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RECRUITMENT INNOVATION CENTER

INFORMED CONSENT GUIDANCE MANUAL

Best Practices for Ensuring Comprehension
and Obtaining Consent



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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.



BEST PRACTICES

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/acclimation 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)

BEST PRACTICES

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

ENSURING COMPREHENSION

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

ENSURING COMPREHENSION

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

ENSURING COMPREHENSION

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.

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 are 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 identity 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*



CONSIDERATIONS FOR OBTAINING CONSENT

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

CONSIDERATIONS FOR OBTAINING CONSENT

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.

CONSIDERATIONS FOR OBTAINING CONSENT

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

CONSIDERATIONS FOR OBTAINING CONSENT

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.



CONSIDERATIONS FOR OBTAINING CONSENT

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

CONSIDERATIONS FOR OBTAINING CONSENT

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](https://www.canada.ca)

CONSIDERATIONS FOR OBTAINING CONSENT

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

CONSIDERATIONS FOR OBTAINING CONSENT

BROAD CONSENT *continued*

There are some limitations 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

TYPES OF CONSENT FORMS

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]

TYPES OF CONSENT FORMS

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

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.

Part 2 of the Consent Form

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 foreseeable 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

RIC BEST PRACTICES FOR INFORMED CONSENT

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

CITATIONS

Abujarad F, Alfano S, Bright TJ, Kanno S, Grant N, Gueble M, Peduzzi P, Chupp G. Building an Informed Consent Tool Starting with the Patient: The Patient-Centered Virtual Multimedia Interactive Informed Consent (VIC). AMIA Annu Symp Proc. 2018 Apr 16;2017:374-383. PMID: 29854101; PMCID: PMC5977640.

ACRP. Patient-Centered Consent Process. <https://www.acrpnet.org/wp-content/uploads/2017/08/job-aids.pdf>

AHRQ Health Literacy Universal Precautions Toolkit. Content last reviewed June 2024. Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/healthlittoolkit2_tool5.pdf

AHRQ. The SHARE Approach: Communicating Numbers to Your Patients. <https://www.ahrq.gov/sdm/share-approach/index.html> AHRQ Pub. No. 25-0005-4-EF October 2024

Assess, Select, and Create Easy-to-Understand Materials: Tool 11. Content last reviewed April 2024. Agency for Healthcare Research and Quality, Rockville, MD. <https://www.ahrq.gov/health-literacy/improve/precautions/tool11.html>

Barata PC, Gucciardi E, Ahmad F, and Stewart DE. Cross-cultural perspectives on research participation and informed consent. Social Science & Medicine, Volume 62, Issue 2, 2006, Pages 479-490, ISSN 0277-9536, <https://doi.org/10.1016/j.socscimed.2005.06.012>

Bierer BE and Baedorf Kassis S (2023) Communicating complex numeric information in clinical research. Front. Commun. 8:1096271. doi: 10.3389/fcomm.2023.1096271

Biros M. Capacity, Vulnerability, and Informed Consent for Research. J Law Med Ethics. 2018 Mar;46(1):72-78. doi: 10.1177/1073110518766021. Epub 2018 Mar 27. PMID: 29991882; PMCID: PMC6035898.

Cambridge University Press & Assessment 2025. <https://dictionary.cambridge.org/dictionary/english/translation>

Centers for Disease Control and Prevention. Measuring Skills and Experiences. October 16, 2024 <https://www.cdc.gov/health-literacy/php/research-summaries/numeracy.html>

Centers for Disease Control and Prevention. Numeracy. October 16, 2024 <https://www.cdc.gov/health-literacy/php/research-summaries/numeracy.html>

Common Medical Conversions. Drugs.com. 2022. <https://www.drugs.com/article/measurement-conversions.html>

Communicate Clearly: Tool 4. Content last reviewed April 2024. Agency for Healthcare Research and Quality, Rockville, MD. <https://www.ahrq.gov/health-literacy/improve/precautions/tool4.html>

CITATIONS

Consent Builder. University of Utah. Accessed March 2025.

