Texas Orthopedic HOSPITAL

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December 20, 2016

Anay Patel, M.D.
Fondren Orthopedic Group
7401 South Main
Houston, TX 77030

Protocol: **TOH203e** / *"Influence of logistical, social and demographic factors on length of stay in a short stay model for total joint arthroplasty"*

Re: Exempt Approval

Dear Dr Patel:

I am pleased to inform you that the Institutional Review Board of Texas Orthopedic Hospital has determined that the above named protocol is appropriate for "Exempt" status as of December 20, 2016.

Should you have any questions regarding this status, please do not hesitate to contact the IRB Secretary, DeDe Wilson in the Medical Staff Office at extension 3560.

Sincerely,

Ajay Vargheese, M.D., Chairman Designee
Texas Orthopedic Hospital
Institutional Review Board

Cc: Barrett Brown, MD; Brad Edwards, MD; Robin Goytia, MD; Richard Kearns, MD; Vasilios Mathews, MD; Gregory Stocks, MD; Joshua Woody, MD; Ugo Ihekweazu, MD

TOH203e

Request for Exemption

TEXAS ORTHOPEDIC HOSPITAL
INSTITUTIONAL REVIEW COMMITTEE

Title of Research Study:
Influence of logistical, social and demographic factors on length of stay in a short stay model for total joint arthroplasty

Principal Investigator: Anay Patel, MD, Fondren Orthopedic Group

Investigators:

Barrett Brown, MD
Fondren Orthopedic Group

Brad Edwards, MD
Fondren Orthopedic Group

Robin N. Goytia, MD
Fondren Orthopedic Group

Richard Kearns, MD
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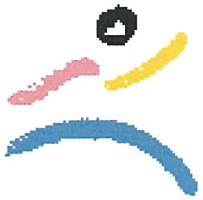
Vasilios Mathews, MD
Fondren Orthopedic Group

Gregory Stocks, MD
Fondren Orthopedic Group

Joshua Woody, MD
Fondren Orthopedic Group

Ugo N. Ihekweazu, MD
Resident, PGY-5
Baylor College of Medicine

Rationale for Exemption from Institutional Review and Informed Consent:
The research will involve the collection and study of existing data, documents, images and other clinical records. The information will be recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.



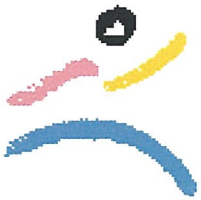
Purpose:
As the incidence of primary total joint arthroplasty increases in the United States, the continued utilization of the procedure to meet the demands of our aging population is expected to result in a pronounced economic burden on the US health care system (Kurz, 2007). In order to address rising costs in hip and knee arthroplasty, in April 2016, Medicare enacted the Comprehensive Care for Joint Replacement (CJR) payment model. CJR is a mandatory 5-year bundled payment program being tested in 67 metropolitan areas. In this trial program, hospitals are paid a lump sum for the entire episode of care, including the initial admission, post-acute care, as well as any complications encountered 90 days from discharge. With the rapidly increasing demand for hip and knee procedures in the U.S., every reduction in cost per surgery at the micro level can translate into a substantial cost savings to the overall system (Teeny, 2005).

In-hospital length of stay has been shown to directly influence total cost of joint arthroplasty (Cram, 2012; Meyers, 1996). Therefore, a collective effort has been placed on implementing measures to reduce length of hospital stay. Recently, there has been a clear trend towards early patient discharge from the hospital as soon as safely possibly. Development of rapid recovery pathways combined with enthusiasm from patients, improvements in anesthesia, as well as surgical and rehabilitation techniques has led to substantial reductions in the length of stay (LOS) without increasing complications (Stambough, 2015). As a result, short in-hospital stay (<2 day) programs are becoming more popular in contrast to the longer more conventional postoperative protocols.

