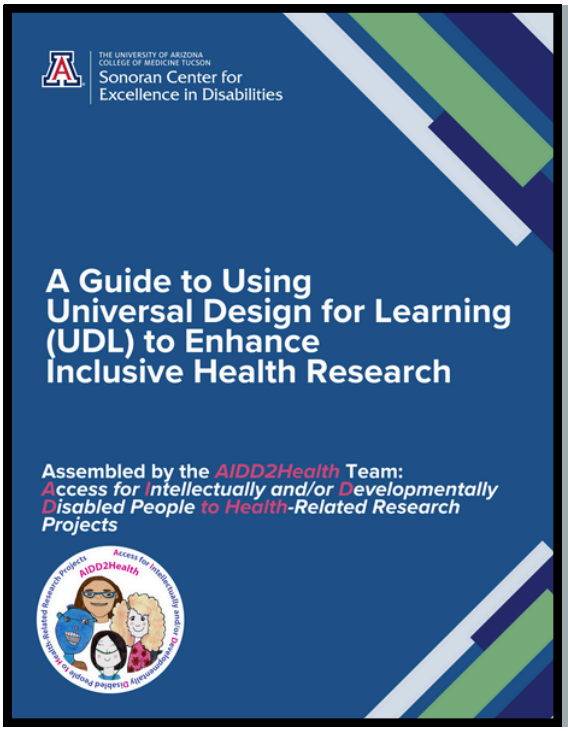

Making Research Accessible: *Key Considerations*

Informed Consent

Access to the Full Guidebook:

Key Considerations

The AIDD2Health Project Team consulted with inclusive research experts in the disability field to identify key considerations for making research projects more accessible and inclusive for people with Intellectual and/or Developmental Disabilities (IDD).

We summarize the **essential points relevant to health researchers who typically do not work with the IDD population.** The aim is to expand their research projects to include people with IDD:

- **Shared Goals and Mutual Benefits**: Ensure that the research project goals align with what is most important to the study participants by clearly stating the research end goals and roles of participants. Re-visiting ideas over time through discussion will make ideas clearer for all participants.
- **Involvement and Representation of People with Disabilities**: Include them throughout the research process—from formulating questions to recruitment, data collection, and information dissemination. They can serve as advisors, consultants, and/or research team members (co-researchers) where feasible and appropriate.
- **Relationship Building**: Listening to each other fosters trust and reciprocity (mutual benefits) with advocates, participants, and researchers.
- **Empowerment**: Encourage participants to speak up, provide feedback and insights, and ask questions in ways that suit their learning styles. This provides opportunities to express their own wants and needs (with support from another person if necessary).

Key Considerations (cont.)

- **Adaptability**: Recognize that equitable access does not mean having the same tasks or expectations for everyone. Meet people with IDD where they are—small adaptations and flexibility can encourage participation. Consider the amount of time needed or other accommodations that will increase access to materials and participation (e.g., offering alternative options: screen reader, transportation, remote participation, extra and/or flexible time).
- **Accessibility**: Adapt and test measures and tools, simplify options, and develop learning modules (e.g., how to answer multiple-choice questions) to make the research process more accessible.
- **Clear Communication and Plain Language**: Use plain language, visuals, and illustrations to enhance accessibility and accommodate different ways of understanding.
- **Enjoyment**: Make the research process fun and enjoyable for participants.
- **Practical Considerations**: Be aware that individuals may need to limit their income to maintain their insurance status and benefits. Find participants from different places and groups. Provide extra time to plan for transportation, activities, and appointment times.
- **Ethical Considerations**: Use accessible consent forms (use plain language and teach-back question methods to assess understanding) and advocate for the use of adapted forms with Institutional Review Boards (IRBs). Recognize that IRBs may not be experts in consent and assent for your participants of interest. Advocating for adapted forms may be necessary. See additional information in the Informed Consent section.
- **Plan Ahead**: Plan grant proposals that include a budget for advocates in paid roles, accessibility tools, and article processing charges. Strive to include people with disabilities as meaningful, compensated members of the research team.

Informed Consent

How to Adapt an Informed Consent Form into Plain Language

- Individual Institutional Review Boards (IRBs) often provide guidance to researchers about informed consent forms. However, everyone must follow U.S. Department of Health and Human Services Guidance for the "elements of consent".[17] Researchers can use plain language approaches to modify consent forms.
- There may be institution-specific language for consent forms. Your IRB will tell you which language is required when they provide feedback on your modified consent form.
    - We modified our institution's informed consent template to use plain language and to include teach-back questions. Teach-back questions enable the researcher to confirm participant understanding rather than making assumptions about capacity to consent.[18]

Strategies and tips for clear communication and plain language are listed in Chapter 2 in the AIDD2Health Guidebook. Here, we highlight a few quick tips for adapting informed consent forms, with an example.

