University of Virginia
Institutional Review Board for Health Sciences Research
Protection of Human Subjects Approval
Assurance Identification/Certification/Declaration
(Common Federal Rule)

HSR # 15443

Event:	Type:	Sponsor(s):
Approval Protocol Continuation - Expedited	Protocol	Sponsor Protocol #:
		Principal Investigator: Mark Abel, MD

Title: Adolescent idiopathic scoliosis spinal fusion surgical outcomes

Assurance: Federal Wide Assurance (FWA)#: 00006183

Certification of IRB Review: The IRB-HSR abides by 21CFR50, 21CFR56, 45CFR46, 45CFR160, 45CFR164, 32CFR219 and ICH guidelines. This activity has been reviewed by the IRB in accordance with these regulations.

Event Date: 06/17/15

Protocol Expiration Date: 06/16/16

Number of Subjects: 3200

HSR Protocol Version Date: 02/09/11

Current Status: Temporarily closed to enrollment

Consent Version Dates:

Committee Members (did not vote):

Comments:
Protocol Expedited by Category #5: Research involving materials (data, documents, records or specimens) that have been collected solely for non-research purposes (such as medical treatment and/or diagnosis).

Modification expedited: minimal risk/minor change: the following personnel change(s) were made per the Status Form: Jennifer Basel, removed from study.

PLEASE REMEMBER:
* If an outside sponsor is providing funding or supplies, you must contact the SOM Grants and Contracts Office/ OSP regarding the need for a contract and letter of indemnification. If it is determined that either of these documents is required, participants cannot be enrolled until these documents are complete.
* You must notify the IRB of any new personnel working on the protocol PRIOR to them beginning work.
* You must obtain IRB approval prior to implementing any changes to the approved protocol or consent form except in an emergency, if necessary to safeguard the well-being of currently enrolled subjects.
* If you are obtaining consent from subjects, prisoners are not allowed to be enrolled in this study unless the IRB-HSR previously approved the enrollment of prisoners. If one of your subjects becomes a prisoner after they are enrolled in the protocol you must notify the IRB immediately.
* You must notify the IRB-HSR office within 30 days of the closure of this study.
* Continuation of this study past the expiration date requires re-approval by the IRB-HSR.

The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed and certification will be provided.

Name:	Name and Address of Institution:
Lynn R. Noland , RN PhD	Institutional Review Board for Health Sciences

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