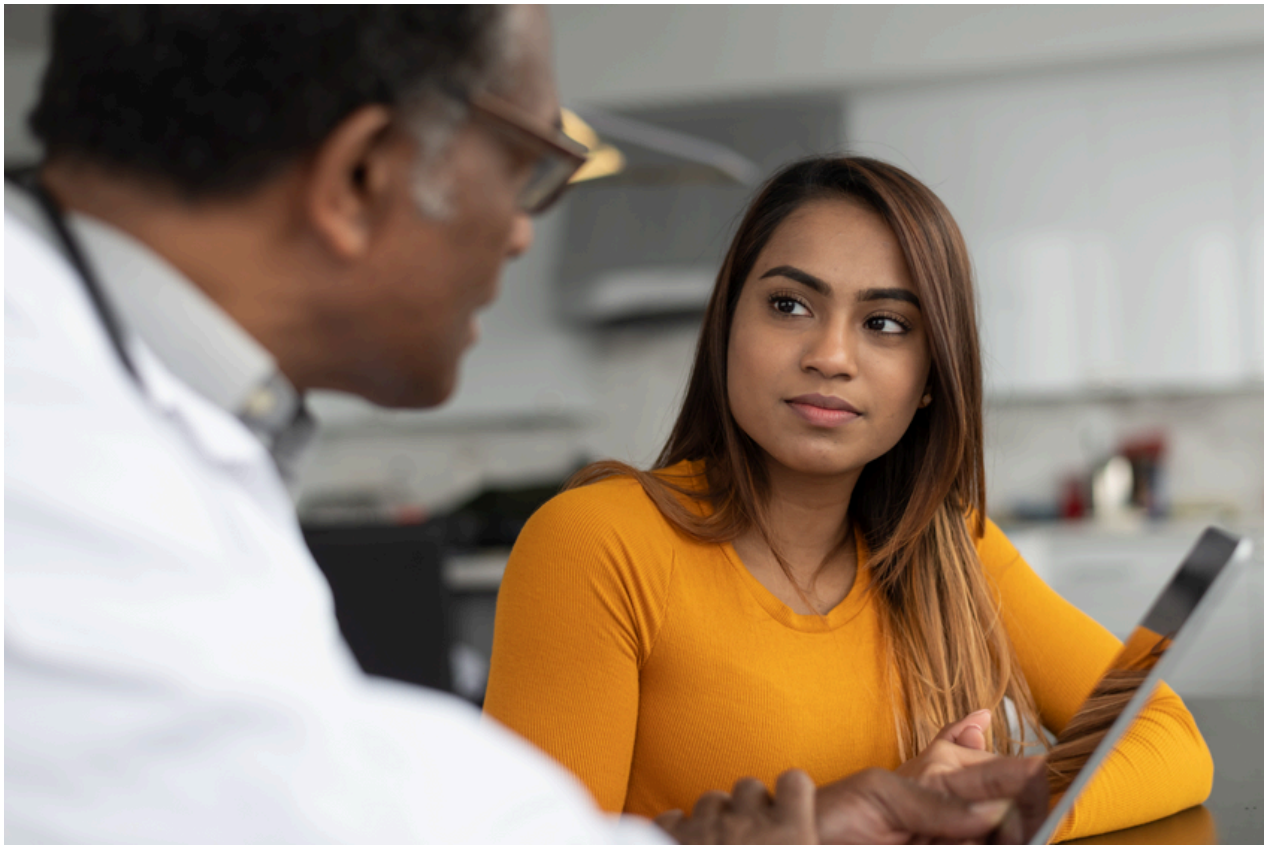
MAY 2025, V.1.0

RECRUITMENT INNOVATION CENTER

INFORMED CONSENT GUIDANCE MANUAL

Best Practices for Ensuring Comprehension and Obtaining Consent

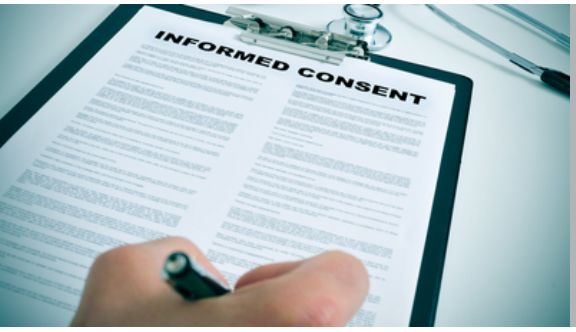


RECRUITMENT INNOVATION CENTER

TABLE OF CONTENTS

INTRODUCTION

The Recruitment Innovation Center (RIC) works in partnership with research teams to provide tailored support and guidance for study recruitment and retention. The **INFORMED CONSENT GUIDANCE MANUAL: Best Practices For Ensuring Comprehension and Obtaining Consent** resource was created to help researchers and study teams engage in a person-centered consent process to facilitate informed decision making about study participation. Research teams can use this educational resource to understand considerations for ensuring participant consent is informed and voluntarily given, apply strategies for supporting a person-centered consent process for empowered decision making, and identify supplemental resources for increasing comprehension during the consent process.



Disclaimer

Any information, methods, attachments, or templates provided in this guide must be approved by your institution's IRB before use.

Key to call out boxes

There are color-coded call out boxes throughout the toolkit to highlight recommendations and links to resources:

All yellow boxes include links to resources for engaging populations historically not engaged in research

All blue boxes include links to resources for increasing comprehension

Visit the **Trial Innovation Network** website to learn more about the RIC and the resources we offer.

ENGAGING STUDY PARTICIPANTS

Informed consent is the process by which individuals are given comprehensive information to make an informed decision about participating in a research study.

