VANDERBILT KENNEDY CENTER

The Informed Consent Process for Adults with Intellectual and Developmental Disabilities

The purpose of this toolkit is to present ways for you to better include individuals with intellectual and developmental disabilities (IDD) in research. It provides strategies to make the informed consent process go more smoothly for your participants with IDD.

Individuals with IDD are often excluded from health-related research. Exclusion from research leads to reduced quality of health care and unknown treatment effectiveness. One of the often-perceived barriers to inclusion of research participants with IDD is the informed consent process. Through this toolkit we aim to provide strategies to make this an easier and more successful process for you as the researcher and your participants with IDD.

↘ What are Intellectual and Developmental Disabilities?

Developmental disabilities (DD) may affect learning, language, and behavior. Intellectual disabilities (ID) may affect cognitive function such as reasoning, learning, and problem solving. Both may impact adaptive behavior such as social and life skills. Together, these are commonly referred to as IDD. Examples of IDD can include autism spectrum disorder (ASD), Down syndrome, fetal alcohol syndrome, spina bifida, Prader-Willi syndrome (PWS), and Fragile X syndrome. These are also referred to as neurodevelopmental disorders.

↘ The Informed Consent Process

An Institutional Review Board (IRB) is a committee at each institution that protect the rights and safety of research participants. IRB policy and procedures vary across institutions, so we encourage you to review your institution's IRB before you begin your project. For the clarity of this toolkit, we will use the Vanderbilt University Medical Center (VUMC) IRB as example.

Since individuals with IDD are considered a vulnerable population, most IRBs will require a rationale for including this population in your research project along with specific safeguards that outline how you will protect their rights. The IRB will evaluate how a participant's impairment might affect their ability to understand the research study, the level of risk associated with the study, and the potential benefits to the individual if they choose to participate.

The informed consent is defined as "an individual's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure" (VUMC IRB, 2019). Individuals with IDD may face challenges in understanding and providing consent as well as in understanding their right to withdraw from research.

The IRB must determine that appropriate precautions are in place for assessing a participant's ability to provide consent or withdraw from the study. This assessment should be supported by evidence addressing one or more of the following aspects related to the individual:

- The ability to make a choice.
- The ability to understand relevant information.
- The ability to appreciate the situation and its likely consequences.
- The ability to use logical reasoning and critical thinking

Since the capacity to consent can fluctuate, the IRB will want to evaluate the process for ongoing verification of a participant's understanding and willingness to participate. The consent procedures should include a plan for this ongoing verification. An example would be planning consistent check-ins to review informed consent with the individual throughout the project.

There are waivers or exceptions of informed consent in specific scenarios (e.g., public benefit or emergency). These waivers must be determined and approved by the IRB.

↘ Assessing Capacity to Consent Individuals with IDD

Research reveals there are various levels of decisional capacity among adults with IDD (McDonald & Kidney, 2012). However, it is still important to recognize concerns surrounding how much participants with IDD understand research procedures and risks outlined in the consent process. Several strategies have been utilized to assess consent capacity for these individuals. One is through a consultation from a qualified professional. Another is to administer a standardized measure. A third approach involves asking participants to explain the study in their own words at a pre-screening. An example of how this has been done in research is outlined below (Horner-Johnson W & Bailey D, 2013):

Meet with participants as a screening procedure, over a video platform (for example, Zoom) or in person, to explain the study and answer any questions. Have the participant demonstrate informed consent by explaining their understanding of study procedures. Ask the participant the following set of questions. The terms within the questions should be explained as needed.

- Please tell me, in your own words, what is this study about?
- What will you be doing if you take part in this study?
- What are the risks of being in this study?
- When I say your taking part is completely voluntary, what does that mean to you?
- When I say that your answers will be kept confidential, what does that mean to you?
- What can you do if you start the study but don't want to finish it?

The questions assess the extent to which participants understand the study information that had been presented to them. The level of understanding will be used to determine appropriateness for participation in the project, and whether they are able to provide informed consent.