Selected Tips with Color Codes:

Yellow – Shorten sentence and paragraph length to focus on one subject per sentence and one topic per paragraph

Green – Use common words or define necessary jargon - Not everyone knows every word, so using common words avoids confusion

Red – Communicate expectations clearly - Not everyone picks up on indirect statements

Blue – Exclude or move less-important information - Too much information can confuse the wrong audience and distract them from the important information

Turquoise – Avoid passive voice and use active voice - Passive voice can be vague and confusing

Dark Red – Use **talk-back (teach-back)** and comprehension checks - Ask open-ended questions and have participants repeat and rephrase information to check for understanding. Provide instructions for the research team on how to explain information differently if someone is not able to answer the teach-back questions.

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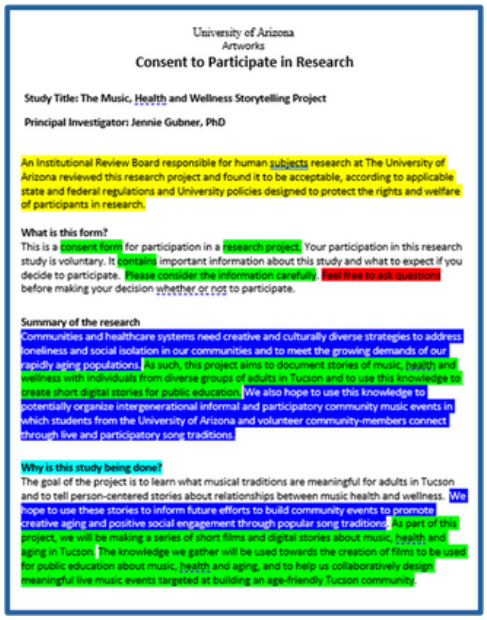
17. U.S. Department of Health and Human Services, Office for Human Research Protections, Informed Consent Checklist, Nind, M. (2017). The practical wisdom of inclusive research. Qualitative Research, 17(3), 278-288. https://doi.org/10.1177/1468794117708123, Accessed 12/18/24

18. National Institutes of Health. Research Involving Individuals with Questionable Capacity to Consent, https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/policies-and-regulations/vulnerable-populations/questionable-capacity, Accessed 12/18/24

Talk-back (teach-back) question examples:

1. What will you do if you are part of this study?
2. What are the risks of this study?
3. What do you get for participating in this study?
4. What does it mean that the study is “voluntary?”
5. What can you do if you want to stop or don’t want to participate anymore?

You can use these questions after each relevant section or all at once before asking consent. Your decision will depend on the study's complexity and participants' level of understanding. These questions can help the research team to develop possible participant answers that can help to assess participant comprehension.



University of Arizona
Artworks
Consent to Participate in Research

Study Title: The Music, Health and Wellness Storytelling Project

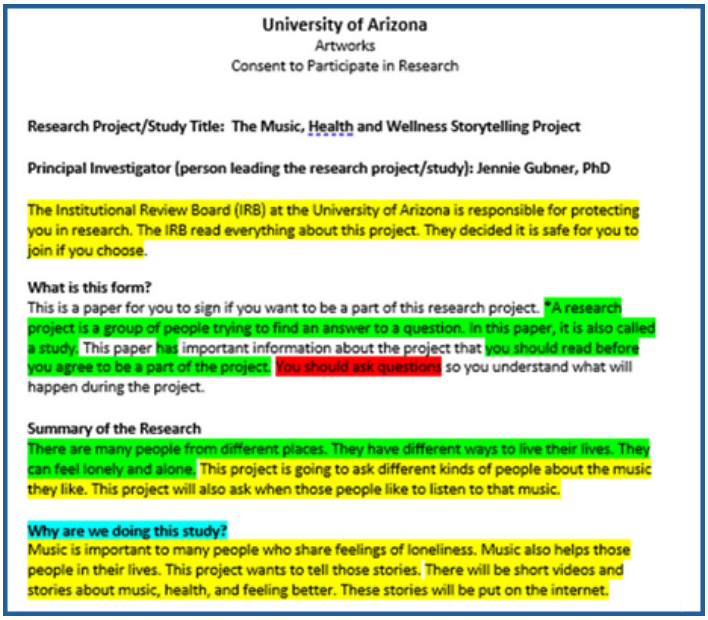
Principal Investigator: Jennie Gubner, PhD

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

What is this form?
This is a consent form for participation in a research project. Your participation in this research study is voluntary. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

Summary of the research
Communities and healthcare systems need creative and culturally diverse strategies to address loneliness and social isolation in our communities and to meet the growing demands of our rapidly aging populations. As such, this project aims to document stories of music, health and wellness with individuals from diverse groups of adults in Tucson and to use this knowledge to create short digital stories for public education. We also hope to use this knowledge to potentially organize intergenerational informal and participatory community music events in which students from the University of Arizona and volunteer community-members connect through live and participatory song traditions.

