In-the-kNOW (Novel Approaches to Optimizing Women's Health): A Mobile Application to Optimize HIV Prevention and Sexual/Reproductive Health Communication Among Black Women in the Southern U.S.

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PROTOCOL TITLE: In-the-kNOW (Novel approaches to Optimizing Women's Health): A mobile application to optimize HIV prevention and sexual/reproductive health communication among Black women in the Southern U.S.

PRINCIPAL INVESTIGATOR:

[redacted], *Deans Office, School of Nursing, ;* [redacted]

EXTERNAL (NON-EMORY) COLLABORATORS N/A ☐:

[redacted], Assistant Professor, Morehouse School of Medicine, and Department of Community Health and Preventive Medicine; [redacted] Georgia Tech, School of Interactive Computing, College of Computing
(This institution's IRB will not review)

VERSION: *Version-2- 06/23/2021.*

FUNDING SOURCE: NIH, NIMH funding pending

REVISION HISTORY

Revision #	Version Date	Summary of Changes
1	06/09/2021	We have indicated the School of Nursing Department. We have made edits to the consenting procedures in which participants will provide electronic consent. In addition, we have made revisions to recruitment flyers and have uploaded additional documents per request in the study application.
2	06/23/2021	More detail has been added to the Lay Summary. We have made additional revisions to the consent template, consent form, and device checklist.
3	02/28/2023	We have included TBD Health as a study partner, and this revision reflects in the consent form along with data sharing and authorization.
4	03/27/2023	We have updated to reflect that we will be collecting specific data points related to test study results from TBD Health.
5	02/19/2024	We updated the recruitment section to utilize the MyChart Recruitment Service.

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1.0 Study Summary

Study Title	In-the-kNOW (Novel approaches to Optimizing Women's Health): A mobile application to optimize HIV prevention and sexual/reproductive health communication among Black women in the Southern U.S.
Study Design	Descriptive
Primary Objective	Evaluate the feasibility, acceptability, and usability of the refined *in-the-kNOW* mobile app. We will employ experimental (n = 30) and control (n = 30) conditions to determine the feasibility and acceptability (retention rates and satisfaction) of both the app and the control condition (e.g., referral to the CDC's online HIV risk reduction tools).
Secondary Objective(s)	Determine feasibility of collecting secondary outcome measures (e.g. PrEP Stigma) for a R01.
Research Intervention(s)/Interactions	N/A
Study Population	Black women (18-44 y.o.)
Sample Size	N= 60 Black women
Study Duration for individual participants	4 months
Study Specific Abbreviations/ Definitions	CBWW: Center for Black Women's Wellness; AHSI: Atlanta Healthy Start Initiative
Study Partner	TBD Health
Funding Source (if any)	NIH, NIMH Funding pending

2.0 Objectives*

2.1 Black women have a significantly higher risk of acquiring HIV compared to their non-Black counterparts. The purpose of this study is to refine and test a mobile HIV Prevention and Reproductive Health app develop specifically for Black women. The overall goal in implementing this study will be to assess the feasibility, acceptability, and usability of the app. The app will be refined using preliminary data obtained through prior research with Black women in which their perspectives towards the use of an HIV and sexual health mobile app were ascertained. Preliminary data obtained from our Community Advisory Board (CAB), which will predominately consist of Black women will guide refinement of the content and features

included within the mobile app, whilst ensuring that the app is tailored towards the needs and perspectives of Black women. We propose to:
Aim 1: Refine the *in-the-kNOW* mobile app for PrEP-eligible Black women. Using a human-centered design approach1, we will conduct a single-arm technology usability pretest to optimize usability, technical functionality, and performance of the app, among n = 10 PrEP-eligible Black women. The mobile app will be refined per pretest feedback.
Aim 2a. Evaluate the feasibility, acceptability, and usability of the refined *in-the-kNOW* mobile app. We will employ experimental (n = 30) and control (n = 30) conditions to determine the feasibility and acceptability (retention rates and satisfaction) of both the app and the control condition (e.g., referral to the CDC's online HIV risk reduction tools). **Aim 2b**. Determine feasibility of collecting secondary outcome measures (e.g. PrEP Stigma) for a R01.

The sample for this study will include young adult Black women 18-44 years of age living in metro-Atlanta who are patients at the Center for Black Women's Wellness (CBWW). Participants will be recruited through flyer distribution and enrollment by CBWW clinic staff during clinic visits, coupled with posting recruitment content on CBWW's website and social media platforms. Written consent will be obtained from participants who agree to participate in the study. The methodology for this study will be descriptive and will employ both quantitative and qualitative data collection through administering online surveys along with semi-structured interviews through the online platform Zoom, as well as participant HIV/STI testing data collected from TBD Health. Survey responses will be anonymous, and interviews will be recorded and transcribed with transcriptions being de-identified to maintain confidentiality.