If you decide to use this method of assessing capacity for consent, then you will need to acquire approval from the IRB. In the consent section of your IRB application, it will be necessary to explain these added steps and you will want to cite the source for the questions listed above.

New strategies have been utilized to assess consent capacity for these individuals. One of these effective strategies involves asking participants to explain the study in their own words.

↘ What if the participant is incapable of informed consent?

If a prospective participant has been determined incompetent or lacks the capacity to consent, then a **legally authorized representative** (LAR), who may be a parent, may grant permission on their behalf for the participant's involvement in the study. A LAR is an individual, judicial, or other body authorized under applicable law to grant permission on behalf of a prospective participant (VUMC IRB, 2019).

LAR examples include:

- A court appointed guardian or conservator,
- A Durable Power of Attorney for Health Care (DPAHC) or a Health Care Decision Maker.

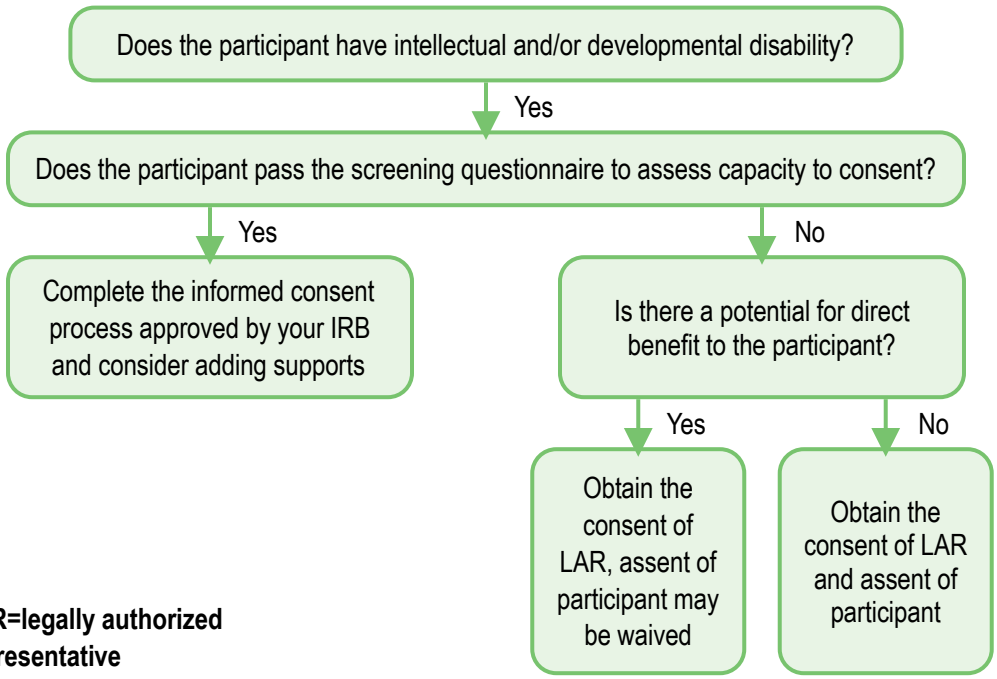
For non-medical studies, a Health Care Decision-Maker cannot be used; another form of LAR must consent on behalf of the cognitively impaired adult.

For medical studies (e.g. study on vaccines), any form of a LAR can be used.

For participants who are deemed to lack decision-making capacity, the permission of the individual's LAR is required, and an assent from the participant should be obtained. However, in research situations where there is the potential for direct benefit to the participant, the IRB may waive the requirement to obtain assent.

An **assent** is the individual's affirmative agreement to participate in research obtained along with **consent** from the individual's LAR (VUMC IRB, 2019). The **dissent** is an individual's negative expressions, verbal and/or non-verbal, that they object to participation in research activities (VUMC IRB, 2019).

Flow Chart for Consenting Adults with IDD.



