

**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO BE A RESEARCH SUBJECT**

Magnetic Resonance Imaging of Intracranial Fetal Anatomy

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A. PURPOSE AND BACKGROUND

Doctors Barkovich, Glenn, Feldstein, Goldstein, Filly, Norton, Vigneron, Henry, Ferriero, Bartha, and Jeremy from the University of California, San Francisco are conducting a pilot study to determine if pictures of the fetal brain obtained using a magnet can help determine if there is an abnormality in my baby's brain. I am being asked to participate in this study because I am having an MRI of my baby's brain. I understand that using the magnet to get pictures of my babies' brains is a relatively new technique and that ultrasound is the standard method for looking at fetal brains. Fetal MRI does seem, however, to be more sensitive than ultrasound in the detection of brain abnormalities.

B. PROCEDURES

If I agree to be in this study, the following will happen:

- 1) I will undergo a magnetic resonance (MR) scan which will be done by putting me in a large magnetic tunnel 6 feet long by 22 inches wide and open at each end. While pictures of my fetus(es) are taken using a computer, I will lie still for about 60 minutes (or 90 minutes if I have twins), during which time there will be some loud machine-like noises.
- 2) I may also be asked to undergo an obstetrical ultrasound if one has not yet been performed at the Medical Center at U.C. San Francisco. I may, however, decline to have an additional ultrasound.
- 3) I may also be asked to undergo a second magnetic resonance (MR) scan in 4 – 6 weeks, which will be just like the first one. If so, then I will be contacted by the study coordinator who will assist in scheduling the second MR scan.
- 4) Any medical information from the scans which would benefit me or my fetus(es) will be released to my obstetrician to assist in taking care of me and my fetuses.
- 5) I will also be contacted in the future and be asked to provide valuable follow-up information over the telephone about the course and outcome of my pregnancy, and when I deliver, how my baby is growing and developing. I will therefore be asked to provide information by which I can be contacted in the future. This may include my phone number and address, the name, phone number and address of physicians who may take care of me and my fetus(es), as well as family members who may know how to get in touch with me, should my current phone number and/or address change in the future.
- 6) When I deliver, I may also be offered free neurodevelopmental testing for my child when he/she is 12 months and 30 months of age. These visits will be arranged at a convenient time for

me and my baby. The neurodevelopmental testing will involve a neurologic exam by Dr. Ferriero and her staff, and a developmental evaluation performed by a certified research psychologist who routinely works with children.

7) Participation in this study will take a total of approximately three hours. All fetal study procedures will be done in the Department of Radiology at China Basin and/or the Medical Center at U.C. San Francisco. All neurodevelopmental assessments will be done in the Pediatric Clinical Research Center at the Medical Center at U.C. San Francisco.

8) Health information: In the course of this study, Dr. Orit A. Glenn and her research team will review my obstetrical medical records, including previous ultrasound results. This information will be used to decide if I am eligible for a free second fetal MRI. This information, as well as information about pregnancy outcome, will also be entered and stored in a research database that will be later used for data analysis. All health information will be kept in password-protected computer files or in locked cabinets accessible only to the research team.

C. RISKS/DISCOMFORTS

1) Information about possible brain abnormalities can be stressful to future parents who may be concerned about future brain symptoms such as seizures, cerebral palsy or mental retardation. The study doctors will provide information to me about my fetus(es)' condition to reduce my concerns whenever possible.

2) No risks of MR to mothers nor to fetus(es) have been described to date. It is possible that MR may cause additional problems that the researchers do not know about yet, but this is unlikely. The scanning procedure does not involve the use of X-rays. However, since the MR pictures are obtained using a large magnet, metal objects containing iron in the MR room could move during the examination, which could in doing so harm me. Precautions have been taken to prevent such an event from happening; loose metal objects are not allowed in the MR room. Certain metal objects which may potentially be in my body could also move and/or not function properly during the examination, which could in doing so harm me. I will be screened to be certain that I do not have any of these objects nor devices in or on my body. Additionally, temporary hearing loss has been reported from the noise the machine makes. I will be given earplugs to protect my ears. I will not be given any medication, nor contrast agents for this study.