<https://medicine.utah.edu/pediatrics/research/data-resource-center/areas-of-support/consent-builder>

Considerations for Recruiting, Engaging, and Retaining People Experiencing Homelessness in Clinicals Trials. <https://trialinnovationnetwork.org/wp-content/plugins/artifact-library/dl-file.php?artifact-file-id=303>

Cook SH, Wood EP, Jaiswal J, Castro R, Calderon L, Qi Y, Llaneza A. Assessing Perceptions of Broad Consent Concerning Biological Specimen Collection in a Cohort of Young Sexual Minority Men. *Arch Sex Behav*. 2021 Oct;50(7):3313-3321. doi: 10.1007/s10508-021-01964-3. Epub 2021 Oct 6. PMID: 34617188; PMCID: PMC8493942

Culturally competent informed consent. Video. Trial Innovation Network. 2024.

<https://www.youtube.com/watch?v=hOw4VwS8tq4>

Díaz-Millón, M., & Olvera-Lobo, M. D. (2021). Towards a definition of transcreation: a systematic literature review. *Perspectives*, 31(2), 347–364. <https://doi.org/10.1080/0907676X.2021.2004177>

Dunlop AL, Leroy ZC, Logue KM, Glanz K, Dunlop BW. Preconsent education about research processes improved African Americans' willingness to participate in clinical research. *J Clin Epidemiol*. 2011 Aug;64(8):872-7. doi: 10.1016/j.jclinepi.2010.11.008. Epub 2011 Feb 17. PMID: 21330104; PMCID: PMC4108901.

Electronic Code of Federal Regulations. 21 CFR 50.25 - Elements of informed consent. <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50/subpart-B/section-50.25>

Electronic Code of Federal Regulations. 46.116 General requirements for informed consent. 2025. <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.116>

Electronic Code of Federal Regulations. Part 46 – Protection of Human Subjects. 2025. <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46>

Faster Together, Enhancing the Recruitment of Marginalized Communities in Clinical Trials. *Addressing health literacy needs in the informed consent document*. <https://www.coursera.org/learn/faster-together-recruitment/supplement/TFaHg/addressing-health-literacy-needs-in-the-informed-consent-document>

Faster Together, Enhancing the Recruitment of Marginalized Communities in Clinical Trials. *Incorporating language preferences in informed consent*. <https://www.coursera.org/learn/faster-together-recruitment/supplement/TZl4f/incorporating-language-preferences-in-informed-consent>

Faster Together, Enhancing the Recruitment of Marginalized Communities in Clinical Trials. *Managing a person-centered consent process*. <https://www.coursera.org/learn/faster-together-recruitment/lecture/1GEwN/managing-an-effective-person-centered-consent-process>

Faster Together, Enhancing the Recruitment of Marginalized Communities in Clinical Trials. *Working with an interpreter*. <https://www.coursera.org/learn/faster-together-recruitment/supplement/pkcPz/working-with-an-interpreter>

CITATIONS

Garrett, W., Verma, A., Thomas, D., Appel, J., and Mirza, O. "Racial Disparities in Psychiatric Decisional Capacity Consultations." *Psychiatric Services*. 2023 Jan 1;74(1):10-16. doi: 10.1176/appi.ps.202100685. Epub 2022 Aug 25. PMID: 36004436.

Garrison, Nanibaa'A., Nila A. Sathe, Armand H. Matheny Antommara, Ingrid A. Holm, Saskia C. Sanderson, Maureen E. Smith, Melissa L. McPheeters, and Ellen W. Clayton. "A Systematic Literature Review of Individuals' Perspectives on Broad Consent and Data Sharing in the United States." *Genetics in Medicine* 18, no. 7 (July 1, 2016): 663–71. <https://doi.org/10.1038/gim.2015.138>.