3.0 Background*

One in 48 Black women will be diagnosed with HIV in her lifetime.[2-5] Although HIV incidence in women has declined, Black women continue to be disproportionately affected. In 2016, Black women accounted for 61% of newly diagnosed HIV infections among women in the U.S.,[2,3] yet they only comprise 13.7% of the U.S. female population.[1] Eight of ten states with the highest rates of new HIV diagnoses are in the South.[5-8] Black women account for 69% of all HIV diagnoses among women in the South.

PrEP offers women an HIV prevention method that is discreet, does not require partner consent, and may be compatible with both contraception and conception as desired. There is considerable research about PrEP awareness and adoption among MSM,[9-16] but far less among women, particularly Black women. The few studies that investigated PrEP attitudes exclusively in women found that most have never heard of PrEP but have generally responded positively to the idea of this prevention method.[17-21] Black women's willingness to consider PrEP depends greatly upon social understandings—whether it is seen as an effective, healthy, and socially acceptable HIV prevention strategy—in addition to cultural and structural factors.[7,18-20,22-25] *In-the-kNOW* will be a culturally relevant and competent digital health communicator for a **local Healthy Start (AHSI) and a National Healthy Start Association** to promote HIV prevention

(including increasing PrEP knowledge) and optimal sexual health to PrEP-eligible Black women. That app also aims to reduce structural barriers to PrEP uptake by: 1) providing secure sensitive data to prevent intimate partner violence [IPV] practices such as partner monitoring, 2) incorporating harm reduction strategies, social support, and communication resources for women facing housing insecurity and other material insufficiencies.

4.0 Study Endpoints*

4.1 Primary endpoint: Refine the in-the-kNOW mobile app for PrEP-eligible Black women. Using a human-centered design approach [1], we will conduct a single-arm technology usability pretest to optimize usability, technical functionality, and performance of the app, among n = 10 PrEP-eligible Black women. The mobile app will be refined per pretest feedback.

4.2 Secondary endpoint: Evaluate the feasibility, acceptability, and usability of the refined in-the-kNOW mobile app. We will employ experimental (n = 30) and control (n = 30) conditions to determine the feasibility and acceptability (retention rates and satisfaction) of both the app and the control condition (e.g., referral to the CDC's online HIV risk reduction tools). **Aim 2b**. Determine feasibility of collecting secondary outcome measures (e.g. PrEP Stigma) for a R01.

5.0 Study Intervention / Design

This is a descriptive study.

6.0 Procedures Involved*

Study overview. We plan to finalize development of our mobile health app and pilot test it with Black women, examining acceptability, feasibility and usability of the app. Upon completion of this R34 (assuming findings are promising), we will have evidence to support a large-scale RCT examining the app's efficacy for promoting HIV prevention and sexual health behaviors.

Participants. Eligible participants will be those who meet the following inclusion criteria: a) 18-44 years of age; b) self-identify as Black c) assigned female at birth and identify as female; d) PrEP-qualified based on CDC criteria for residence in high HIV incident areas—reside in a Fulton, Cobb, Gwinnett, or Dekalb counties; e) sexually active within the last 6 months; f) HIV-negative; and g) own an Android smartphone. The procedures for each specific aim are described below:

Specific Aim 1: Refine *in-the-kNOW* with Black women. With regular input from Black women enrolled in AHSI, we will assemble culturally- and contextually-targeted HIV prevention and optimal sexual health messaging within the app. We will then finalize the app, integrating findings from a pilot usability study. We will also finalize control condition materials with Black women and refine study eligibility and outcome assessments.

Data Collection Procedures*:* App Usability Pretest (n = 10 Black women)

We will conduct a 2-month, single-arm pilot study with 10 Black women, using the same eligibility and recruitment strategies described below (Section D.2.a). During an in-person or virtual enrollment visit (approximately 1.5 hours), participants will download the *in-the-kNOW* app and answer a web-based questionnaire on socio-demographics, time spent using mobile technology per day, and risk behaviors. Study staff will use an enrollment checklist to walk participants through procedures for downloading and using the app. Participants will then be encouraged to use all app components over the pilot period (2 months), including ordering and using the HIV/STI test kit at least once. Upon completion of the usability pretest, all participants will complete an exit interview with qualitatively-trained study staff to provide feedback on functionality, technical performance, errors and bugs encountered, overall experiences with the app, feasibility and acceptability, and feedback for further refinement. The exit interview (approximately 45-60 minutes) can be scheduled in-person or via Zoom (HIPAA-compliant video chat). We will assess satisfaction with the app using the System Usability Scale (SUS).[26-29] Exit interviews will be audio-recorded and transcribed for analysis by the research team. Transcribed interview data will be reviewed for overall impressions of content, materials, activities, and delivery of the app. Descriptive statistics will be generated for SUS data. We will also review participant HIV/STI test results and test kit ordering history to evaluate whether having access to testing resources through the app impacts testing behavior. Informed by these data, the app will be finalized for feasibility testing.

