Implementing Keep It Up! – An HIV Prevention E-Health Program

Request for Proposals

Northwestern University
Institute for Sexual and Gender Minority Health and Wellbeing
625 N. Michigan Avenue, Floor 14
Chicago, IL 60611
http://isgmh.northwestern.edu/
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I. Purpose of this RFP

Northwestern University’s Institute for Sexual and Gender Minority Health and Wellbeing is requesting proposals from community-based organizations (CBOs) and other HIV service organizations to implement Keep It Up! (KIU!), an online e-health HIV prevention intervention, as part of their existing HIV testing services. The goal of this project is to understand how CBOs can best implement KIU!, the first eHealth HIV prevention intervention the Centers for Disease Control and Prevention (CDC) classified as “best evidence.” We hope that what is learned in this project will help CBOs successfully implement KIU! and other emerging eHealth HIV-related programs in the future.

II. Background

KIU! is an online, interactive individual-level intervention for young men who have sex with men (YMSM). It can be used across devices (i.e., phones, tablets, and computers), and it uses a variety of content (e.g., videos, interactive animation, and games) to increase HIV knowledge, motivate and teach safer behaviors, and instill self-efficacy for HIV prevention strategies. KIU! was recently designated by the CDC as a best evidence risk-reduction intervention and is the first online HIV prevention program developed for young gay and bisexual men to be included in the Compendium of Evidence-based Interventions and Best Practices for HIV Prevention1. The intervention was developed with intensive feedback from diverse YMSM and through collaboration with CBOs to be easily integrated into standard HIV testing programs. As such, KIU! allows CBOs to offer an effective HIV prevention program for YMSM who test negative. Since KIU! was designed to be integrated into ongoing HIV testing programs and is delivered online, it can be implemented cost-effectively by CBOs.

KIU! has been demonstrated to be highly effective throughout the past decade in multiple randomized control trials and program evaluations of the intervention delivered by CBOs. Previous implementations of KIU! by CBOs not only found it was effective at reducing HIV risk behaviors and sexually transmitted infections, but also that offering KIU! helped CBOs reach and engage diverse YMSM in other HIV prevention services, such as testing. Participants across racial/ethnic groups and geographic regions have rated KIU! very positively and describe it as an intervention they are glad they did and that they would encourage their friends to do. As one recent participant said, “Cool animations and ‘real-world’ mini films. The future of gay sex ed.” See Appendix A for more details about KIU!.

The latest phase of the development of KIU! is a national implementation research trial funded by the National Institutes of Health (NIH). For this trial, researchers at Northwestern University, partnering with co-investigators at Weill Cornell Medical College and Boston Medical Center, will study the implementation, effectiveness, and cost-effectiveness of providing KIU! in CBOs.

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1 https://www.cdc.gov/hiv/research/interventionresearch/compendium/rr/index.html
and other HIV service organizations throughout the United States, as compared to a direct-to-consumer delivery approach. The KIU! team has already identified a first cohort of 14 CBOs with which we are working to implement KIU!. This RFP solicits applications to identify and fund a second cohort of 8 CBOs/HIV service organizations in different counties to integrate KIU! into their existing HIV testing and prevention services. See Appendix F for a brief description of how counties were selected.

Successful applicants will be early adopters of this intervention. Following the trial, KIU! will likely be scaled up as an intervention funded nationwide by large funders, like the CDC. Early adopters will be well-positioned to apply for and secure significant funding to offer KIU! to their populations. We seek the experiences of CBOs now to help make sure that KIU! and other future eHealth programs meet their needs.

For the purposes of this trial, CBOs will be service providers and will provide data to evaluate program implementation and cost-effectiveness. CBOs will not be conducting research.

Additional details on the CBO’s role in the research aspects of this project can be found in Appendix D.

III. Eligibility

Organizations that meet the three eligibility requirements listed below are eligible to apply for funding under this RFP.

1) Eligible applicants must be considered a nonprofit public or private organization with 501(c)(3) IRS status (other than institutions of higher education). This includes community-based, medical, or other social service agencies.
2) Eligible applicants must offer HIV prevention and testing services.
3) Applicant organizations must provide HIV prevention and testing services in one of the 30 counties listed in Appendix F.

IV. Funding and Award Notification

An estimated $160,000 per year over a two year Project Period will be available through this RFP to fund 8 organizations to implement KIU! and participate in the study. Awards are expected to be announced during November 2019. Selected applicants will be funded for two years at an average of $20,000 per year, inclusive of overhead and dependent on factors discussed during negotiations between Northwestern University and funded CBOs, to perform the required activities.