Gettysburg College. Broad Consent. <https://www.gettysburg.edu/offices/provost/irb/broad-consent>

George S, Duran N, Norris K. A systematic review of barriers and facilitators to minority research participation among African Americans, Latinos, Asian Americans, and Pacific Islanders. *Am J Public Health*. 2014 Feb;104(2):e16-31. doi: 10.2105/AJPH.2013.301706. Epub 2013 Dec 12. PMID: 24328648; PMCID: PMC3935672.

Golbeck, Amanda L., Carolyn R. Ahlers-Schmidt, Angelia M. Paschal, and S. Edwards Dismuke. "A Definition and Operational Framework for Health Numeracy." *American Journal of Preventive Medicine* 29, no. 4 (2005): 375–76. <https://doi.org/10.1016/j.amepre.2005.06.012>.

Government of Canada. Research Ethics Board: Consent Process. May 2024. <https://www.canada.ca/en/health-canada/services/science-research/science-advice-decision-making/research-ethics-board/consent-process.html>

Hamilton RKB, Phelan CH, Chin NA, Wyman MF, Lambrou N, Cobb N, Kind AJH, Blazel H, Asthana S, Gleason CE. The U-ARE Protocol: A Pragmatic Approach to Decisional Capacity Assessment for Clinical Research. *J Alzheimers Dis*. 2020;73(2):431-442. doi: 10.3233/JAD-190457. PMID: 31868663; PMCID: PMC7388558.

Hawley ST, Morris AM. Cultural challenges to engaging patients in shared decision making. *Patient Educ Couns*. 2017 Jan;100(1):18-24. doi: 10.1016/j.pec.2016.07.008. Epub 2016 Jul 4. PMID: 27461943; PMCID: PMC5164843.

Jeste, Dilip V., Barton W. Palmer, Paul S. Appelbaum, Shahrokh Golshan, Danielle Glorioso, Laura B. Dunn, Kathleen Kim, Thomas Meeks, and Helena C. Kraemer. "A New Brief Instrument for Assessing Decisional Capacity for Clinical Research." *Archives of General Psychiatry* 64, no. 8 (August 1, 2007): 966–74. <https://doi.org/10.1001/archpsyc.64.8.966>.

Kim, J.Y., Florez, M., Botto, E. et al. The influence of socioeconomic status on individual attitudes and experience with clinical trials. *Commun Med* 4, 172 (2024). <https://doi.org/10.1038/s43856-024-00586-9>

Maloy JW, Bass PF 3rd. Understanding Broad Consent. *Ochsner J*. 2020 Spring;20(1):81-86. doi: 10.31486/toj.19.0088. PMID: 32284687; PMCID: PMC7122261.

McCrorie AD, Donnelly C, McGlade KJ. Infographics: Healthcare Communication for the Digital Age. *Ulster Med J*. 2016;85(2):71-75.

MRCTcenter.org: <https://mrctcenter.org/health-literacy/tools/overview/numeracy/>

CITATIONS

Nápoles, A.M., Stewart, A.L. Transcreation: an implementation science framework for community-engaged behavioral interventions to reduce health disparities. *BMC Health Serv Res* 18, 710 (2018). <https://doi.org/10.1186/s12913-018-3521-z>

National Institutes of Health Office of Intramural Research. Office of Human Subjects Research Protections. "Consent of Non-English Speaking Persons." <https://irbo.nih.gov/confluence/display/ohsrp/Consent+of+Non-English+Speaking+Persons>

Numeracy: Health Literacy and Clear Communication for Numbers and Statistics, July 25, 2018. <https://www.youtube.com/watch?v=cJnZuip8IY0>

Office Apps Live. Sample Note to File. https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fconsenttools.org%2Fwp-content%2Fuploads%2F2020%2F11%2FSample-Note-to-File_LARs.doc&wdOrigin=BROWSELINK

Paramasivam A, Jaiswal A, Minhas R, Wittich W, Spruyt-Rocks R. Informed Consent or Assent Strategies for Research With Individuals With Deafblindness or Dual Sensory Impairment: A Scoping Review. *Arch Rehabil Res Clin Transl*. 2021 Feb 22;3(2):100115. doi: 10.1016/j.arrct.2021.100115. PMID: 34179751; PMCID: PMC8212005.

