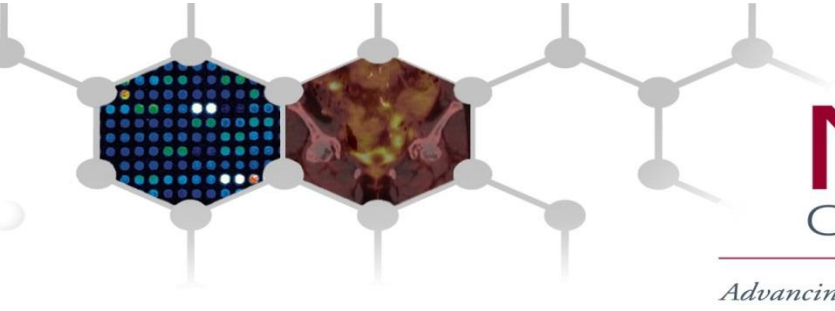

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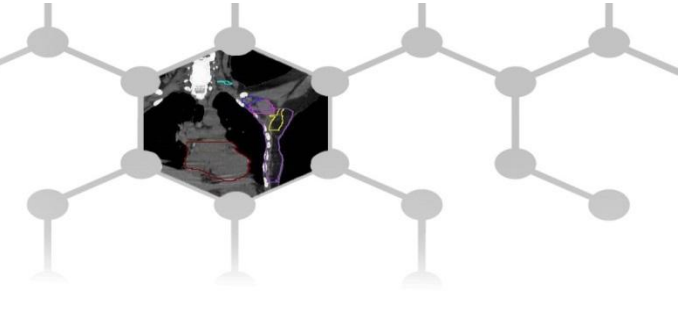

Informed Consent: What Every Research Coordinator Should Know

Jamie Saunders, M.S. & Belinda Buehl, B.S.

Protocol Support Committee

Discuss With Us

May 20, 2026

Disclosures

None of the speakers have any financial disclosures to report

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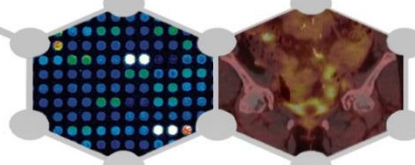

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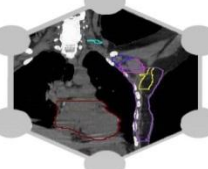


Multiple Choice: The process of informed consent honors which Belmont Report principle?

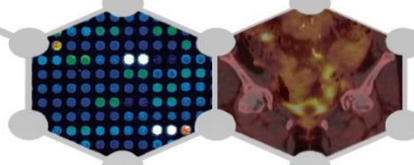
Beneficence

Justice

Respect for Persons

Belmont Report

- Individuals should be treated as autonomous agents.
- Individuals must voluntarily choose whether to participate in research, with adequate understanding of the risks, benefits, and purpose of the study.



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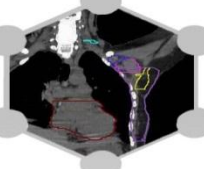
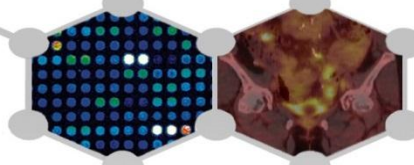


Word Cloud: What is informed consent?



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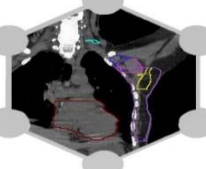

Word Cloud: Why is informed consent necessary?

What is Informed Consent?

Why is this necessary?

