

Guidance

Navigating Parental Permission & Recruitment

Professional Standards for Children's Wisconsin Researchers

The integrity of research at [Children's Wisconsin](#) and the Belmont ethical principle of Respect for Persons relies on a rigorous parental permission and informed consent process, which goes beyond a mere signing of the consent document. This document provides a unified workflow for the consent discussion, and regulatory verification.

I. Pre-Consent Preparation

High-quality research begins with documentation accuracy. Before entering a patient room or clinical space, ensure all administrative requirements are met.

The "eBridge" Audit

- **Study Requirements:** Review study-specific requirements in eBridge (Sections 38-48).
- **IRB Determinations:** Review the IRB approval form for specific mandates:
 - Is the signature of both parents required, or is one acceptable?
 - What are the specific age requirements for minor subject assent?
- **Version Control:** Verify the consent form date matches the newest version in eBridge.
- **Packet Integrity:** Confirm all pages are present and stamped with the correct IRB version date.

Subject Identification & Age Requirements

Check your specific IRB approval letter and Section 41.6 of your study's eBridge PRO. While requirements vary by study, the following is an example:

Subject Age	Action Required
Age 0-6	Assent waived. Print Parental Permission (Consent) only.
Age 7-13	Separate Assent Form required. Print Assent and Consent.
Age 14-17	Assent integrated into Parental Permission form. Print Consent only.
Adult (18+)	Print Informed Consent form.

Note on Dyad Studies: If a parent is also a subject, they must provide informed consent for themselves *in addition* to permission for their child. This requires separate discussions and signatures for each role.

II. Recruitment & The Clinical Encounter

In a medical setting, the "Power Dynamic" is often skewed. Researchers must maintain **Clinical Neutrality** to ensure families do not feel pressured to participate to please the institution.

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The 30-Second Clinic Pitch

- **The Opener:** "Hi, I'm [Name], may I discuss a research study with you? This is completely separate from your appointment and won't affect your care at all."
- **The Hook:** "We're doing a quick study to learn how children like [Child's Name] interact with new environments. [state the purpose of the particular study]"
- **The Choice:** "It takes about [Number] minutes. Would you be open to hearing more while you wait, or would you prefer to focus on your visit? No pressure either way."

Best Practices for Neutrality

- **Safety Valve:** If asked for medical advice, use the script: *"That is a great question for your clinical team. I'd be happy to wait while you ask the doctor."*
- **Environment:** Sit at eye level; do not stand over the parent. Maintain a respectful physical distance from the child.
- **The Guided Tour:** Point to the **Voluntary** and **Withdrawal** sections. Highlight that they can quit at any time. Offer a clean copy in a folder for their records. If applicable and you are able, show any tools/tablets/toys that will be used.
- **Body Language:** Watch for "The Speed Read." If they flip straight to the signature, pause and explain: *"I'm required to ensure I've explained the risks and tasks before we sign."*

III. Conducting the Consent Discussion

Verbally cover these 11 **Essential Points**:

1. **Purpose:** What is the study about?
2. **Inclusion:** Why this participant specifically?
3. **Procedures:** What will happen?
4. **Expectations:** What is expected of the subject?
5. **Collection:** What information/specimens are we gathering?
6. **Risk/Benefit:** A candid reality check of potential outcomes.
7. **Costs/Payments:** Any financial implications or reimbursements.
8. **Timeline:** Project duration.
9. **Voluntariness:** Emphasize that "no one will be mad" if they decline.
10. **Questions:** Pause for participant inquiry.
11. **Final Interest:** Confirm willingness to proceed.

You can then leave the room to give the family a few minutes to read over the consent in private. When you return, ask open-ended questions to assess comprehension and ensure voluntary agreement to participate.

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For Example:

- "We've gone over a lot of information, and I want to be sure I explained everything clearly. In your own words, could you please tell me what you will be doing during this study?"
- "Can you describe to me what the main goal of this research study is?"
- "What are some of the potential risks or side effects we discussed, and how might they affect you?"
- "What would you do if you decided you no longer wanted to be in this study?"
- "What questions do you have?" (preferred over "Do you have any questions?")
- How would you explain to your family what this study is about and what you will be doing?"
- If you were to take part in the study, what benefits might you get?

IV. Post-Consent Documentation & Verification

Immediately audit all documents to prevent deviations and ensure compliance.

Quality Review & Administrative Completion

- **Signatures:** Verify all parties signed and dated correctly. Use a single-line strike-through for errors (no white-out).
- **EPIC Documentation:** Document the discussion in the **Research Tab** section of EPIC. Note who was present, the family's comprehension, and the final decision.
- **Medical Records:** Send a copy of the signed form to Medical Records immediately.
- **Enrollment:** Update the Enrollment Log and retain original signatures in the regulatory binder.

The 5-Year Test

Ask yourself: "If a reviewer saw this five years from now, would they understand exactly what happened during this consent process?" If not, add a clarifying note to your source documentation.

V. Core Ethics: The "Do's and Don'ts"

- **The 8th-Grade Rule:** Use plain language. Substitute "longitudinal" with "over time" and "cohort" with "group."
- **Respect the "Veto":** When an IRB requires assent, if a child says no, you cannot proceed, even if the parent said yes.

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- **No Coercion:** Avoid "social proof" (e.g., "everyone else is doing it") to influence decisions.
- **Graceful Refusals:** A "No" is a success—it means the parent felt empowered. Validate the decision:
"I completely understand! I'll let you get back to your visit."

If you have any study- or scenario-specific questions or need help during the study, send an email to cwhrpp@childrenswi.org.