

UNIVERSITY  
OF MIAMI



# Special Office Hour Session

## Consenting and flexibility within regulations

Vivienne Carrasco, MPH, CIP  
Human Subject Research Office



## **Objectives:**

- **Understand when flexibility is permitted within consent regulations**
- **Identify the most appropriate consent approach for your study**
- **Apply practical strategies to avoid unnecessary delays and rework**

Roadmap can be overwhelming...

# CONSENT IN RESEARCH

Many Paths. One Purpose: Respect, Understanding, and Autonomy.

Consent is a process, not just a form.

**START HERE:**  
What's the best approach for your participants and research?

## FULL INFORMED WRITTEN CONSENT

The standard approach. Comprehensive information provided in writing and signature documented.



## WAIVER OF DOCUMENTATION OF CONSENT

Consent is obtained but the IRB waives the requirement to sign a consent form.

Examples:

- Minimal risk research
- Confidentiality concerns
- Cultural considerations



## WAIVER OF CONSENT

The IRB waives the requirement to obtain consent.

Examples:

- Minimal risk
- Impracticable to obtain
- Rights and welfare not adversely affected



## ALTERATION OF CONSENT

The IRB approves changes to some or all elements of the consent process.

Examples:

- Shorter form
- Verbal consent
- Delayed information
- Modified documentation



## KEY CONSIDERATIONS

- Risk level
- Practicability
- Participant population
- Cultural context
- Regulatory requirements

## THE FOUNDATION (ALWAYS TRUE)



- ✓ Legally effective consent
- ✓ Sufficient information to make a decision
- ✓ Voluntary participation
- ✓ Opportunity to ask questions
- ✓ Minimize coercion and undue influence
- ✓ Understandable language

## RE-CONSENT / NOTIFICATION

New information arises that might change willingness to participate.

Examples:

- New risks
- New alternatives
- Changes in compensation
- Conflict of interest



## SHORT FORM / SUMMARY CONSENT

Key information provided in a concise format when full consent is impracticable at the time.



## TRANSLATED CONSENT

Information provided in the participant's preferred language.

Requires IRB approval.



## REMOTE / ELECTRONIC CONSENT

Consent obtained using technology (e-consent, video/phone, digital signature, etc.).

Must ensure identity verification, security, and documentation.



## ASSENT / PARENTAL OR LAR CONSENT

For children or individuals who cannot consent for themselves.

Includes assent from the participant when possible and permission from parent or legally authorized representative.



## BROAD CONSENT

For storage, maintenance, and future research use of identifiable biospecimens or private information.



## REMEMBER

Flexibility in the regulations allows consent to be tailored—but never to be meaningless.



## REGULATORY FOUNDATION

- 45 CFR 46.116 & 46.117 (Common Rule)
- 21 CFR 50.20–50.27 (FDA)
- OHRP Guidance on Informed Consent
- ICH E6(R2)


Different studies. Different people. Different needs.  
The right consent approach builds trust and protects what matters most.

---

# Basics of Consent

## Why We Consent

- Respect for persons
  - We ensure that every participant makes their own decision
  - Understands what they are agreeing to
  - Participates voluntarily, without pressure or coercion
  - Is treated with dignity, autonomy, and transparency

 Consent is not paperwork — it is about protecting people

## Standard- Always True (unless waived)

- Obtained before research participation begins
- Legally effective
- Provide sufficient information
- Language the participant understands
- Allow time for questions
- Voluntary and free from coercion or undue influence
- No penalty

---

# What Do We Mean by Flexibility?

## **Flexibility is built into the regulations!**

- Flexibility does not mean lowering protections. It means tailoring the consent process to the research and participant context.
- Examples of flexibility:
  - Waiver of consent
  - Alteration of consent
  - Waiver of documentation of consent
  - Short form consent
  - Remote or electronic consent
  - Assent with parental permission or LAR consent
  - Re-consent or notification
- **Bottom line: The process may be different, but the ethical purpose remains the same.**

# Common Misconceptions

Misconception	Better framing
“No signature means no consent.”	Consent may occur without signed documentation if approved. A consent document is still required.
“Minimal risk means no consent needed.”	Minimal risk alone is not enough for a waiver.
“Remote consent is easier, so we can use it anytime.”	Remote consent still requires an approved process; can be more complicated because witnesses are required.
“Waiver means the IRB is not involved.”	Waiver requires IRB review, documentation and approval.
“Consent is done once signed.”	Consent is ongoing.