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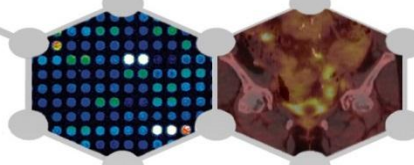

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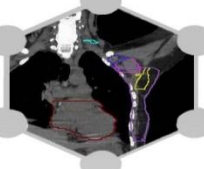
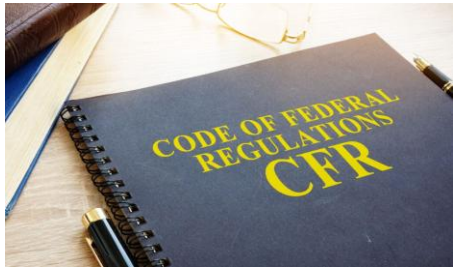


Word Cloud: What are the elements of informed consent?

Elements of Informed Consent

- Involves research, explanation of the purpose, approximate duration of participation, description of the procedures involved, and identification of experimental procedures.
- Risks or discomforts
- Potential benefits
- Alternative procedures or other courses of treatment
- Confidentiality
- Compensation for participation
- Medical care/compensation for research related injury & contact information
- Contact information for questions.
- Participation is voluntary, there is no penalty nor loss of benefits for refusal, and the participant has the option to discontinue participation at any time.



Additional Elements of Informed Consent

1. Reproductive risks which are currently unforeseeable.
2. Investigator termination
3. Additional costs that may result from participation in the research.
4. Significant new findings discovered during the study and may impact the participant's willingness to continue participation will be provided.
5. Expected enrollment

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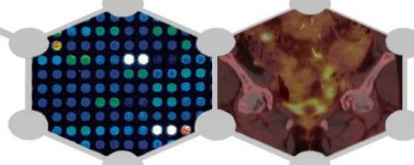

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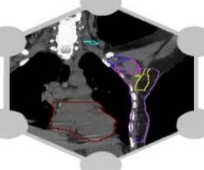

Multiple Choice: Which study site personnel are responsible for ensuring the ICF document contains the required elements?

IRB
Regulatory
Coordinators
PI

Documenting Informed consent

- Occurs after the consent form has been discussed and obtained but prior to any study related activities.
- Requires obtaining the signatures of both the participant, or legally authorized representative (LAR) and the person obtaining consent. This includes printing the name, signature, and the date of the consent.
- A witness signature may be required in the following situations
    - Participant is unable to sign due to physical /cognitive impairments
    - Legally authorized representative signs on behalf of the participant.
    - Consent process is conducted remotely
    - Consent is obtained language other than the participant's primary language.
- The inclusion of the witness' signature on the consent form is dictated by local institutional policy.
- Participant must be given a copy of the completed ICF, and the original must be kept in the participant's research folder.

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Other Things to Consider

- Use easily understandable language
- Encourage questions and use the “teach back” method to determine and assess understanding.
- Allow sufficient time for participants to review, discuss with family and/or friends, and ask questions
- Avoid medical terminology

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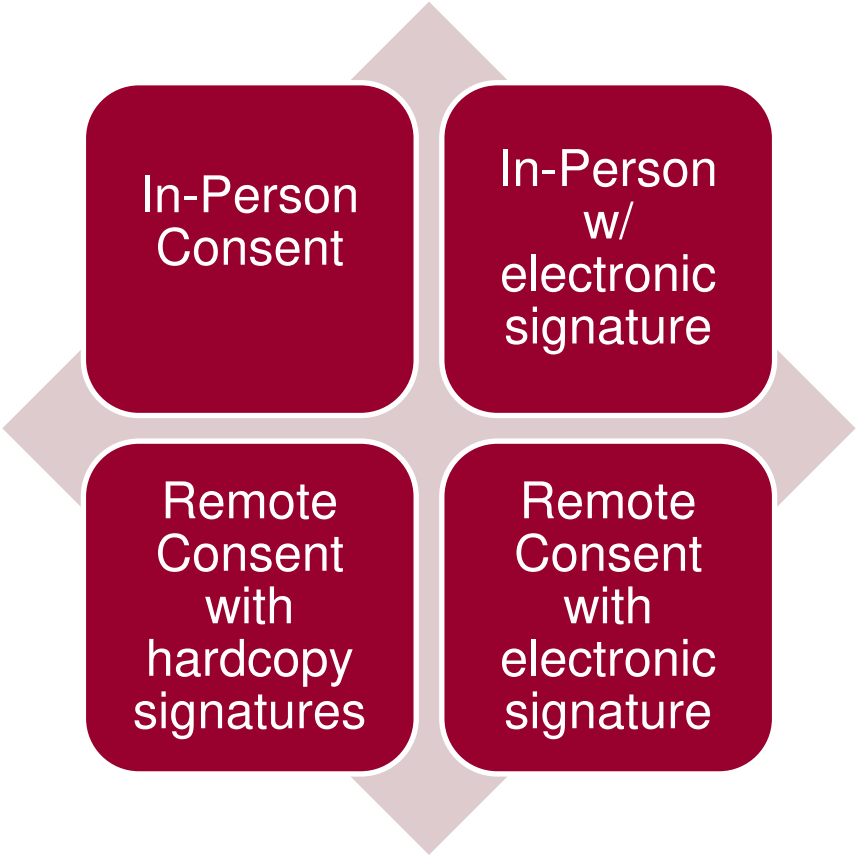
Discussion & Documentation



