RESEARCH SUBJECT CONSENT FORM

Title:	Normative data collection for the California Cognitive Assessment Battery
Protocol No.:	None WIRB® Protocol #20201196
Sponsor:	Neurobehavioral Systems, Inc.
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RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you participate is up to you.
- If you don't participate, it won't be held against you.
- You can participate now and drop out later, and it won't be held against you.
- If you don't understand any portion of the information provided, please ask questions.
- Ask all the questions that you want before you decide to participate.

How long will I be in this research?

You will be tested in
[FOR SUBJECTS IN EXP. 1]

- One 2-hour enrollment session with computerized cognitive tests.
- One 2-hour session with computerized cognitive tests and one 2-hour session with manually administered cognitive tests within ten days of each other.
- A second 2-hour session with computerized tests within 10 days of previous tests.

[FOR SUBJECTS IN EXP. 2]

- One 2-hour enrollment session with computerized cognitive tests.
- Two 2-hour sessions with computerized cognitive tests within ten days of enrollment; and
- Six 2-hour sessions with computerized cognitive tests administered at six-month intervals over a three-year period.

[FOR SUBJECTS IN EXP. 3]

- One 2-hour enrollment session; and
- Two 2-hour sessions with computerized tests within ten days of enrollment.

[FOR SUBJECTS IN EXP. 4]

- A 1-hour enrollment session, which will include a 30-minute computerized cognitive test; and
- [Exp. 4a] Four 30-minute computerized cognitive tests at 3, 6, 9, and 12 months after enrollment;
- [Exp. 4b] Two 30-minute computerized cognitive tests at 6 and 12 months after enrollment; or
- [Exp. 4c] One 30-minute computerized cognitive test 12 months after enrollment.

Why is this research being done?

The purpose of this research is to gather data on the performance of normal, healthy individuals on the computerized cognitive tasks that we are developing to measure attention and memory. Eventually, your results and the results from other normal healthy subjects will be statistically compared with the results from patients to enable caregivers to more effectively diagnose and treat diseases that impair cognitive function.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the procedures will include:

- **Computerized Questionnaires:** At enrollment, researchers will ask you about your medical history and current medications, and you will be given computerized questionnaires about your background (e.g., age, years of education, sex, etc.), health, concerns about your memory, and feelings of depression and anxiety. During each subsequent testing session, you will be asked several questions about your mood and health status.
- **[Exp. 1] Manually administered neuropsychological tests.** You will be given manual (pen-and-paper) neuropsychological tests by an examiner.

- **Computerized Neuropsychological Testing:** During and after enrollment, you will complete a series of computerized tasks that examine how well you can pay attention and remember things. The number of frequency, duration and content of testing will depend upon which Experiment you are participating in.

Could my participation in this research hurt me?

The most important risks or discomforts that you may experience from taking part in this research could include fatigue, boredom, or frustration. In most cases you will be tested in your home. Every precaution will be taken to ensure your comfort during these tests, including frequent rest breaks. There are no known legal, social, or employment risks associated with this study.

Will being in this research benefit me?

It is not expected that you will personally benefit from this research.

What else should I know about this research?

The research team will record your voice during different portions of this study. These recordings will be collected to enable computers to analyze the responses that you give to test questions. The computerized tests will be administered remotely by a member of the research team. You will be able to communicate with the team member through a video chat connection. We may store video recordings of the test sessions to improve the quality of the test experience. Video and audio recordings will be encrypted and stored on secure computers and will only be accessible to authorized research staff affiliated with Neurobehavioral Systems, Inc. (NBS).

DETAILED RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you participate is up to you.
- You can choose not to participate. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to participate and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand any of the information provided in this form or by the research team, ask questions.
- Ask all the questions you want and take as much time as you need to review this form before you decide.

Why is this research being done?

The purpose of this research is to examine the performance of healthy individuals on newly developed computerized cognitive tasks and understand how test results from normal, healthy individuals change as a function of age. The data will allow caregivers to compare your test scores

and those of other normal individuals with the scores from patients to assist in the diagnosis and treatment of cognitive impairments.