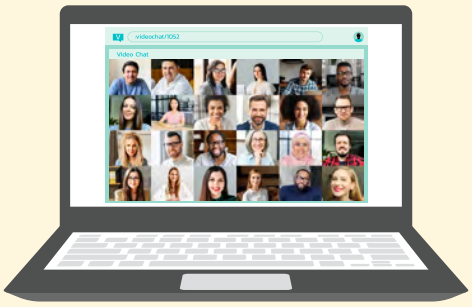
LAR=legally authorized representative

↘ Helpful Tips on Informed Consent Document (ICD)

It is important that the consent is written in a way the participant understands. The consent can even include pictures, or tables to help explain. The use of **electronic consents** (e-consents) can be especially helpful. An e-consent has a lot of great functionalities. For example, the viewer can have the consent read out loud, watch embedded videos, share reader-friendly lists/bullets, and prompt clarifying questions. All of these enhance the informed consent process and ensure the prospective participants understand what they are consenting to do. As a reminder, the e-consent will still require a signature (not typed name), unless a waiver has been granted.

Consent Photo/Visual Support Example

You will be asked to participate in online sessions with a health coach and other participants that will involve the use of live video meetings (Zoom) for six months, with two sessions to occur each month.



Visual Story Example

↘ Step by Step Guide:

Understand the Population:

- » Recognize that individuals with IDD may have unique needs, abilities, and communication styles. Some may have mild impairments while others may have more significant challenges in understanding information or expressing consent.
- » Simplified Communication: Aim for written language of about a fourth grade reading level and avoid complex terminology.
- » Utilize visual aids, such as pictures, diagrams, or videos, to supplement oral or written explanations and enhance understanding.
- » Break down information into smaller portions, and repeat key points as needed.
- » Consider factors such as sensory sensitivities (e.g., bright light, loud noises, textures), communication impairments, cultural background, and language proficiency.
- » Use alternative communication methods, visual supports, sign language, or assistive communication devices, as needed.
- » Remember that the process of informed consent is a continuous process and should be reviewed throughout your research project.
- » Consider creating an advisory board or adding a team member with IDD to better understand this population and receive feedback on your project.

Assess Capacity:

- » Assess each individual's capacity to understand the research study before you begin the informed consent process. This can be done through the strategy suggested above or through other structured capacity assessment tools. You may also consider consulting a healthcare professional with experience working with individuals with IDD on this process. This process will need to be specified within your IRB application.
- » Recognize that an individual's capacity may vary depending on factors such as fatigue, stress, or the complexity of the study.
- » Offer comprehensive information about the research study in simple and plain language and allow for ample opportunity for the individual to ask questions and seek clarification on any aspects of the study.

Obtain Consent:

- » Allow plenty of time to go over the informed consent document and for the participant to process information.
- » Provide supports or accommodations as needed, allowing the individual to express their thoughts and concerns at their own pace.
- » Emphasize the voluntary nature of participation and assure individuals that they can withdraw from the study at any time without repercussions.
- » Obtain informed consent from the individual, ensuring they understand the nature, risk, and benefits of the study and agree to participate willingly.
- » If an individual lacks the capacity to provide consent themselves, then seek consent from a Legally Authorized Representative (e.g., guardian or conservator) while fully involving the individual in the decision-making process when possible. This may include an assent, depending on the study.

Document the Process:
Always maintain detailed documentation of the consent process, including the information provided, discussions held, any adaptations made, and the individual's demonstrated understanding and agreement to participate. The IRB has an Informed Consent Process (ICD) Checklist that can be used, or you can create a separate "Note to File" to document the details of your consent process. Consider keeping the checklist or Note separate from the ICD so you still have documentation of consent in the event something was to happen to the signed consent form.