A **person-centered approach** is foundational to informed consent best practice. This approach involves meeting a person "where they are at." It places value and emphasis on the participant's perspective, autonomy, and unique life experience. It requires us to use inclusive and affirming language, including a participant's preferred terms, to show respect and build trust that is essential for the informed consent process.

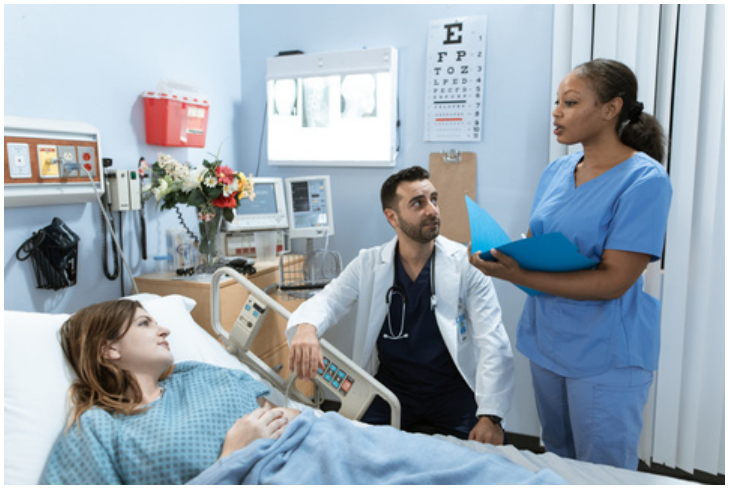
ARTICLE: Improving Informed Consent with Minority Participants: Results from Researcher and Community Surveys

ARTICLE: A systematic review of barriers and facilitators to minority research participation among African Americans, Latinos, Asian Americans, and Pacific Islanders

ARTICLE: Pre-consent education about research processes improved African Americans' willingness to participate in clinical research

Click on the topics below to learn more about considerations for a person-centered consent process

- Accessibility
- Cultural/community/religious values
- Demographics
- Educational attainment and/or learning style
- Employment status
- Experiencing homelessness
- Healthy literacy and numeracy
- Illness and/or illness severity
- Immigration status/acculturation level
- Preferred language
- Socioeconomic status



TOOL: Person-Centered Consent Process Reflection Checklist

ARTICLE: Building an Informed Consent Tool Starting with the Patient: The Patient-Centered Virtual Multimedia Interactive Informed Consent (VIC)

ENGAGING STUDY TEAMS

The informed consent process involves three key features: (1) disclosing to potential participants information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about research participation [DHHS, 2025]. Informed consent planning should incorporate considerations about the **study team members, their training, and available resources.**

Team Members

- **Personnel:** Do team members reflect the communities from which participants will be consented?
- **Team size:** Is this team size sufficient for the anticipated enrollment and frequency of informed consent?
- **Expertise:** Do team members have experience working with communities and populations that will be consented?
- **Availability:** Are there limits to team member availability (e.g., time of day that participants may be consented; weekend hours)?

Training

Has the Study Team received the following training:

- The study protocol and its requirements
- Consent best practices
- Meaningful engagement of research participants from all communities

Resources

- **Space:** Are there private, quiet environments available for consenting?
- **Materials development:** What materials can be developed to enhance the consent process based on the study population?
- **Technology:** Will eConsent be utilized (including integration of video/images, 'read to me' accessibility, document upload)

ENSURING COMPREHENSION

EFFECTIVELY COMMUNICATING HEALTH INFO

Comprehension in informed consent requires that the participants have the time and opportunity to read, understand, evaluate and consider the information being presented. We can increase comprehension by utilizing best practices to ensure health literacy.

health literacy / [helth lit·er·a·cy]

noun

1. The degree to which individuals have the capacity to obtain, process, and understand basic health information needed to make appropriate health decisions.

Source: healthy people 2030

Everyone is susceptible to limited health literacy at times. For example, anyone making a medical decision can be frightened, sleep-deprived, or feeling ill—all of which can reduce their ability to process information. **Health literacy universal precautions** are the steps taken when we assume that all patients may have difficulty comprehending health information. These include strategies to:

- **Improve SPOKEN Communication** with participants and confirm comprehension so that the risk of miscommunication is minimized
- **Improve WRITTEN Communication** to ensure written documents are easy to read and understand

The **Teach-Back method** is "a way of checking understanding by asking participants to state (in their own words) what they need to know or do about their health" [AHRQ Health Literacy Universal Precautions Toolkit, 2nd Edition]. After reviewing a section of the consent document, ask open-ended questions such as: who, what, when, where, and why to ensure comprehension. Watch this **video** for an example of the Teach-Back method.

AHRQ Resources to improve SPOKEN Communication

- **TOOL**: Communicate Clearly
- **TOOL**: Teach-Back Method

AHRQ Resources to improve WRITTEN Communication

- **TOOL**: Assess, Select, Create easy-to-understand materials
- **TOOL**: Use Health Education Materials Effectively

EFFECTIVELY COMMUNICATING NUMBERS

The ability to use and make sense of numbers is a required skill for study participants to be able to understand the risks of being in a clinical trial and carry out the necessary study activities, such as managing study medication doses over time, following study instructions, and adhering to the study schedule [MRCT Center, 2023]. Lacking this skill, people may not understand research options—an essential part of informed decision making. We can increase comprehension by utilizing best practices to ensure health numeracy.

health numeracy / [helth num·er·a·cy]

noun

1. the degree to which individuals have the capacity to access, process, interpret, communicate, and act on numerical, quantitative, graphical, biostatistical, and probabilistic health information needed to make effective health decisions.

