do not strictly belong to the informed consent process but are useful for its improved development.

### **4. LIST OF i-CONSENT'S SCIENTIFIC DELIVERABLES & PUBLICATIONS (Pp. 51-54)**

This section contains a list of public deliverables and publications prepared in the framework of the i-CONSENT project, with links to each publication.

These publications have been used to produce the guidelines.



## The core elements of the i-CONSENT acronym

The acronym i-CONSENT contains the core elements of a comprehensive consent process (Table 1):

**Table 1.** The i-CONSENT acronym and core elements of the consent process

<b>I</b>	<b>Information</b>	Complete and clear information is essential for the potential participant to be able to make an autonomous decision.
<b>C</b>	<b>Co-creation</b>	The inclusion of potential participants during the design and review of study information materials is key to ensuring that they are understandable and address the target population's needs and preferences.
<b>O</b>	<b>Ongoing process</b>	Consent should be a two-way continuous communication process that begins at first contact with the potential participant, and continues until the end of the study.
<b>N</b>	<b>New technologies, methods, and (innovative) processes</b>	The consent process should include technical and methodological innovations to facilitate the participant's experience. Their appropriateness from a social, methodological, legal and ethical point of view should always be taken into consideration.
<b>S</b>	<b>Self-determination (autonomy)</b>	Autonomy is a fundamental principle. The purpose of the informed consent is to ensure that the potential participant is able to make an autonomous and free decision.
<b>E</b>	<b>Empowerment</b>	Participants should be empowered to make their own decisions.
<b>N</b>	<b>Nonstandard (inclusive and tailored)</b>	Research should be inclusive to meet the needs of the potential participants and respect the basic bioethics principle of justice. There is no single best way to conduct the consent process. The 'ideal' solution will differ in every setting and therefore needs careful design. Where possible, the consent process should be tailored to the needs of the target population.
<b>T</b>	<b>Trusted</b>	Good practices are essential to build trust between investigators and potential participants, and to increase society's trust in research.

**Source:** Own elaboration



# 3. FACT SHEETS AND TOOLS

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The fact sheets deal with aspects directly related to the informed consent process, while the tools include aspects that do not strictly belong to the informed consent process but are useful for its better development.

## 3.1 FACT SHEETS

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- FACT SHEET I. Communicating at the appropriate health literacy level for participants
- FACT SHEET II. Presenting study information
- FACT SHEET III. Advertising the study
- FACT SHEET IV. Information to give to potential participants during the information phase
- FACT SHEET V. Investigator-participant relationship during the consent process
- FACT SHEET VI. How to assess participant's comprehension
- FACT SHEET VII. The use of decision aid tools
- FACT SHEET VIII. When is re-consent needed?
- FACT SHEET IX. The informed consent process in clinical research involving healthy participants
- FACT SHEET X. Informed consent and the use and storage of biological samples and data
- FACT SHEET XI. Ethical considerations of using placebo control in clinical trials

## 3.2 TOOLS

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- TOOL I. How to become a good communicator
- TOOL II. How to gain participants' feedback
- TOOL III. Guidance on creating "thank you" letters
- TOOL IV. Creating a summary of the results for laypersons
- TOOL V. Methodologies and tools to incorporate the participants' perspective
- TOOL VI. Fake news and the reliability of sources



## FACT SHEET I.

### COMMUNICATING AT THE APPROPRIATE HEALTH LITERACY LEVEL FOR PARTICIPANTS

#### Introduction

For many people in society, complex health concepts can be difficult to understand. Health literacy refers to the degree to which individuals have the capacity to comprehend, access and apply health information in order to make an appropriate health decision. Study information should be adapted to the health literacy level of the potential participant to enable them to make an appropriate decision about whether or not to take part. Participants'

comprehension of the information provided through the informed consent process is one indicator of its quality. To enable comprehension, appropriate, accurate and relevant information should be provided in a language and format that is understood by participants. New technologies can be useful for communicating consent information. Investigators should ensure the accuracy of the information provided and the suitability of its communication.

#### Recommendations

Some practical tips for increasing health literacy include:



Use a glossary of terms to explain the more complex concepts. The use of dictionaries and links to "further information" is also recommended.



Ask open questions to assess understanding.



Provide information at a level of at least three years of education less than the average level of the target population. See FACT SHEET II.v



Employ multimedia tools for a specific objective, always taking into consideration the characteristics of your target population.