CBOs will have staggered start dates for implementation. The Project Period is expected to begin in Winter 2020 and last for two years following awardee’s start date. The contract agreement will describe the payment methodology. Payment will be conditioned on the applicant’s performance in accordance with the terms of its contractual agreement.
V. Application and Submission Requirements

In order to be considered for this announcement, applicants must provide HIV prevention and testing services to YMSM in the target county for which the organization is applying. See Appendix F for a list of all target counties. For the purposes of this proposal, YMSM is defined as young men between the ages of 18-29 who have had anal sex with at least one man in the previous year. The KIU! program was developed for and evaluated primarily among individuals assigned a male sex at birth who have a male gender identity. Transgender individuals may participate and benefit from the KIU! program, but may feel it is less relevant to their experiences and needs.

Successful applicants will conduct the following activities:

1) Offer KIU! to YMSM who test negative in their existing HIV testing services.
2) Offer or facilitate Sexually Transmitted Infections (STI) testing at the beginning of the intervention and at a 12-month follow-up.
3) Enroll 100-300 YMSM clients into KIU! during the two-year funding period. To fulfill the requirements for this funding, all enrolled clients must reside in the target county for which the organization is funded.

Project Narrative

The Project Narrative must include all of the bolded headings shown in this section. The Project Narrative should be succinct, self-explanatory, and in the order outlined in this section. When completing the Project Narrative, please use the letter or number of the heading, sub-heading, or question to delineate your answers. In the case of ‘c) Population served by your organization’, please use the table template provided to record your responses.

The Project Narrative must address the activities described below that will be conducted over the entire project period. Your Project Narrative should be succinct and should not exceed 10 pages, single-spaced, one-inch margins. See Appendix A: Overview of KIU! and Appendix B: Program Design for a brief description of the intervention and examples of implementation which are provided to assist you in generating ideas for integrating KIU! into your services.

1) Background: Provide a description of relevant background information that describes your HIV and STI testing and prevention programs. More specifically, applicants should describe the following:

   a) Service catchment area
       Describe the geographic area you serve.

   b) HIV and STI testing and prevention services
       Describe the HIV, and STI if applicable, prevention and treatment services offered by your organization to YMSM in the target county, including the following:
i. The process and venues your organization uses to conduct HIV testing.

ii. How often do you recommend your HIV negative clients repeat HIV testing?

iii. Indicate if you provide STI testing, and if so, describe the STI tests offered; your process for recruitment; how frequently you recommend STI testing; and the funding mechanisms to cover STI testing.

iv. A list and brief description of the HIV prevention services offered to YMSM by your organization, including any evidence-based risk-reduction programs, as defined by the Centers of Disease Control and Prevention such as condom distribution, pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), and Treatment as Prevention (TasP).

v. A list and brief description of the HIV treatment services offered to YMSM by your organization.

vi. Your programs and/or referral services for people newly diagnosed with HIV.

c) Population served by your organization – Complete the following table:

<table>
<thead>
<tr>
<th>Question</th>
<th>Number*</th>
</tr>
</thead>
<tbody>
<tr>
<td>People receiving HIV and/or STI testing services in the past three years</td>
<td></td>
</tr>
<tr>
<td>Years providing services for YMSM</td>
<td></td>
</tr>
<tr>
<td>YMSM who have accessed HIV and/or STI testing services in the past 3 years by race</td>
<td></td>
</tr>
<tr>
<td>American Indian/Alaskan Native =</td>
<td></td>
</tr>
<tr>
<td>Asian =</td>
<td></td>
</tr>
<tr>
<td>Black or African-American =</td>
<td></td>
</tr>
<tr>
<td>Native Hawaiian/Other Pacific Islander =</td>
<td></td>
</tr>
<tr>
<td>White =</td>
<td></td>
</tr>
<tr>
<td>Multiracial =</td>
<td></td>
</tr>
<tr>
<td>Other/Unknown =</td>
<td></td>
</tr>
<tr>
<td>YMSM who have accessed HIV and/or STI testing services in the past 3 years by ethnicity</td>
<td></td>
</tr>
<tr>
<td>Hispanic/Latino =</td>
<td></td>
</tr>
<tr>
<td>Not Hispanic/Latino =</td>
<td></td>
</tr>
<tr>
<td>Unknown=</td>
<td></td>
</tr>
<tr>
<td>People who received at least one HIV test in 2018</td>
<td></td>
</tr>
<tr>
<td>YMSM who received at least one HIV test in 2018</td>
<td></td>
</tr>
<tr>
<td>YMSM who tested positive for HIV in 2018</td>
<td></td>
</tr>
<tr>
<td>YMSM who received STI testing in 2018</td>
<td></td>
</tr>
<tr>
<td>YMSM who were diagnosed with an STI in 2018</td>
<td></td>
</tr>
</tbody>
</table>

