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Certificate of Approval

THE FOLLOWING WERE APPROVED

INVESTIGATOR: John Meding MD
1199 Hadley Road
Mooresville, Indiana 46158

BOARD ACTION DATE: 07/15/2016
PANEL: 2

STUDY APPROVAL EXPIRES: 08/12/2017

STUDY NUM: 1126808

WIRB PRO NUM: 20111241

ONLINE TRACKING:

INVEST NUM: 207353

WO NUM: 1-948102-1

CONTINUING REVIEW: Annually

SITE STATUS REPORTING: Annually

INST. NUM:

SPONSOR: Joint Replacement Surgeons of Indiana (JRSI) Research Foundation

PROTOCOL NUM: 1055

AMD. PRO. NUM:

TITLE:

A Prospective Database of Joint Replacement Surgery

APPROVAL INCLUDES:

Study and Investigator for an additional continuing review period. This approval expires on the date noted above.

WIRB APPROVAL IS GRANTED SUBJECT TO:

WIRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:

Midwest Specialty Surgery Center, 6920 Gatwick Drive, Suite 100, Indianapolis, Indiana 46241

JRSI Foundation, 1199 Hadley Road, Mooresville, Indiana 46158

Franciscan St. Francis Health – Mooresville, 1201 Hadley Road, Mooresville, Mooresville, Indiana 46158

If the PI has an obligation to use another IRB for any site listed above and has not submitted a written statement from the other IRB acknowledging WIRB's review of this research, please contact WIRB's Client Services department.

ALL WIRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research in accordance with the protocol, applicable laws and regulations, and the principles of research ethics as set forth in the Belmont Report.
2. Although a participant is not obliged to give his or her reasons for withdrawing prematurely from the clinical trial, the investigator should make a reasonable effort to ascertain the reason, while fully respecting the participant's rights.

IF YOU HAVE ANY QUESTIONS, CONTACT WIRB AT 1-800-562-4789

This is to certify that the information contained herein is true and correct as reflected in the records of the Western Institutional Review Board (WIRB), OHRP/FDA parent organization number IORG 0000432, IRB registration number IRB00000533. WE CERTIFY THAT WIRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) REGULATIONS, AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