3) There is a small chance that I may become dizzy and/or uncomfortable during the MR scan because of laying on my back. If I do, I will alert the radiologist or technologist, who will temporarily stop the procedure and let me shift position so that the dizziness and/or discomfort goes away.

4) There is a strong possibility that I may feel like I am in a tight, enclosed space when I am placed in the magnet. If I do, I will alert the radiologist or technologist, who will temporarily stop the procedure until the feeling goes away. If the feeling persists and I cannot proceed with the MRI, then the study will be stopped.

5) There are no known risks of ultrasonography during pregnancy. In fact, many people are moving toward routine obstetrical sonography because of this.

6) Neurodevelopmental assessment: There are no risks or discomforts with routine neurologic and developmental examinations.

7) Confidentiality: Participation in research may involve loss of privacy. My research records will be handled as confidentially as possible within the law. While my name and other demographic information will be on the research records, these records will be accessible only to

study investigators; my name will not be used in any reports or publications resulting from this study.

Treatment and compensation for injury:

If I or my fetus(es) are injured as a result of being in this study, treatment is available. The costs of such treatment may be covered by the University of California depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, I may call the office of the Committee on Human Research at (415) 476-1814.

D. BENEFITS

The study investigators believe that the information gained by MRI scanning of the brains of my fetus(es) will provide my doctors and me with information about his/her/their condition. It is also hoped that the information gained from this study will be valuable to future parents of fetus(es) with possible brain abnormalities and will permit the investigators to learn more about why and when this condition occurs in some cases. For mothers with twins with abnormal blood supply, it is also hoped that the information obtained will help to determine if different forms of treatment (including, but not limited to, withdrawing amniotic fluid and/or surgically blocking abnormal blood vessels) are options for me.

E. ALTERNATIVES

If I choose not to participate in this study, I will receive standard medical care for this condition. This might include some additional ultrasound scanning or procedures. These studies would occur at the discretion of my obstetrician. My refusal to participate in this study will not have any effect on the care that my baby and I receive.

F. COSTS

There are no research-related costs for being in this study. However, clinically ordered studies, such as the fetal MRI, will be billed to me or my insurance company through routine billing channels. If I am having this fetal MRI as part of the study on Isolated Mild Ventriculomegaly, then both fetal MRIs, when performed at UCSF as a part of this study, will not be billed to me or my insurance company. If an ultrasound is offered to me at UCSF as part of this study and not as part of my routine clinical care, then I will not be charged for the research ultrasound. Any other routine laboratory and/or diagnostic tests and hospitalization costs deemed necessary by my obstetrician will be billed to me or to my insurance company. There are no research related costs for the postnatal neurodevelopmental assessments as part of this study.

G. REIMBURSEMENT

I will not be reimbursed for participation in this study. However, if I bring my child back for a free neurodevelopmental evaluation, I will receive a parking voucher to pay for the UCSF parking.

H. QUESTIONS

This study has been explained to me by Dr. _____ and my questions were answered. If I have any other questions about the study, I may call Dr. Barkovich at 353-1655 or Dr. Glenn at 353-2526.

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CHR Approval No.: H10727-17810-09C
(suspected abnormality)
CHR Approval Date: 8/1/08
CHR Expiration Date: 4/17/09

I. CONSENT

I have been given a copy of this consent form and the Experimental Subject's Bill of Rights to keep. PARTICIPATION IN RESEARCH IS VOLUNTARY. I have the right to decline to participate or to withdraw at any point in this study without jeopardy to my medical care.

I have been asked to give my permission for me to participate in this study. If I wish to participate, I should sign below.

CONTACT INFORMATION:

Patient's email address _____ **Father's email address** _____

Patient's name _____ **Father's name** _____

Address _____ **Father's address** _____

Phone numbers (area code) _____ **Father's number** _____

Physician's name _____

Address _____ Phone number (area code) _____

Contact Name (& relationship) _____

Address _____

Phone number (area code) _____ **Email address** _____

Contact Name (& relationship) _____

Address _____

Phone number (area code) _____ **Email address** _____

Contact Name (& relationship) _____

Address _____

Phone number (area code) _____ **Email address** _____

Patient's signature

Date

Person obtaining consent

Date

Interpreter's signature

Date