Partners Human Research Committee
Partners Human Research Office
116 Huntington Avenue, Suite 1002
Boston, MA 02116
Tel: (617) 424-4100
Fax: (617) 424-4199

Amendment: Notification of IRB Approval/Activation

Protocol #: 2009-P-000329/43; BWH

Date: 02/11/2013

To: Nitin Jain, MD, MSPH
Orthopedics

From: Isabel Middleton Suzarte
PHS Research Management
HN116

Title of Protocol:	Rotator Cuff Tears: Optimizing Diagnosis and Treatment Strategies
Version Date:	02/10/2009
Sponsor/Funding Support:	Foundation for Physical Medicine and Rehabilitation
IRB Amendment #:	31
IRB Review Type:	Expedited
Minimal Risk:	45 CFR46.110 and 21 CFR56.110
Expedited Category/ies:	(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves; using medical devices cleared/approved for marketing. (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
IRB Approval Date:	02/01/2013
Approval Effective Date:	02/11/2013
IRB Expiration Date:	02/07/2014

This Amendment to ongoing approved project has been reviewed and approved by the BWH IRB. During the review of this Amendment to ongoing approved project, the IRB specifically considered (i) the risks and anticipated benefits, if any, to subjects; (ii) the selection of subjects; (iii) the procedures for securing and documenting informed consent; (iv) the safety of subjects; and (v) the privacy of subjects and confidentiality of the data.

NOTES:

- *Adding optional testing of selected biomechanical factors for enrolled subjects including scapular kinematics, measure of subacromial space, and scapular muscle activity.*
- *Subjects electing this additional assessment will be compensated an additional $50 for their participation each time the procedures are performed ($100 total).*
- *The revised Protocol Summary (December 2012), Detailed Protocol (10/2/12) and the Consent Forms have been approved.*

As Principal Investigator you are responsible for the following:

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1. Submission in writing of any and all changes to this project (e.g., protocol, recruitment materials, consent form, study completion, etc.) to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB.
2. Submission in writing of any and all adverse event(s) that occur during the course of this project in accordance with the IRB's policy on adverse event reporting.
3. Submission in writing of any and all unanticipated problems involving risks to subjects or others.
4. Use of only IRB approved copies of the consent form(s), questionnaire(s), letter(s), advertisement(s), etc. in your research. Do not use expired consent forms.
5. Informing all physicians listed on the project of changes, adverse events, and unanticipated problems.

The IRB can and will terminate projects that are not in compliance with these requirements. Direct questions, correspondence and forms (e.g., continuing reviews, amendments, adverse events, safety reports) to Isabel Middleton Suzarte, 617-424-4115.

cc: Catherine E. Sutherland, CIP, Research Management, 125 Nashua Street Boston, MA 02114
Nitin Jain, MD, MSPH, Orthopedics
Peter Douglass

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Continuing Review: Notification of IRB Approval/Activation

Protocol #: 2009-P-000329/43; BWH

Date: 02/11/2013

To: Nitin Jain, MD, MSPH
Orthopedics

From: Isabel Middleton Suzarte
PHS Research Management
HN116

Title of Protocol:	Rotator Cuff Tears: Optimizing Diagnosis and Treatment Strategies
Version Date:	02/10/2009
Sponsor/Funding Support:	Foundation for Physical Medicine and Rehabilitation
IRB Continuing Review #:	4
IRB Review Type:	Expedited
Minimal Risk:	45 CFR46.110 and 21 CFR56.110
Expedited Category/ies:	(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves; using medical devices cleared/approved for marketing. (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
IRB Approval Date:	02/07/2013
Approval Effective Date:	02/07/2013
IRB Expiration Date:	02/07/2014

This Project has been reviewed and approved by the BWH IRB. During the review of this Project, the IRB specifically considered (i) the risks and anticipated benefits, if any, to subjects; (ii) the selection of subjects; (iii) the procedures for securing and documenting informed consent; (iv) the safety of subjects; and (v) the privacy of subjects and confidentiality of the data.

NOTES: Reviewed and approved by the IRB: Detailed Protocol 8/17/12, Protocol Summary July 2011, Consent Form and Enrollment Report.

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