Data Analysis plan: **Quantitative** analysis will be descriptive in nature for the App usability pretest (N=10), focusing on feasibility and usability of the app. Summary statistics (mean/Sd, frequency/percent) of item scores of the SUS will highlight common issues faced by the participants. Participants' testing data will also be subject to quantitative analysis to assess usability of the app for accessing testing services. **Qualitative.** Using thematic framework analysis, each exit interview will be digitally recorded and transcribed verbatim; content analysis will be used to map themes. Two members of the research team will independently evaluate interview transcripts to ensure congruence with extracted themes using MAXQDA software. Upon completion of individual analyses, the researchers will convene to discuss and compare their findings. Transcribed text and field note data will be reviewed for overall impressions and then will move to line-by-line review for extraction of significant statements. Meaning will be formulated from these statements and then organized into themes. Trustworthiness of data will be determined by: (a) debriefing after each interview, (b) providing an audit trail of how and why study components were executed, (c) using the same basic interview guide for all interviews, and (d) presentation of rich data with sample and setting descriptions.

Specific Aim 2. Evaluate the feasibility, acceptability, and usability of the refined *in-the-kNOW* mobile app. We will employ experimental (n = 30) and control (n = 30) conditions to determine the feasibility and acceptability (retention rates and satisfaction) of both the app and the control condition (e.g., referral to the CDC's online HIV risk reduction tools). Aim 2b. Determine feasibility of collecting secondary outcome measures (e.g. PrEP Stigma) for a R01.

After the *in-the-kNOW* app is refined and optimized through the findings from the technology usability pretest, we will evaluate the feasibility and acceptability of *in-the-kNOW* through a pilot feasibility trial. A total of 60 PrEP-eligible Black women will be randomized to the *in-the-Know* intervention (n = 30) or the control condition (n = 30) and complete baseline and 4-month follow-up assessments. We will also determine the feasibility of the study procedures and collecting outcome measures for both the intervention and control conditions in preparation for a R01 proposal.

Data Collection Procedures: *in-the-kNOW*

After completion of the written consent process, each participant will complete baseline assessments using REDCap, an online survey platform and will confirm they are HIV-negative by taking a screening test, after which she will be granted access to all app components depending on the arm she is randomized into. To restrict access to the *in-the-kNOW* app to the intervention arm participants only, participants will be provided with a single-use registration code that will need to be entered to gain access to the app. AHSI staff will be trained to assist participants in downloading the app, provide instruction on its use, and assist with reminder set-up. Study staff will use an enrollment checklist to walk participants through procedures for downloading and using the app. Each participant will have 4 months to engage with the app, including the option to order at least one HIV/STI test through TBD Health (the results of which will be shared with Emory), with e-reminders in time intervals preferred by the participants (a minimum of 3 times per week) via push notifications. During the 4-month study period, participants will receive push notifications to encourage use of all app domains: My Logger, My Test, My Resources, and My Circle. For confidentiality purposes, reminder notifications are nonspecific. Reminders (e.g., "Order your goodies," "Log your activity," or a custom message option) will be dictated by the participant as a notification setting option for exact days of the week and times of the day. We will ask that participants schedule reminders during their peak times of cell phone use. Research staff will complete 2-month check-ins via phone call or video chat with participants in both the intervention and control conditions. Research staff will contact control group participants and determine if they wish to be retained in the study. At month 4, all participants will complete their post-assessment survey and an exit interview.

Quantitative Data Analysis Plan. The response data will be exported from Qualtrics to IBM SPSS 27 for processing and analysis. Because the focus of this pilot study is to establish feasibility and acceptability, statistical analysis will be mostly descriptive.

For demographic characteristics, categorical variables will be described by percentages; continuous variables will be described by mean, standard deviation, range, and median. For all outcome measures (e.g., PrEP/PEP knowledge), a mean score and 95% confidence interval will be calculated, and distributional assumptions will be assessed. The mean change in outcome measure scores between pre-test (T0) and post-test (T1) will be compared (paired-samples t-test) for trends in the expected direction or no change. The literature on effect size estimates, from pilot studies and NIH recommendations, confirms that attempting to obtain valid estimates of effect sizes cannot be statistically justified.[30-41] We have identified feasibility and acceptability as the primary outcomes of this pilot. This approach is supported by the literature.[30-41] We have indicated target metrics that will substantiate feasibility, and we will use

both a quantitative survey and qualitative interview data to determine the acceptability of both the mobile app and the control condition.

