



# UDSv4 Digital Voice

## Consent & IRB Protocol

### Informed Consent

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**Purpose:** Clearly explain the reason for the audio recording and how it will be used.

**LEADS Study Example Language**

*“We will audio record your responses to some of the memory and language tests. Recording your responses will allow researchers to write out (transcribe) your responses exactly as they were spoken. These audio recordings and transcriptions will allow researchers to analyze your responses to answer important questions such as behavioral markers of speech, language and cognitive decline.”*

**Helpful Suggestion!**

*Keep the purpose and details of the study procedure general and non-specific to avoid limiting yourself in the future.*

**Confidentiality:** Describe how the recordings will be kept confidential and the measures in place to protect a participant’s privacy.

**LEADS Study Example Language**

*“Your recordings will be maintained on secure servers used for this study and only those with privacy training and permission from the study team will have access to them.”*

**I-CONNECT Study Example Language**

*“We will protect your privacy when sharing audio recordings by only sharing the recordings with approved researchers. We will not share any parts of the audio recordings that contain identifying information like your name, telephone number, or other information we think could be used to tell your identity.”*

**Data Sharing:** Specify who will have access to the recordings and who the data will be shared with.

**Example Language**

*“In the future, your recordings and information may be given to researchers for other research studies. However, you will not be identified in any of these recordings. Your data will be given a unique study identification number.”*

**Benefits and Risks:** Explain any potential benefits and risks associated with the audio recording.

**I-CONNECT Study Example Language**

*“However, because everyone’s voice is unique, it’s possible that someone listening to the recording could identify you from the sound or pattern of your voice.”*

Have questions? Reach out to [naccmail@uw.edu](mailto:naccmail@uw.edu)

Developed in collaboration with NACC and the CTF Technology Workgroup. 2024.



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**Additional consent is required** if the audio recording is not an essential part of the study. Consider adding the following language: “Do you give us permission to audio record your responses to some of the memory and language tests?”

### IRB Study Protocol

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**Objective:** Clearly state the purpose of the study and the role of audio recordings in achieving the study objectives.

***I-CONNECT Study Example Language***

*“The administration of select language and memory tests will be audio recorded for every participant, at every visit. This data will be collected to allow for additional analyses.”*

**Data Sharing:** Specify who will have access to the recordings and who the data will be shared with.

***Example Language***

*“In the future, your recordings and information may be given to researchers for other research studies. However, you will not be identified in any of these recordings. Your data will be given a unique study identification number.”*

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**Recording Procedure:** Specify 1) what will be recorded, 2) the setting and method of data collection, and 3) the equipment being used to record.

***I-CONNECT Study Example Language***

*“The administration of select language and memory tests will be audio recorded for every participant, at every visit.”*

*“A recording device, such as the Olympus VN-722PC digital voice recorder or a similar digital recording device, will be used.”*

*“The I-CONNECT video chat system is a secure, scalable, and cost-effective video chat platform for conducting in-home telehealth with geriatric populations.”*

**Storage:** Describe the measures that will be put in place to protect participant confidentiality.

***LEADS Study Example Language***

*“The audio files acquired in this study will be securely transmitted and stored in databases being used for the study. Sites will be responsible for ensuring that no PHI is included in the recordings prior to upload.”*

***Helpful Suggestion!***

*Privacy & security of data should be protected in the same manner as other data types like imaging & genotyping. (e.g., local storage in HIPAA-compliant solutions, access limited to IRB-approved study staff, & data transmitted securely to NACC.*

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**De-identification** tools that will be used for de-identifying digital voice data are still being reviewed and developed. This data will not be shared until we are confident that the data is de-identified.