# Where flexibility fits

## WHERE DO WE START?

Understand the context of your study before choosing a consent approach.



### TYPE OF RESEARCH

What kind of study are you conducting?

- Interventional (e.g., clinical trial)
- Observational
- Survey / Interview
- Use of existing data or specimens

### START HERE:

What is the context of your study?



### RISK LEVEL

What is the level of risk to participants?

- Minimal risk
- Greater than minimal risk



### TIMING

When does the research interaction or data use occur?

- Prospective (future)
- Concurrent / Real-time
- Retrospective (existing data)



### LOCATION / SETTING

Where and how will consent be obtained?

- In-person (clinic, hospital, research site)
- Community / Home
- Remote / Online / Telehealth
- Multi-site / Multiple settings



### CONTEXT DRIVES THE CONSENT APPROACH.

Consider all four factors to choose the most appropriate and ethical consent pathway.



Different studies. Different people. Different needs.  
The right consent approach builds trust and protects what matters most.



- Everything applies conceptually, even when:
  - Consent is waived, elements are altered, documentation is waived
- 🙌 The IRB is essentially saying: “We are modifying the process, not abandoning the principles.”

## The Decision Framework



- Flexibility starts with the facts of the study.
  - What type of research is this?
  - What is the risk level?
  - Will there be interaction or intervention?
  - Is the data/specimen identifiable?
  - When is the research occurring — prospective, concurrent, or retrospective?
  - Where will consent occur — clinic, community, remote, online?
  - Who is the participant population?
  - Is consent practicable?
  - Is written documentation necessary or appropriate?

# Waiver of Consent

- Use when: The IRB determines that obtaining consent is not required because the regulatory criteria are met.
- Common examples: Retrospective chart reviews, Secondary use of existing data, Some minimal risk research where contacting participants is not practicable
- Key criteria: Research involves no more than minimal risk, Research could not practicably be carried out without the waive, If identifiable private information or identifiable biospecimens are used, the research could not practicably be carried out without using them in identifiable form, Waiver will not adversely affect rights and welfare, When appropriate, participants receive additional information afterward
- A waiver of consent is not convenience-based. It must be justified.
- Prospective data collection- why can't consent be obtained?

UNIVERSITY  
OF MIAMI



## WHAT IS AN ALTERATION?

The participant still goes through a consent process, but one or more elements *need to be* omitted or modified with IRB approval.

### COMMON EXAMPLES



Deception research



Incomplete disclosure



Full upfront disclosure would compromise the research purpose

### THINK AHEAD: PLANNING QUESTIONS



What element(s) of consent are being altered—and why?



How does the alteration support scientific integrity?



What will the participant experience? Will they understand enough to make an informed decision?



Could an alternative consent approach work instead?



What is the potential impact on autonomy, trust, and welfare?



How will additional information be provided (if applicable)?



Are there population-specific considerations (e.g., vulnerability, culture, language)?



Are there overlapping requirements (e.g., HIPAA, FERPA)?  
*Alteration of consent ≠ alteration of HIPAA authorization.*

### Use when:

The participant still goes through a consent process, but one or more elements need to be omitted or modified with IRB approval.