We will use mobile app analytics (e.g., Google Analytics) to assess trends in app engagement, like duration and number of app/module/social media forum engagement, clicks, modules viewed/completed, GPS solicitation, and correct/incorrect responses to questions. These analytics, in turn, will allow us to explore links between usage characteristics and primary outcomes.

In order to inform intervention testing, we will collect data on the number and yield of screened participants enrolled, recruiting sources that yielded the largest number of enrolled individuals, recruitment methods used for successful enrollment, the elapsed time from first contact to enrollment, the amount of app interactions, and technological challenges (or other connection challenges.). Feedback about the content, delivery, payment method, and transportation options will also be elicited through surveys and focus group sessions and analyzed for themes. We will collect data on participants' ownership of smartphones and preferred app formats. These measures will help determine the time, resources, and workload involved in implementing the HIV prevention mobile app for Black women; whether users perceived the app as beneficial; and whether alternatives (in app content and/or delivery) can be determined.

We will collect data on the participants' test results from TBD Health as described in Section 11 (Study Partner) below in order to assess usability of the app for accessing testing services (such as TBD Health) and whether use of the app has an impact on testing behavior.

Qualitative Data Analysis: Exit interviews (e.g. What about the app did you use most? Which features could be revised, and how?) will be audio-recorded, and recordings will be stored using password-protected encryption software and only accessible to the research team. Codes, transcripts, and memos will not contain any identifying information. [redacted] will analyze audio-recordings using MAXQDA software, provided free to Emory faculty. Interviews will be first transcribed by a professional transcriptionist trained in using MAXQDA and the encryption software. We will then code the sessions based on emerging themes using an inductive approach, developing during the review of interview transcripts and comparing passages. We will apply the codes to text in an iterative process of reading and refining codes when new codes emerge.

Stipend for Intervention and Control arm. Participants will receive compensation for completion of the baseline assessment ($50) and for completion of the post-assessment/exit-interview ($80).

Control condition.

The control condition will be a one-time virtual women's health counseling session with a healthcare provider. Content will be finalized with input from the CAB. Participants will be given information on: 1. STI/HIV prevention, 2. Family planning, and 3. General health promotion (e.g., exercise and diet). More specifically, the control condition provides access to HIV

prevention materials that are publicly available but that do not offer the dynamic and individually customized features of the health communication/new media research approach proposed herein. Control group participants will continue to receive the usual care associated with AHSI enrollment. The control group will not have access to intervention content (e.g., commodity ordering) until after the study has concluded. Including a control condition helps to inform the next stage of what the enrollment and retention rates will be for that group.

Long Term Follow-up. There are no plans for long-term follow-up or for further data collection after all research-related procedures are complete.

7.0 Data and Specimen Banking*

N/A

8.0 Sharing of Results with Participants*

N/A

9.0 Study Timelines*

Study enrollment and implementation is anticipated to last no longer than 6 months. Analysis and dissemination will likely persist for 1-1.5 year(s)

10.0 Subject Population*

Eligible participants will be those who meet the following inclusion criteria: a) 18-44 years of age; b) self-identify as Black c) assigned female at birth and identify as female; d) PrEP-qualified based on CDC criteria for residence in high HIV incident areas—reside in a Fulton, Cobb, Gwinnett, or Dekalb counties; e) sexually active within the last 6 months; f) HIV-negative; and g) own an Android or IOS smartphone. We will exclude:

- Adults unable to consent
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners
- Cognitively impaired or Individuals with Impaired Decision-Making Capacity
- Individuals who are not able to clearly understand English

11.0 Study Partner

TBD Health is a vendor partner on the Savvy HER study that, upon request of a participant, may provide at-home sample collection kits for STI/HIV tests to Savvy HER study participants and make the results available for participants once received from their third-party laboratory. TBD Health's mission is to provide best-in-class sexual healthcare services that are accessible, approachable, and affordable. Savvy HER study participants will use the at-home

sample collection kits that they can ship to TBD Health's third-party lab vendors for analysis. Participants will complete an online account with TBD Health and complete separate consent forms as part of the normal course of TBD Health's operations and in accordance with its policies. Results will be shared with participants through the TBD Health platform. TBD Health will provide the following data points regarding participants to Emory solely for use in the Savvy HER study:

- Unique participant ID number,
- Date of birth,
- The test kit(s) ordered from TBD Health and the date of sample collection,
- Test results,
- Whether any medications were prescribed based on the test results, and
- The number of messages exchanged between the participant and TBD Health in connection with the test(s) and an aggregated summary of the content of the messages (NOTE: the actual content of the messages will not be shared)

12.0 Vulnerable Populations*

- N/A

13.0 Local Number of Participants

13.1 N=60 Black women

14.0 Recruitment Methods

Recruitment strategy: We will use passive and active recruitment approaches including flyer distribution and enrollment by CBWW clinic staff during clinic visits. We will also post content on the CBWW website and social media platforms, targeting participants enrolled in AHSI. [redacted] is a family nurse practitioner who has access to women who seek care at CBWW, our study site. In addition, we will work with the Georgia CTSA to utilize the MyChart Recruitment Service to send invitations for our study to potentially eligible patients as defined by study inclusion/exclusion criteria which are able to be queried from the Epic Clinical Databases and by having not opted out of direct research contact. These invitations will be sent by the MyChart Recruitment Service staff with the patient-facing description below, and the study team will follow up with individuals who respond as interested.

