



Akron
Children's
Hospital

Akron Children's Hospital - FWA #00000917 - Expiration 1/10/2017
IORG #0001126 - Expiration 1/10/2015

January 26, 2012

Neville Irani, M.D.
Radiology
Akron Children's Hospital
One Perkins Square
Akron, OH 44308

Re: TCD Screening in Sickle Cell Disease: The Implications of Using Peak Systolic Criteria
IRB No. 120103

Dear Dr. Irani:

The IRB Chair has reviewed the application and protocol for the above study. It is a retrospective re-analysis of existing studies to determine if a new proposed analytic criterion is superior to the standard criterion. A request to do the study without consent is made. The period covered by the review and the number of subjects make it impractical to obtain consent and yet the study cannot be done without obtaining the patient data. Identifiers will be removed from data as early as possible. It is granted waiver of consent.

The study is minimal risk. It is granted expedited approval under Subpart D 46.404 (21 CFR 50.51) subject to the following:

1. Approval is for one year 25 Jan 2012 to 24 Jan 2013 and ends unless appropriately renewed.
2. Any serious incidents or events associated with the survey be promptly reported to the IRB.
3. No changes will be made to the conduct of the study unless they are first reviewed and approved by the IRB.
4. All individuals who will participate in this study must provide the IRB evidence of completion of the Protecting Human Research Participants on-line training course prior to any involvement in the study. This can be found at <http://phrp.nihtraining.com/users/login.php>

Sincerely,

Robert W. Novak, M.D.
Chairman, Institutional Review Board

RWN/has