

Institutional Review Board for Human Research (IRB) Office of Research Integrity (ORI) Medical University of South Carolina

> South Park Plaza 1 South Park Circle, Bldg. 1, Suite 401 Charleston, SC. 29407 Federal Wide Assurance # 1888

APPROVAL: Protocol: MS42_Pro00053742 MUSC Amendment #: Ame42_Pro00053742 Amendment Title: Amendment 42 for IRB Study #Pro00053742 Sponsor Amendment #: A Version Date: 1/11/2024

This is to certify that the amendment to the research proposal entitled: Comparative Effectiveness of Pulmonary Embolism Prevention after Hip and Knee Replacement: Balancing Safety and Effectiveness

Submitted by: Vincent Pellegrini Department: ORTHOPAEDICS & PHYSICAL MEDICINE - MUSC Sponsor: PCORI

for consideration has been reviewed by **IRB-II** - **Medical University of South Carolina** and approved with respect to the study of human subjects as adequately protecting the rights and welfare of individuals involved, employing adequate methods of securing informed consent from these individuals and not involving undue risk in the light of potential benefits to be derived therefrom. No IRB member who has a conflicting interest was involved in the review or approval of this amendment, except to provide information as requested by the IRB. If this amendment required a change in the currently approved Informed Consent, then all previous Informed Consent documents should be marked obsolete.

Approval Date: 3/14/2024

Amendment Type: **Expedited**

Administrator, IRB - Medical University of South Carolina

* Summer Young, MPH, CIP

* *Electronic Signature*: This document has been electronically signed by the IRB Administrator through the HSSC eIRB Submission System authorizing IRB approval for this study as described in this letter.