Date

Signature of Participant

10. To be free of pressure when considering whether you wish to agree to be in the study.

9. To receive a copy of the signed and dated consent form.

8. To refuse to participate or to change your mind about participating after the study is started.

7. To be told what sort of medical treatment is available if any complications arise.

6. To be allowed to ask any questions concerning the study, both before agreeing to be involved and during the course of the study.

5. To be told the other choices you have and how they may be better or worse than being in the study.

4. To be told if you can expect any benefits from participating and if so, what the benefits might be.

3. To be told about the potential and/or important risks, side effects, or discomforts of the different forms that might be used in standard practice.

2. To be told what will happen to you and whether any of the procedures, drugs, or devices is experimental.

1. To be told what the study is trying to determine.

As an experimental subject, you have the following rights:

The rights below are the rights of every person who is asked to be in a medical research study.

Principal Investigator: Lyn Robertson
Title of Study: Attentional Disorders in Patients with Brain Injury
Subject Name:

Date:

(Title of Subjects Bill of Rights)
We do not plan to share your PHI outside the research team.

The study process. This may include:

- The research team may also need to disclose your information to others as part of the research system.
- No information will be disclosed outside the VA Northern California Health Care System.
- Information will be disclosed outside the VA Northern California Health Care System from the following hospitals, clinics, providers, or other entities:

The researcher named above and his or her research staff may obtain your PHI

VANCCHS

Parties Who May Disclose Your Protected Health Information (PHI)

- Radiology Images
- Medications
- Diagnoses
- Birth Date
- Address
- Name

Information about you:

By signing this document, you will authorize the parties listed below to provide the following:

Protected Health Information (PHI) to be Used or Disclosed

- Regions:
- MRI or CT scans will be used to determine the site and extent of any brain
- Study, MRI, or CT scans will be used to determine the site and extent of any brain

Researchers will use your PHI to determine suitability as a participant in this study. We request your permission to use and release your PHI.

PHI for research. We request your permission to use and release your PHI.

The Health Insurance Portability & Accountability Act (HIPAA) allows you to

AUTHORIZATION FOR THE USE AND RELEASE OF PHI

Principal Investigator: Lyn Robertson

Title of Study: Attentional Disorders in Patients with Brain Injury

VA: VANCCHS

Subject Name:

(Continuation Page 2 of 11)
VANCHCS. Information released outside of VANCHCS may be re-disclosed.

Potential for Re-disclosure

collected information about you after you revoke the authorization.

The research team will not

that was collected before receipt of the revocation. The research team can continue to use information about you

The investigator and the research team can continue to use information about you

requesting in writing. Please mail your request to Lyn Robertson, The researchers will respond to your

Toman Hall #5/50 Berkeley, CA 94720. The address is also

this in writing. Please mail your request to Lyn Robertson. The address is also

You may request not to allow researchers to share your information. You must do

Right to Revoke Your Authorization

Related treatment.

not take part in this research study. In addition, you will not receive research

There are some exceptions. If you decide not to sign this authorization, you will

authorize or refuse) deciding whether you sign this authorization.

This authorization to release PHI is voluntary. VANCHCS may not condition

This authorization will be used indefinitely.

Authorization will expire October 3, 2010. However, the data collected with this

Researchers cannot use your PHI indefinitely without your knowledge. This

Duration of Investigator Access and Use of Your Protected Health

Information (PHI)

☐ Other:

☐ The study sponsor:

☐ U.S. Food and Drug Administration (FDA)

☐ VANCHCS Human Studies Subcommittee/IRB

Principal Investigator: Lyn Robertson

Title of Study: Attentional Disorders in Patients with Brain Injury

Subject Name:

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Authorization for PHI Use for Research

Department of Veterans Affairs
Subject's Initials

Subject Committee
APPROVED
JANAN STUDIES

VOID AFTER OCT 3 2009

OCT 2 2009

Date

Signature of Participant

Authorize the use of my PHI as described in this form.