*Note: Provide only unduplicated numbers of clients.*
2) Approach:

a) Describe how your organization intends to incorporate and use KIU! to enhance/support your HIV prevention activities.

b) Describe your organization’s work plan to implement KIU! and to address the requirements described in Section V: Application and Submission Requirements and describe the following:

i. How you will identify and recruit YMSM for HIV testing.

ii. How you propose to enroll 100-300 HIV negative YMSM into KIU! and your plans to retain YMSM through completion of KIU!. Include a description of how you will communicate reminders for clients to complete 3- and 6-month booster sessions, as well as processes for working with clients who may be lost to follow-up.

iii. How you propose to meet the requirement to offer or facilitate STI testing at the beginning of the intervention and at 12-month follow-up.

3) Organizational Capacity of Applicants to Implement the Project:

Applicants must describe the organizational capacity to implement KIU! and meet the requirements listed in Section V: Application and Submission Requirements. Description of your organization’s capacity should include the following:

a) Overall organizational HIV testing infrastructure; staff size; and the scope of your organization’s work and capacity to implement KIU!.

b) Description of how long your organization has provided HIV and STI testing and prevention services.

c) Description of the kind of HIV tests your organization currently offers (i.e., point of care, laboratory-based, or both).

d) Describe your organization’s Information Technology (IT) infrastructure and most commonly used internet browsers. Please include information about computers or tablets which your organization will use to enroll participants into KIU!.

e) Describe your organization’s experience in implementing other HIV prevention interventions.

f) Describe any federally-funded HIV-related grants your organization has carried out in the past 3 years. Record ‘Not Applicable’ if your organization has not administered federally-funded grants in the past 3 years.

g) Describe any other e-health interventions your organization has implemented. Record ‘Not Applicable’ if your organization has not implemented e-health interventions.
4) Staffing and Budget Narrative

Applicants must describe the staffing plan and the staff member roles to carry out the activities required under this announcement and submit an itemized budget narrative (not included in the Project Narrative’s page limit specified below), including budget justification. The budget must include detail for both years of funding being requested. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative. The budget must include the following:

- **Salaries and Wages:** Enter the total cost of salaries proposed to be covered by this funding. Provide a justification for the requested funds, including the name, title, and total annual salary for each staff member employed by your organization who will be directly funded by these funds. Include the FTE equivalent for each staff member. Describe how salary costs were calculated. Include a description of other funding which contributes to individuals’ salaries and how those funded programs will relate to KIU!.

- **Fringe Benefits:** Enter the cost of fringe benefits provided to each employee described above.

- **Supplies:** Enter the total cost of any additional supplies which your organization proposes to purchase with this funding. Provide a justification for the requested funds. Limit the request to purchases which are allowable under NIH funding.

- **Local Travel:** Enter the total cost of any travel which your organization proposes to cover with this funding. Provide justification which includes type of travel (e.g., organization-owned van vs personal vehicles), projected costs (e.g., mileage reimbursement rates), how those costs were calculated, and the programmatic outcomes (e.g., XXX number of YMSM tested at mobile testing events and successfully referred to KIU!) you project will result. Note: this funding does not support travel outside of the purpose of the provision of the service (e.g., travel to testing events).

- **Other Categories:** Should your program design include additional categories to those delineated above, enter the total cost of these categories. Provide a justification which includes the category name, definition of the category, and the item(s) which you intend to purchase with this funding under this category. Limit the request to purchases which are allowable under NIH funding.

- **Total Direct Costs:** Enter the sum of all direct costs your organization proposes to cover with this funding.

- **Total Indirect Costs:** Enter the total indirect costs your organization proposes to cover with this funding. Note: indirect costs are capped at 10%.

Remember: your program design must include only allowable expenses. Visit https://grants.nih.gov/grants/policy/nihgps/html5/section_7/7.9_allowability_of_costs_activities.htm to learn more about allowable expenses. Email KIUCommunity@northwestern.edu if you have questions about allowable expenses.
See Appendix C: Brief Program Budget Narrative Examples for several possible, though not exhaustive, ideas of how to structure your organization’s budget for this program.