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In-Person Consent

Participant and study team member are at the same location for the consent discussion.

Signatures are obtained on a hardcopy document.

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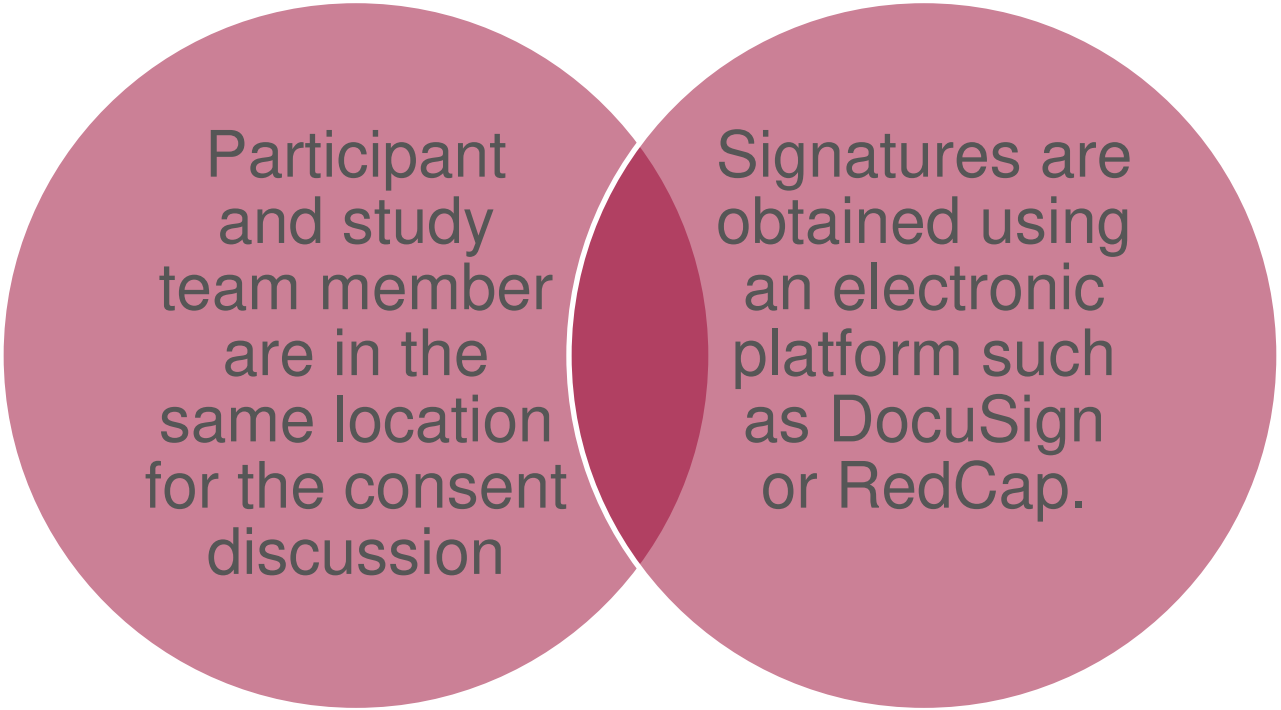
In-Person with Electronic Signature



