

Plain Language Informed Consent Forms

and Processes to Promote Empowered Decision Making for
People Underrepresented in Research



Tufts Medical
Center



VANDERBILT  UNIVERSITY
MEDICAL CENTER



CTSA Clinical & Translational
Science Awards Program

Informed Consent Innovations Work Group: Promoting Multi-site Research and Collaboration

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Disclosure

The presenter for this session is:

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I have no relevant financial relationship(s) in connection with this educational activity

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Informed Consent



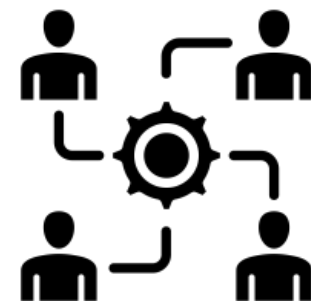
- The **process** by which a potential participant is informed about the research being conducted so that they can decide whether to take part
- Includes his/her rights, the purpose of the study, procedures to be undertaken, potential risks and benefits of participation, expected duration of the study, and extent of personal identification
- A **legal and ethical requirement** for research involving human participants
- Informed consent supports participants entering into research voluntarily with full information about what it means for them to take part

Challenges to Informed Consent



- Lack of consideration of **health literacy** of potential participants
- Ineffective patient – provider/researcher **communication**
- Lack of consideration of **cultural issues** when developing materials
- **Remote** consent requirements

Trial Innovation Centers



- Innovation Centers are focused on operational excellence, operational innovation, and quality by design
- The **Trial Innovation Centers** are charged with coordinating and providing innovative, high quality operational support for clinical trials
- The **Recruitment Innovation Center** is charged with developing evidence-based recruitment and retention strategies
- The individuals and teams presenting today have collaborated across the network to improve consent forms and processes

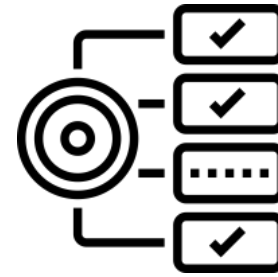
Informed Consent Innovations



Work Group that shares learnings, workshops ideas, and advises on evaluation, implementation, and dissemination of informed consent innovations

- User Experience Perspectives on What Makes Research Informed Consent Forms and Processes Hard to Read, Understand, and Act Upon
- Development of the Informed Consent Form Readability, Understandability, and Actionability of Key Information (RUAKI) Indicator
- Effective Person-centered Consent for Minoritized Populations
- Consent Builder & I-Consent: Informed Consent Process Improvement and Communication Interventions

Panel Session Objectives



- **Literacy, language and cultural** issues when consenting minority participants and strategies for person-centered and empowered decision making
- **Plain language principles** and meeting the new Common Rule requirements for concise and focused key information on informed consent forms
- **Implications for single IRB** approaches that can streamline multi-site research informed consent forms and processes.