Source: Golbeck, et al., 2005

Use numbers clearly to help participants make sense of numbers

Source: AHRQ SHARE Approach

- Provide estimated numbers (e.g., 1 out of every 2 people may develop a headache).
- Use frequencies instead of decimals or percentages (e.g., “18 out of 100” instead of “.18” or “18 percent”).
- Keep denominators and timeframes the same when you compare numbers.
- Present outcomes in both positive and negative terms. For example, say, "With this treatment, 2 out of 10 people get side effects, and 8 out of 10 people do not get side effects."
- Use the preferred measurement system of your patient (e.g., standard or metric). For example, say, "Would you like me to explain using ounces or grams?"

VIDEO: Using Metric Measurements in Healthcare | Workplace Essential Skills

TOOL: Conversion Calculator

EFFECTIVELY COMMUNICATING NUMBERS *continued*

Make numbers meaningful to help participants make choices and take actions

Source: AHRQ SHARE Approach

- Make unfamiliar data (e.g., test results) meaningful by providing context. Patients need to know not only a normal value versus an out-of-range result but also which out-of-range values require urgent attention and which do not
- Use everyday words to explain percentages (e.g., “49 percent is about half”).
- Do the math and perform the calculations for your participants.
- Use analogies and comparisons to familiar objects (e.g., "A gallstone can be as small as a grain of sand or as big as a golf ball”).
- Show pictures (e.g., use the Wong-Baker FACES pain scale rating to help patients communicate their level of pain).

Communicate risk with visual aids to help participants understand abstract mathematical concepts

Source: AHRQ SHARE Approach

- Pictographs to show ratios.
- Pie graphs to show ratios.
- Bar graphs to compare numbers.
- Line graphs to show change over time.

ARTICLE: Health Numeracy: Perspectives About Using Numbers in Health Management from African American Patients Receiving Dialysis

ARTICLE: Communicating complex numeric information in clinical research

RESEARCH SUMMARIES: Numeracy

TOOLS: Measuring Skills and Experiences

ARTICLE: Strategies to Enhance Numeracy Skills

VIDEO: Numeracy: Health Literacy and Clear Communication for Numbers and Statistics

LANGUAGE

U.S. Department of Health and Human Services (DHHS) regulations for the protection of human participants require that informed consent information be presented "in language understandable to the subject" and, in most situations, that informed consent be documented in writing (45 CFR §46.116 and §46.117). To be in accordance with regulations, "the written consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent. Subjects who do not speak English should be presented with a consent document written in a language understandable to them." We can increase comprehension by **utilizing interpreters** and modifying the informed consent document using translation and transcreation [DHHS, 2025].

translation / [tranz·LAY·shuhn]

verb

1. the activity or process of **changing the words** of one language into the words in another language that have the same meaning.e.

Source: Cambridge Dictionary

Best practices for translating words from one language to another:

- Ensure the original language consent form is written at a 5th grade level.
- Translate the original document into the preferred new language (e.g., from English into Spanish). This is called "forward translation".
- To check the content, another translator who has not seen the original version of the consent form translates it back into the original language (e.g., from Spanish back into English). This is called "back translation".
- Note: Some discrepancies identified in the back translation are not necessarily errors in translation - they may be different yet equivalent ways of saying the same thing.
- Conduct a careful comparison of the original and translated consent forms to reveal subtle but problematic issues to be addressed.
- Conduct cognitive testing of the translated materials with native speakers to assess comprehensibility, clearness, and cultural appropriateness.
- Final IRB approval of the translated informed consent document will be required prior to using it with study participants.

LANGUAGE *continued*

transcreation / [tranz·kree·AY·shuhn]

noun

1. a translation-related activity characterized by the **re-interpretation** of a message...while conveying the same style, tone, images and emotions from the source language to the target language, paying special attention to the cultural characteristics of the target audience.

Source: Díaz-Millóna and Olvera-Lobo, 2021

Best practices for transcreating content into a different language (translation) with the addition of something new (creation).

- Ensure the original English consent form is written at a 5th grade level.
- Transcreators should be fully bilingual and the target language should be their native language. This is a must in order to facilitate a quality Transcreation.
- Transcreators assess the content in a creative way, classifying the differences in language, culture, beliefs and behavior.
- The original content is then adapted to fit the target audience's needs and preferences. This may involve changing the consent form's tone, style, or structure.
- Once the transcreation is complete, it will need to be proofread and edited by a second native speaker to ensure accuracy.
- Final IRB approval of the transcreated informed consent document will be required prior to using it with study participants.

NOTE: When presenting translated and transcreated informed consent information to participants, working with a medical interpreter can help facilitate clear and comprehensible communication.

ARTICLE detailing a Transcreational framework for community-engaged behavioral interventions

CONSIDERATIONS FOR OBTAINING CONSENT

IN-PERSON CONSENT

Informed consent involves a detailed conversation between a participant and an informed research staff member who has been trained in all aspects of good clinical practice and best practices for informed consent. The informed consent document should be used as a tool to help guide the discussion and to document the responses, but the document itself should not be the only focus of informed consent. Considerations for performing **in-person** consent include:

Who?

- Are sufficient staff available on-site to consent potential individuals?
- Are investigators required to consent, or can consenting be done by coordinators?
- Are staff able to speak the language of the targeted population and perform a **culturally competent informed consent process?**

What?

- Are sufficient consenting materials ready and available for use by the study team?
- Are multiple copies needed for additional decision makers helping the participant?
- Are accessibility and resource provisions in place to accommodate the disabled and those who are hearing or visually impaired?

When?

- What hours and days are staff available to consent?
- How might this limit inclusion of potential participants in the consent process?
- Can staff be available off-hours to consent?
- Can consenting be scheduled ahead of time, or might consent be imminently required (e.g., critical care or emergency department study
- Have you planned for extra time to reengage the participant at a later date after they have had the chance to discuss the research with family and providers?

Where?

