FLORIDA STATE UNIVERSITY
OFFICE *of the* VICE PRESIDENT *for* RESEARCH

APPROVAL

January 9, 2023

Lisa Hightow-Weidman
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Dear Lisa Hightow-Weidman:

On 12/15/2022, the IRB reviewed the following submission:

Type of Review:	Full Committee
Title:	Expanding PrEP in Communities of Color (EPICC+)
Investigator:	Lisa Hightow-Weidman
Submission ID:	STUDY00003652
Study ID:	STUDY00003652
Funding:	None
IND, IDE, or HDE:	None
Documents Reviewed:	• EPICC+ClinicAssessment_Baseline-Final_11.01.2022.pdf, Category: Other; • EPICC+ClinicAssessment_Every6Months_11.01.2022.pdf, Category: Other; • EPICC+Cohort_BaselineMRA_CRF_11.01.2022.pdf, Category: Other; • EPICC+Cohort_BaselineSurvey_11.01.2022.pdf, Category: Survey/Questionnaire; • EPICC+Cohort_BaselineSurvey_Spanish_11.01.2022.pdf, Category: Survey/Questionnaire; • EPICC+Cohort_BloodCollectionInstructions_11.01.2022.pdf, Category: Other; • EPICC+Cohort_BloodCollectionInstructions_Spanish_11.01.2022.pdf, Category: Other; • EPICC+Cohort_Consent_11.01.2022.pdf, Category: Consent Form;

	• EPICC+Cohort_Consent_Spanish_11.01.2022.pdf, Category: Consent Form; • EPICC+Cohort_ContactInfoSurvey_11.01.2022.pdf, Category: Survey/Questionnaire; • EPICC+Cohort_ContactInfoSurvey_Spanish_11.01.2022.pdf, Category: Survey/Questionnaire; • EPICC+Cohort_ExitInterview_Guide_11.01.2022.pdf, Category: Other; • EPICC+Cohort_ExitInterview_Guide_Spanish_11.01.2022.pdf, Category: Other; • EPICC+Cohort_FollowUpMRA_CRF_11.01.2022.pdf, Category: Other; • EPICC+Cohort_FollowUpSurvey_11.01.2022.pdf, Category: Survey/Questionnaire; • EPICC+Cohort_FollowUpSurvey_Spanish_11.01.2022.pdf, Category: Survey/Questionnaire; • EPICC+Cohort_HIPAAForm_SAMPLE_11.01.2022.pdf, Category: Other; • EPICC+Cohort_HIPAAForm_Spanish_SAMPLE_11.01.2022.pdf, Category: Other; • EPICC+Cohort_RecruitmentPlan_11.01.2022.pdf, Category: Recruitment Materials; • EPICC+Cohort_RecruitmentPlan_Spanish_11.01.2022.pdf, Category: Recruitment Materials; • EPICC+Cohort_Screener_11.01.2022.pdf, Category: Survey/Questionnaire; • EPICC+Cohort_Screener_Spanish_11.01.2022.pdf, Category: Survey/Questionnaire; • EPICC+FocusGroup_Consent_11.01.2022.pdf, Category: Consent Form; • EPICC+FocusGroup_Guide_11.01.2022.pdf, Category: Other; • EPICC+FocusGroup_PreSurvey_11.01.2022.pdf, Category: Survey/Questionnaire; • EPICC+FocusGroup_RecruitmentPlan_11.01.2022.pdf, Category: Recruitment Materials; • EPICC+Training&Cohort_Protocol_11.01.2022.pdf, Category: IRB Protocol; • EPICC+Training_Consent_11.01.2022.pdf, Category: Consent Form; • EPICC+Training_PostSurvey_11.01.2022.pdf, Category: Survey/Questionnaire; • EPICC+Training_PreSurvey_11.01.2022.pdf, Category: Survey/Questionnaire; • EPICC+Training_RecruitmentPlan_11.01.2022.pdf, Category: Recruitment Materials; • FSU IRB_Verification_of_Translation_Signed[1].pdf, Category: Other;

The IRB approved the protocol, effective from 12/14/2022 to 12/13/2023 inclusive. Before 12/13/2023 or within 30 days of study close, whichever is earlier, you are to submit a completed continuing review and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 12/13/2023, approval of this protocol expires on that date.