***Study Title**:* SavvyHER Mobile App Study

***Description**:* We are looking for participants to test SavvyHER, an HIV Prevention and Reproductive Health app that is developed by Black women for Black women. This app gives you education on sexual and reproductive health topics, links to local doctors, and community resources including ways to access at-

home STI test kits. We want to understand how women feel about using the app, compared to standard online CDC tools. If you participate in the study, you may use the app for 4 months and check in with our study staff via phone or video during that time. To be in the study, you must be a Black woman, ages 18 to 44, and own a smartphone. You must also be HIV-negative and have been sexually active in the last 6 months. If you are interested or would like more information, the study staff can discuss with you and answer any of your questions.

Randomization Procedures

After all baseline assessments are completed, participants will be randomized 1:1 to either intervention or control using a randomization schedule generated by our statistician using a permuted block procedure (www.randomization.com).

Screening. Interested individuals, upon signing the informed consent form for the study, will complete a web-based screening survey and read a brief description of the study. Interested individuals must also take an STI/HIV test and receive a negative result in order to be eligible. If eligible, participants will provide contact information (e.g. by calling or texting the study phone) for a research team member to contact them and establish an intake meeting for completion of the baseline assessments. Recruitment strategies will be evaluated weekly to determine if recruitment goals are met and to adjust goals as needed.

Incentives. Participants will receive compensation for completion of the baseline assessment ($50) and for completion of the post-assessment/exit-interview ($80).

No tax information is required

15.0 Withdrawal of Participants*

Participants will be informed that they can withdraw from the study at any time. If a participant completes any incentivized component of the study for any amount of time, they will be given the incentive.

16.0 Risks to Participants*

List of potential risks and discomforts: Black Women

The risks associated with the proposed study are minimal. There is a slight risk of loss of confidentiality; however, we will take appropriate precautions to minimize this risk. Participation in the study will not affect the care the participants receive at the Center for Black Women's Wellness in any way. Although we do not expect this to occur, should study participants experience mental health or physical problems during a study visit, they will be referred to appropriate healthcare providers (e.g. behavioral health department at CBWW) or emergency services as needed.

Loss of confidentiality is the main potential risk associated with participation in this study. We will take appropriate precautions to minimize loss of confidentiality. Identifying information will be stored separately from health and behavioral information. Health and behavioral data will be identified only with a subject ID. Individuals will not be identified in any reports or publications of the research. All data on the participants maintained for the study will be kept in locked file cabinets in locked office suites, or as password-protected computer files on secure servers, and will be accessible only to the project staff via encrypted computers.

Security and privacy are our top priority; therefore, for the design and development of our mobile health app, we have partnered with the Wellness Technology Lab at Georgia Tech to maximize security. Access to the app will be restricted, utilizing aliases and user-selected passwords, to enhance the security of the app. Participants will be automatically logged off if the app has not been in use for more than 10 minutes. The Wellness Technology Lab at Georgia Tech will employ the known best practices for developing HIPAA-compliant apps and will closely work with Georgia Tech's Institute for People and Technology (IPaT) team to review the in-the-KNOW architecture and conduct security testing of the app on an iterative basis, to ensure the highest level of security. This team is knowledgeable about current regulations around mobile requirements for healthcare data and applications and collaborates with researchers across Georgia Tech to develop and host healthcare software applications that achieve the highest levels of security.

Confidentiality of groups during peer interaction via the app. To address confidentiality, a password will be required to gain entry into the group. Upon entry, group moderator(s) will explain that the research team will keep conversations confidential and that participants should not discuss outside of the group what is shared inside the group. We will also let all participants know that, realistically, we cannot guarantee absolute confidentiality. Participants will be required to agree to a Terms of Participation document that will require maintaining confidentiality of group members/content and failure to do so, will result in suspension or revocation of access to the group. In order to facilitate a candid discussion, we will permit use of filters that can hide a participant's identity and the use of aliases to hide real names.