Pleasant, A., M. Rooney, C. O'Leary, L. Myers, and R. Rudd. 2016. Strategies to Enhance Numeracy Skills. NAM Perspectives. Discussion Paper, National Academy of Medicine, Washington, DC. University of Iowa Human Subjects Office. Human research Protection Program (HRPP). <https://hso.research.uiowa.edu/get-started/human-research-protection-program-hrpp>

Quinn SC, Garza MA, Butler J, Fryer CS, Casper ET, Thomas SB, Barnard D, Kim KH. Improving informed consent with minority participants: results from researcher and community surveys. *J Empir Res Hum Res Ethics*. 2012 Dec;7(5):44-55. doi: 10.1525/jer.2012.7.5.44. PMID: 23324203; PMCID: PMC3685140.

Sankary LR, Zelinsky ME, Ford PJ, Blackstone EC, Fox RJ. Overcoming barriers to informed consent in neurological research: Perspectives from a national survey. *Res Ethics*. 2023 Jan;19(1):42-61. doi: 10.1177/17470161221131497. Epub 2022 Oct 30. PMID: 37901309; PMCID: PMC10609656.

Schaeffer MH, Krantz DS, Wichman A, Masur H, Reed E, and Vinicky JK. The impact of disease severity on the informed consent process in clinical research. *The American Journal of Medicine*. March 1996. Volume 100, Issue 3, p261-268. doi: 10.1016/S0002-9343(97)89483-1

Shepherd, Victoria. "An Under-Represented and Underserved Population in Trials: Methodological, Structural, and Systemic Barriers to the Inclusion of Adults Lacking Capacity to Consent." *Trials* 21, no. 1 (May 29, 2020): 445.

Sward KA, Enriquez R, Burr J, et al. Consent Builder: an innovative tool for creating research informed consent documents. *JAMIA Open*. 2022;5(3):ooac069. Published 2022 Jul 27. doi:10.1093/jamiaopen/ooac069

Teach-Back: culturally competent informed consent. Video. Trial Innovation Network. 2024. <https://www.youtube.com/watch?v=kfzNPL5yWdC>

CITATIONS

The Informed Consent Process for Adults with Intellectual and Developmental Disabilities.
<https://trialinnovationnetwork.org/wp-content/plugins/artifact-library/dl-file.php?artifact-file-id=338>

The Role of Medical Interpreters in the Informed Consent Process. Acutrans. February 22, 2024.
<https://acutrans.com/the-role-of-medical-interpreters-in-the-informed-consent-process/>

Trial Innovation Network. <https://trialinnovationnetwork.org/>

Trial Innovation Network: Informed Consent Toolkit. <https://trialinnovationnetwork.org/tin-toolbox/>

University of California Irvine (UCI) Office of Research. Decision Making Capacity Assessment Tool. July 2022. University of Iowa Human Subjects Office. Human research Protection Program (HRPP).
<https://hso.research.uiowa.edu/get-started/human-research-protection-program-hrpp>

University of California San Francisco (UCSF) Human Research Protection Program. Enrolling Individuals with Cognitive Impairments and Assessing Decisional Capacity. September 2023

University of Iowa Human Subjects Office. Human research Protection Program (HRPP).
<https://hso.research.uiowa.edu/get-started/human-research-protection-program-hrpp>

U.S. Department of Health and Human Services (DHHS). 21 CFR 50.20(a).
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm>

U.S. Department of Health and Human Services (DHHS). 45 CFR 46.102.
<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.102>