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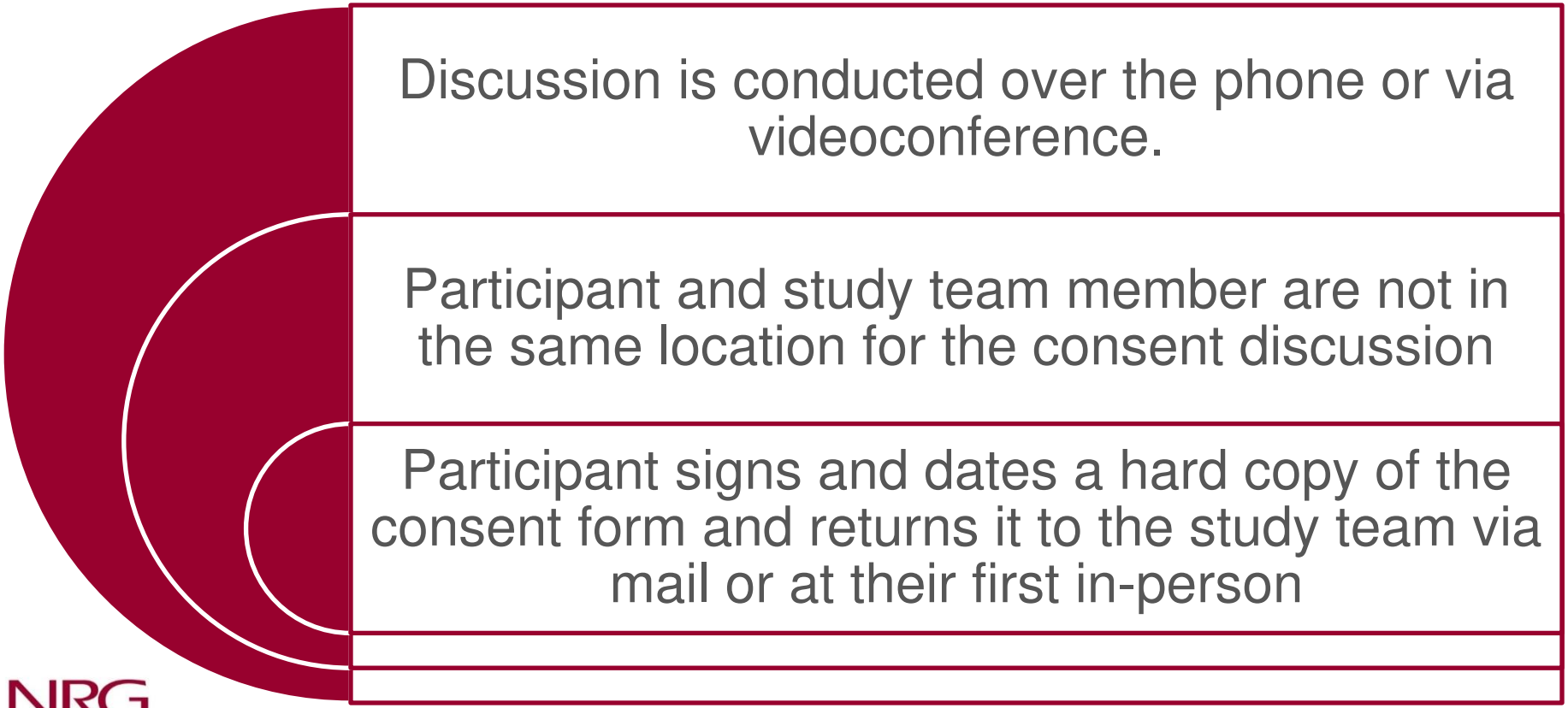
Remote Consent with Hardcopy Signatures