COVID-19 Information for Research Involving Human Subjects: Note that the U.S. is operating under the national emergency Proclamation 9994 concerning the COVID-19 pandemic and that this national emergency remains in effect until rescinded or terminated by the President of the U.S. (go here for the Proclamation letter). Conditions are dynamic and related policies or guidance evolve accordingly; as applicable, refer to the U.S. Centers for Disease Control and Prevention website specific for universities or refer to our COVID-19 and Human Research Studies web page to learn more about how you should or may protect persons (whether vaccinated or unvaccinated) involved in any of your in-person research activities.

Other Information:

This study meets the definition of a clinical trial as it involves the assignment of one or more human subjects to one or more interventions (procedure, device, or drug, including use of placebo or control) to evaluate the effects of the interventions on biomedical or behavioral health outcomes. Please note that the approved IRB consent form must be posted to a publicly available Federal web site by an awardee of federal department or agency funding and for any study that is an applicable clinical trial under FDA regulations. The consent must be posted after the research has been closed to recruitment and no later than 60 days after the last study visit of any subject. Visit this FSU Office for Clinical Research Advancement (OCRA) page and related procedure for additional and OCRA contact information as well as specific instructions.

You are advised that any change or revision to the protocol for this project must, through a study modification, be reviewed and approved by the IRB prior to implementation of the proposed modification(s).

Federal regulations require that the Principal Investigator promptly report, through a Report of New Information, any incident involving, for example, the following: a new or increased risk or safety issue; harm experienced by a study participant; non-compliance with federal regulations or the determinations of the IRB; audits, monitoring reports or inspections by study sponsors, monitors or federal agencies; breach of confidentiality; complaint of a study participant; etc.) (see the Investigator Manual (HRP-103), which can be found in RAMP IRB, under the IRB, Library and General tabs).

You are required to submit a Continuing Review at least 60 days before the protocol expiration date of 12/13/2023 to request continuing approval or closure. If the continuing

review approval is not granted before the expiration date, approval of this protocol expires on that date.

In conducting this protocol, you are required to follow the requirements listed in the Investigator Manual (HRP-103).

FSU IRB standard operating procedures (HRP-090) require that investigators use only the most current IRB-approved (i.e., "stamped") version of consent, assent and parental permission forms as well as other materials given to research participants or used for study purposes, and that are applicable to the specific study and study activity. IRB-approved materials for this study are located in the study's RAMP IRB workspace; to find your IRB-approved materials, first navigate through the IRB and Submissions in the top row, then under Submissions, navigate to the table below and click the Active tab and search for this study by study ID or study Name. Second, select this study by clicking on the study Name. Once in this study's workspace, navigate to the Resource tabs located under the workflow diagram and click the "Documents" tab; there, in the Study or Site Related Documents section, locate the IRB-approved materials by category (e.g., Consent Form, IRB Protocol, Recruitment Materials), and for study activities use only the most current IRB-approved version listed in the "Final" column.

Note that in accordance with applicable federal law and FSU policy, all approved or cleared studies are subject to post-IRB approval monitoring throughout a study's life cycle. Studies are subject to random as well as other assessments (audits) to ensure on-going protection of study participants and adherence to applicable law, ethics, policy and the IRB-approved/cleared study protocol. For additional information about this monitoring, refer to the FSU IRB's HRP-059 Standard Operating Procedure (SOP) – Post Approval Compliance Monitoring, available in RAMP IRB, under the IRB, Library and Standard Operating Procedures tabs.

Sincerely,

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