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# Informed Consent: 6 Approaches To Increase Participant Comprehension

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DESCRIPTION

Ensuring participants have appropriate knowledge of a study is a crucial goal of the informed consent process. This paper describes six research-based approaches for improving informed consent and supporting participants' understanding of the studies they are asked to join.

TOPICS

- BEST PRACTICES
- EMPHASIZED INFORMED CONSENT DISCUSSION
- TEACH BACK
- TOOLS AND TECHNIQUES
- TRUST AND SUPPORT
- AWARENESS

# 6 Approaches to Increase Participant Comprehension

Studies of the informed consent process have documented the challenge of assuring participant comprehension—and offered possible solutions. Here are six research-based approaches that can improve informed consent and support participants' understanding of the studies they are asked to join.

## 1. Apply health literacy best practices to consent forms

In some studies, simplified, reformatted consent forms have enhanced participant comprehension, as compared with more complex and less visually accessible documents. Consent forms that seem to support comprehension include less text, less complexity, and more design-conscious elements than standard consent forms. Studies have found at least moderate success with specific approaches such as:

- "Less unnecessary information, simpler vocabulary, bullets, larger font, other formatting"
- "Less redundant material, text reorganized, simpler writing, graphics, focus groups"
- "Simplified text in booklet format with color. 7th grade reading level"
- "Simplified paper document developed by a working group of clinical research nurse, IRB member, and healthy volunteer"
- "Simplified paper document developed by a working group and by systematic readability improvement"
- "Simplified paper document with revised layout, text styling, and language"[1, 2, 3]

But how to best apply health literacy principles to reform the wording, content, and appearance of consent documents presents a kind of riddle for researchers. Not all simplified and reformatted consent forms—even ones that followed prescriptions similar to what is listed above—result in participant comprehension, while some seem to only result in modest improvements.[4, 5, 6] More investigation is needed on how to best streamline, redesign, and use consent forms so that they consistently improve the informed consent discussion and participant comprehension (across all literacy levels and cultures).

In addition, not every organization has a team of consent form editors or designers at its disposal to transform consent documents. And stakeholders in the research process have raised questions (or even doubts) regarding how much information can be removed from the consent form, or presented in a separate document, without compromising compliance with applicable regulations, laws, and guidance.[7] Quorum Review's experience with simplifying consent forms, however, suggests that regulatory compliance and clarity in consent can go hand-in-hand.

## 2. Emphasize the informed consent discussion

Research indicates that discussions between prospective participants and research staff (or independent educators) are potentially more effective than any other intervention in improving participant comprehension during the informed consent process. A 2013 overview of research conducted on informed consent interventions observed that "even the most exquisitely-designed form, be it on paper or computer screen, should not be expected to suffice. Arguably there is still no substitute for a good conversation, which facilitates opportunities for questions and interaction."[8] Examples of effective discussions described in literature include:

- A 30-minute phone call with a nurse
- Repetition of information about the study
- More meetings with research staff
- Discussions structured with a questionnaire intended to promote comprehension of the research objectives, design, procedures, and the consent process itself [9, 10]

That said, researchers have found that not all consent discussions improve comprehension. As is the case with consent forms, more investigation is needed to identify what approaches during the informed consent discussion consistently support participant understanding.

## 3. Use teach-back

If participant comprehension is elusive, it is important to know whether the informed consent process has enabled it.[11]

Teach-back—asking prospective participants to discuss the study in their own words—may allow for gauging comprehension and identifying gaps in participants' understanding.

Researchers point to the effectiveness of teach-back in evaluating patient understanding of standard-of-care procedures. Though additional tests could reveal more about the viability of this technique in research contexts, existing

studies are promising and suggest that teach-back is a useful approach for communicating with a hard-to-reach, vulnerable population: participants with low literacy.[12, 13, 14]

Before consent, a question such as, "Can you tell me about the purpose of this

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study, in your own words?" could reveal what a prospective participant knows and does not know—perhaps more effectively than a general inquiry such as, "Do you have any questions about the study purpose?" And beyond the initial informed consent process, experts have tentatively suggested (though not evaluated) teach-back as a way to support an ongoing consent process and participant comprehension of procedures conducted during the study.[15]

## 4. Develop awareness of general literacy levels and health literacy levels, and shape communication on the assumption that participants may have low literacy

Bear in mind the possibility of low literacy in writing for and speaking with participants. Consider:

- About 30 million Americans have below-basic literacy.[16]
- Individual studies and overviews of research on informed consent interventions suggest that low literacy can hamper understanding of a study even when efforts are made to improve the consent document or process.[17]
- Specific populations can have unique needs: For example, researchers have recommended evaluating participants' health literacy before consent for glaucoma research with the Rapid Assessment of Adult Literacy in Medicine (REALM), in part because that condition impacts an age group that studies have associated with low health literacy.[18]
- Regardless of the study condition or population, laypersons are potentially unacquainted with concepts such as placebo, randomization, voluntariness, and the differences between the nature of research and the nature of standard, therapy-oriented health care. Communication that emphasizes these concepts in an accessible way can pave the way to truly informed consent.

## 5. Leverage tools and techniques that studies show can improve patient comprehension for standard-of-care procedures, such as decision aids and informational supplements

Researchers have not extensively investigated the effect of these approaches on participant comprehension, and there is a need to do so before decision aids and informational supplements can be confidently used to improve participant understanding during the research consent process.

Yet studies on the use of these methods in non-research settings show that they can meaningfully enhance patients' knowledge of standard-of-care procedures,[19, 20] and experts suggest that they may offer similar value in research contexts.[21] Note also that at least one study has verified the ability of decision aids to improve prospective participants' knowledge during informed consent for clinical research.[22]

Consider: A decision aid is a document or other tool that states the decision being made and that discusses alternatives, risks, and benefits. Could it improve prospective participants' understanding of the study before they determined whether or not they wanted to be a part of it? Could supplementary material that expands on unfamiliar research concepts—such as placebo, randomization, and the investigational nature of studies—improve understanding?

Research is moving toward more interactive consent form formats that support individual readers' information preferences and needs—such as tiered consent forms and eConsent. Supplemental information and decision aids are compatible with those formats, and there may be increasing opportunity to integrate and test the effectiveness of these tools in the informed consent process for research.

## 6. Trust and support research staff [23]

In every aspect of supporting informed consent and comprehension—during the first informed discussion and throughout the study—the role of research staff is fundamental. So ensure that research team members have the time, support, resources, and training they need to understand a given protocol as well as prepare for and conduct informed consent discussions. And involve them in answering the question of how to improve informed consent. Solicit feedback from experienced research staff—as subject matter experts—to effectively streamline consent forms and advise on how to enhance the informed consent process.

Research (and common sense) point to one basic conclusion: an improved informed consent process can never be a reality without involvement of the research staff who ultimately facilitate it.

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[23] The conclusions in this section are influenced by the following report: Center for Information and Study on Clinical Research Participation (CISCRP). (2014). Research Participant Concerns – Factors That Most Inform and Educate Clinical Research Participants:Findings from CISCRP Focus Groups with study volunteers. Retrieved from https://www.ciscrp.org/wp-content/uploads/2014/03/ciscrp_ research_participant_concerns.pdf

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