March 27, 2023

Rebecca Schnall
802010X - NUR Div of Scholarship & Rsch

Protocol Number: IRB-AAAT8812
Title: mChoice: Improving PrEP Uptake and Adherence among Minority MSM through Tailored Provider Training and Adherence Assistance in Two High Priority Settings
Protocol Version #: 2.06.23
Grant #: U01PS005229
Approval Date: 03/22/2023 Expiration Date: 07/25/2023
Event Identifier: Modification (Y02M05)

The above-referenced event was reviewed by Columbia University IRB 1.

Level of review and outcome: Convened IRB review IRB Meeting Date: 03/22/2023

To view a list of documents that were included in this approval (if applicable) and all other currently approved documents for this study, please refer to the Print Menu for this Event in Rascal. It is important to confirm the status of each document, e.g., active, stamped, etc. Only stamped, active documents can be used with research participants.

Study Status: Open to enrollment or ongoing review of records/specimens

Consent Requirements:
-Informed consent with written documentation will be obtained from the research participant
-Informed consent will be obtained but a waiver of written documentation of consent has been granted

HIPAA Authorization:
-Authorization will be obtained

Important reminder:
As you plan on enrolling Spanish speaking subjects, administrative IRB approval of the Spanish-translated patient-facing documents (e.g., consent, recruitment materials, questionnaires, etc.) is required prior to their enrollment. Please see the IRB's policy on the Enrollment of Non-English-Speaking Subjects in Research for further details: https://research.columbia.edu/sites/default/files/content/HRPO/Nonenglishspeakingsubjects.Revised.FINAL%20111909.pdf

Please access the following link for a list of tasks that should be addressed prior to your next submission: https://www.rascal.columbia.edu/irb/protocol/AAAT8812/373311/researcherTasks

The following modifications are approved:

- PSIS and Letter of Acknowledgment from UAB with change of PI information;
- Clean and tracked versions of formative protocol (inclusion of surveys for FG participants and updated provider interview procedures);
- Clean and tracked versions of the protocol for aims 1-3 (version 2.06.23);
- Aim 1 recruitment materials;
- Aim 1 Patient Screener (REDCap PDF);
- Aim 1 baseline and follow up surveys (REDCap PDFs);
- Aim 1 urine sample CRF;
- Clean and tracked versions of Aim 1, 2, 3 Consent forms (all sites; change of contact for UAB site);
- Clean and tracked versions of Aim 3 consent to screen, provider screener & interview guide;
- Clinic assessment tool (REDCap PDF);
- Seroconversion and social harm CRFs;
- Clean and tracked versions of Formative interview guide (old version was called Aim 1 interview guide);
- Clean and tracked versions of Formative interview consent (all sites; change of contact for UAB site);
- Formative survey for FG participants (REDCap PDF)
- Email invites for formative survey and formative provider interviews;
- Consent form for formative survey with FG participants (CU is the only site conducting FGs / surveys)
- Clean and tracked version of the formative cognitive interviews consent (to clarify compensation).
- Lead Institution/Coordinating Center section: In Lead Institution/Coordinating Center replaced Dr. Batey with Dr. Kempf (new UAB PI)
- Recruitment And Consent section: Updated to indicate that subjects will be consented prior to participating in surveys
- Research Aims & Abstracts section: Updated name of app being used
- Subjects section: Updated compensation section with compensation amounts for the formative work with providers and cisgender MSM and Aims 1&2 MSM participants and Aim 3 provider participant
- Changes in study personnel: adding Shanaz Ghandhi and Fiona Sanders; removing Sergio Ozoria Ramirez

Electronically signed by: Borvice, Pilar

Researcher Responsibilities:

Any proposed changes in the protocol must be immediately submitted to the IRB for review and approval prior to implementation, unless such a change is necessary to avoid immediate harm to the participants.

Any unanticipated problems that involve risks to subjects must be reported to the IRB in accordance with the Unanticipated Problems: Reporting to the IRB of Unanticipated Problems Involving Risks policy. All submissions for modifications and unanticipated problems must be submitted through Rascal.

Renewal applications should be submitted 60 days before the expiration date of this study through Rascal. Failure to obtain renewal of your study prior to the expiration date will require discontinuance of all research activities for this study, including enrollment of new subjects.

You must file a Closure Report in Rascal when your study has been completed.