Note: The RFP assumes that applicant organizations will already have funds for recruitment and testing services. KIU! funding is primarily intended to cover your organization’s time spent referring participants to the intervention and following-up with them to encourage intervention completion.

Note: STI test kits are an allowable expense if your organization does not currently have a funded STI testing program. Technical assistance may be available to support agencies to integrate STI testing into existing services. See Appendix E for a brief description of the technical assistance available. For additional information, email KIUCommunity@northwestern.edu.

5. Additional Materials Requested

With your application, please include the following information as attachments.

- Your organization’s IRS 501(c)(3) designation notification letter
- Organizational chart, highlighting where HIV and STI testing and prevention activities fall within the organization
- Your organization’s most recent audited financial statements (for most CBOs, your Form 990)
- DUNS number
- SAM.gov registration information, if you are registered
- Federal EIN number

VI. Application Review Process

The review process will take place in two Phases. During Phase I, applications will be reviewed for completeness by KIU! staff to ensure eligibility criteria have been met. Incomplete applications and applications that do not meet the eligibility criteria will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility or RFP requirements.

During Phase II, the following process will be followed for all applications. All eligible applications will be assigned to objective reviewers selected from a pool of public health and CBO leaders as well as experts in intervention design and implementation. The KIU! team will provide guidance on scoring all applicationsobjectively using the Evaluative Criteria listed below.
### Table 1: Evaluative Criteria and Potential Maximum Scores

<table>
<thead>
<tr>
<th>Evaluative Criteria</th>
<th>Potential Maximum Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documented experience and capacity providing HIV testing and other prevention services for YMSM offered in-house, including number of staff to provide these services</td>
<td>15</td>
</tr>
<tr>
<td>Documented capacity conducting referrals to external HIV prevention and care services if not all offered in-house</td>
<td>10</td>
</tr>
<tr>
<td>Documented capacity offering STI testing or a clear strategy for facilitating it</td>
<td>15</td>
</tr>
<tr>
<td>Soundness of plan to recruit 100-300 YMSM in their county</td>
<td>20</td>
</tr>
<tr>
<td>Comprehensiveness and soundness of proposed program approach and work plan to deliver the intervention</td>
<td>30</td>
</tr>
<tr>
<td>Soundness of proposed budget and respondent’s financial capacity and stability to manage proposed program</td>
<td>10</td>
</tr>
</tbody>
</table>

**Total Maximum Points:** 100

### Table 2: Point Values and Their Meanings

<table>
<thead>
<tr>
<th>Point Value</th>
<th>Points will be assigned for each item listed as follows:</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Applicant’s application or capability is exceptional and exceeds expectations for this criterion.</td>
</tr>
<tr>
<td>4</td>
<td>Applicant’s application or capability is superior and slightly exceeds expectations for this criterion.</td>
</tr>
<tr>
<td>3</td>
<td>Applicant’s application or capability is satisfactory and meets expectations for this criterion.</td>
</tr>
<tr>
<td>2</td>
<td>Applicant’s application or capability is unsatisfactory and contains numerous deficiencies for this criterion.</td>
</tr>
<tr>
<td>1</td>
<td>Applicant's application or capability is not acceptable or applicable for this criterion.</td>
</tr>
</tbody>
</table>
Once the objective review process is completed, the KIU! team will fund 8 CBOs based on highest scores, requested budget, and geographic representation. The KIU! team will rely heavily on the objective review findings. However, the KIU! team reserves the right to make final decisions based on what is best for the research purposes of the project.

Proposal Organization

The proposal should be organized with the Sections and Sub-Sections described below. Project Narrative (i.e., Background, Approach, and Organizational Capacity) should not exceed 10 pages, single-spaced, one-inch margins. The entire application package should not exceed 15 pages, excluding required additional materials.

Table 3: Proposal Order, including Sections, Sub-Sections, and Page Maximums

<table>
<thead>
<tr>
<th>Sections</th>
<th>Sub-Sections</th>
<th>Page Maximums</th>
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<tbody>
<tr>
<td>Title Page</td>
<td></td>
<td>1 page</td>
</tr>
<tr>
<td>Table of Contents</td>
<td></td>
<td>1 page</td>
</tr>
<tr>
<td>Background</td>
<td>Service Catchment Area</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HIV and STI Testing and Prevention Services</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Population Served</td>
<td>10 pages</td>
</tr>
<tr>
<td>Approach</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organizational Capacity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staffing and Budget Narrative</td>
<td></td>
<td>3 pages</td>
</tr>
<tr>
<td>Additional Materials Requested</td>
<td></td>
<td>N/A - Required Attachments</td>
</tr>
</tbody>
</table>