Mitigation of psychological and social distress via My Circle app feature. We will mitigate any psychological distress, bullying, or stigma during peer interactions via the My Circle app feature by requiring participants to agree to a Terms of Participation document that states that any displays of bullying, harassment, threatening, abusive, or otherwise harmful behavior will result in suspension or revocation of access to the My Circle feature of the app. We will also inform participants that any concerns around the conduct of others in My Circle can be reported to the research team. Participants who are identified as experiencing stress (through self-report or notification of study team staff by another participant) caused by using our app will be referred for psychological support to the CBWW behavioral health department for further evaluation.

Mitigation of potential harms per commodity ordering. In addition to the discreet packaging described in the application, when a participant selects their commodities they will be prompted to provide a delivery address and a preferred delivery date. The prompt will also provide two reminders: 1) that they do not have to have commodities shipped to their home address, and 2) that shippers do not have complete control of mail delivery arrival dates/times. They will also be provided with an option to receive a tracking number so that a delivery – wherever it is to be sent – can be tracked and planned for.

To secure sensitive private data and prevent IPV practices such as partner monitoring, in-the-kNOW will implement standard mobile application security features in addition to IPV-specific security features. Standard features include requiring system-level security, app-specific PIN code creation during setup, and PIN code re-authorization on app close or background events. IPV-specific features include a no-PIN-code reset option and a safe mode PIN. The safe mode PIN will show the user content that does not relate to HIV or sexual health. Dr. Drenna Waldrop-Valverde will advise on any mental health distress related to the study and our referral system to behavioral health at CBWW will be initiated.

Any participant who does not feel comfortable answering any questions in the survey or continuing participation will be reminded that study participation is voluntary and that they may withdraw at any time. Prior to initiating the audio-recording of CAB sessions and exit interviews, participants will be asked to not use any names, and all names stated inadvertently will be deleted from transcripts. During these interviews and all study interactions, participants will be in a private Zoom account provided by Emory University. All audio-recorded files will be deleted upon completion of the study. All data will be collected for the purpose of this proposed research only and will be password-protected and viewed on the Emory University or partnering institutions' (e.g., Georgia Tech) secure network. [redacted] will consult with the Emory University Institutional Review Board for guidance throughout the course of the study.

17.0 Potential Benefits to Participants*

List of potential benefits:

Participants may potentially benefit through an improved ability to engage with creditable HIV prevention content (including HIV testing, initiation of PrEP, condom use, and improved communication with their HCP). Participants may also benefit from access to various resources and online social network engagement. Improving engagement in care could lead to improved quality of life and reduced HIV acquisition. If the study finds that the app is feasible and acceptable, an intervention will be implemented to determine the effectiveness and efficacy of *in-the-Know* on uptake of HIV prevention behaviors (e.g., PrEP initiation/persistence; HIV testing) by Black women at high risk for acquiring HIV.

18.0 Data Analysis, Management* and Confidentiality

Using thematic framework analysis, [42] each focus group/interview will be digitally recorded and transcribed verbatim; content analysis will be used to map themes.[43,44] Two members of the

research team will independently evaluate focus group/interview transcripts to ensure congruency with extracted themes using nVIVO software. Upon completion of individual analyses, the researchers will convene to discuss and compare their findings. Transcribed text and field note data will be reviewed for overall impressions and then will move to line-by-line review for extraction of significant statements. Meaning will be formulated from these statements and then organized into themes. Trustworthiness of data will be determined by: (a) debriefing after each focus group/interview, (b) providing an audit trail of how and why study components were executed, (c) using the same basic interview guide for all groups/interviews, and (d) presentation of rich data with sample and setting descriptions.

19.0 Provisions to Monitor the Data to Ensure the Safety of Participants*

- N/A

20.0 Provisions to Protect the Privacy Interests of Participants and Confidentiality of Participants' identifiable data

The Data and Safety Monitoring Plan (DSMP) for the proposed study incorporates the policies on human subject data and safety monitoring specified by the Emory University Institutional Review Board (IRB). Additionally, all computers used for this research will be Emory University, Georgia Tech, or Morehouse School of Medicine computers that have active anti-virus, host-based firewall, and encryption software. All electronic systems will be password-protected. Devices will be configured to "lock" and require user to re-authenticate if left unattended for more than 10 minutes. Data from participants will be recorded in a password-protected file, which will be kept on the Emory University server, and all study related text messages (e.g., notifications or reminders) will be deleted at the end of the study. All emails will be through the Emory University or Georgia Tech network. Each interview will be audio-recorded stored on an encrypted volume. At the end of each interview, data will be transferred to an encrypted volume created using an encryption software. This encrypted volume can only be opened using a password and will only be accessible to the study investigators and the study staff. Codes, transcripts, and memos will not contain any identifying information. The project staff will review data for accuracy and completeness on a weekly basis and bring any illogical entries or issues to [redacted] attention.

