APPROVED
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WIRB®

Research Subject Information Sheet

BrainBaseline CARE
For Research Purposes

TITLE: BrainBaseline CARE: Feasibility study on a Cancer Patient Cognitive Assessment Platform

PROTOCOL NO.: 03012017
WIRB® Protocol #20170497

SPONSOR: Digital Artefacts LLC

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STUDY-RELATED PHONE NUMBER(S): Joan Severson, BA, MS
319-431-3278

SUMMARY
Joan Severson and her associates at Digital Artefacts LLC are conducting a research study to examine the feasibility of a cancer patient cognitive assessment platform to screen for cognitive decline in individuals who are, or have been, diagnosed with cancer. There is no limit on the time since diagnosis. Recent research has found that a lot of patients experience cognitive impairment during treatment, and many experience cognitive impairment at least one year following treatment. It is unclear what may be causing this decline; possibilities include the treatment of the disease, the cancer itself, or secondary effects of treatment such as stress, fatigue, and depression. Our goal is develop a screening instrument capable of detecting cognitive impairment in cancer patients to improve treatment and advance research into the causes of cancer-related cognitive impairment. If you decide to participate in this study, you will be assigned to one of three groups. Each group will take a series of neuropsychological assessments and surveys. The total length of the study will be two months, but group 1 will participate bi-weekly, group 2 will participate monthly, and group 3 will participate bi-monthly.

To be in a research study you must give your informed consent. The purpose of this form is to help you decide if you want to participate in this study. Please read the information carefully. If you decide to take part in this research study, you will be given a copy of this signed and dated consent form. If you decide to participate, you are free to withdraw your consent, and to discontinue participation at any time.

You should not join the research study until all of your questions are answered.

Participating in a research study is not the same as receiving medical care. The decision to join or not join the research study will not affect your medical benefits.

PROCEDURES
If you agree to participate in this study, you will need to download the free study application on your iPad. The following will happen:

1. Using an iPad, you will take a series of cognitive assessments on a bi-weekly, monthly, or bi-monthly basis for a month. These assessments have been designed to be self-administered. This means you will follow the instructions that appear on the screen. The iPad tests consist of an evaluation of your thinking skills, including tests of attention, processing speed, executive function, visuospatial processing, memory, motor control, and verbal learning.
2. You will be asked to complete surveys about your health, demographics, exercise habits, nutrition, fatigue, sleep habits, cognitive function, and mood.

We will send notices on your device asking you to complete these activities and surveys. You may choose to complete the activities or ignore them, but certain activities will only be available for a limited time. Each activity should take between two to five minutes. You can complete the tests and surveys in any order at any time that is convenient for you. You do not need to complete all the activities in one session, but you will only have a week to complete all the activities.

ISSUES TO CONSIDER
Participation in this study may involve some added risks or discomforts. These include:

1. The mental effort and emotional stress of answering some of the questions or participating in some of the tests. If you are concerned about your performance, you should consult with your physician. However, please keep in mind that many factors (e.g., amount of sleep, time of day, etc.) may contribute to variations in test performance, and many of the tests are designed to be difficult.
2. Despite every possible safeguard, there exists the slight risk that confidential information regarding your history, substance use or health diagnosis may become known outside of the research setting. Although such an event is unlikely, it could be potentially damaging to your insurability and/or employability.

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

How long will I be in the research?
We expect the study to last approximately 2 months, however, the app can remain on your phone for multiple years. We make no guarantees about its continued functionality. We encourage you to delete the app after you are done participating in the study from you iPad.

POTENTIAL BENEFITS
You will receive no direct benefit from participating in this study. The knowledge gained may help others in the future.

UNFORESEEABLE RISKS
There may be some risks that are not currently known. If the principle investigator learns of any additional risks, we will attempt to notify you via an update or e-mail.

ALTERNATIVE TO PARTICIPATING IN THIS STUDY
The alternative to participating in this study is to choose not to participate. Participation in this research is entirely voluntary.
Financial Disclosure
Joan Severson has controlling interest in the Sponsor . Please feel free to ask any further questions you might have about this matter.

NEW FINDINGS
You will be told of any new, relevant information that comes out while you are in this study that might lead you to change your mind about staying in the study. To provide you with this information, we may send an e-mail to the account you register with the application. Insights discovered from the study will be posted on blogs, the study website, and research publications.

WITHDRAWAL/ REMOVAL FROM THE STUDY
Participation in this research is entirely voluntary. You may refuse or withdraw participation in this study at any time. Likewise, you may be withdrawn from the study (1) if you do not follow the instructions given to you by study personnel, or (2) if the study is cancelled by the investigators or the sponsor. If you are taken off this study for any reason, you will be notified. Deciding not to participate, your withdrawal from the study, or removal from the study, will not result in any penalty or loss of benefits to which you are entitled.

- You should not feel obligated to participate in this study.
- Your questions should be answered clearly and to your satisfaction.
- By agreeing to participate you do not waive any of your legal rights.

You may withdraw from this study by clicking the appropriate "withdraw from study" link on the profile section of this application.

COMPENSATION
You will receive no compensation for participating in this study. There will be no cost to you for participating in this study.

QUESTIONS

Contact Joan Severson, BA, MS at 319-431-3278 for any of the following reasons:

- if at any time you feel you have had a research-related injury, or
- if you have questions, concerns, or complaints about the research

If you have questions about your rights as a research subject or if you have questions, concerns, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

PROTECTING YOUR DATA

Participant records are maintained in a confidential and secure manner. Data collection forms carry only study identification numbers. All records are stored securely on HIPAA compliant servers. Standard measures exist for all computerized records, which limit data access to selected research project personnel. The electronic data are protected by four secure layers of authentication; specifically, to access the electronic data an individual needs a) access to a machine on the internal network b) access to the database server c) access to the database d) access to the database table.

Research records will be kept confidential to the extent allowed by law. Research records may be reviewed by WIRB and other regulatory agencies such as the US Food and Drug Administration. We will do everything we can to keep others from learning about your participation in the research. Despite careful safeguards, information regarding your history, drug use, or medical diagnosis may become known outside of the research setting. Although such an event is very unlikely, accidental disclosure of your history or medical information could be potentially damaging to your insurability and/or employability.

The Principal Investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. If the Principal Investigator determines reporting to authorities is necessary because of imminent serious danger to yourself or others, then he would only disclose information in your records to the extent necessary to prevent such imminent danger.

DATA USE

Data from this study are available to study investigators, study partners, and authorized personnel. To guard confidentiality, only a special code number will be used as an identifier on questionnaires, and all records, forms, and data will be kept on secure servers. De-identified data may be shared with other authorized researchers after the completion of the study.

CONSENT

I have read about this research study .All my questions about the study and my part in it have been answered. I freely consent to be in this research study and I authorize the use and disclosure of my unnamed, coded data for use in research as indicated in this informed consent agreement. If you have any questions or research related problems, you may contact Joan Severson at joan@digitalartefacts.com. Alternatively, technical assistance can be received at support@brainbaseline.com.

Byjoining this study , I have not given up any of my legal rights.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTOOD THE ABOVE INFORMATION AND THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED. A COPY OF THIS FORM IS AVAILABLE TO DOWNLOAD AND PRINT ON THE WEBSITE AND IS AWAYS AVAILABLE FOR REVIEW INSIDE THE APPLICATION.

First Name	Last Name	Signature	Date