Factors influencing prolonged LOS under conventional postoperative pathways for hip and knee arthroplasty has been previously described in the literature (Rissanen, 1996, Forrest, 1998). One recent study has highlighted the impact of scheduling on LOS in patients undergoing TKA with standard postoperative LOS (Keswani, 2016) while another publication considered patients in a short stay model (Edwards, 2016). Another institution that has successfully implemented a short stay protocol has investigated the influence of preoperative patient characteristics and perioperative surgical factors related to prolonged LOS (Sibia, 2017, Sibia, 2016). To our knowledge, none have focused on logistical factors such as hospital staffing, surgical scheduling and distance traveled and social factors such as marriage status, in addition to pre-and perioperative variables in a short stay model.

The primary purpose of this study will be to assess the influence of logistical factors such as hospital staffing, surgical scheduling and distance traveled as well as social factors on length of stay in a short stay model for total joint arthroplasty.

Methodology:
Subjects:
A retrospective chart review will be performed for a consecutive series of unilateral primary elective THA, TKA and TSA's, from January 2016 to January 2017. Only patients undergoing unilateral primary total hip, knee or shoulder arthroplasty will be included in the study. No other patients will be excluded. All surgeries were performed by experienced surgeons.



Procedures:
This study is a retrospective review; therefore, there will be no new interventions. Patients will be identified based on whether they received unilateral primary total knee arthroplasty within the study period stated above. Patient charts and operative reports will be retrospectively reviewed for basic demographic and clinical information including age at time of surgery, date of surgery, gender, BMI, American Society of Anesthesiology (ASA) class, anesthesia records, past medical and surgical history, social history, physical therapy records, implant type (need for stems, augments or increased constraint), distance traveled for surgery, pre-op use of anti-depressants or pain medication, and hospital staffing records.

Step-by-step:
Patients who underwent unilateral primary total knee arthroplasty during the study period will be identified by the operating surgeon's office records. Operative reports and in-patient hospital data will be reviewed by co-author (UI). No patients will be contacted for this study. Data analysis will be performed by a statistician with a history of collaboration with the institution.

Risks/Benefits:
This study involves no direct or indirect risks to any patient since only existing radiographs and medical record data are being analyzed. No benefits to any patients are anticipated.

Confidentiality:
In order to maintain confidentiality, there will be no paper records, all electronic records will be kept in a database that is password protected in a secure server of the Fondren Orthopedic Group under a secure drive. Sensitive data including patient date of birth and social security numbers will not be included in the database. Study data will not leave Texas orthopedic hospital or Fondren Orthopedic Group. No other entity will be involved in the study. Only the investigators or his/her office staff involved with this study will have access to it. If the results of this study are published, the data will be reported collectively without mention of any subject's identity, thereby ensuring subject anonymity.

References:

Cram P, Lu X, Kates SL, et al. Total knee arthroplasty volume, utilization, and outcomes among Medicare beneficiaries, 1991-2010. JAMA 2012;308(12): 1227

Edwards P, Hadden K, et al. Effect of total joint arthroplasty surgical day of the week on length of stay and readmissions: a clinical pathway approach. J Arthroplasty 2016; 31, 2726-2729

Forrest G, Fuchs M, Gutierrez A, et al. Factors affecting length of stay and need for rehabilitation after hip and knee arthroplasty. J Arthroplasty 1998;13:186.

Keswani A, Beck C, Meier KM et al. Day of Surgery and Surgical start time affect hospital length of stay after total hip arthroplasty. JOA, 2016. 2426-2431.

Kurtz S, Ong K, Lau E, et al. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am 2007;89(4):780.

Meyers SJ, Reuben JD, Cox DD, et al. Inpatient cost of primary total joint arthroplasty. J Arthroplasty 1996;11(3):281.

Rissanen P, Aro S, Paavolainen P. Hospital- and patient-related characteristics determining length of hospital stay for hip and knee replacements. Int J Technol Assess Health Care 1996;12:325.

Sibia U, MacDonald P. Predictors of Hospital Length of stay in an enhanced recovery after surgery program for primary total hip arthroplasty. The Journal of Artroplasty,2016. Vol 31 Issue 10; 2119-2123.

Stambough JB, Nunley RM, Curry MC, et al. Rapid recovery protocols for primary total hip arthroplasty can safely reduce length of stay without increasing readmissions. J Arthroplasty 2015;30(4):521.

Teeny SM, York SC, Benson C, et al. Does shortened length of hospital stay affect total knee arthroplasty rehabilitation outcomes? J Arthroplasty 2005;20(7 Suppl 3):39.