Altogether, about 2000 subjects will take part in this research at different test sites.

How long will I be in this research?

[EXPERIMENT 1]
You will be tested in one 2-hour enrollment session, one 2-hour session with computerized tests, one 2-hour session with manually administered paper-and-pencil tests, and a second 2-hour session with computerized tests. All tests should be completed within three weeks of enrollment. You will participate in a total of 8 hours of testing over a three-week period.

[EXPERIMENT 2]
You will be tested in one 2-hour enrollment session, two 2-hour sessions with computerized tests within ten days of enrollment, and six 2-hour sessions with computerized tests administered at six-month intervals over a three-year period. You will participate in a total of 18 hours of testing over a three-year period.

[EXPERIMENT 3]
You will be tested in one 2-hour enrollment session, and two 2-hour sessions with computerized tests within two weeks of enrollment. You will participate in a total of 6 hours of testing over a two-week period.

[EXPERIMENT 4a]
You will be tested in a 1-hour enrollment session which will include a 30-minute computerized test, and retested with the same 30-minute computerized test at three 3-month intervals over the following year. You will participate in a total of 2 ½ hours of testing over a one-year period.

[EXPERIMENT 4b]
You will be tested in a 1-hour enrollment session which will include a 30-minute computerized test, and retested with the same 30-minute computerized test at two 6-month intervals over the following year. You will participate in a total of 2.0 hours of testing over a one-year period.

[EXPERIMENT 4c]
You will be tested in a 1-hour enrollment session which will include a 30-minute computerized test, and retested with the same 30-minute computerized test one year later. You will participate in a total of 1 ½ hours of testing over a one-year period.

What happens to me if I agree to take part in this research?

Each computerized test session will normally take place in a quiet room in your home using a sanitized tablet computer, headphones, and a computer mouse that will be delivered by the research team prior to your first session. The research team will administer these test sessions remotely and will communicate with you through video chats before, after, and in-between tasks. Each of the test sessions will last between one-half hour and two hours.

During the enrollment session, members of the research team will gather information you about your medical history, medications, personal information, overall health, emotional state, and concerns about memory and other cognitive abilities.

During enrollment and subsequent testing sessions, you will be asked to complete a series of manually administered or computerized tests designed to measure your attention, memory, and processing speed. The computerized tests will be administered in your home through the tablet computer and will be controlled remotely by a member of our research team. You will have a chance between tests to take short rest breaks, get a drink, and ask the experimenter for any clarification of test instructions.

Repeated test sessions will include computerized tests like those in the enrollment session.

The focus of this research is to understand how test scores from normal healthy individuals change as a function of age. As such, the results of your individual tests will not currently provide any clinically relevant or diagnostic information.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for:

- Completing each of the assigned test sessions.
- Reporting any changes in your medication or mental or physical health.

Could being in this research hurt me?

- Physical risks
  - The physical risks associated with neuropsychological testing are very small but could include fatigue. Every precaution will be taken to ensure your comfort during these tests, including adjustable seating and frequent breaks.
  - The tablet computer, headphones, computer mouse, and equipment is sanitized prior to each delivery. The member of our team delivering the kits will wear a mask, gloves, and will maintain social distancing for contactless delivery and pickup of the testing kit. These measures are taken to prevent potential infection from Covid-19.
- Psychological risks
  - You may find the neuropsychological tests boring or frustrating, but there are no other foreseeable mental risks. To minimize boredom, we have designed all the tests to be brief, with most lasting less than five minutes. Each testing session has breaks programmed in, and additional rest breaks can be taken whenever you need them.
- Privacy risks
  - We will make every effort to protect your data privacy, personal information, cognitive test scores, private health information, and video/audio recordings. All personal identifying information will be removed before your results are analyzed. All files will be encrypted and preserved on a secure server, complying with strict data privacy standards. Nevertheless, a security breach is always possible.
- Legal risks
  - There are no known legal risks associated with this study.