VII. Important Dates

- August 7, 2019: KIU! RFP Released
- August 21, 2019, 11am-1pm Central Time: Bidder’s Conference – the Bidder’s Conference will be an optional, BlueJeans-enabled, recorded call for interested CBOs to ask any questions. A summary of the recording will be made available on our website following the call.
  To join the call: https://bluejeans.com/448309866. To join via phone, dial 866.226.4650 and enter Conference ID: 448309866, followed by #.
- August 28, 2019: Intent to Apply (Strongly Encouraged/Not Required). Email KIUCommunity@northwestern.edu with your intent to apply.
VIII.  Reporting and Other Requirements for Successful Respondents

Successful awardees will need to meet the following requirements to ensure continued funding throughout the project period.

1) Work with clients to ensure they successfully complete the KIU! intervention. Guidance and technical support will be provided for this purpose.
2) Enter into a data sharing agreement with Northwestern University to enable sharing of HIV and STI testing results.
3) If your organization has an internal Institutional Review Board then either (a) meet criteria for not being engaged in the research activities; or (b) enter into an agreement to defer to the Institutional Review Board (IRB) at Northwestern University. See Appendix D for additional details.
4) Inform the KIU! team of any changes to key personnel as soon as they occur.
5) Collect, enter, and share data to monitor implementation and evaluation of KIU!, including information regarding costs associated with implementation. KIU! will inform funded CBOs of the data elements required for reporting during the onboarding phase of the program.
6) Participate in in-person site visits or teleconferences for program monitoring.
7) Ensure Staff access to computers that meet KIU! web browser requirements.
Appendix A

Overview of Keep It Up!

KIU! is a web-based, e-health intervention designed for YMSM. KIU! is accessible across multiple platforms, including PC, tablet, and smart phone. The intervention is a vehicle for primary HIV and STI prevention as well as bolstering skills in relationship communication. The intervention achieves these aims through a mix of scripted and unscripted videos, animations, games, and goal setting exercises. The innovation in KIU! is that it leverages the cognitive dissonance following an HIV negative test result to provide YMSM the tools they need to continue making healthy sexual choices – or to keep it up (making healthy sexual choices) – to remain HIV negative, to reduce STI incidence, and to encourage healthier relationships.

KIU! has proven effective in previous research. Based on the Information-Motivation-Behavioral Skills Model for HIV Preventive Behavior and principles of e-learning, KIU! has been tested in two efficacy trials and two program evaluations in the context of delivery as an HIV prevention service. Among 901 YMSM in one randomized controlled trial across three major cities, participants in the KIU! arm significantly reduced recent condomless anal sex from 70% to 40% - a 17% greater decrease than in the control arm – and reductions were maintained for 12 months post-intervention. Further, KIU! reduced STI rates by 40% compared to the control.

The Intervention

In its current iteration, KIU! contains seven modules, which are spread across three defined intervention steps, as well as a 3-month booster, and a 6-month booster. KIU! is a timed intervention. Once a participant has registered for the intervention, the first intervention step, which contains Modules 1-3, is the only intervention step available. Once the participant has completed the first intervention step, the technology requires an 8-hour waiting period prior to opening the second intervention step, which contains Modules 4-5. The third intervention step opens 8 hours following the completion of the second intervention step and contains Modules 6-7. Finally, as their names imply, the 3- and 6-month boosters open to participants three months and six months following the beginning of the intervention. Further, participants are expected to complete the first, second, and third intervention steps within two weeks of initiating the intervention.

See http://isgmh.northwestern.edu/keepitup/ for more information on the intervention, including an overview video and brief descriptions of each module.

What’s Next for the KIU! Intervention

As with all things health and tech related, the Intervention must adapt over time. For example, much of the content in the current iteration of KIU! was developed prior to the latest science on pre-exposure prophylaxis or the knowledge that people living with HIV who are undetectable pose no risk of transmission. As such, the KIU! team at Northwestern University is actively redeveloping all of the content of the intervention to match the state-of-the-science of
HIV prevention. The team at Northwestern University is working with community leaders, YMSM, and intervention design experts to ensure that the objectives of this effective intervention remain intact in this and future iterations.
Appendix B

Program Design

We invite CBOs to be creative in program design. A primary goal of this trial is to study the various ways in which KIU! can be incorporated into existing HIV testing services.