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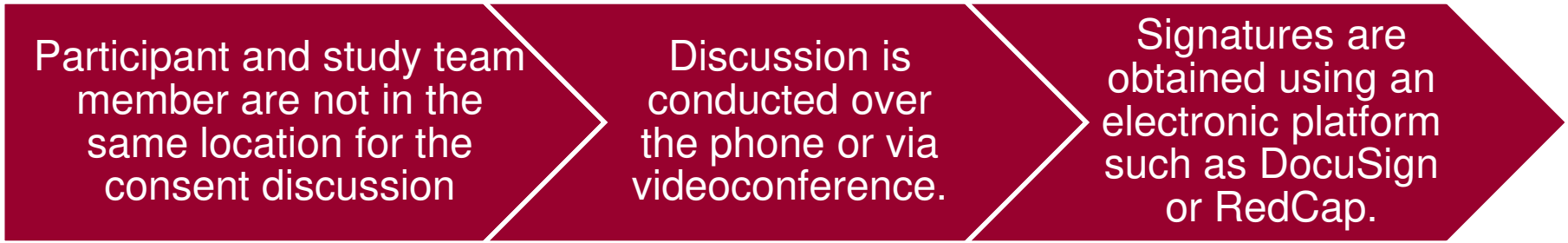
Remote Consent with Electronic Signature



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Electronic Consent

- Can occur in person or remotely
- Refers to how the signatures were obtained not to how the discussion was conducted.
- Must use a system that is able to document legally binding signatures
- FDA regulated (drug or device), requires a Part 11 compliant system

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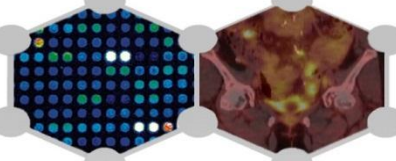

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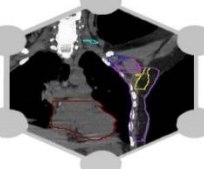

Multiple Choice: Does the NCI CIRB require special documentation when using remote consent?

Yes

No

I don’t know

CIRB Required Language

CIRB SOP section 2.3.1.

Under the signature line, the investigator/designee must document a brief reason for performing the informed consent remotely, the method remote consent was conducted, the date of the informed consent discussion, and the date the signed consent form was received.

