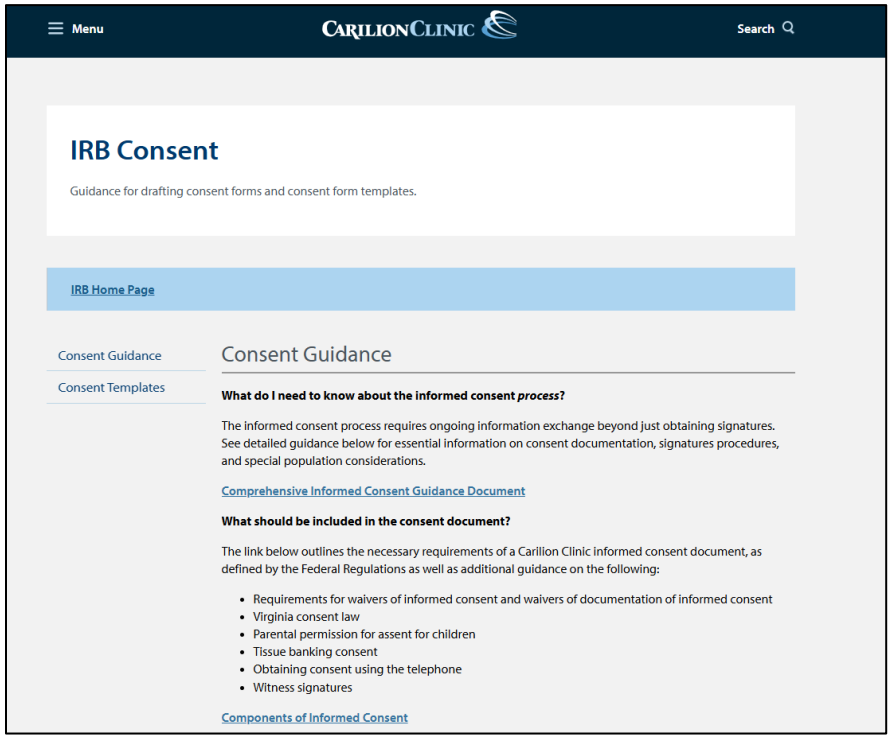
Assessing & Evaluating Key Elements of Informed Consent Process

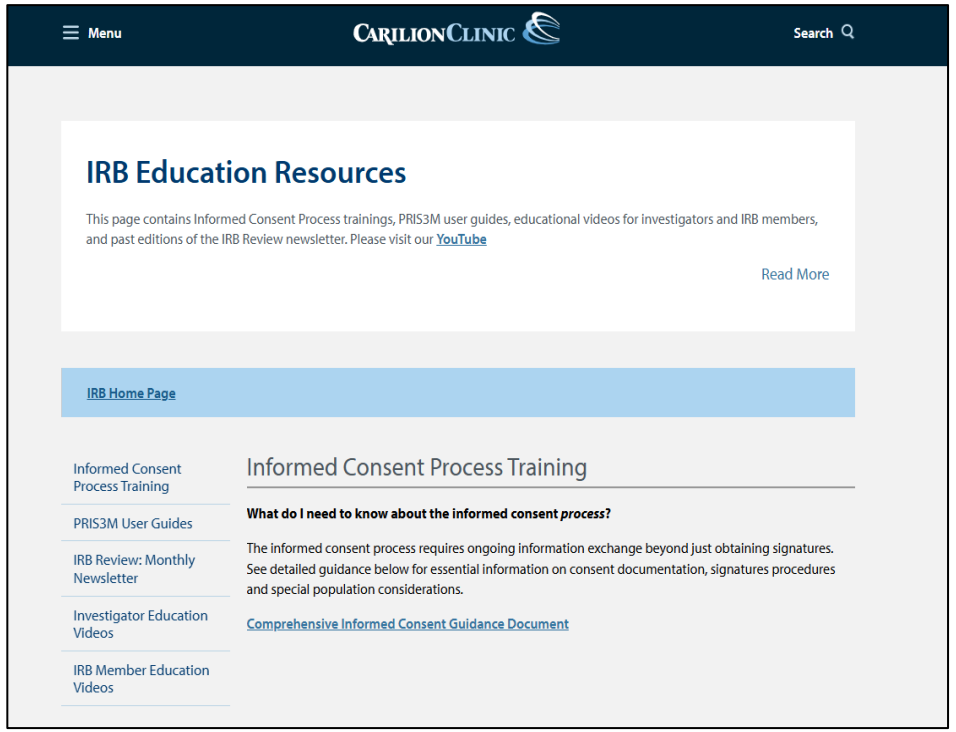
January IRB Members Education Session

CARILION CLINIC

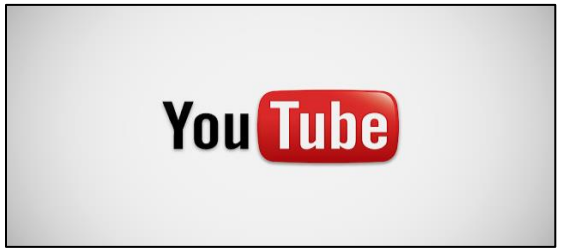
New Educational Materials

Comprehensive Informed Consent Guidance Document—2 locations on website





Learning Channel



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Learning Objectives

1. Define the key elements of an effective informed consent process
2. Identify essential practices that ensure proper consent documentation
3. Recognize practices that compromise the integrity of the consent process

Evaluating the Informed Consent Process Framework

When reviewing consent procedures, verify:

- Process extends beyond signature collection
- Information exchange includes all required elements:
  - Review of recruitment materials
  - Assessment of verbal description of study/plans
  - Methods used to enhance participant understanding
- PI and research team has outlined clear steps for voluntary informed consent

Essential Do's in the Consent Process

- Review study submission:
  - Clear description of staff training on consent procedures
  - Verification process for IRB approval of team members
  - Methods to ensure process matches approved procedures
  - Research team's system for tracking required signatures

Identifying “Red Flags” in Consent Procedures

Be conscientious of protocols that:

- Require short timeframes
- Use excessive medical terminology
- Lack clear participant protection measures
- Show insufficient time for decision-making
- Lack clear separation between informed consent and study procedures

Assessing Special Population Protections

Parental Permission

- Child-friendly documents limited to one page when possible
- Age-appropriate and study-specific forms
- Ensure forms treat children respectfully while conveying essential information

Decisionally-Impaired Participants

1. Capacity Assessment
   - How capacity was determined
   - Extent of cognitive impairment

2. LAR information
   - Periodic reassessment of capacity plans, if applicable (i.e., in populations where capacity to consent can improve or fluctuate)

Non-English speaking participants

Review details for:

- Qualified translator requirements
- Documentation of translation certification
- Witness protocols
- Short form procedure accurate

Guiding Questions

- Is the consent process clearly defined and comprehensive?
- Are there adequate safeguards for participant protection?
- Is study submission sufficiently detailed?
- Are special populations appropriately protected?

Upcoming


Future-Forward:
Navigating
Artificial Intelligence (AI)
Ethics in Research
Join us for the
LIVE! webinar
Friday, January 17, 2025
12-1 PM
AI
ETHICS
These thought leaders will discuss implementing ethical practices in human research within today's rapidly evolving landscape of AI.
Dr. Jessica Vitak is a
Dr. Benjamin Silverman is an