I authorize the use of my PHI as described in this form.

Date

Signature

Principal Investigator: Lyn Robertson

Title of Study: Attentional Disorders in Patients with Brain Injury

Subject Name:

Continuation Page 4 of 11

AUTHORIZATION FOR PHI USE FOR RESEARCH
If you volunteer to take part in this study, we will ask you to do the following things: You

Standard Procedures being done because you are in this study:

1. Pre-study Tests:
   - Conduct this study for 6 years.
   - There will be about 350 subjects taking part in this study at VANCs. Researchers will
     2. Study Procedures:
     - Personal and no financial interest in this study.
     - The study investigator and staff are conducting this study entirely for research. They have no
   1. Researchers' Financial Disclosure:
     - These sessions will last between 2 and 4 hours.
     - Between 2-3 months from now and about 9 months later. These will be at your convenience.
     - You will be in this study for 1-2 hours with scheduled breaks whenever you request. We may
     - Study Length:
     - Problems in vision due to brain injury.

The purpose of this study is to learn more about how the brain processes objects and their
You qualify to take part in this project because you are between the ages of 18-100

Research Study. Please take your time to make your decision. Ask questions about anything you do not understand before deciding if you want to be in this study. You should read the information that follows. Please do not have to be in this research study. You should read the information that follows. Please do not have to be in this research study. You should read the information that follows. Please do not have to be in this research study. You should read the information that follows. Please do not have to be in this research study. You should read the information that follows.
You might be invited to take part in other studies that are ongoing at UC Berkeley. You would only be asked to participate in those studies if you are doing all procedures for research.

You will be given a copy of the MRI picture. You can take the MRI pictures with you. If you have a problem with the MRI machine, the researcher will help you obtain a more complete review of your MRI scan by a specially trained radiologist. The radiologist will cover your name when the doctor discusses the possible problems with you.

Tell the researcher in charge of this study if you agree with the MRI pictures. They happen to those who have had similar findings. However, the pictures may not lead to negative outcomes. MRI pictures can be part of your care at a clinic or hospital. Specialized health care is not used to evaluate these MRI pictures.

Mr. Procedure: We will also ask you to let the trained technicians at the VA take an image of your brain using a magnetic resonance imaging (MRI). The MRI is a standard medical tool.

Principal Investigator: Lyn Robertson
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Subject Name: [Redacted]

(Continuation Page 6 of 11)
pacemaker.

Fragrument in your eye, ear, nose, or mouth, or any other foreign objects in the body. Examples would be a needle, toothpick, or a piece of metal in your body. Researchers will not allow you into the MRI room if you have a pace-maker. If you have a pace-maker, you will not be allowed in the MRI room. Researchers will not allow you into the MRI room if you have a pace-maker. If you have a pace-maker, you will not be allowed in the MRI room.

MRI machine: A large magnet. It could move iron-containing objects in the MRI machine. If you have a pace-maker, you will not be allowed in the MRI room. Researchers will not allow you into the MRI room if you have a pace-maker. If you have a pace-maker, you will not be allowed in the MRI room.

MRI procedure:

• Other risks are not expected, but unforeseeable events could occur.

Employment or Economic Risks: Because this study takes time out of your schedule, it could happen.

However, we take great care to protect the patient's confidentiality.

Legal risks: The patient may experience legal risk if they are not informed.

Privacy risks: There is a minimal risk of breach of privacy. However, we will store all information in a locked cabinet, in a locked office, and only certified research personnel will have access to the data.

Psychological risks: Some people may find the tests difficult, intimidating, or boring. There is a small possibility that you will feel fatigued.

Behavioral tests: You may have adverse events or discomforts while on this study.

Potential risks and discomforts:

Principle Investigator: Lynn Robertson
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Subject Name:

Communication Page 7 of 11
Subject's Initials

Right to Withdraw from the Study
Your taking part in this research is voluntary. You can stop taking part at any time.

Alternative is not to take part. Future care may not be affected.