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Consent Method

Type & Risk

Burden Participants

Participant Capabilities

Protocol & IRB

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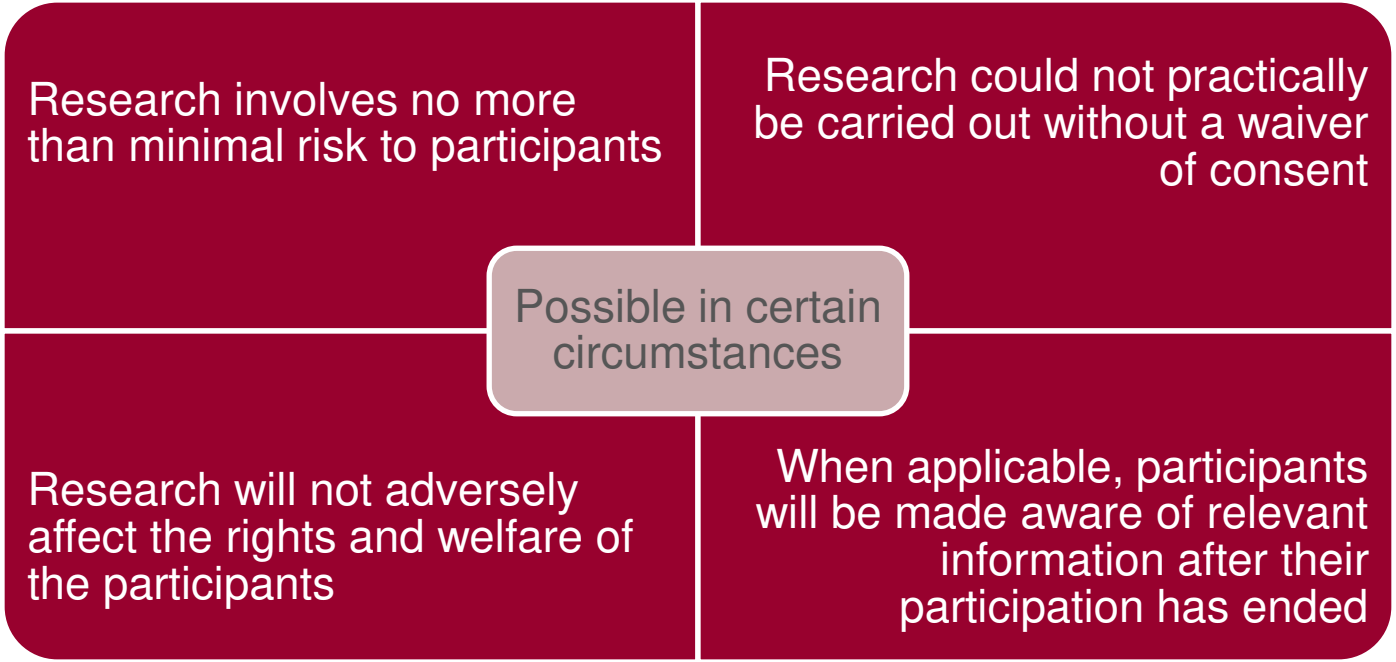
Waiver of Consent