» vkc.vumc.org/assets/files/vkc/Consent_Process_Checklist.docx

Follow Up:

» Provide ongoing support and assistance to individuals throughout their participation in the research study.
» Monitor their well-being and address any concerns or issues that may arise promptly.
» Maintain open communication channels and be responsive to the individual's needs and preferences.
» Send summaries of each study visit to each participant (what happened, the use of data, updates with relevant interim reports) when possible.
» Add surveys to your project to assess satisfaction and encourage engagement.
» Provide tangible benefits such as resources for the families like toolkits, books, or compensation when possible. It is important to explain to participants how research helps the community, but the tangible benefits are a strong motivator for participation as well.
» Schedule check-ins with participants that allow enough time to review all study documents and ask questions. Often understanding is hard to assess, so frequent communication is helpful.
» Always share the results of your study with your participants.

Training and Support:

» Offer guidance on best practices, communication strategies, relaxation, and de-escalation techniques to staff and ethical considerations specific to working with this population. Great resources for these can be found on iddtoolkit.org
» Remember that clinic settings can be anxiety-inducing to individuals with IDDs due to some having heightened sensory perceptions and often previous trauma in healthcare settings. When possible, provide the participant photos of the facility and/or the protocol that will be taking place. This is considered a visual support and can help individuals with IDD find other ways to understand and communicate with visual rather than auditory information. A participant could also visit the facility ahead of time to become more comfortable in a new setting.

By following these steps, researchers can ensure that the process of obtaining consent from individuals with intellectual and developmental disabilities for research is conducted in an ethical, and respectful manner, promoting the rights and well-being of participants.

↘ Citations:

Horner-Johnson W, Bailey D. *Assessing Understanding and Obtaining Consent from Adults with Intellectual Disabilities for a Health Promotion Study*. J Policy Pract Intellect Disabil. 2013;10(3):10. PMID: 24223054; PMCID: PMC3821759).

McDonald KE, Kidney CA. What Is Right? Ethics in Intellectual Disabilities Research. Journal of policy and practice in intellectual disabilities : JPPID. 2012;9(1):27-39. doi:10.1111/j.1741-1130.2011.00319.x

Vanderbilt University Medical Center Institution Review Board. (2019, January 19). *Legally Effective and Prospectively Obtained Informed Consent*. Informed Consent Process. https://vanderbilt.policytech.com/dotNet/documents/?docid=15493&public=true

Vanderbilt University Medical Center Institution Review Board. (2019, January 19). *Assent/Dissent by Children or Cognitively Impaired Adults Who Lack Decision Making Capacity.* Informed Consent Process. https://vanderbilt.policytech.com/dotNet/documents/?docid=15493&public=true

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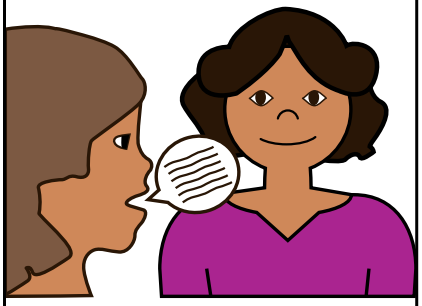
Sample Images for Consent Process and Medical Procedures

Talk 	Read 	Signature 
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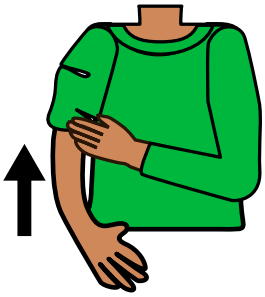
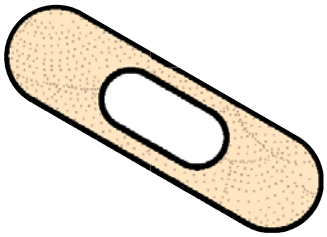
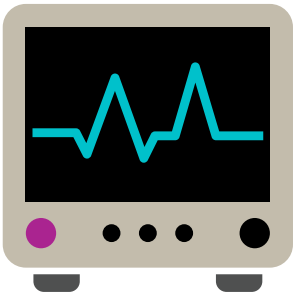
Push up sleeve 	Feel pinch 	Bandaid 
Doctor visit 	EKG 	MRI