RTI International's CONSENT+

Promoting Informed Decisions for Clinical Trial Participation

Benefits

- Uses evidence-based communication science strategies, including principles of plain language, clear communication, and health literacy
- Includes IRB -required elements, such as the purpose of the study, risks and benefits of participating, and the ability to withdraw participation
- Provides an indication of an individual's decisional capacity to give consent via a built-in assessment tool
- Features an interactive sorting exercise to allow prospective participants to consider the reasons for and against clinical trial participation
- Designed to enhance understanding of the purpose and procedures associated with a clinical trial
- Targets the enrollment of the most appropriate patients, which may save time/money and lead to a more successful trial
- Developed to strengthen participant engagement
- Standardizes delivery of informed consent information

Traditional informed consent documents for clinical trials are several pages long, contain complex medical terminology, and are written at a high reading level. RTI International has developed CONSENT+, a decision support tool to help patients make more informed decisions about clinical trial participation.

Features

CONSENT+ provides the information required by Institutional Review Boards (IRBs) to obtain informed consent. It uses engaging animations and accompanying narration to convey challenging concepts to help participants understand clinical trial involvement.

CONSENT+ incorporates an assessment tool for clinicians and researchers to help assess the decisional capacity of prospective participants. This research-based component of the tool provides a state-of-the-art measurement of a participant's ability to engage in decision making about clinical trial participation.

Development

Currently, CONSENT+ is tailored for use with individuals who have cognitive impairments, including fragile X syndrome and autism. However, CONSENT+ is adaptable for a variety of conditions or target populations.

For more information or to learn how you may use CONSENT+ in your clinical trial, please contact **Lauren McCormack at Lmac@rti.org**

About Us

Research-based communication and marketing interventions enable individuals and communities to make better decisions regarding health and other behaviors. Our communication sciences professionals develop, test, implement and evaluate communication and social marketing interventions aimed at promoting behavior change. We examine important outcomes including knowledge, attitudes, and beliefs and the extent to which they influence positive change. Our approach includes investigating how people seek, use, and process information related to behaviors and testing innovative tools and interventions. We also analyze the impact of messages and promotional materials in the context of behavior change and use this knowledge to develop evidence-based interventions that promote communication and informed decision making.

Our goal is to create evidence-based, theory-driven materials, communication and social marketing plans that create the conditions for behavior change. To achieve this, our communication science and health behavior experts conduct comprehensive formative and summative evaluations for a variety of topics and deliver solutions that are grounded in theory and evidence-based.

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