- Is there a private, quiet environment available for consenting?
- Are there private clinic or hospital rooms available?
- What happens if a participant and/or their decision-making team is in a public waiting room?

Why?

- For what reasons might obtaining informed consent in person be the best method for the participant and/or study team?
- Could/should this be done in conjunction with remote consenting?
- Does in-person consenting create any barriers?

CONSIDERATIONS FOR OBTAINING CONSENT

REMOTE CONSENT 

Technological platforms can streamline communication between study teams and participants and make electronic signing of the consent form possible. Remote and e-consent methods may differ depending on the study (e.g., telephone vs. video conferencing; sending documents via email vs. platforms). All consent methods are subject to institutional-specific regulatory requirements. Considerations for performing **remote consent** include:

Who?

- Are sufficient staff available to provide real-time communication for addressing participant questions?
- Are sufficient staff available on-site to address any tech issues (e.g., internet access; device compatibility)?
- Are staff able to speak the language of the targeted population and ensure a **culturally competent informed consent process** that is remote?

What?

- Is special training needed for remote or e-consent (e.g., data management or video platforms, special recruitment scripts?)
- Are there special tech considerations?
- What electronic/paper consenting materials need to be available?
- Are accessibility and resource provisions in place to accommodate the disabled and those who and hearing or visually impaired?

When?

- What hours/days are staff available to provide real-time communication for addressing participant questions?
- Can staff be available off hours?

Where?

- Are staff members consenting from the office, remotely, or both?
- Do staff and participants have access to private areas for discussion during the remote/e-consenting process?

Why?

- For what reasons might obtaining informed consent remotely be the best method for the participant and/or study team? Does remote consent create any barriers to participation (e.g., excluding less tech-savvy populations)?
- Can/should this process be done in conjunction with in-person consenting?

How?

- How is study staff connecting with participants (e.g., platforms)?
- What will be presented visually, verbally, sent to participant ahead of time?
- How will you perform identify verification?
- How will staff assess comprehension in the remote consent process?
- How will staff provide alternative consent options if technology fails?
- How might this limit inclusion of potential participants (e.g., the elderly)?

DECISIONAL CAPACITY

In addition to being adequately informed about a clinical trial, research participants must have the ability to make a decision about participating in a study without the influence, pressure, or coercion from others. Evaluating a prospective participant's ability to make an autonomous decision is crucial prior to obtaining informed consent.

decisional capacity / [duh·SIZH·uhn·uhl kuh·PASS·uh·tee]

noun

1.the ability of a potential research participant to understand and logically process the information that is necessary to make an informed decision regarding study participation.

Source: Biros, 2018

Decisional capacity is **study specific** and **situation specific**. A participant may have capacity to consent to a low-risk research protocol in usual circumstances, but not have the capacity to consent to a high-risk protocol or when under duress [UCSF HRPP, 2024] .

Reduced decisional capacity occurs when an individual lacks sufficient ability *at the time of consent* to make an informed decision. These individuals may require specific provisions during the informed consent process.

Investigators should work with the IRB to ensure that "additional safeguards have been included in the study to protect the rights and welfare" of all participants that are "likely to be vulnerable to coercion or undue influence." [DHHS, 2025].

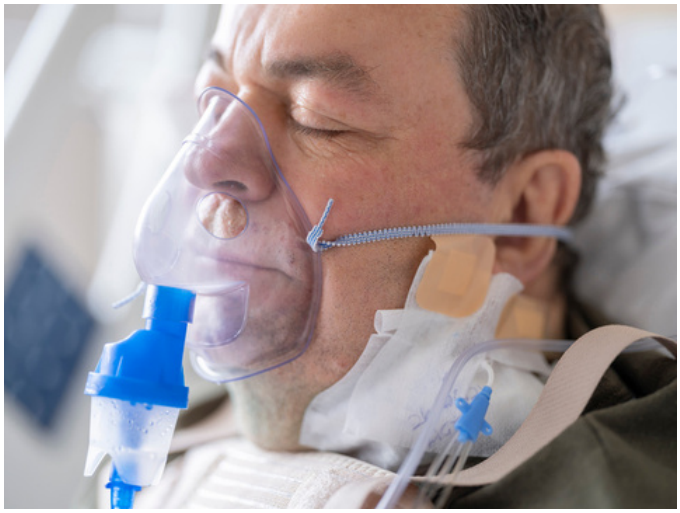
Some examples and considerations:

- **Individuals with short or long-term cognitive impairment**
  - *Consideration: Requires a surrogate or legally authorized representative*
- **Individuals are under 18 years of age (i.e., pediatric patients)**
  - *Consideration: Requires parental consent and child assent*
- **Individuals have diverse linguistic considerations**
  - *Consideration: Requires an interpreter and translated consent documents*

ARTICLE: Cultural Challenges to Engaging Patients in Shared Decision Making

DECISIONAL CAPACITY *continued*

Clinicians and study teams should **assess decisional capacity at all stages of the consent process** and subsequent study participation. Adjustments should be made accordingly.



Keep in Mind: Decisional capacity may fluctuate depending on circumstance. Some examples include:

- Individuals living with dementia
- Individuals living with mental disabilities
- Unconscious, recently sedated, or anesthetized individuals
- Individuals on a ventilator
- Pediatric participants who turn 18 during the course of study participation

NOTE: If a participant regains consciousness or recovers their capacity to understand the research study, the participant must be afforded the opportunity to consent for themselves.