**Common examples:** Deception research, Incomplete disclosure, Studies where full upfront disclosure would compromise the research purpose

### Key Points:

- The IRB may approve an altered process only when regulatory criteria are met.
- “Practicable” ≠ convenient  
Why is altering consent elements necessary for scientific validity?
- Will participants still understand enough to make an informed decision?
- Alteration of consent ≠ alteration of HIPAA authorization. HIPAA waivers have separate, stricter criteria

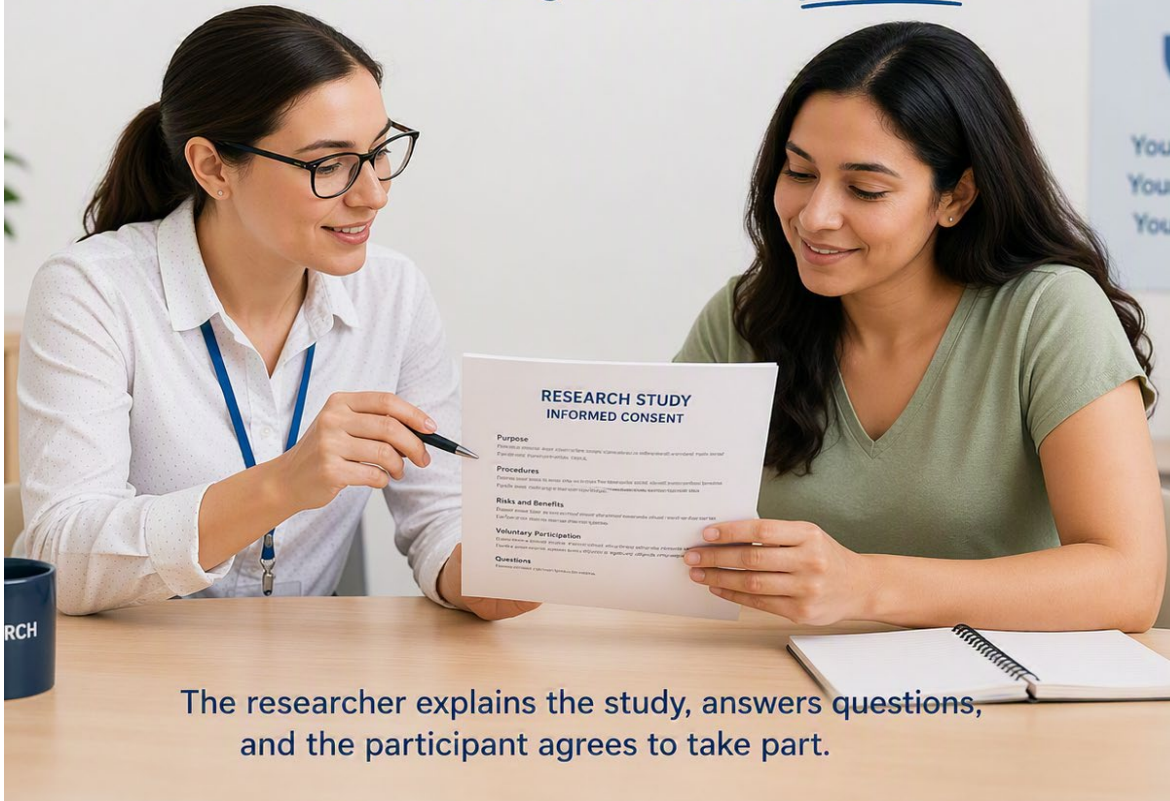
This is often misunderstood. Alteration does not mean the study team can simply leave something out. The IRB must determine that the alteration is appropriate.

# Waiver of Documentation of Consent

Consent happens, but signature is waived

## Waiver of Documentation of Consent

Consent *is* still given. It is a process.



UNIVERSITY  
OF MIAMI



### Key distinction:

A waiver of documentation is **not** a waiver of consent.

