APPROVED
AS MODIFIED
Sep 05, 2013
WIRB®

RESEARCH SUBJECT INFORMATION FOR INFORMED CONSENT

TITLE: Brain Function in Aging

PROTOCOL NO.: None
WIRB® Protocol #20091320

SPONSOR: Cerebral Assessment Systems, Inc.

INVESTIGATOR: Charles J. Duffy, M.D., Ph.D.
10 Pond View Drive
Pittsford, New York 14534
United States

SITE(S): Lifetime Care
3111 South Winton Road
Rochester, New York 14623
United States

Lifetime Health Medical Group
West Seneca Health Center
120 Gardenville Parkway West
West Seneca, New York 14224
United States

Legacy Senior Living
Legacy at Clover Blossom
100 McCaukey Drive
Rochester, New York 14610
United States

Brown Square Health Center
322 Lake Avenue
Rochester, New York 14608
United States

Woodward Health Center
480 Genesee Street
Rochester, New York 14611
United States

Linda Rice
1742 E Ridge Road
Rochester, New York 14622
United States

Neurology Consultants
101 Sullys Trail
Pittsford, New York 14534
United States

Richard Constantino
1445 Portland Avenue
Rochester, New York 14622
United States

Hilton Health Care
279 E Avenue #2
Hilton, New York 14468
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Lattimore Internal Medicine
125 Lattimore Road
Rochester, New York 14620
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Partners in Internal Medicine
Suite 310
30 Hagen Drive
Rochester, New York 14625
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Cahn-Hidalgo, M.D.
Suite 100
300 White Spruce Boulevard
Rochester, New York 14623
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Sleep Insights
Suite 200
10 Hagen Drive
Rochester, New York 14625
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Greater Rochester Neurology
Building #1
2101 Lac De Ville Boulevard
Rochester, New York 14618
United States

Oasis
259 Monroe Ave.
Rochester, New York 14607
United States

Cloverwood Senior Living
1 Sinclair Dr
Pittsford, New York 14534
United States

STUDY-RELATED PHONE NUMBER(S): Charles J. Duffy, M.D., Ph.D.
585-230-5253 (24 hours)

Please ask the study staff to explain any words or information that you do not clearly understand.
This consent form describes a research study sponsored by Cerebral Assessment Systems, Inc., a company developing computerized systems for testing brain function related to aging, disease, and drug effects. This consent form describes what you may expect if you decide to participate in this study. You are encouraged to read this consent form carefully and to ask the person who presents it any further questions you may have before deciding whether or not to participate.

Description of Study Procedures
You are being asked to participate in a research study because you are an adult age 55-85.
If you agree to participate, you will be asked to spend up to 15 minutes doing the following:

1) Provide your full name and date of birth;
2) Answer questions about your medical conditions and treatments;
3) Move a wheel to point to scenes on a computer screen.

We ask that you allow us to review your medical records to understand your condition.

Risks of Participation

1) Questionnaire: This may be tiresome. Rest breaks will be available as needed.
2) Wheel Responding: If you become tired of turning the wheel you can take a break.

There may be risks or side effects which are unknown at this time.

You will be told about any new information that might change your decision to be in this study.

Benefits of Participation
There are no direct benefits that you can expect to receive as a result of this study.

Costs/Payment
There is no cost or payment to you to participate in this research study.

Financial Disclosure
Dr. Duffy is an owner of the sponsor company. Please ask any questions you have about this.

Alternatives
Your alternative is to not be in this study.

Voluntary Participation
Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. In such an event, we will ask that you help us maintain clear records by telling us why you decided to withdraw. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any of the following reasons:

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- or for any other reason.

Confidentiality of Records and HIPAA Authorization
While we will make every effort to keep information we learn about you private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

Contact Person
If you ever feel you have had a research-related injury, or if you have questions, concerns or complaints about the research, you should contact Dr. Duffy as listed above.

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®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
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.

SIGNATURE PAGE FOR INFORMED CONSENT

Signature/Dates

I have read the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

Study subject: _____ PRINT NAME

_____ SIGNATURE

_____ DATE

Person Conducting Informed
Consent Discussion: _____ PRINT NAME

_____SIGNATURE

_____ DATE

Investigator: _____ PRINT NAME
(if different from above)

_____ SIGNATURE

_____ DATE

APPROVED
AS MODIFIED
May 08, 2014
WIRB®

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: Brain Function in Aging

PROTOCOL NO.: None
WIRB® Protocol #20091320

SPONSOR: Cerebral Assessment Systems, Inc.

