LOMA LINDA UNIVERSITY
HEALTH

INSTITUTIONAL REVIEW BOARD
RESEARCH PROTECTION PROGRAMS
24887 Taylor Street • Suite 202 • Loma Linda, CA 92350
(909) 558-4531 (voice) • (909) 558-0131 (fax)

Extension Requested Approval Notice - Full Board *IRB# 5140083*

To: **Bartnik-Olson, Brenda Lynn**
Department: **Radiology**
Protocol: **Measuring cerebral blood flow using pseudo-continuous arterial spin labeling perfusion magnetic resonance imaging**

At the regularly scheduled meeting of the Institutional Review Board on 13-Apr-2016, your request to extend the approval period for the protocol indicated above was reviewed. The action of the IRB is as follows::

Extension Request:	**Approved**
Risk to research subjects:	**Minimal**
Approval period begins:	**13-Apr-2016** and ends **12-Apr-2017**
Stipulations of approval:	**Enrollment is limited to subjects between 18-90 years of age.**

Consent Form

If this study was approved on the condition that a consent form is required AND subjects are still being enrolled, only the consent form bearing the IRB authorization stamp can be used. This will become your OFFICIAL consent form for the dates specified and should be used as the new master for making copies to give prospective subjects.

☑ Master consent form with up-dated authorized stamp enclosed.

☐ Updated consent form not required. Approval limited to data analysis or follow-up of currently enrolled subjects only.

IRB Communications

Thank you for your cooperation in LLU's shared responsibility for the ethical use of human subjects in research.

IRB Chair/Designee

5/11/16
Date

IRB Chair:
Travis Losey, MD
Department of Neurology
(909) 558-4531, tlosey@llu.edu, Pager #4290 for emergencies

IRB Administrator:
Linda G. Halstead, MA, Director
Research Protection Programs
Ext 43570, Fax 80131, lhalstead@llu.edu

IRB Analyst:
Anuradha Diekmann, MPH, CCRP, CIP
Research Protection Programs
Ext 86215, Fax 80131, adiekmann@llu.edu

CALIFORNIA EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in an experimental clinical procedure. Before you decide whether you want to participate in the experimental procedure, you have a right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of any signed and dated written consent form used in relation to the experiment.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

I have carefully read the information contained above in the "California Experimental Subject's Bill of Rights" and I understand fully my rights as a potential subject in a medical experiment involving people as subjects.

_____ _____

Date Patient

_____ _____

Time Parent/Legal Guardian

If signed by other than the patient, indicate relationship:

_____ _____

Relationship Witness

Loma Linda University
Adventist Health Science Center
Institutional Review Board
Approved 5/11/16 Void after 4/12/2017
#5140083 Chair

LOMA LINDA UNIVERSITY
HEALTH

CONTROL SUBJECT INFORMED CONSENT
Loma Linda University

Study Title: Measuring Cerebral Blood Flow Using Pseudo-Continuous Arterial Spin Labeling Perfusion Magnetic Resonance Imaging.

Principal Investigator: Brenda Bartnik Olson, Ph.D.

Purpose and Procedure
You are invited to volunteer to have a brain magnetic resonance imaging (MRI) study that will test a new MRI sequence that measures cerebral blood flow (CBF). Because this technique for measuring CBF is new, there is little information on what the normal values for different regions of the brain should be. Information from your study will be used to establish normative CBF values for the brain, enabling us to reliable use this technique in the injured and/or diseased brain.

The examination that you will have uses a high field magnet. Some devices, such as pacemakers or other electronic devices will not operate properly in a strong magnetic field, therefore if you choose to participate you will be asked to fill out a questionnaire that will determine if it is safe for you to have a MRI exam.

The exam will require you to lie on your back for approximately 30 minutes to one hour. A coil will be place around your head. You will be given headphones to listen to music to reduce the noise level normally produced during the scan. You will be able to communicate with the operator of the MRI at all times during the study and will be able to stop at any time if you choose.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Should any significant information be discovered as a result of the study procedures, you and your physician will be notified by the Study Doctor.

Risks
The committee at Loma Linda University that reviews human studies (Institutional Review Board) has determined that participating in this study exposes you to minimal risk. As stated above, you will be asked to fill out a MRI safety questionnaire to determine if you have any

Date:_____
Initial:_____

A Seventh-day Adventist Organization
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11234 Anderson Street, Room B623, Loma Linda, California 92354
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metal or electronic/magnetic devices that are not MRI compatible and may cause harm to you if you are scanned. If you answer "yes" to any of these questions, you will not be able to participate in this study.

Benefits
It is not anticipated that there will be any direct benefit to your participating in testing this new sequence.

Participants' Rights
Participation in this study is voluntary. You may choose to decline the MRI scan at any time during the study, including requesting that the study scans be stopped.

