

# Assessing & Evaluating Key Elements of Informed Consent Process

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January IRB Members Education Session

# New Educational Materials

Comprehensive  
Informed Consent  
Guidance Document—  
2 locations on website

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IRB Consent

Guidance for drafting consent forms and consent form templates.

IRB Home Page

Consent Guidance

Consent Templates

Consent Guidance

What do I need to know about the informed consent process?

The informed consent process requires ongoing information exchange beyond just obtaining signatures. See detailed guidance below for essential information on consent documentation, signatures procedures, and special population considerations.

[Comprehensive Informed Consent Guidance Document](#)

What should be included in the consent document?

The link below outlines the necessary requirements of a Carilion Clinic informed consent document, as defined by the Federal Regulations as well as additional guidance on the following:

- Requirements for waivers of informed consent and waivers of documentation of informed consent
- Virginia consent law
- Parental permission for assent for children
- Tissue banking consent
- Obtaining consent using the telephone
- Witness signatures

[Components of Informed Consent](#)

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IRB Education Resources

This page contains Informed Consent Process trainings, PRIS3M user guides, educational videos for Investigators and IRB members, and past editions of the IRB Review newsletter. Please visit our [YouTube](#)

Read More

IRB Home Page

Informed Consent Process Training

PRIS3M User Guides

IRB Review: Monthly Newsletter

Investigator Education Videos

IRB Member Education Videos

Informed Consent Process Training

What do I need to know about the informed consent process?

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Learning Channel

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# Learning Objectives

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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

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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

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- 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

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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

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## 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

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Review details for:

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



# Guiding Questions

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- 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



Dr. Jessica Vitak is a



Dr. Benjamin Silverman is an

These thought  
leaders will discuss  
implementing  
ethical practices in  
human research  
within today's  
rapidly evolving  
landscape of AI.