- Social risks
  - There are no known social risks associated with this study.
- Economic risks
  - To avoid any economic hardship, we can schedule appointments that work with your existing schedule.
- Unforeseeable risks
  - The research team does not know all the side effects that may occur. You may experience a side effect or new risk that the researchers do not know about at this time.

Will it cost me money to take part in this research?

Participation in this research study will not cost you money.

Will being in this research benefit me?

There are no benefits to you from your participation in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include the creation of improved tests of brain function that can be used by doctors to help diagnose individuals with mental or psychological problems.

What other choices do I have besides taking part in this research?

This research is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the research.

What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or review this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the National Institutes of Health and US Food and Drug Administration (FDA)
- The Institutional Review Board (IRB) that reviewed this research

Members of the research team may publish the results of this research, but they will not reveal your name or identity. Your research data will always be stored with a research code (number) rather than your name. Only the research team will have access to the link between you and your assigned research code. Paper-based study data will be kept in a locked filing cabinet in private research offices, accessible only to the research team. Electronic/digital study data files will be kept on encrypted, password-protected research servers that are accessible only to approved research staff. All information that might be used to identify you personally will be removed from the data before analysis.

When the research is completed, the data will be archived in a secure filing cabinet or stored electronically on secure computer servers. All personally identifiable data will eventually be deleted or shredded once the study is complete. Once all information that might be used to identify you personally has been removed, the data from the computerized tests may be distributed to

qualified scientists, including personnel at Neurobehavioral Systems, Inc., and scientists at other research institutions.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

If you are injured or get sick because of being in this research, call and notify the test examiner or study investigator immediately. If you need emergency medical treatment, call 911. Your insurance may be billed for this treatment. To the legal extent required, the sponsor will pay any charges that are not covered by the insurance policy or the government, provided the injury was not due to your underlying illness or condition and was not negligently caused by you or some other third party. No other payment is routinely available from the study doctor or sponsor.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest;
- You have a side effect that requires stopping the research;
- The research team believes you are not performing to the best of your abilities on the tests;
- The research is canceled by the sponsor; or
- You are unable to keep your scheduled appointments.

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research. If you are removed from this research for any of the reasons noted above, you will be compensated for your hours of participation at the time of your removal.

What happens if I agree to be in this research, but I change my mind later?

Taking part in this research is voluntary, and you may choose to stop participating at any time.

If you choose not to take part in this study, you will not be penalized or lose any benefits to which you are entitled. Please tell the researcher if you are thinking about stopping or decide to stop.

Your decision will not affect your relationship with the researcher. If you choose to withdraw from the study, any data that has already been collected may continue to be reviewed, but no further data will be collected.

Will I be paid for taking part in this research?

You will be paid $25/hour for taking part in this research. In addition, if you complete all of the study sessions in a test sequence lasting more than one month, you will be given a bonus of 15% of all previous payments in the final test session.

Payments will be made at the end of each scheduled test session. If you choose to stop participating, payment will be adjusted based on the amount of time remaining in the current session. If withdrawal is made between sessions, no additional payments will be made.

Statement of Consent:

Your signature documents your consent to take part in this research.

Signature of adult subject capable of consent	Date
Signature of person obtaining consent	Date

Health Information Portability and Accountability Act (HIPAA): Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, work to protect your privacy. By signing this form, you provide your permission, called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information such as your medical history, diagnoses, radiology findings, and drug or alcohol abuse.

This permission will be good until December 31, 2070.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to David L. Woods (at this facility) or ask a member of the research team to give you a form to revoke the authorization. Your request will be valid once it has been received by David L. Woods. If you revoke this authorization, Dr. David Woods and his research team can continue to use information about you that was collected before the receipt of your request to withdraw from the study. The research team will not collect information about you after you revoke the authorization.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

While this study is being conducted, you will not have access to the research results.

Your signature documents your consent to take part in this research.

Signature of adult subject capable of consent	Date
Signature of person obtaining consent	Date