U.S. Department of Health and Human Services (DHHS). 45 CFR 46.116.
<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.402>

U.S. Department of Health and Human Services (DHHS). 45 CFR 46.402(a).
<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.402>

U.S. Department of Health and Human Services (DHHS). Informed Consent FAQs. 2025.
<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html>

U.S. Department of Health and Human Services (DHHS). Office of Disease Prevention and Health Promotion. Healthy People 2030. Health Literacy. <https://odphp.health.gov/healthypeople/priority-areas/social-determinants-health/literature-summaries/health-literacy>

U.S. Department of Health and Human Services (DHHS). Subpart D — Additional Protections for Children Involved as Subjects in Research. <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html>

U.S. Department of Health and Human Services (DHHS). The Secretary's Advisory Committee on Human Research Protections (SACHRP) Attachment C-Recommendations for Broad Consent Guidance. <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-c-august-2-2017/index.html>

CITATIONS

Use Health Education Material Effectively: Tool 12. Content last reviewed February 2024. Agency for Healthcare Research and Quality, Rockville, MD. <https://www.ahrq.gov/health-literacy/improve/precautions/tool12.html>

Use the Teach-Back Method: Tool 5. Content last reviewed April 2024. Agency for Healthcare Research and Quality, Rockville, MD. <https://www.ahrq.gov/health-literacy/improve/precautions/tool5.html>

Using Metric Measurements in Healthcare | Workplace Essential Skills. Video. KET Adult Education Classroom Resources. 2024. <https://tn.pbslearningmedia.org/resource/ket-workready-33/using-metric-measurements-in-healthcare-video-workplace-essential-skills/>

Van Schaik P, Renaud KV. Gauging the Unemployed's Perceptions of Online Consent Forms. Proceedings of the 57th Hawaii International Conference on System Sciences. 2024. <https://scholarspace.manoa.hawaii.edu/bitstreams/72bbcba3-1924-4c76-8feb-69bfe4ad9f70/download>

Vanderbilt University Medical Center REDCap. Informed Consent Discussion Script Template. <https://redcap.vumc.org/surveys/?s=C7A83EKC8N8JEW7>

Wagner JK. Ethical and Legal Considerations for the Inclusion of Underserved and Underrepresented Immigrant Populations in Precision Health and Genomic Research in the United States. *Ethn Dis*. 2019 Dec 12;29(Suppl 3):641-650. doi: 10.18865/ed.29.S3.641. PMID: 31889769; PMCID: PMC6919971.

Washington University in St. Louis School of Medicine. ConsentTools. 2024. <https://consenttools.org/>

Washington University in St. Louis School of Medicine. Talking Points on Appointing a Legally Authorized Representative. <https://consenttools.org/wp-content/uploads/2020/11/Talking-points-on-Appointing-an-LAR.pdf>

Wong-Baker FACES Pain Scale. Wong-Baker FACES Foundation. 1983. www.WongBakerFACES.org

Wright Nunes, Julie A., Chandra Y. Osborn, T. Alp Ikizler, and Kerri L. Cavanaugh. "Health Numeracy: Perspectives about Using Numbers in Health Management from African American Patients Receiving Dialysis." *Hemodialysis International* 19, no. 2 (2015): 287–95. <https://doi.org/10.1111/hdi.12239>.

YouTube: How to Help Participants Appoint an LAR. October 2022. <https://www.youtube.com/watch?v=A6WuPk28kOE>

Zisman-Ilani, Yaara, Shely Khaikin, Margot L. Savoy, Anuradha Paranjape, Daniel J. Rubin, Regina Jacob, Thomas H. Wieringa, et al. "Disparities in Shared Decision-Making Research and Practice: The Case for Black American Patients." *The Annals of Family Medicine* 21, no. 2 (March 1, 2023): 112. <https://doi.org/10.1370/afm.2943>.