Udai S. Sibia, MD, MBA, Paul J. King, MD, James H. MacDonald, MD *Who Is Not a Candidate for a 1-Day Hospital-Based Total Knee Arthroplasty? JOA 2017; 32: 16-19

TOH203e

Texas Orthopedic Hospital Institutional Review Board
Waiver Form

Name of Study: "Influence of logistical, social and demographic factors on length of stay in a short stay model for total joint arthroplasty"

Principal Investigator (PI): Anay Patel, MD

Satisfaction of Waiver: The IRB committee has determined that the waiver, in whole or in part, of the otherwise required authorization, satisfies all of the following criteria:

1. The use or disclosure of protected health information (PHI) involves no more than a minimal risk to the privacy of the individual(s) based on, at least, the presence of the following elements:

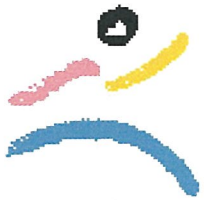
   X An adequate plan to protect the identifiers from improper use and disclosure;

   Describe plan to protect identifiers: The information will be recorded in such a manner that human subjects cannot be identified from the final database to be analyzed. A separate file containing identifying numerical codes linked to the subjects' names will be available only to the Principal Investigator. This file will be stored on a password-protected hard drive in the Principal Investigator's office. The subject numbers will be assigned essentially randomly (no systematic order to reading charts; not alphabetical or by medical record number or date of service, etc.).

   X An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

   Describe plan to destroy identifiers The file containing identifying information will be destroyed/deleted once data collection is complete and the data have been screened for errors. The data will be stored on a secure hard drive that is accessible only by the Principal Investigator.

   X This document constitutes adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study or for other research for which the use of disclosure of PHI would otherwise be permitted under the HIPAA Privacy Rule; and



__X__ The research could not practicably be conducted without the waiver or alteration: The research will not have direct contact with research subjects due to this being a retrospective chart study and consenting all subjects may entail costs that would make the research impracticable.

and

__X__ The research could not practically be conducted without access to and use of the PHI: Subject PHI is necessary for this research proposal. The PHI will not be used or disclosed.

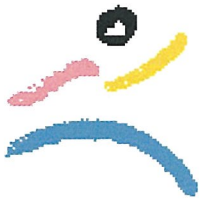
2. **Necessary Information**. The following is a brief description of the minimum PHI for which use or access is sought:
The clinical records will be evaluated to identify and determine the factors influencing prolonged length of stay following primary total knee arthroplasty at Texas Orthopedic Hospital.

Principal Investigator: As the Principal Investigator of this research protocol, I hereby certify that the information I have provided above is accurate and truthful. I understand that the IRB will use this information to make the decision whether to grant or deny a Waiver of Authorization as set forth in the HIPAA Privacy Rule.

Signature of Principal Investigator: _____

Date: 12/20/16

TOH203e



IRB Response to Request for Patient Authorization Waiver

IRB Membership. This waiver to the otherwise required written authorization for the use or disclosure of protected health information ("PHI") has been approved by and Texas Orthopedic Hospital Institutional Review Board established in accordance with Health and Human Services regulations set forth at 45 C.F.R. Section 46.107 or other equivalent regulations.

Identification of IRB and Date of Action.

A. The name of the IRB approving this waiver is Texas Orthopedic Hospital Institutional Review Board.
B. The date on which the IRB named above approved this waiver is _____ day of _____, 20____.

Review and Approval Procedures. This alteration or waiver of authorization has been reviewed and approved under either of the following [check one]:

_____Normal review procedure
_____Exempt status procedures
_____Expedited review status

Decision Regarding Waiver: The IRB named above has decided to:

_____Waive the otherwise required authorization
_____Decline waiver
_____Alter the required patient authorization as noted below:

_____

_____

Required Signature. This waiver or alteration has been approved as evidenced by the signature below of the Chairman of the IRB or his/her designee (who is an IRB member).

Signature: _____ Date: 12/20/16

Printed Name: Ajay Varghese

_____Chairman of IRB

__✓__Designee of Chairman of IRB