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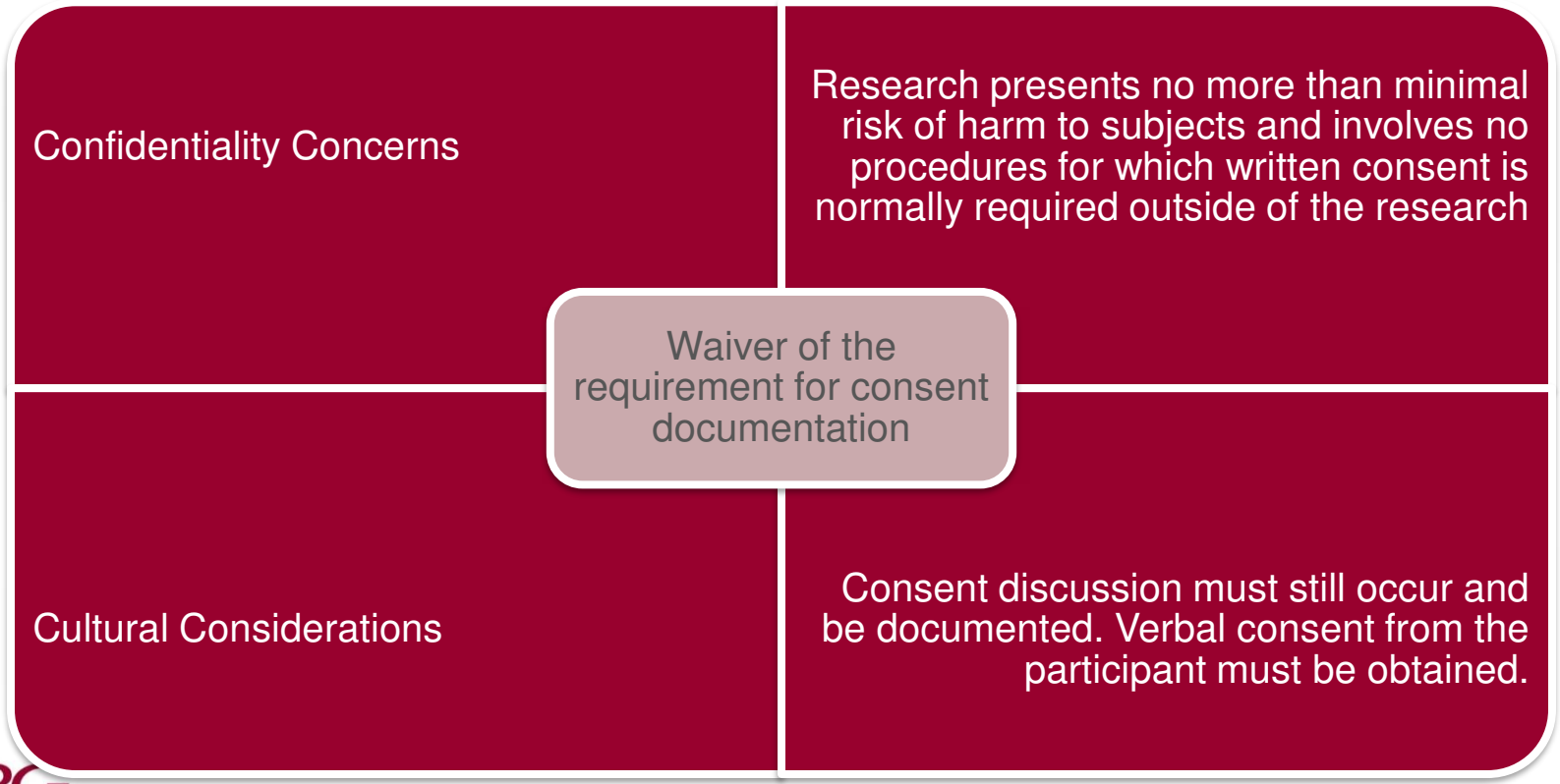
Waiver of Consent Documentation



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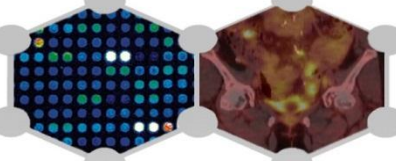

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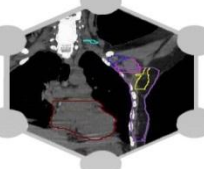

Multiple Choice: If the IRB has approved a waiver of documentation of consent, does that also waive documentation of HIPAA authorization?

Yes

No

I don’t know

Waivers

Waiver of documentation of consent and HIPAA are not interchangeable.

A study could be approved for one but not the other.

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What should the consent note contain?

- How, when, and by whom were the informed consent documents initially provided to the participant
- Participants were given time to review the documents before the consent discussion(s)
- Who was present, including consenter name and credentials, participant name, and any others who were present
- When the discussions took place
- How the discussions took place (remote, in-person)
- Study Information and ICF (including version dates)
- A statement that includes what was reviewed, including procedures involved, risks, alternatives, and follow-up

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What should the consent note contain cont?

Statement regarding participant understanding of the research, that participation is voluntary and that they may withdraw at any time

A statement indicating that the participant had adequate time to review the documents and that all their questions were answered to their satisfaction

How the participant signed

How the participant received a completed copy

A statement that no research activities were performed prior to consent

If a witness is required, then documentation of the witness should also be included