Your organization may want to consider dedicated staff time within your HIV/STI testing program to recruit and retain clients in the KIU! intervention. In other KIU! implementations, HIV/STI testing staff have been best suited to recruit participants, to provide the necessary reminders for participants to complete the intervention, and to provide training to new staff and volunteers. Recruiting participants for the intervention has usually been most successful immediately after HIV testing or even in conversation while a rapid test is running. Recruitment is brief, and past experience indicates it is best completed by the HIV test counselor completing the participant’s test. Below, we have included two real world examples of how KIU! has been implemented into CBO services in previous research, ideas generated from a brainstorm of CBO leaders, some practical advice on the amount and types of work your organization can expect, and an example workflow. Your organization may adapt the ideas below or develop your own. These examples are intended to inspire not constrain.

**Agency A – Chicago, IL**

Agency A, in partnership with KIU!, received a multi-year grant from the Chicago Department of Public Health (CDPH) to implement KIU! as a service for Agency A’s clients. Agency A used a blend of outreach and incentives for recruitment and retention. Agency A recruited from youth serving organizations and Facebook ads, and they hosted small events with pizza in their cyber center to engender social connection. Agency A first tried incentivizing completion of KIU! with a quarterly raffle drawing but found that providing gift cards to all clients who completed the intervention to be more effective. Further, Agency A gave lower value gift cards to clients who had completed the intervention but who referred friends for the service. Finally, Agency A leveraged their human resources – including Agency A’s Director of HIV/AIDS & STD Services, CDPH Project Coordinator, and a full-time Health Educator – and the expertise of the KIU! team to work with clients to encourage them to complete the intervention.

**Agency B – Jackson, MS**

Agency B adapted KIU! to be an entry point into their program, “The SPOT.” The SPOT is designed as a “safe space” for Black gay and bisexual men which was created in an effort to eliminate barriers and challenges to HIV testing and to act as a bridge to prevention, care, and treatment. Participants complete KIU! at The SPOT as part of the required programming, and they gain access to programming which includes HIV prevention and testing as well as resume building, developing communication techniques through a strength building context, and open discussions about current policies and procedures that impact discrimination and harassment. Further, The SPOT created The SPOT Advisory Board (TSAB) comprised of Black gay and bisexual
men who provide insight, input, and feedback in the implementation of The SPOT. TSAB members may also access a mentorship program which provides members with important tools and resources to enhance and support their growth and empowerment into leaders.

**Ideas from CBO Leaders**

Leverage human and built resources for recruitment. Hang recruitment materials in common areas and waiting rooms. Have receptionist or other greeter provide information to clients regarding the intervention. Post peer navigators, paid or volunteer, in the common areas and waiting areas to register clients in the intervention and help them start while waiting to be called for the service they are there to access. Peer navigators may also work with clients to register them during or following the service, work through parts of the intervention with the client, and use the intervention to spur conversation around the topics raised in the module they view together. Use the knowledge of the intervention modules to create in-person services to bring together clients to discuss what they are learning or to access additional services which address some need which arises through interaction with the intervention. Tie recruitment and registration together with HIV testing initiatives.

**Practical Considerations**

When designing your organization’s program, keep the following in mind.

- You will need to include time for affected staff and volunteers to receive required KIU! training as well as to access technical assistance specific to your program.
- Staff and volunteers who are charged with recruitment will need to add time at the end of testing counseling sessions in which a YMSM has tested negative to describe and offer the program. Of those who express interest, staff and volunteers will spend some additional time describing what the participant can expect and assisting the participant with sign-up.
- Staff and volunteers who are responsible for retention will need to plan on approximately 3 reminder contacts during the first two weeks following a participant’s sign-up to ensure that the participant completes the intervention. Many programs will also have staff and volunteers discuss what participants are learning to offer reinforcement of the material.
- Many programs will want to set aside time for communication between your staff and volunteers who are dedicated to KIU! and your other program staff to tailor programming at your organization to what participants are learning in the intervention.
- If programming is developed in response to KIU!, you will want to include time for the appropriate staff and volunteers to communicate with participants about that programming.
- Your program design should include time for reminders for the 3- and 6-month boosters as well as the 12-month STI testing required for this funding.
- You will need to include time for documenting all of the above.
• Communicating with the KIU! team as needed and providing timely reporting will be required.
• Finally, depending on your program design, additional time may be spent on a range of issues including, but not limited to, administering incentives, working with clients in-house if your organization chooses to host the intervention in your computer lab, integrating STI testing into your existing programming, etc.