ARTICLE detailing the methodological, structural, and systemic barriers to trial participation for adults lacking capacity to consent

ARTICLE detailing potential inequality and biases in the placement and outcomes of decisional capacity evaluations across races

ARTICLE detailing the preferences, needs, and challenges of Black American patients to enhance shared decision making

ARTICLE: The U-ARE Protocol: A Pragmatic Approach to Decisional Capacity Assessment for Clinical Research

TOOL: UCI Decision Making Capacity Assessment

ARTICLE: University of California, San Diego Brief Assessment of Capacity to Consent (UBACC)

ARTICLE: Capacity, Vulnerability, and Informed Consent for Research

LEGALLY AUTHORIZED REPRESENTATIVES

When potential participants do not have sufficient decisional capacity to consent to research, another person *may* have the ability to consent on their behalf. Federal regulations permit researchers to obtain consent from a legally-authorized representative (LAR) via a surrogate informed consent process and IRB approval (45 CFR 46.116, and 21 CFR 50.20(a)).

legally authorized representative (LAR)

noun

1. an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research (45 CFR 46.102(i)).

Source: Code of Federal Regulations

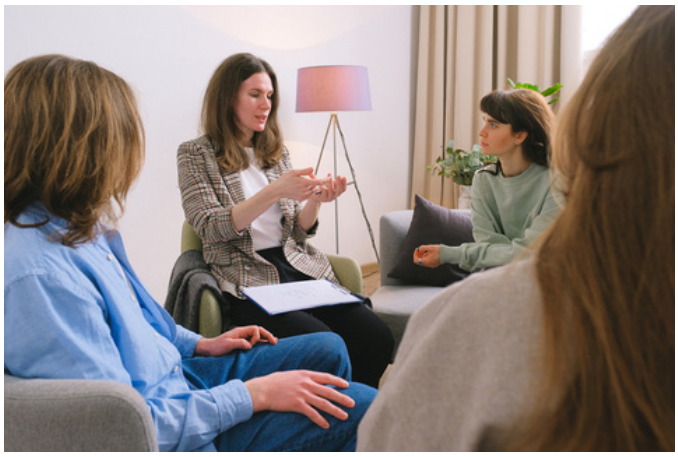
Per the U.S. Department of Health and Human Services (DHHS):
"The issue as to who can be an LAR is determined by the laws of the jurisdiction in which the research is conducted (e.g., local or state law). Some states have statutes, regulations, or common law that specifically address consent by someone other than the subject for participation in research." [DHHS, 2025]

If an adult lacks capacity to consent as a result of trauma, mental challenges, some forms of mental illness, dementia, etc. - whether temporary, progressive, or permanent - only a legally authorized representative for that adult can give consent for participation in the research, unless the requirement to obtain informed consent is waived by the IRB or in accordance with the provisions for emergency waiver [DHHS, 2025]

Should the subject regain or develop the capacity to consent, then his or her consent must be obtained for any further research, as the consent of the legally authorized representative is no longer valid.

LEGALLY AUTHORIZED REPRESENTATIVES *continued*

Having an **LAR** may affect the informed consent process, so it is best to check with the appropriate entities/institutions to ensure regulatory compliance. This distinction may affect necessary documents, needed signatures, and whether a witness is required.



Remember to allow extra time to re-engage LARs for consent after they have a chance to discuss the research with family.

When conceptualizing provisions for the informed consent process that may require LARs and/or surrogates, additional populations may include:

- Minors with children
- Children in the foster care system
- Individuals with a non-English speaking preference
- Older adults experiencing cognitive decline

Guidance for engaging LARs in the consent process:

VIDEO: How to help participants appoint an LAR

TOOL: Talking Points on Appointing a Legally Authorized Representative

TOOL: Note to file template to document participant's wishes regarding an LAR

ASSENT FOR PEDIATRIC PARTICIPANTS

By definition, children are unable to provide informed consent to participate in research, although they might be able to give their **assent** - an affirmative agreement to participate in research. This means the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. In addition to the child's assent, permission for the child to participate in research should be obtained by the parent(s) or legal guardian(s).

assent / [as·sent]

noun

1. a child's affirmative agreement to participate in research. Mere failure to object should not be construed as assent.

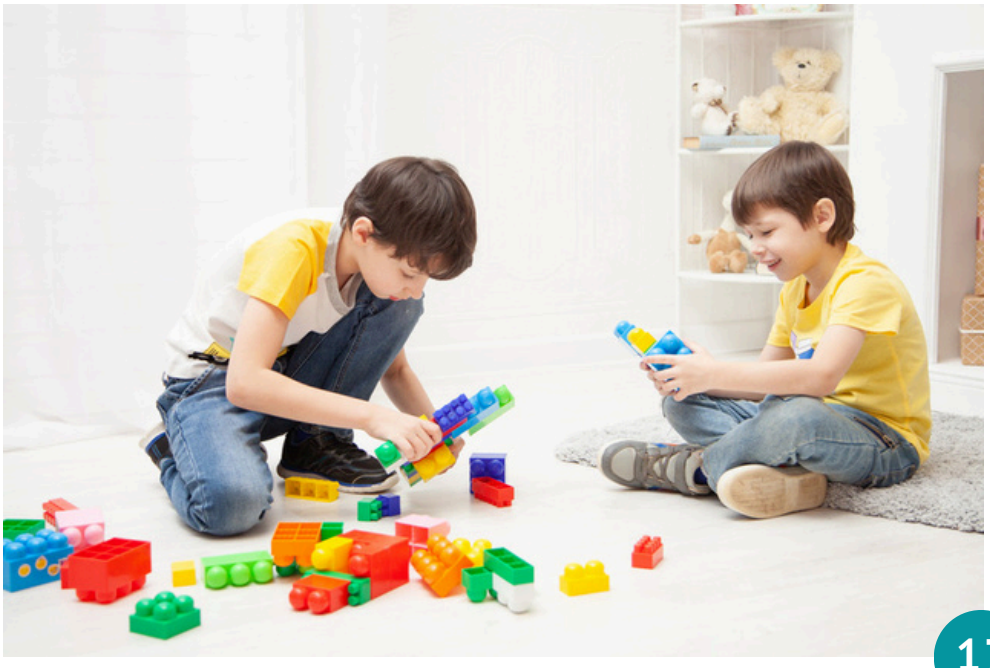
Source: (45 CFR 46.402(b)).