### What changes:

*The participant may still receive all required information and agree to participate, but the IRB waives the requirement for a signed consent form.*

**Common examples:** Surveys, Interviews, Online research, Minimal Risk studies (examine context), situations where the signed form is the only link to the participant and the main risk is confidentiality harm

**Gold Standard** for One-time minimal risk surveys (generally exempt)

### Key Takeaway:

**No signature does not mean no consent.**

# Remote and Electronic Consent

- *Different setting, same standard*
- Consent may occur outside an in-person setting when appropriate.
- Remote/e-consent still requires explanation, questions, comprehension, voluntariness, and documentation.
- The modality changes, but the ethical and regulatory expectations remain.
- Examples: Video consent, Telephone discussion with documented process, REDCap/e-consent, Digital signature, Secure electronic communication
- Remote consent is not a shortcut. It is a different way to conduct the same meaningful consent process.
- → Thought: If minimal risk, would a waiver of documentation of consent be appropriate???
- *“How to” Investigator Manual Chapter 7.8*



# Language and Short Form

## **Consent must be understandable**

- Consent information must be in language understandable to the participant or LAR.

If non-English-speaking participants are expected, translated materials should be planned.

- Short form may be used when a translated full consent is not immediately available and the IRB has approved the process (normally about 5).

- Short form requires careful documentation and appropriate signatures.

- This requirement applies to all studies — regardless of risk level.

- → Think: If measures need to be given in a translated language, shouldn't consent be asked well?

**Understanding is the standard. Translation is one way we meet it. Tailoring the consent to the population is another.**



---

# Understandability

-  Good Consent Practices  
(Understanding-Focused)

- Uses plain, clear language (no unnecessary jargon)
- Researcher walks through the consent, not just hands it over
- Participant is encouraged to ask questions
- Researcher checks for understanding (teach-back or discussion)
- Consent is treated as an ongoing conversation, not a one-time event
- Environment supports decision-making (no pressure, appropriate setting)
- Materials and approach are tailored to the population
- Participant leaves knowing what they agreed to and

-  Poor Consent Practices  
(Form-Focused)

- Relies on dense, technical language
- Researcher simply says “read and sign”
- No time or space for questions
- No effort to confirm participant understanding
- Focus is on getting a signature, not informed agreement
- Consent occurs in a rushed or distracting environment
- No adaptation for language, literacy, or context
- Participant signs but may not fully understand the study










# Assent, Parental Permission, and LAR Consent

- When someone cannot consent for themselves:
- Children require parental permission and, when appropriate, assent.
- Adults who lack capacity may require LAR/proxy consent.
- Assent is the participant's affirmative agreement when they can understand enough to express a choice. Assent is not always feasible.
- Respect for the individual remains central, even when another person provides permission.
- *Flexibility also includes matching the decision-maker to the participant's capacity and legal context.*

## ASSENT: CHILDREN & COGNITIVELY IMPAIRED

Assent = the individual's **affirmative agreement**.

Permission/consent comes from the Parent or LAR, but the individual's voice still matters.

 <b>CHILDREN</b> (Assent + Parent/LAR Permission)	 <b>COGNITIVELY IMPAIRED</b> (Assent + LAR Permission)
<p>Provide information at the child's <b>age and maturity level</b>.</p> <p>Use <b>simple, clear, honest</b> language.</p> <p>Encourage <b>questions and conversation</b>.</p> <p>Check <b>understanding</b> (can they explain it back?).</p> <p>Child provides <b>assent</b> when <b>capable</b>.</p> <p>Parent/LAR provides <b>permission</b>.</p> <p>Respect the child's <b>dissent</b>.</p>	<p> Provide information the individual can reasonably understand.</p> <p> Use <b>plain language</b> and <b>supportive communication</b>.</p> <p> <b>Assess ability</b> to provide meaningful assent.</p> <p> Allow the individual to express <b>willingness or resistance</b>.</p> <p> Seek assent to the extent possible.</p> <p> LAR provides legally effective consent.</p> <p> Do not override resistance.</p>

### WHAT TO FOCUS ON

 Capacity and ability to understand.	 Clear, supportive communication.	 Respect for willingness and hesitation.	 Role of the LAR for permission.
---	--	---	---



### KEY TAKEAWAY:

Assent is a process of engagement—not just permission. Willingness matters. Resistance matters. Both must be respected.