a. Risk Assessment - Minimal Risk

This study represents minimal risk. It involves a series of interviews and questionnaires of persons who meet the eligibility criteria. Although we will collect sensitive information, like HIV/STI results we have instituted safeguards that is standard to other electronic medical records. Linkage to care for any positive results will be facilitated by CBWW.

b. Description of Adverse Event Grading and Anticipated Adverse Events

An adverse event is here defined as any unfavorable and unintended sign (regardless of whether it is considered related to a study visit) that occurs during the study. In this study, we do not anticipate moderate, severe, life threatening, disabling, or fatal adverse events. Anticipated adverse events include loss of confidentiality. The PI, in consultation with the

research team, is responsible for evaluating each adverse event as it occurs and for notifying Emory University IRB and NIMH of the occurrence of an adverse event.

c. Description of Monitoring Study Progress and Safety of Human Subject Participants

The PI has primary responsibility for the overall conduct of the study and for the safety of participating human subjects. The PI will ensure that (1) the informed consent process is conducted appropriately and that informed consent is obtained prior to proceeding with any study procedures; (2) only eligible subjects, per protocol eligibility criteria, are enrolled in the study; (3) data are collected and analyzed per protocol requirements; (4) procedures are implemented to ensure that the project is consistently monitored for possible adverse events; (5) adverse events are reviewed promptly and reported as required to the Emory University IRB and NIMH; and (6) the privacy and confidentiality of study subjects is maintained. While implementation of aspects of the DSMP may be delegated to members of the research team, the PI maintains ultimate responsibility for the project and for the safety of study participants.

The project staff will meet with the PI on a weekly basis to review the progress of the study and address any human subjects' issues that occur. These discussions may involve adverse event prevention measures, subject accrual issues, research staff training on protection of human subjects, as well as occurrence of adverse events. The project director will report any participant complaint, or possible protocol violation or adverse event to the PI immediately (i.e., such information will not wait for the weekly meeting to be exchanged).

The Emory University IRB application and consent forms all adhere to HIPAA regulations. IRB members have been trained to examine applications and consent forms with HIPAA protection requirements in mind. HIPAA training is required of all investigators at Emory University. The members of this application have both Human Subject Protection Training Certification as well as HIPAA Training Certification.

[redacted] will work with the Wellness Technology Lab at Georgia Tech to create this mobile health app. The director of the Wellness Technology Lab, [redacted], is affiliated with and will work in collaboration with the Institute for People and Technology (IPaT) at Georgia Tech to build the proposed app within the known best practices for developing HIPAA-compliant apps and review the app's architecture on an iterative basis. IPaT works with researchers across Georgia Tech to develop HIPAA-compliant apps and has the infrastructure to support the risk assessment process necessary for apps of this type. To ensure the security of the mobile app in this project, [redacted] and the Wellness Technology Lab at Georgia Tech will build this app within the known best practices for developing HIPAA-compliant apps and will utilize IPaT's Protected Health Data Infrastructure (PHDI). PHDI supports projects and datasets from any Georgia Tech unit with Protected Health Information/Personally-Identifiable Information compliance needs, including HIPAA. PHDI is a secure enclave with resources that will be provisioned to host the mobile app that will be built in this project. Furthermore, the PHDI has physical, technical, and administrative safeguards in place to ensure the security of applications hosted on its servers (see Facilities document for further details).

As this is a relatively small, single-site minimal risk behavioral study, a Data and Safety Monitoring Board will not be assembled.

d. Plans for Assuring Compliance with Requirements Regarding the Reporting of Adverse Events

The PI will inform the research team about any reported adverse events and implement appropriate training or protocol changes, as approved by the IRB. The PI will report adverse events to the Emory University IRB and Nell Hodgson Woodruff School of Nursing (NHWSON) Office of Nursing Research Associate/Assistant Dean as soon as reasonably possible. Adverse events will be reported in writing within 10 working days of the occurrence. This means that the project staff will be trained to recognize, respond to, and record adverse events when they occur or immediately after they occur to ensure the safety of the human subjects, and to report adverse events to the PI in a timely manner to ensure compliance with institutional policies on human subject protection. This also means that the study staff engaged in data collection can contact the PI as soon as an adverse event occurs. Reports of adverse events will include (1) all serious adverse events associated with the study procedures, and/or (2) any incidents or problems involving the conduct of the study or study participation, including problems with the recruitment and/or consent processes.