Why is this study being done?
The goal of the project is to learn what musical traditions are meaningful for adults in Tucson and to tell person-centered stories about relationships between music health and wellness. We hope to use these stories to inform future efforts to build community events to promote creative aging and positive social engagement through popular song traditions. As part of this project, we will be making a series of short films and digital stories about music, health and aging in Tucson. The knowledge we gather will be used towards the creation of films to be used for public education about music, health and aging, and to help us collaboratively design meaningful live music events targeted at building an age-friendly Tucson community.



University of Arizona
Artworks
Consent to Participate in Research

Research Project/Study Title: The Music, Health and Wellness Storytelling Project

Principal Investigator (person leading the research project/study): Jennie Gubner, PhD

The Institutional Review Board (IRB) at the University of Arizona is responsible for protecting you in research. The IRB read everything about this project. They decided it is safe for you to join if you choose.

What is this form?
This is a paper for you to sign if you want to be a part of this research project. *A research project is a group of people trying to find an answer to a question. In this paper, it is also called a study. This paper has important information about the project that you should read before you agree to be a part of the project. You should ask questions so you understand what will happen during the project.

Summary of the Research
There are many people from different places. They have different ways to live their lives. They can feel lonely and alone. This project is going to ask different kinds of people about the music they like. This project will also ask when those people like to listen to that music.

Why are we doing this study?
Music is important to many people who share feelings of loneliness. Music also helps those people in their lives. This project wants to tell those stories. There will be short videos and stories about music, health, and feeling better. These stories will be put on the internet.

You can access:
1) the color coded, side-by-side, example documents
2) the power point presentation at the AIDD2Health Homepage.

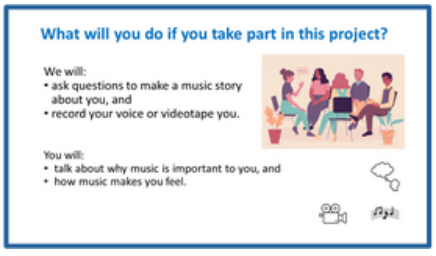
Key Points of the Informed Consent Document with Illustrations

During the consent process, it is also helpful to present key points of the informed consent document with illustrations in PowerPoint.

What is this project about?

There are many people from different places. They have different ways to live their lives.

This project is going to ask:
- different kinds of people about the music they like.
- when, how and why people like to listen to that music.



What will you do if you take part in this project?

We will:
- ask questions to make a music story about you, and
- record your voice or videotape you.

You will:
- talk about why music is important to you, and
- how music makes you feel.

What can you do if you want to start this project, but do not want to finish?

You are a volunteer, so you can quit when you want!

Guardianship and Consent

It is important to know that only some people with IDD have a guardian who must provide consent.

- Many states are moving to an alternative to guardianship for people with IDD called "supported decision-making." This means that a person with IDD may have a person with power-of-attorney to make certain decisions (for example, financial decisions) and have a support network to help them make decisions about other aspects of their life (for example, health).
- Ask the potential participant when you start the consent process, "Do you have a guardian? Can you decide to participate in this research yourself or does someone else make those decisions? Do you need to do some research or talk to someone else about your participation?"
- If someone does have a guardian to provide consent, it is important to have an Assent process for the adult participant with IDD. Participants who have a guardian may be able to understand the research, and they should assent to their participation.
    - Consent and **assent** may be in the same document.

Assent is a process for explaining the purpose and activities of a research study to people who cannot legally provide consent to participate. Assent may include a question about whether the participant agrees to join the study, which is not "consent" but promotes autonomy and agency. Stanford University's Research Compliance Office has an assent model for adults who have a guardian: https://researchcompliance.stanford.edu/panels/hs/for-all-researchers/consent/assent-process

Regulatory Considerations

IRBs outline special considerations for people with cognitive disabilities. You may use documents that support people with cognitive disabilities. It can help everyone who participates. You should not need to submit special paperwork to enroll people with cognitive disabilities who can consent for themselves or who have a guardian who provides consent, if they are part of a general population of participants with/without cognitive disabilities. Talk to your IRB for guidance.

Suggested Citation

Shirai, Y., Armin, J., Thompson, M., & AIDD2Health Project Team (2024). *A Guide to Using Universal Design for Learning to Enhance Inclusive Health Research*. Sonoran University Center for Excellence in Disabilities, Retrieved from https://sonorancenter.arizona.edu/research/pcori