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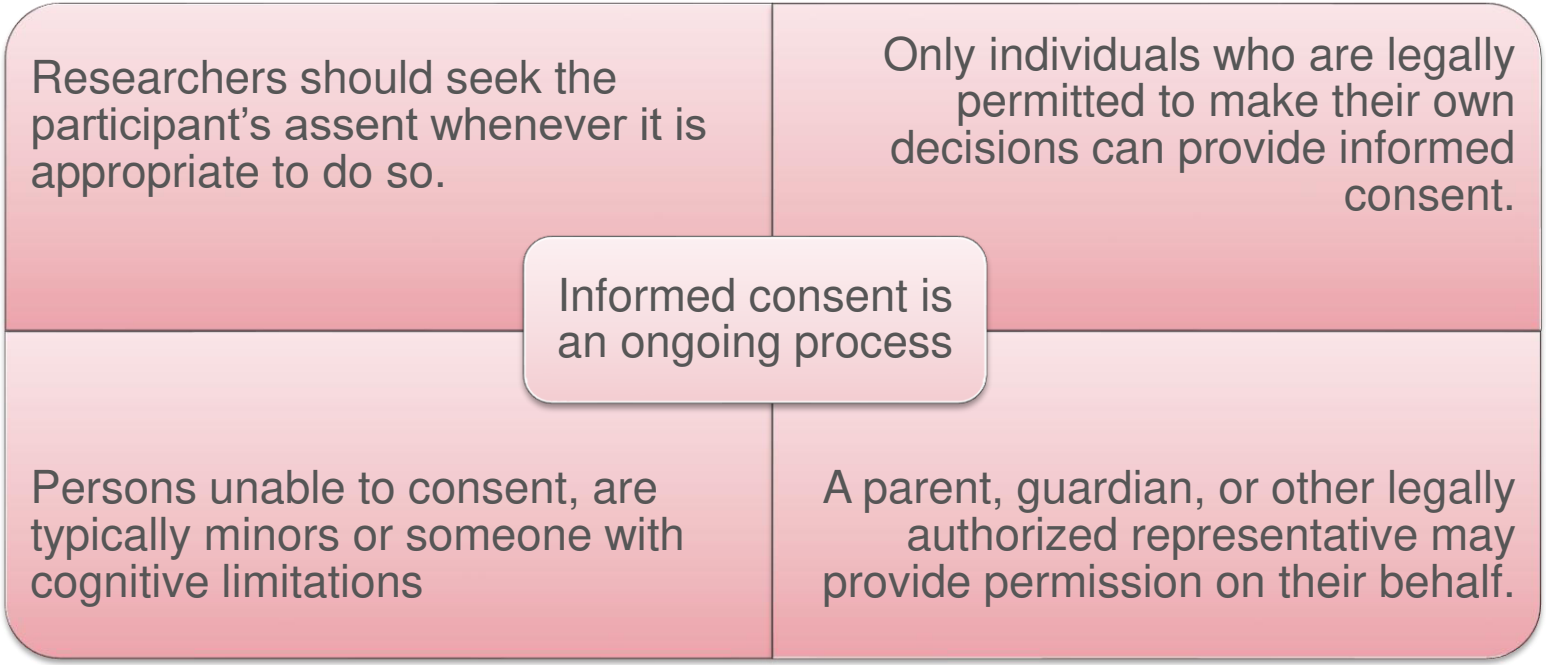
Informed Consent & Assent in Research



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How is Assent Demonstrated

Behaviorally

In writing

Verbally

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Differences Between Consent & Assent

- Legal Authority
- Who Provides It
- Documentation

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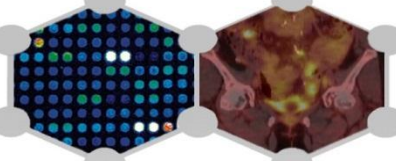

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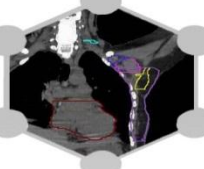

Multiple Choice: How should capability of assent be assessed?

Age & Maturity

Psychological State of Patient

Nature of Proposed Research

Consent & Assent: Working Together

Consent provides the legal basis for participation, while assent ensures that individuals who cannot legally consent still have an active role in the decision to participate.

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Questions?

Questions?

Questions?

Questions?

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Thank you for attending!

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