e. Plans for Performance of Safety Reviews, for Assuring Data Accuracy and Security, and Assuring Protocol Compliance

f. Reportable Events. The PI [redacted] will be responsible for notifying NIMH of any reportable event(s). More specifically, if we experience suspension or termination of IRB approval the PI will notify the NIMH PO within 3 business days of receipt. If a death related to study participation occurs, the PI will notify the NIMH PO immediately (no later than within 5 business days) of first learning of the death. Unanticipated Serious Adverse Events (SAEs), unanticipated problems involving risks to subjects or others, and serious or continuing noncompliance notification from IRB will be reported to the NIMH PO within 10 business days of the PI learning of the event. For all Adverse Events and Serious Adverse Events that are deemed expected and or/unrelated to the study will be submitted to the NIMH PO in the annual progress report. Lastly, any protocol violations will be reported to the NIMH PO in the annual progress report. Documentation for reportable events will include all information specified in the NIMH Reportable Events Policy (e.g. the date on which the event occurred and the date at which the PI became aware of the event; a detailed description of the event and impact on the participant(s); a detailed description of the measures taken [including clinical] in response to the event [if any]).

The PI will conduct quarterly safety reviews that will include: (1) an evaluation of study recruitment, retention and follow-up procedures; (2) compliance with study protocols; and (3) assessment of adverse events, if any.

21.0 Compensation for Research-Related Injury

21.1 N/A

22.0 Economic Burden to Participants

22.1 Participants may incur transportation or childcare costs, but we hope to offset this potential financial burden by providing an incentive for participation.

23.0 Consent Process

23.1 Consent documents will be discussed for at least 10 minutes or as long as a participant needs clarity about the study. Participants will be permitted to clarify any questions prior to the focus group/interview, participants will be asked to provide electronic confirmation with a statement of 'yes' when the moderator queries 'Do you understand the terms of this study and do you consent to participate in this study?' Electronic consent will be obtained from each participant prior to initiating the focus group/interview. We will provide an electronic copy of the consent to each participant.

Non-English-Speaking Participants ☐

- N/A

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception) ☐

- N/A

Participants who are not yet adults (infants, children, teenagers) ☐

- N/A

Cognitively Impaired Adults ☐

- N/A

Adults Unable to Consent ☐

- N/A

24.0 Process to Document Consent in Writing

24.1 *N/A*

25.0 Setting

The Center for Black Women's Wellness (CBWW) is in Fulton County, identified as one of 48 Ending the HIV Epidemic high-burden counties. This site presents an opportunity to augment access to HIV prevention for women most in need. For 30 years, the CBWW has worked with predominantly Black women and underserved communities in Atlanta, GA to design, implement, and evaluate culturally appropriate healthcare interventions aimed at eliminating racial and ethnic disparities across a range of areas. The study will be conducted with women enrolled in their Atlanta Healthy Start Initiative (AHSI), a site of National Healthy Start (NHS). The NHS program is an ideal vehicle to deliver HIV prevention and sexual and reproductive health information to women at high risk for HIV. The integration of the in-the-kNOW app with the NHS program can increase the dissemination of HIV prevention services to a wider audience. NHS has tremendous reach, serving some of the nation's poorest and most at-risk families in 101 communities in 34 states, Washington, DC, and Puerto Rico.

AHSI has been implemented at CBWW over 20 years to improve perinatal health for high-risk, predominantly Black families living in Atlanta, GA. AHSI communities are located in South Atlanta and are majority African American (88%); have an average household income of $23,243, a 21% unemployment rate, and a 38% poverty rate; and are ranked the lowest on a constellation of neighborhood health and quality of life factors compared to other parts of Atlanta.125,126 Key AHSI services include community outreach, education, and case management for 300 families annually. Sustainability of in-the-kNOW App will occur through AHSI, which will implement the app as a service to clients. Specifically, clients will be offered the app as an extension of AHSI enrollment, and AHSI staff will orient and train women on use of the app

Exit Interviews will occur online via the HIPPA compliant platform Zoom (https://zoom.us/docs/doc/Zoom-hipaa.pdf) afforded to Emory Faculty and Staff.

26.0 Resources Available

CBWW is a safety net clinic and will serve as the referral option for any adverse health events.

27.0 Multi-Site Research*

Emory University is the lead institution on this grant and data collection that involves human subjects, which will be implemented by [redacted] (the PI) with support from Georgia tech and Morehouse School of Medicine.

Georgia Institute of Technology will co-lead with Emory and Morehouse School of Medicine in the design and creation of in-the-Know (mobile app). The app will be used to obtain feasibility/acceptability content to determine desired revisions to in-the-Know app. [Georgia Tech role: Technology development and support for data collection]

Morehouse School of Medicine will collaborate/consult with the Georgia Tech and Emory team to ensure that the content incorporated within the app is relevant to community per study inclusion criteria. Morehouse will also assist in designing the interface for the app through undertaking a human-centered design approach. [MSM role: Liaison to the community and support for data collection]

Although the study will include a multidisciplinary team of scientist from different institutions, the human subjects management and interaction will be solely managed by Emory; therefore, we are only submitting the IRB request at Emory for review.

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