Other Options to Taking Part in this Study
Your taking part in this study may help us to learn more about visual and attentional problems. You may find the tests interesting. Subjects in similar studies have reported satisfaction and called the experience “fun.”

Expected Benefits to Others
You may not benefit from taking part in this research. However, you may help us to diagnose and treat people with neurological diseases that result in visual and attentional problems.

Expected Benefits to Subjects
We hope to learn more about visual and attentional problems. Your taking part in this study may help us to diagnose and treat people with neurological diseases that result in visual and attentional problems.

Unforeseeable Risk
The researcher does not know all the side effects that may happen. You may experience a side effect or new risk that the researchers do not know about at this time.

For more information about risks and side effects, ask the researcher or contact Lynn Robertson at 225-370-4104.

Because the risks to a fetus from MRT are unknown, pregnant women cannot take part in this study.

Having an MRT may mean some added discomfort for you. In particular, you may be bothered by feelings of claustrophobia and by the loud banging noise during the study. Temporary hearing loss has been reported from this loud noise. This is why researchers will ask you to wear earplugs. At times during the test, researchers may ask you to not swallow for a while, which can be uncomfortable.
9. Research Related Injury

In this research, VA policy requires that a note be placed in your medical record that identifies you as taking part
in the study. The Institutional Review Board is a committee whose purpose is to review and monitor research studies that involve human subjects. The Institutional Review Board at VA NCCHS reviews the human subject's rights and is the consumer advocate. One of these is the Institutional Review Board (differentiate known as the Human Subjects Review Board). The Institutional Review Board has the authority to review and approve-individually or in conjunction with other VA facilities nationally and internationally-
research proposals that fall within the scope of this policy. Federal law requires participants to be informed of
Researcher's name and title. The results of this study will be published in scientific journals. Participants will
not be identified by name. If you are interested in obtaining a copy of your research records, you may be contacted by phone or mail. The research team also reserves your privacy. You may be contacted by phone or mail. The

8. Confidentiality

If you choose not to take part in this study, you will not be penalized or lose any benefits to

Principal Investigator: Lynn Robertson
Title of Study: Attentional Disorders in Patients with Brain Injury

[Signature]

[Date]

[Name]
Regional Counsel: The phone number is (415) 750-2288.
Research Protection Program: The phone number is (916) 366-5359. You may also call the VA.

You may have questions about your research subject rights. You may also have questions that

13. Questions About Research Subject Rights

Robertson at 510-524-9471.

12. Questions About this Study

If you have any questions about this study, contact one of the researchers on this study: Lynne

11. Payment for Taking Part in the Study

$12.00 per hour. If your hourly pay exceeds $12, you will be reimbursed for your time and travel

as a research subject, you will be reimbursed for your time and travel.

10. Costs to Study Subjects

counsel at 415) 750-2288. For further information about this study, you may call the VA.

form. For further information about this study, you may call the VA. If your legal rights to seek

interests of the Department of Veterans Affairs and the study sponsor, do not normally provide

Principle Investigator: Lynne Robertson

Title of Study: Attentional Disorders in Patients with Brain Injury

Subject Name:

VA MC: VANCOHS

RESEARCH CONSENT FORM

Department of Veterans Affairs

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signed copy of this consent form. I understand that the study is about and how and why it is being done. I will receive a
study. I understand my rights as a research subject, and I voluntarily consent to participate in this
emergency care. If any medical problems occur in connection with this study, the VA will provide
hours. If any medical problems occur in connection with this study, the VA will provide
in case there are medical problems or questions, I have been told I can call Lyn Robertson,
by law. The results of this study may be published, but my records will not be released unless required.
study at any time without penalty or loss of VA or other benefits to which I am entitled. I may withdraw from this
understand that I do not have to take part in this study, and my refusal to participate
of the choices of treatment available to me.
I have been told of the risks of discomforts and possible benefits of the study. I have been told
has explained the study to me and answered all of my questions.
NAME: VAANCHE
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