Of course, the bullets above and the example workflow on the next page largely assume a linear timeline of events for a single participant. As you think through your program design, consider that the practical considerations and work flow steps will be taking place simultaneously across multiple participants, with some at the beginning stages and, over time, others nearing the 12-month STI follow-up test. Your affected staff and volunteers will need to be prepared for this variability. Consider that, at peak recruitment and retention, your organization may have more than 100 participants at various stages.

Making KIU! Your Own

The KIU! team encourages applicant organizations to be creative in program design and think of ways to make KIU! complement your existing HIV prevention services. While some of this can be accomplished through program design, KIU! is also building features into the technology to enable CBOs to customize the intervention. While features are still being finalized as of dissemination of this RFP, we anticipate CBOs being able to create custom content with your organization’s existing client base, add information specifically about your programs and services, and provide a welcome video from your organization. Additional features will be included and will be offered to all funded CBOs as options.
Example KIU! 3.0
CBO Staff/Volunteer Workflow

Client completes HIV/STI testing and tests negative for HIV.

CBO Staff or Volunteers inform Client about the KIU! project.

If interested, CBO Staff or Volunteers register Client by entering their email address and phone number into the KIU! phone application.

If potential Participant consents, they will proceed to an online survey in REDCap that includes demographic information (e.g. age, sex assigned at birth, gender)

Potential Participant will be confirmed as either eligible or ineligible.

Eligible Participant will go through KIU! intervention steps over a 2-week period.

CBO Staff or Volunteers follow-up to ensure all steps have been completed and leverage KIU! content for in-person services.

In-person services occur.

CBO Staff or Volunteers send reminders to complete 3 month booster.

In-person services occur.

CBO staff or volunteers send reminders to complete 6 month booster session.

In-person services occur.

Participant will complete STI testing at 12 months.

Meanwhile...

Once Client is registered, the KIU! application will automatically send an email to them with a link to an online consent form hosted in REDCap.

Those who are not eligible to participate in the KIU! project will be given access to the KIU! intervention steps. Northwestern staff will notify Client that they are ineligible and will be unable to complete follow-up assessments.

Northwestern Staff will send reminders to participants to complete online study assessment at baseline.

Northwestern Staff will send reminders to participants to complete online study assessment at 3 months.

Northwestern Staff will send reminders to participants to complete online study assessment at 6 months.
Appendix C

Brief Program Budget Narrative Examples

Example 1: Single Coordinator

Salaries and Wages: A single coordinator, TBN, will be primarily responsible for recruitment and retention of YMSM into KIU!. The coordinator’s total annual salary is $45,000. The coordinator will work .3 FTE on KIU!. Therefore, the organization proposes total direct salary costs of $13,500 to KIU! The coordinator’s remaining .7 FTE is covered by a local department of public health (DPH) grant for outreach and recruitment of YMSM into our organization’s primary prevention and HIV and STI testing services. The DPH-funded program will serve as our primary point of entry for clients who will be referred to KIU!.

Fringe Benefits: Our organization calculates fringe benefits at a rate of 33% of an employee’s total salary. As this proposal requests a total direct salary cost of $13,500, the total fringe benefits cost will be $4,455.

Equipment: N/A

Supplies: N/A

Local Travel: N/A

Other Categories: N/A

Total Direct Costs: $17,955

Total Indirect Costs: Our organization requests the maximum 10% indirect costs rate, which totals $1,795.50.

Example 2: Testing Manager, Volunteers, and Incentives

Salaries and Wages: A single testing manager, TBN, will be primarily responsible for managing volunteer testing counselors who recruit and retain YMSM into KIU!. The manager’s total annual salary is $50,000. The coordinator will work .1 FTE on KIU!. Therefore, the organization proposes total direct salary costs of $5,000. The testing manager’s remaining salary is covered at .6 FTE from a grant funded by our state health department to conduct primary prevention HIV and STI outreach and education to MSM in our catchment area, and the remaining .3 FTE is derived from a foundation grant focused on improving social media strategies in engagement and sexual health education of MSM. The testing manager’s funding will by a key component of our KIU! strategy by making the manager primarily responsible for recruitment of YMSM into our volunteer-driven testing program and leveraging the manager’s expertise in education and social media engagement to support volunteers in retaining those clients who are successfully referred to KIU!. 
Fringe Benefits: Our organization calculates fringe benefits at a rate of 33% of an employee’s total salary. As this proposal requests a total direct salary cost of $5,000, the total fringe benefits cost will be $1,650.

Equipment: N/A

Supplies: N/A

Local Travel: N/A

Other Categories: Our organization proposes an additional category for incentives. An integral component of our proposed program design includes $10 gift card incentives for participants who complete the first three intervention steps, 3 month booster, 6 month booster, and 12 month STI test. This will total $40/participant. Assuming 300 participants who complete all four milestones, the total cost of this proposed category will be $12,000.