# Re-Consent and Notification

- Consent does not end when the form is signed.
- Participants must be informed when new information may affect their decision to continue. The IRB determines how that information is shared.
- Examples include: New risks, new alternatives, changes in compensation, changes in study procedures, new conflict of interest, participants reaching adulthood during the study.
- Essential to complete the Modification Information question on study status and inform the IRB where changes apply. Context is important!
- *If the change impacts participation → Re-consent*
- *If the change informs participation → Notify*

---

# What HIPAA Adds...

-  HOW IT CHANGES THE CONSENT PROCESS
- Participants are agreeing to two things: Participation in research and use of their health information
- Normally combined into one document,
- Even if consent is waived or altered, HIPAA may still require authorization

-  WHAT TO THINK ABOUT:
- Will the study access medical records or identifiable health data?
- Is authorization required, or is/ should a waiver being requested? CONTEXT IS IMPT!
- Does your consent process clearly explain how PHI will be used and protected?
- *HIPAA can make flexibility more limited...but it doesn't eliminate flexibility. It just adds a second layer of requirements that must be independently justified.*



# CONSENT QUICK REFERENCE



**Consent is a process, not a form.**

Focus on understanding, not just signatures.

Approach depends on study design, risk, and population.



## FLEXIBILITY (WHEN ALLOWED)

Flexibility must be **justified—not convenient.**

**Driven by:**

- ✓ Risk level
- ✓ Type of interaction/intervention
- ✓ Identifiability of data
- ✓ Practicability of obtaining consent

**IRB may allow:**

- ✓ Alteration of consent
- ✓ Waiver of consent
- ✓ Waiver of documentation

## WAIVER OF DOCUMENTATION



**Consent still occurs—no signature required.**

Typically for minimal risk studies.

**Must still:**

- ✓ Provide required information
- ✓ Allow questions
- ✓ Document the process when appropriate

## ASSENT



Required when individuals **cannot legally consent** (e.g., children, cognitively impaired).

**Key points:**

- ✓ Seek affirmative agreement when possible
- ✓ Tailor to level of understanding
- ✓ Respect dissent
- ✓ Pair with Parent/LAR permission

## UNDERSTANDABILITY



Applies to all studies **(not risk-dependent).**  
Must be understandable to participant or LAR.

**Strategies:**

- ✓ Plain language
- ✓ Discussion + questions
- ✓ Teach-back
- ✓ Translation / short form when needed

## RE-CONSENT vs. NOTIFICATION



**RE-CONSENT**  
When changes affect participation.

**Examples:**

- ✓ New risks
- ✓ Changes to procedures or burden
- ✓ New key disclosures



**NOTIFICATION**  
When informing is sufficient.

**Examples:**

- ✓ General updates
- ✓ Administrative changes (e.g., PI, contact info)
- ✓ New findings (informational)

## HIPAA



**Separate from consent.**  
Required for use of identifiable health information (PHI).

**Cannot access medical records without:**

- ✓ Authorization, or
- ✓ IRB-approved waiver

**HIPAA waivers:**

- ✓ Have stricter criteria than consent waivers
- ✓ Must justify why research cannot be done otherwise

## DECISION FRAMEWORK

When designing your consent approach, ask:



Does this impact participant understanding or decision-making?



Is the approach justified and appropriate for the study?



Are you addressing both:  
• Participation (Consent)  
• Information use (HIPAA)



**BOTTOM LINE**



Clear



Flexible  
(when justified)



Participant-centered



Compliant  
with regulatory requirements

Good consent protects participants and supports ethical research.

UNIVERSITY OF MIAMI



---

# We are here to help!

- Contact the HSRO/IRB for thoughts.
  - <https://hsro.uresearch.miami.edu/contact-us/index.html>
- Work with mentors, colleagues that have previous experience within your research realm.
- Available resources on campus to align your consent process to your research:
  - <https://miamictsi.org/resources/navigating-research/research-navigator/>

---

**ANY QUESTIONS?**

UNIVERSITY  
OF MIAMI

