The UNIVERSITY of VERMONT
Committees on Human Subjects
Serving the University of Vermont
and the UVM Medical Center

RESEARCH PROTECTIONS OFFICE
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Exemption Certification - Initial

To:	Nathaniel Nelms
From:	Ryann Guayasamin, Research Review Analyst
Approved Date:	January 6, 2020
Study#:	CHRMS (Medical): STUDY00000725
Study Title:	Accuracy of a Simple Intra-operative Fluoroscopic Parallel Line Technique to Evaluate Leg Length Discrepancy During Anterior Approach Total Hip Arthroplasty
Sponsor:	Internal Funding
Finalized Documents:	Fluoro Protocol ; Research_Data_Management_and_Security_Plan_0_1.pdf ;

The study referenced above was reviewed by the Chair of the IRB (or an authorized designee) using the exempt procedures set forth under 45 CFR 46.104. While the project is exempt from IRB review, it is required that researchers follow all human subject protection regulations and notify the IRB of any problems that arise during the conduct of the project.

Exemption Category: (4) Secondary research on data or specimens (no consent required)

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems

of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

Consent/HIPAA/Waiver Determinations:

•Waiver of Consent and UVM/UVMMC HIPAA Authorization under 46.116(f)(1)(3), 46.164.512(i)(1)(2)

This determination applies only to the activities described in this IRB submission and will no longer apply should any changes be made. If changes are necessary, please submit a modification for consideration of a continued exemption.