Confidentiality
Your name will not be used or associated with data acquired in this study. Any published document resulting from this study will not disclose your identity without permission. The US Food and Drug Administration, the Department of Health and Human Services, and/or their designee(s) may inspect the records relating to your participation in this study.

Additional Costs and Reimbursement
There are no additional costs to you will result from your participation in this study. You will not be paid to participate in this study.

Impartial Third Party Contact
If you want to contact an impartial third party not associated with this study regarding any question or complaint you may have about the study, you may contact the office of Patient Relations (patientrelations@llu.edu), Loma Linda University Medical Center, Loma Linda, 92354, phone (909) 558-4647 for information and assistance.

Date:_____
Initial:_____

Measuring Cerebral Blood Flow Using Pseudo-Continuous Arterial Spin Labeling Perfusion Magnetic Resonance Imaging.

Informed Consent Statement

I, or my legal representative, have read the contents of the consent form and have listened to the verbal explanation given by the investigator. Questions concerning this study have been answered to my satisfaction. I hereby give voluntary consent to participate in this study. Signing this consent document does not waive my rights nor does it release the investigators, institution or sponsors from their responsibilities. I may call Brenda Bartnik Olson, PhD, during routine office hours at (909) 558-4010 or during non-office hours at (909) 558-4800 and ask the operator to page Dr. Bartnik Olson, pager number 6551, if I have additional questions or concerns.

I have been given a copy of this consent form.

I have received a copy of the California Experimental Subject's Bill of Rights and have had these rights explained to me.

_____ _____

Signature of Subject Date

I, Dr. Brenda Bartnik Olson, attest that the requirements for informed consent for the medical research project described in this form have been satisfied – that the participant has been provided with a copy of the California Experimental Subject's Bill of Rights, that I have discussed the research project with the participant and explained to him or her in nontechnical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to incur. I further certify that I encourage the participant to ask questions and that all questions asked were answered.

_____ _____

Signature of Investigator Date

Date:_____
Initial:_____

INSTITUTIONAL REVIEW BOARD
Authorization for Use of Protected Health Information (PHI)

Per 45 CFR §164.508(b)

OSR#

OFFICE OF SPONSORED RESEARCH
Loma Linda University • 11188 Anderson Street • Loma Linda, CA 92350
(909) 558-4531 (voice) / (909) 558-0131 (fax)

TITLE OF STUDY: **Measuring Cerebral Blood Flow Using Pseudo-Continuous Arterial Spin Labeling Perfusion Magnetic Resonance Imaging.**

PRINCIPAL INVESTIGATOR: B Bartnik Olson, PhD

Others who will use, collect, or share PHI: B Holshouser, PhD

Loma Linda University
Adventist Health Science Center
Institutional Review Board
Approved 5/11/16 Void after 4/12/2017
#5140083 Chair Travis Loney

The study named above may be performed only by using personal information relating to your health. National and international data protection regulations give you the right to control the use of your medical information. Therefore, by signing this form, you specifically authorize your medical information to be used or shared as described below.

The following personal information, considered "Protected Health Information" (PHI) is needed to conduct this study and may include, but is not limited to: name, address, telephone number, date of birth, medical records and charts, including the results of all tests and procedures performed.

The individual(s) listed above will use or share this PHI in the course of this study with the Institutional Review Board (IRB) of Loma Linda University, health care providers who provide services to you in connection with this study, central labs, central review centers and central reviewers.

The main reason for sharing this information is to be able to conduct the study as described earlier in the consent form. In addition, it is shared to ensure that the study meets legal, institutional, and accreditation standards. Information may also be shared to report adverse events or situations that may help prevent placing other individuals at risk.

All reasonable efforts will be used to protect the confidentiality of your PHI, which may be shared with others to support this study, to carry out their responsibilities, to conduct public health reporting and to comply with the law as applicable. Those who receive the PHI may share with others if they are required by law, and they may share it with others who may not need to follow the federal privacy rule.

Subject to any legal limitations, you have the right to access any protected health information created during this study. You may request this information from the Principal

Investigator named above but it will only become available after the study analyses are complete.

- This authorization does not expire, and will continue indefinitely unless you notify the researchers that you wish to revoke it.

You may change your mind about this authorization at any time. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for this study. However, study personnel may continue to use the health information that was provided before you withdrew your permission. If you sign this form and enter the study, but later change your mind and withdraw your permission, you will be removed from the study at that time. To withdraw your permission, please contact the Principal Investigator or study personnel at 909-558-4000, ext. 85216.

You may refuse to sign this authorization. Refusing to sign will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are entitled. However, if you do not sign this authorization form, you will not be able to take part in the study for which you are being considered. You will receive a copy of this signed and dated authorization prior to your participation in this study.

I agree that my personal health information may be used for the study purposes described in this form.

Signature of Patient *or* Patient's Legal Representative	Date
Printed Name of Legal Representative (if any)	Representative's Authority to Act for Patient
Signature of Investigator Obtaining Authorization	Date

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