TEMPLE UNIVERSITY®

**Office for Human Subjects Protections**
**Institutional Review Board**
Medical Intervention Committees A1 & A2
Social and Behavioral Committee B

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## Research Review Committee A

## Certification of Approval for a Project Involving Human Subjects

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|---|---|
| Protocol Number: | **12180** |
| PI: | **MULCAHEY, MJ** |
| Approved On: | 08-Jan-2009 |
| Review Date: | 08-Jan-2009 |
| Committee: | A1 - MEDICAL INTERVENTION |
| Department: | Shriners Hospitals for Children |
| Project Title: | Diffuse Tensor Imaging and the Pediatric Spinal Cord: Validity and Reliability Testing with Pediatric SCI |

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In accordance with the policy of the Department of Health and Human Services on protection of human subjects in research, it is hereby certified that protocol number 12180, having received preliminary review and approval by the department of Shriners Hospitals for Children was subsequently reviewed by the Institutional Review Board in its present form and approved on 08-Jan-2009 with respect to the rights and welfare of the subjects involved; appropriateness and adequacy of the methods used to obtain informed consent; and risks to the individual and potential benefits of the project.

In conforming with the criteria set forth in the DHHS regulations for the protection of human research subjects, and in exercise of the power granted to the Committee, and subject to execution of the consent form(s), if required, and such other requirements as the Committee may have ordered, such orders, if any, being stated hereon or appended hereto.

**It is understood that it is the investigator's responsibility to notify the Committee immediately of any untoward results of this study to permit review of the matter. In such case, the investigator should call Richard Throm at 707-8757.**

**MICHAEL R. JACOBS, PHARM.D.**
**CHAIRMAN, IRB**

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**MEMORANDUM**

To: **MULCAHEY, MJ**
Shriners Hospital

From: Richard C. Throm
Institutional Review Board

Date: 29-Jan-2009

Re: Subpart D Status for IRB Protocol:
**12180**: Diffuse Tensor Imaging and the Pediatric Spinal Cord: Validity and Reliability Testing with Pediatric SCI

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**Addendum to the IRB Approval Certificate - append to certificate**
CFR Subpart D: Additional Protections for Children Involved as Subjects in Research

Federal regulations classify permissible research involving minors into four categories, based on degree of risk and type of prospective benefit. These categories are described in relation to "minimal risk".

**Minimal risk** is defined as the probability and magnitude of harm or discomfort anticipated in the **research** are not greater in and of themselves from those ordinarily encountered in daily life of during the performance of routine physical or psychological examination or tests.

**Greater than minimal risk** is a term used in defining Category 2 [45 CFR 46.405] and Category 3 [35 CFR 46.406]. The regulations do not provide any further definition or clarification of this term except for specifying "a minor increase over minimal risk" in regards to Category 3 only. Therefore, the protocol application should clearly describe the study risks so the IRB, in consultation with the investigator's assessment, make an appropriate determination for category of approval.

Operative Definitions.
(a) Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.
(b) Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
(c) Permission means the agreement of parent(s) or guardian to the participation of their child or ward in research.
(d) Parent means a child's biological or adoptive parent.
(e) Guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

This protocol was reviewed and approved under category:

**Research Category 2:** Greater than minimal risk, but prospect of direct benefit to subject

Requires:
1. Permission of ONE parent/legal guardian
2. Assent of minor (if child is 7 years of age or older (18)
3. Risk be justified by anticipated benefit
4. Relation of the benefit to the risk is at least favorable to the subjects as that presented by available

alternative approaches