1 PURPOSE

The purpose of this SOP is to describe the procedures to be followed when administering cognitive assessment(s) to participants and to ensure testing consistency and accuracy.

2 REVISIONS FROM PREVIOUS VERSION

2.1 Version 1.0, 23Sept2024: Initiation of new SOP

3 POLICY

N/A

4 RESPONSIBILITIES

4.1 CRU Director or Assistant Director

- 4.1.1 Oversee the cognitive testing process.
- 4.1.2 Work with the principal investigator (PI) to ensure that all study personnel receive the training necessary to accurately perform cognitive testing.
- 4.1.3 Ensure that training certificates are appropriately stored in study regulatory binder and/or credentials binder.
- 4.1.4 Ensure to provide a quiet, distraction-free environment.
- 4.1.5 Secure necessary resources, including study personnel, to support cognitive assessment(s) for research studies.
- 4.1.6 Establish and maintain quality control measures to ensure accuracy and reliability of cognitive assessment(s).
- 4.1.7 Ensure informed consent has been obtained from participants and/or their legal representatives prior to performing cognitive assessment(s).
- 4.1.8 Ensure compliance with the protocol and address any issues that may arise during the cognitive assessment process.

4.2 CRU Research Coordinator/Research Nurse

- 4.2.1 Ensure that the protocol and cognitive assessment(s) have been approved by the IRB.
- 4.2.2 Ensure that participants and/or their legal representatives signed informed consent prior to beginning the cognitive assessment(s).
- 4.2.3 Ensure that participants and/or their legal representatives understand the purpose of the cognitive assessment(s), potential risks, benefits, and right to refuse or withdraw.
- 4.3.4 Follow standardized procedures outlined in the cognitive assessment(s) instructions to ensure reliability and validity of test results.
- 4.3.5 Provide appropriate accommodations based on the participants' needs during the testing session to ensure that they are comfortable.

4.3 Principal Investigator

4.3.1 Ensure that the protocol and cognitive assessment(s) have been approved by the IRB.

4.3.2 Ensure that all study personnel have received the necessary training on the protocol and cognitive assessment(s).

4.3.3 Oversee the cognitive testing process, as well as the collection, entry, and correction of all data obtained during the cognitive assessment(s).

4.3.4 Ensure that participants and/or their legal representatives signed informed consent prior to cognitive assessment(s).

4.3.5 Ensure that participants and/or their legal representatives understand the purpose of the assessment, potential risks, benefits, and right to refuse or withdraw.

5 PROCEDURE

5.1 Ensure all necessary test materials are gathered and available in the room prior to beginning the cognitive assessment(s).

5.2 Ensure that the room is quiet, private, well-lit, and distraction-free.

5.3 Offer snacks and/or water prior to testing and during the assessment(s) and ensure that participants are comfortable.

5.4 Provide clear and concise instructions for each cognitive test, following the standardized procedures outline in the test instructions.

5.5 Use language that is appropriate for participants, based on their age, education level, and cognitive abilities.

5.6 Answer any questions the participant may have regarding instructions before proceeding to the test.

5.7 Strictly adhere to the specified time limits for each test question. Use a timer or stopwatch to ensure accuracy.

5.8 Administer assessment(s) in the recommended order.

5.9 If a participant requests clarification on a test item, provide a neutral response without giving hints or suggestions. Refer the participant back to the original instructions.

5.10 When the testing visit is finished, ensure that each assessment has been fully completed and scored according to the instructions.

5.11 Answer any questions that a participant may have about the test and/or assessment process, if applicable.

5.12 Write participant ID, visit number, date, and your initials on the top of each page of the visit packet. Ensure that scoring is clear and concise.

5.13 Ensure to enter the data into REDCap, or any other platform used for study data collection, by the end of the day.

5.14 Ensure that all documents are stored securely, in a locked cabinet, in a locked room.

6. REFERENCES

6.1 Alzheimer's Association

7 SIGNATURES

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Date: 05Nov2024

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Date: 05 Nov 2024