December 27, 2013

COLUMBIA UNIVERSITY
MEDICAL CENTER

Institutional Review Board
154 Haven Avenue, 1st Floor
New York, NY 10032
212.305.5883 Tel
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William Macaulay
ORT Orthopaedic Surgery - 753200X
Presbyterian Hospital
11-1146

Protocol Number: IRB-AAAA5922
Title: Prospective Data Collection for the Center for Hip and Knee Replacement
Approval Date: 05/03/2013
Expiration Date: 05/02/2014

Dear Dr. Macaulay,

On May 03, 2013, the renewal for the above-mentioned study was reviewed and approved by expedited review, category 7, by the Chair of Columbia University Medical Center Institutional Review Board (IRB) Exp. You may now continue human research for this study.

Important reminder:
- The new data security policy has been released and as of 2/1/2013 will be effective for all protocols including Protected Health Information (PHI) and Personally Identifiable Information (PII). Any multi-user system that will store human subject data containing PHI or PII must be assessed and certified by the CUMC IT Information Security Office. Any human subject data that is stored on an End User Device must be protected by a strong password with the data encrypted at all times. Existing protocols that do not meet this criteria will be required to provide an updated data security plan. For additional information, please view the policy at: http://www.cumc.columbia.edu/dept/irb/documents/DataSecurityPolicyfinaleffective02012013.pdf.

During the approval period, all subjects enrolled must provide voluntary informed consent to participate in the study. The requirement to obtain written informed consent has been waived in accordance with 45 CFR 46.117(c).

The following study-related materials were approved:
- CHKR Updated Information Sheet, attached 04/12/2013
- UCLA Activity Score Survey, attached 08/28/2008
- Post-op Patient, attached 05/01/2008
- Pre-op Patient, attached 05/01/2008
- Post-op Non Patient, attached 04/26/2004
- Pre-op Non Patient, attached 04/26/2004

The following HIPAA document was approved for use for this study: HIP-AAAI5003

The following changes included with the renewal were also approved:
- Information Sheet has been revised to include HIPAA elements;
- Submission of HIPAA Form B as subjects will not provide signatures;
- Removal of co-investigator, Jonathan Lee, from the study team;
- Addition of Louis Bigliani as department approver.

Any proposed changes in the protocol must be immediately submitted to the IRB for review and approval prior to implementation, unless such a change is necessary to avoid immediate harm to the participants. Additionally, any unanticipated problems that involve risks to subjects must be reported to the IRB in accordance with the CUMC Unanticipated Problems: Reporting to the IRB of Unanticipated Problems Involving Risks policy, dated January 24, 2008. All submissions for modifications and unanticipated problems must be submitted through RASCAL.

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Association for the Accreditation of Human Research Protection Programs, Inc. — Full Accreditation

Renewal applications should be submitted 60 days before the expiration date of this study through RASCAL. Failure to obtain renewal of your study prior to the expiration date will require discontinuance of all research activities for this study, including enrollment of new subjects. You must inform the IRB in writing when your study has been completed.

If you have any questions regarding this approval, please contact Susie Kim at (212) 342-3058 or sjk2142@columbia.edu.

Columbia University appreciates your commitment towards the ethical conduct of human research.

Sincerely,

Susie J. Kim, CIP
Manager, IRB 5-Expedited

Electronically signed by: Butaud-Rebbaa, Laurence