How do you define "children"?

- "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (45 CFR 46.402(a)).
- In the United States the legal age of adulthood is a matter of state and local law. This means that who is legally considered a child may vary from state to state

Do both parents need to provide permission for their child to participate in research?

In general, permission should be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

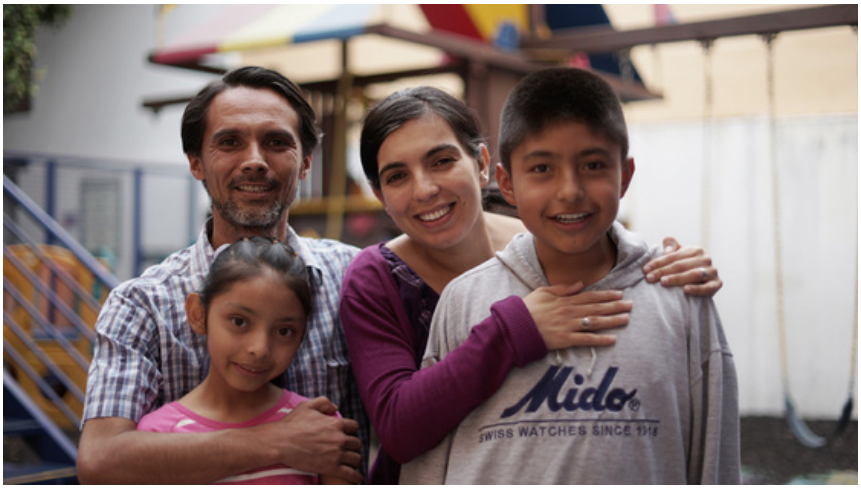


ASSENT FOR PEDIATRIC PARTICIPANTS *continued*

In general, one or both parents or a guardian must be provided with the information ordinarily required for informed consent, so that they may decide whether to allow the child to participate

How To Engage Parents/LARs

- Emphasize safety precautions, as applicable.
- Clearly explain the randomization process. This study design feature is a way to reduce parental guilt and responsibility if there are safety concerns.
- Educate nursing staff regarding the trial. Parents often seek advice from the bedside nursing staff (e.g. "What would you do if it was your child?")



How To Engage Children

- Utilize a Child Life Specialist whenever possible
- Use IRB-approved supplemental materials (e.g., videos, flip charts) to explain the study

Consent Strategies

- Consider mailing trial information in advance to allow parents time to consider the research and discuss it with family members and healthcare providers.
- Offer pre-recorded video testimonials from real parents who already consented to the research
- Offer a non-research related counseling session (can be virtual) as an additional benefit of trial participation
- Leave contact information in case there is a change of mind

ONGOING CONSENT

It is important to keep in mind that **ongoing consent** is an important part of the Informed Consent process. Study teams must continually assess their participants' willingness to participate in their trial. Researchers are responsible for providing, on an ongoing basis, any new information that has become known during the conduct of the study, especially if it relates to the study intervention or patients' rights, safety, and well-being and might be relevant to the subject's willingness to continue participation in trial.

The IRB may require re-consent of participants based on:

Altered Risk/Benefit Ratio
For participants ON study treatment: • Identification of new risks to individuals • Changes in standard of care that research participants cannot utilize while in the trial • Discovery of a life threatening or severely debilitating side effect For participants OFF study treatment, but with long term follow-up: • Identification of potential late-term effects for individuals
Changes to Study Visits/Procedures
• Additional monitoring procedures required • New instruments or questionnaires • Collection of new or different information from participants
Changes to Costs/Payments
• A drug previously paid for by the study must now be covered by insurance or the participant's personal funds • Payment for study participation is increased or decreased
Study Treatment Changes
• Dosing frequency changes • Route of administration changes

! The PI is responsible for assessing the potential impact on all current and previously enrolled participants. This assessment should be submitted to the IRB to determine if re-consent is necessary

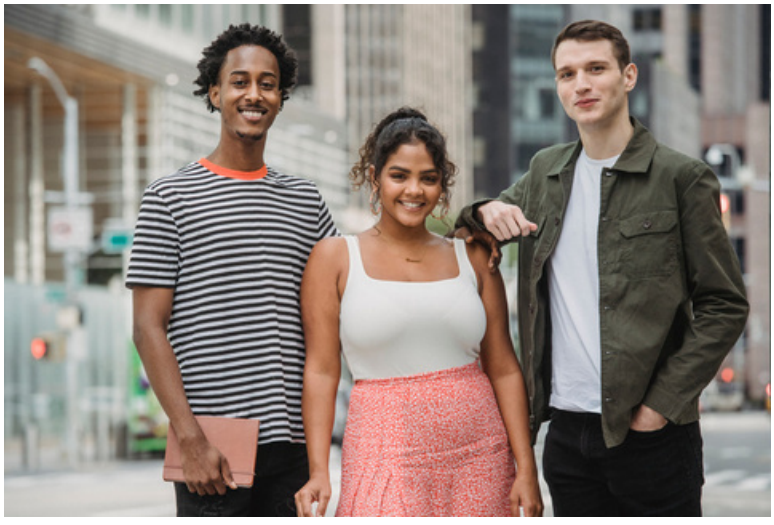
ONGOING CONSENT *continued*

Consenting pediatric participants when they turn 18

When minors turn 18, it is generally required that they be consented to continue their participation in research. In general, this looks like a new consent process, even if they are in the midst of participating.

