

Board Action Date: 02/03/2026	Work Order Number: 1-1935312-1
Sponsor: RegenMed, Inc.	Protocol Approval Expires: 02/03/2046
Sponsor Protocol Number: None Amended Sponsor Protocol Number:	Continuing Review Frequency: No CR Required
IRB Tracking Number: 20260305	
Protocol Title: MOTIV™ Total Knee Arthroplasty (TKA) Observational Protocol	

THE FOLLOWING ITEMS ARE APPROVED:

- Clinician Operative Survey #45446755.0 - As Submitted (source: Clinician Operative Survey)
- Clinician Post-Operative Evaluation Survey #45446756.0 - As Submitted (source: Clinician Post-Operative Evaluation Survey)
- Clinician Post-Operative Surveyrepeated #45446757.0 - As Submitted (source: Clinician Post-Operative Survey)
- Clinician Pre-Operative Evaluation Survey #45446758.0 - As Submitted (source: Clinician Pre-Operative Evaluation Survey)
- Incytes License Terms and Conditions #45420427.0 (source: incytes license terms and conditions)
- Patient Post-Operative Followup Survey #45446759.0 - As Submitted (source: Patient Post-Operative Follow-Up Survey)
- Patient Pre-Operative Survey #45446760.0 - As Submitted (source: Patient Pre-Operative Survey)
- Protocol (01-26-2026) Version 1.0 (source: motiv total knee arthroplasty protocol pdf)

Please note the following information about this review:

EXMPT D1-6 - The research [is] exempt under [45 CFR 46.104(d)(4)]. Per submission form no information collected in the study will be submitted to or held for future submission to the FDA. This exemption determination can apply to multiple sites, but this does not apply to any institution that has an institutional policy of requiring an entity other than WCG IRB (such as an internal IRB) to make exemption determinations. WCG IRB’s determination of an Exemption only applies to US regulations; it does not apply to regulations or determinations for research conducted outside of the US. Future changes to the project may affect its exempt status, and you may want to contact WCG IRB about the effect these changes may have on the exemption status before implementing them. WCG IRB does not impose an expiration date or closure requirements on its IRB exemption determinations. As indicated above, the protocol was determined to meet criteria not requiring ongoing IRB oversight. As a result, all collaborating investigators at your institution may participate regardless of only the submitted Investigator being listed on the Certificate of Action and HIPAA Waiver documentation if provided.

ALL WCG IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

- Ensure the consenting process included in the submission is being followed. Any changes to this process must be submitted to the IRB for review
- Consistent with AAHRPP’s requirements in connection with its accreditation of IRBs, the individual and/or organization submitting shall promptly communicate or provide, and where necessary cause each investigator to promptly communicate or provide, the following information relevant to the protection of human subjects to the IRB in a timely manner:
- Upon request of the IRB, a copy of the written plan between sponsor or CRO and site that addresses whether expenses for medical care incurred by human subject research subjects who experience research related injury will be reimbursed, and if so, who is responsible in order to determine consistency with the language in the consent document.
 - Any site monitoring report that directly and materially affects subject safety or their willingness to continue participation. Such reports will be provided to the IRB within 5 days.
 - Any findings from a closed research when those findings materially affect the safety and medical care of past subjects. Findings will be reported for 2 years after the closure of the research.
 - Please note that any advertisements or subject material that contain both English and translated content must be submitted through the translations process in addition to standard review to have the translated content approved.

This is to certify that the information contained herein is true and correct as reflected in the records of WCG IRB. WE CERTIFY THAT this IRB 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.



For Investigator's Brochures, an approval action indicates that the IRB has the document on file for the research. When the Board approves subject materials and/or advertisements, any redline changes that were provided by the submitter or required by the Board for approval will remain visible in the outcome document(s); however, recipients are expected to accept the tracked changes in the document before using. Do not make any additional modifications (including font size and visual effects) to the approved materials. If this study includes data monitoring committee/data safety monitoring board, please note that the reports of all meetings of this committee should be submitted to the IRB even if the outcome of the meeting results in no changes to the study.

Federal regulations require that the IRB conduct continuing review of approved research. You will receive Continuing Review Report forms from WCG IRB when the expiration date is approaching.

Thank you for using WCG IRB to provide oversight for your research project.

DISTRIBUTION OF COPIES:

Contact, Company

Alyssa Johncola, RegenMed, Inc.

Michael Tierney, RegenMed, Inc.

Investigator List

The following PIs received some or all of the approvals specified in this Certificate of Action (COA). Please review the COA for each PI listed below to confirm which approvals apply for each PI.

Wickline, Andrew