INVESTIGATOR:
Charles J. Duffy, MD, PhD
10 Pond View Drive
Pittsford, New York 14534
United States

SITE(S):
Lifetime Care
3111 South Winton Road
Rochester, New York 14623
United States

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West Seneca Health Center
120 Gardenville Parkway West
West Seneca, New York 14224
United States

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Rochester, New York 14607
United States

Cloverwood Senior Living
1 Sinclair Dr
Pittsford, New York 14534
United States

STUDY-RELATED PHONE NUMBER(S): Charles J. Duffy, M.D., Ph.D.
585-230-5253 (24 hours)

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Introduction

This consent form describes a research study sponsored by Cerebral Assessment Systems, Inc., a new company developing computerized systems for testing brain function related to aging, disease, and drug effects. This consent form describes what you may expect if you decide to participate in this study. You are encouraged to read this consent form carefully and to ask the person who presents it any further questions you may have before deciding whether or not to participate. In addition, it is recommended you use the bathroom before the test begins.

You are being asked to participate in a research study because you are an adult who meets the requirements of the study.

This consent form describes the known possible risks and benefits of this study. You are completely free to choose whether or not to participate in this study.

Purpose of Study

You are participating in a study that is being conducted by Dr. Charles Duffy of Cerebral Assessment Systems, Inc. to assess the effects of aging on your ability to see patterns clearly on a computer

screen. The computerized system to collect the information obtained during the study is investigational and will be evaluated in this research.

Approximately 3000 subjects will take part in this study during the coming year, up to 500 subjects at this test site.

Description of Study Procedures

If you agree to participate, you will be asked to spend up to 90 minutes doing the following:

1) Provide your full name and date of birth;
2) Answer questions about your medical conditions and treatments;
3) Move a wheel to point to scenes on a computer screen.
4) Up to 40 minutes of standard neuropsychological tests.

We also ask that you allow us to review your medical records at this site to better understand your conditions and treatments.

Risks of Participation

1) Questionnaires: These may be tiresome. Rest breaks will be available as needed.
2) Wheel Responding: If you become tired of turning the wheel you can take a break.

There may be risks or side effects which are unknown at this time.

Benefits of Participation

The information obtained in this research study may benefit patients in the future by computerizing and standardizing these tests improving the quality of the information collected.

Costs

There is no cost to you to participate in this research study.

Payment

You will receive $20 per session for your participation in the study.

Alternatives

This is not a treatment research study. Your alternative is to not be in this study.

Source of Funding

Funding for this research study will be provided by Cerebral Assessment Systems, Inc.

Financial Disclosure

Dr. Duffy is a partial owner of the sponsor company. Please feel free to ask any further questions you might have about this matter.

Voluntary Participation

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. In such an event, we will ask that you help us maintain clear records by telling us why you decided to withdraw. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any of the following reasons:

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- or for any other reason.

Circumstances for Leaving the Study

The exact duration of the study depends on the computer's efficiency working with you. If the computer system has difficulty measuring your responses, or if it appears that continuing in the study would present a hardship for you, we will terminate your testing.

Confidentiality of Records and HIPAA Authorization

While we will make every effort to keep information we learn about you private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we either create or use as part of research. This permission is called an Authorization. We will use your research record, related information from your medical records, results of laboratory tests, and both clinical and research observations made while you take part in the research.

We will use your health information to conduct the study, to monitor your health status, to determine research results, and possibly to develop new tests, procedures, and commercial products. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies, and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the study doctor for one.

To meet regulations or for reasons related to this research, the study doctor may share a copy of this consent form and records that identify you with the following people: the Department of Health and Human Services (DHHS), the Western Institutional Review Board® (WIRB®), your physicians, doctors or student doctors involved in this research.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study doctor. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization affects only use and sharing of information after the study doctor receives your request. Information gathered before then may need to be used and given to others. For example, by Federal law, we must send study information to the FDA for medical device studies that it regulates. Information that may need to be reported to the FDA cannot be removed from your research records.

As stated in the section on voluntary participation above, you can also refuse to sign this consent/Authorization and not be a part of the study. You can also tell us you wish to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above.

Contact Person

For more information concerning this research, if at any time you feel you have had a research-related injury, or if you have questions, concerns or complaints about the research, you should contact:

Charles J. Duffy, M.D., Ph.D.
Chief Science Officer
Cerebral Assessment Systems, Inc.
10 Pond View Drive
Pittsford, New York 14534
Telephone: 585-230-5253 (24 hours)

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.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will receive a copy of this consent form for your records and future reference.

Signature/Dates

I have read the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

Study subject: _____ PRINT NAME

_____ SIGNATURE

_____ DATE

Person Conducting Informed
Consent Discussion: _____ PRINT NAME

_____SIGNATURE

_____ DATE

Investigator: _____ PRINT NAME
(if different from above)

_____ SIGNATURE

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