Best Practice Considerations:

- How can a participant's age be tracked so that consent can be obtained when they turn 18?
- Keep in mind that subjects may not be actively participating in interventions when they turn 18, but they still may be part of a study (e.g., when data is being longitudinally collected).
- If patients are not actively coming into a clinic, consider what methods may be necessary to have in place to obtain consent (e.g., e-Consent, remote consenting processes, can they be seen a part of a separate clinic visit). It is important to consult with institutional policies and stakeholders to ensure proper procedure).
- Some institutions may require assent be obtained when a child turns 6 or 7.
- Ongoing consent should be in place regardless of minority or majority status.
- Consider how contact information will change for a participant once they turn 18.
- Consider that parents or guardians may still be an active part of the consent process for minors turning 18. While minors are required to consent, they may actively want to consult with others when considering their ongoing (or new!) participation in research.



"Free, Informed, and ongoing consent" is part of ethical research

Research Ethics Board: Consent process – Health Canada and Public Health Agency of Canada - Canada.ca

BROAD CONSENT

Under certain circumstances, your study team may opt to obtain broad consent for future, secondary research utilizing **identifiable** private information or biospecimens. Broad consent is **not** study specific and there are specific guidelines for obtaining this form of consent, as identified in 45 CFR §46.116(d).

broad consent / [brawd kuhn·sent]

noun

1. Consent for the storage, maintenance, and secondary use of **identifiable** private information or biospecimens in association with a current study for use in **future** research without having to re-consent the research participant (45 CFR 46.116(d).

Source: Code of Federal Regulations

To utilize Broad Consent, the consent form document must include:

- A description of the types of secondary research that may be conducted
- Statements describing the private information or biospecimens that might be used in research, whether sharing of the information or biospecimens might occur, and the types of institutions or researchers that might conduct research with the information or biospecimens
- Information on how long the information or biospecimens may be stored, maintained, and used
- A statement that subjects will or will not be informed of the details of any subsequent research
- A statement that research results will or will not be disclosed to subjects
- Contact information for obtaining answers to questions about the subjects' rights regarding storage and use of information or biospecimens and whom to contact regarding research-related harm

The use of broad consent requires the researcher to maintain records of which research subjects gave broad consent and which ones declined.

Broad consent is *not* required if the researcher plans to maintain ***deidentified***, anonymous information or biospecimens for possible secondary research

BROAD CONSENT *continued*

There are some <u>limitations</u> for the use of Broad Consent:

- Broad consent cannot be used for **primary** research (research involving an interaction or intervention with the research subject).
- Broad consent is strictly limited to secondary research (research conducted using data or specimens that were collected or obtained in prior research).
- Broad consent cannot be used for materials collected for non-research purposes (e.g., specimens that are left over from routine clinical diagnosis or treatment).
- Broad consent is limited to research involving identifiable private information or biospecimens
- Broad consent is not available for research that is not human subjects research
- If a research subject declines to give broad consent, the IRB cannot subsequently grant a waiver of consent

ARTICLE: A systematic literature review of individuals' perspectives on broad consent and data sharing in the United States

ARTICLE: Assessing Perceptions of Broad Consent Concerning Biological Specimen Collection in a Cohort of Young Sexual Minority Men

GUIDANCE: Attachment C - Recommendations for Broad Consent Guidance | HHS.gov)

GUIDANCE: Attachment D - Recommendations for a Broad Consent Template

ARTICLE: Understanding Broad Consent

ARTICLE: Gettysburg College: Broad Consent

SHORT FORMS FOR NON-ENGLISH SPEAKERS

Short forms are utilized when an investigator unexpectedly encounters a non-English speaking, potential research participant but has not had the IRB-approved Informed Consent Document (ICD) translated into a language understandable to the individual.

A short form consent document attests that the elements of informed consent, as required by DHHS and the FDA [21 CFR 50.25], have been presented **orally** to either the participant or the participant's legally authorized representative [LAR]. The short form does **not** contain specific study information. Therefore, it is used in conjunction with an **oral presentation** of the IRB-approved English version of the Informed Consent Document (ICD), in a language understandable to the potential subject [University of Iowa HRPP, 2024]

Generally, the short form process may be used **twice** for a particular language in a study. After the second use of the short form consent process, the informed consent document must be translated into that particular language as it can be anticipated you will encounter additional potential participants that understand that language.

To utilize a short form consent process, the investigator must:

- Utilize an IRB-approved written summary of what will orally be said to the participant or LAR.
- Utilize an IRB-approved short form document that will be signed by the potential participant.
- Have confirmation that:
  - The oral presentation will be conducted in the participant's language.
  - The person obtaining consent is authorized by the IRB.
  - There will be a witness to the oral presentation fluent in both English and the language of the participant.
  - The short form will be signed by the participant and the witness.
  - The written summary will be signed by the witness and the person actually obtaining consent.
  - A copy of the oral summary and the short form will be given to the participant.

TOOL: NIH approved Short Form Consent Templates [English and 40+ other languages]

MULTI-SITE (2-PART) CONSENT FORMS

For multi-site studies where the research is taking place at several different locations, a study team might utilize a two part consent form: Part 1 of the document includes information that applies to all study sites. Part 2 of the consent form includes information specific to the study site where the participant is being asked to enroll.

Part 1 of the Consent Form	Part 2 of the Consent Form
General language describing the study information, study procedures, duration, risks and benefits, Certificate of Confidentiality (if applicable), etc. Part 1 is used by all sites and cannot be modified by the participating sites Part 1 language may be separately reviewed/approved by the Single IRB (SIRB) along with the initial study application if desired.	Local language describing site-specific procedures and risks; compensation information; costs to take part; local contact information; any state law requirements; Local conflict of interest disclosures; Confidentiality language for how records and data/specimens will be stored and maintained and who will have access; locally required HIPAA language, etc. **Key point:** Any SITE-specific information changes to Part 2 of the consent form have to be approved by the local Human Research Protections Program and main IRB

NOTE: Part 2 of the Consent Form should be completed for each participating site AFTER the IRB has approved Part 1 of the template for the study.