Use storytelling formats when appropriate, e.g with children.



Train your participants to improve their digital and health literacy. Critical thinking skills can empower citizens to freely decide which sources of information they prefer and what they share on social media.

## TOOL I. HOW TO BECOME A GOOD COMMUNICATOR

Effective communication is a skill all healthcare professionals need. It matters not only “what” is said but also “how” and by “whom”. In a single day, healthcare professionals may speak to people of varying educational, cultural and social backgrounds and they must do so in an

effective, caring and professional manner to convey the message and contribute to a participant’s autonomy and understanding of the process.

Here are some key elements to consider:

<p><b>Consider your environment</b></p>	<p>Time and place</p> <ul style="list-style-type: none"> <li>• Approaching a participant in a confusing area with lots of people can hinder communication, and therefore participant’s comprehension of the delivered information</li> <li>• Being in a chaotic place may require you to raise your voice which may have a negative impact: intimidation/lack of effective communication and consequently altering free consent</li> <li>• If you are going to be asking personal questions, finding a more private environment is essential to safeguard the privacy of the participant.</li> </ul>
<p><b>Building rapport</b></p>	<p>Listen and ask questions.</p> <ul style="list-style-type: none"> <li>• Listening without interrupting is vital, as it conveys interest and respect for another’s point of view. Maintain eye contact to keep attention.</li> <li>• Use questions beginning with ‘why’, ‘what’, ‘when’, ‘where’ and ‘how’. Open-ended questions provide the most effective way of understanding another person.</li> <li>• Use the valuable time you have to open the discussion slowly.</li> </ul>
<p><b>Body language &amp; non-verbal communication</b></p>	<p>Use positive body language</p> <ul style="list-style-type: none"> <li>• Eye contact is important.</li> <li>• Keep your hands and arms in front of your body, without crossing them.</li> <li>• Relax your facial expressions to prevent from grimacing, twisting or pursing your lips, lifting your eyebrows, or scowling.</li> <li>• Tone can help de-escalate a distressed and angry participant. This is referred to as the ‘emotional contagion effect’, where your emotional state can affect how another person feels.</li> </ul>



## TOOL I. HOW TO BECOME A GOOD COMMUNICATOR

### Inclusive communication

- Be patient: It is essential to always respect the participants and dedicate the right amount of time to allow them to express themselves, so to get the whole story.
- Be mindful of your language: Using complicated medical terminology, or 'jargon', is not an effective way to communicate with any participant. Try to use language that is simple, clear and non-threatening, while remaining accurate. Base your language on the questions asked to you and the cognitive ability of the patient you are speaking with.
- If an adult is not able to consent and the consent is given by a family member, their assent must always be respected.
- Take into account participants' age and their level of understanding, and tailor your explanation to meet their needs.
- Regarding older adults: Including the family is often a big part of communicating with older participants. Always try to keep them involved in the conversation.
- Regarding children: Although the parents/guardians may ask most of the questions, it is important to include the child and obtain their assent when talking about procedures and their health.

Some recommendations about what to do and not to do during the consent process, from a communication perspective:

DO:	DO NOT:
<ul style="list-style-type: none"> <li>• Establish a positive relationship with the participant</li> <li>• Make sure the participant feels comfortable to ask questions and clarify their understanding</li> <li>• Provide trustworthy and clear information</li> <li>• Use a plain and understandable language</li> <li>• Use short sentences</li> <li>• Receive appropriate training to ensure that verbal communication is delivered in a balanced and complete manner</li> <li>• When children are involved, focus in both, the child and the parents.</li> </ul>	<ul style="list-style-type: none"> <li>• Overwhelm potential participants with extensive and complex study information</li> <li>• Make gender-based assumptions</li> <li>• Encourage participation, using undue influence (offering an excessive, unwarranted, inappropriate or improper reward or another overture for participating) or unjustified pressure (when people in a position of authority or with influence urge the subject to participate).</li> <li>• Use coercive language (presenting intentionally threat of harm to obtain compliance)</li> <li>• Employ vague expressions</li> <li>• <a href="#">Use exculpatory language</a></li> <li>• Use too technical or complex terms</li> </ul>

#### Note:

Remember to be careful to use neutral language when communicating with the participant.

