# Certificate of Action

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| **Board Action Date**: 12/10/2023 | **Work Order Number**: 1-1720935-1 |
| **Sponsor**: Centers for Disease Control and Prevention | **Protocol Approval Expires**: 01/19/2024 |
| **Sponsor Protocol Number**: None<br>**Amended Sponsor Protocol Number:** none | **Continuing Review Frequency**: Annually |
| **IRB Tracking Number**: 20225896 | |
| **Protocol Title**: Understanding HIV/STD Risk and Enhancing PrEP Implementation Messaging in a Diverse Community-Based Sample of Gay, Bisexual, and Other Men Who Have Sex with Men in a Transformational Era (MIC-DROP Study) | |

**THE FOLLOWING ITEMS ARE APPROVED:**
Template Consent Form [S4]

**Please note the following information about this review:**
Please present all future participants with the Consent Information Sheet(s) specified in this approval.

**ALL WCG IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:**

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.

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**
Erin Rogers, Emory University/Rollins School of Public Health/Department of Epidemiology
Ruth Dana, Emory University/Rollins School of Public Health/Department of Epidemiology
Rebecca Moges-Banks, Emory University

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.

# 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.

Horvath, Keith
Schneider, John
Sullivan, Patrick