ARTICLE: Consent Builder: an innovative tool for creating research informed consent documents

SUPPLEMENTAL RESOURCES

Concise Summary Templates

A one-page concise summary template to present the key information that is most likely to assist a prospective participant in understanding the reasons why one might or might not want to participate in the research. ·Refer to the free Informed Consent Concise Summary template included in the Trial Innovation Network (TIN) Informed Consent Toolkit.

Videos

Videos can be a useful tool in conjunction with the informed consent discussion to educate potential participants about the trial. Videos can add an engaging and visual element to the discussion, and use different faces, voices, and animation to help explain the study for its intended audience. We recommend working with a professional communications team to oversee the process, and the use of a professional videographer who can use ideal lighting, camera positioning and editing techniques to make the video as effective as possible.

Refer to the NIH's Elements of a Successful Informed Consent Video for an example of a clinical investigator and a potential research participant engaged in an informed consent discussion about a clinical research protocol. A narrator introduces the required elements of an effective informed consent discussion and makes communication and contextual recommendations.

Infographics

Infographics are a method of visually communicating information in an engaging, colorful, and concise manner. When infographics are used to communicate important study information during the informed consent process, it can improve participant understanding and enhance their decision-making capabilities.

Refer to the peer reviewed publication, Infographics: Healthcare Communication for the Digital Age for information on different infographic formats and how they may be used to communicate healthcare information.

Utilize Canva's free online infographic maker to create visually striking infographics

Discussion Scripts

Preparing an oral consent script in advance can help make sure that participants are provided with the information they need in order to make an informed decision about participating. The Informed Consent Discussion Script template may be used as a starting point but should be modified so that it is appropriate to the nature and context of the research.

SUPPLEMENTAL RESOURCES *continued*

Websites and Applications

REDCap-based eConsent is an electronic consenting resource that provides research participants with the ability to rapidly review and sign consent documentation via web, tablet or smartphone. Features can be programmed to enhance participant engagement and understanding, including 'read it to me' accessibility options; triggers for 'help needed' events; 'wet' signatures; document upload; and camera integration for photos and images. This resource is available to all REDCap users who enable the eConsent Framework.

iConsent is a web-based platform that can be utilized to improve participant knowledge, satisfaction, and clarity of information. The platform provides frameworks for investigators to customize for any study utilizing interactive techniques within a user-friendly human-computer interface that works on any electronic device (i.e., smartphones, computers, tablets). Some key features include use of visual imagery to reinforce text, audio recorded text, infographics, and teach-back questions. This resource is available through consultation with University of Utah Trial Innovation Center.Contact Mary Pautler at mary.pautler@hsc.uta.edu

Consent Builder is a web-based tool used by study teams to aggregate study information and compile the data to produce a high-quality informed consent document in PDF format. Consent language is collected via a web-based survey and consent forms are generated with the click of a button. This resource is available through consultation with University of Utah Trial Innovation Center. Contact Mary Pautler at mary.pautler@hsc.uta.edu

RIC BEST PRACTICES FOR INFORMED CONSENT

CONSENT PROCESS CHECKLIST

ENVIRONMENT

I have considered:

- ☐ Consent is occurring in a private, non-threatening place
- ☐ Any family/friends are included as desired by the participant

PARTICIPANT'S NEEDS

I have considered:

- ☐ Learning style
- ☐ Language facility
- ☐ Education Level
- ☐ Health Literacy
- ☐ Interest in learning as much as possible
- ☐ Comfort with numbers/probabilities
- ☐ Disabilities that may hinder the ICP
- ☐ Providing as much time as needed for the participant to review the ICF

PURPOSE & KEY POINTS

I have described:

- ☐ Purpose of the research
- ☐ All research procedures (including any that are experimental)
- ☐ Duration of participation
- ☐ Any forseeable risks/discomforts
- ☐ Any potential benefits to participants or others
- ☐ Compensation for research-related injury
- ☐ Additional costs to to participant for study participation
- ☐ Voluntary nature of participation
- ☐ Confidentiality of records
- ☐ Available alternative treatments
- ☐ Who to contact for questions/injury
- ☐ Reasons for terminating participation by research team
- ☐ Options for, and consequences of, research participation withdrawal

CONSENT AND RECRUITMENT MATERIALS CHECKLIST

PACKET CONTENTS

- ☐ Patient specific appointment information with Study Participant ID noted
- ☐ Participant Screening and Consent Script
- ☐ Screening Informed Consent document, if needed
- ☐ Informed Consent (2 copies of most currently approved/STAMPED VERSION)
- ☐ Contact Information Preference Form
- ☐ Baseline instruments - paper copy or electronic bookmark
- ☐ Gift Card or electronic request form, as applicable
- ☐ Gift Card Distribution Receipt, as applicable
- ☐ Study materials Packet
- ☐ Pen and Paper
- ☐ Laptop/tablet/device and charger
- ☐ Copier access codes for printing electronically signed consent

DOCUMENTATION AND STUDY REMINDERS

- ☐ Complete screening/enrollment tracking documentation
- ☐ Document participant name, date and study participant ID on all forms
- ☐ Document that no study procedures were performed prior to consent
- ☐ Verification that the study participant meets all eligibility/exclusion criteria
- ☐ Comprehension of consent confirmed and documented
- ☐ Complete any randomization reports
- ☐ Scan copy of gift cards distributed
- ☐ A copy of the signed and dated consent was given to the study participant
- ☐ Retain and file any original study documentation

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