Total Direct Costs: $18,650

Total Indirect Costs: Our organization requests the maximum 10% indirect costs rate, which totals $1,865.00.
Appendix D

IRB Considerations for KIU! 3.0 Implementation Trial

For any project that involves multiple organizations participating in research with people, a question that has to be decided is which organizations need IRB review of their activities. The HHS Office for Human Research Protections has issued guidance on this question, and that guidance describes which types of activities trigger the need for IRB review and which types of activities do not require IRB review. In order for CBOs not to have to undergo IRB review of their activities on this project, we want to maintain a “firewall” between activities that involve the normal course of CBO business (e.g., HIV and STI testing), as well as implementation of the KIU! 3.0 program, and the research activities being done by personnel from Northwestern University and our research collaborators to evaluate implementation of the KIU! 3.0 intervention.

**Examples of activities that do not trigger the need for IRB review**

- Inform prospective subjects about the availability of the KIU! 3.0 prevention service project (e.g. advertise and recruit)
- Provide prospective subjects with information about the research components (which may include a copy of the relevant informed consent document and other IRB approved materials)
- Provide prospective subjects with information about contacting researchers, and obtaining prospective subjects’ permission for researchers to contact the subject
- Release to the research team identifiable private information or identifiable biological specimens pertaining to the subjects of the research (e.g. HIV and STI testing results), with appropriate consent procedures for the release of that information and compliance with any applicable HIPAA requirements
- Monitor clients’ progress within KIU! 3.0 and retain clients in the prevention service project for six months. CBO staff are **not** responsible for clients completing activities that involve only collection of research data (e.g., online assessments that the research team will ask KIU! 3.0 participants to complete).
- Limited customization of the KIU! 3.0 platform
  - Upload logo
  - Embed information about services (e.g., hours for HIV testing)
  - Tailor reminder message content
  - Select from a library of welcome videos that best resonate with their community
  - Assess areas of need (e.g., addiction treatment, housing services, etc.) within KIU! program
Examples of activities that would trigger the need for IRB review

- Enroll or obtain the informed consent of human subjects to be in the research study. This will be done online by Northwestern staff and IT systems.
- Interact or intervene for research purposes (e.g. post-test assessments) with any human subject of the research. Data collection is being performed by NU staff and IT systems and universities with subcontracts.
- Obtain for research purposes identifiable private information or identifiable biological specimens from any source. Identifiable private information being obtained by CBO staff is for the purpose of service provision – some information collected by CBOs in the course of carrying out the KIU! 3.0 program and other standard CBO responsibilities (e.g., STI test results) will be shared with researchers if the research participant consents to sharing of that information.

References

Appendix E

Technical Assistance

The KIU! team will develop Technical Assistance for groups of CBOs as well as work with individual CBOs to ensure that their organizations’ implementations maintain fidelity to the intervention while fostering successful programmatic integration. Below, we have provided several examples of Technical Assistance which our team will be preparing. We anticipate additional Technical Assistance being developed.

Recruitment & Retention

Sometimes the hardest part of providing a service is getting your target audience in the door. The KIU! team has a decade of experience in identifying and successfully recruiting YMSM for our service, including working with a range of CBOs to develop recruitment strategies. We also understand that funded CBOs will face challenges in retaining YMSM in the intervention, and we will be here to support your organization in identifying strategies to keep YMSM engaged.

Adaptation

Our tech team is working to provide features of the intervention which can be adapted by CBOs. While the full list of adaptable features is currently being finalized, the KIU! team will work individually with CBOs on those features which are adaptable so that your organization can make KIU! as much of your own as possible.

Technology

As an e-health intervention, KIU! will face technical difficulties during its lifespan. Whether those difficulties happen to CBO staff or to participants, the KIU! team will have dedicated support.

Facilitating STI Testing

If your organization does not currently offer STI testing, the KIU! team will work with you individually to identify ways that you can fulfill the requirement of facilitating STI testing for this trial.

Integrating STI Testing Into Your Programming

The KIU! team will recommend Hologic to those funded CBOs who would like to integrate STI testing into their existing programming. Hologic has a branch of their company which provides technical and capacity building assistance to CBOs for designing STI programming. They can work with your organization on everything from product education to billing and reimbursement. Their model is intended not only to set up new programs but also to follow-up with your organization to ensure your program is sustainable.
### Appendix F

#### Target Counties

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#### How Counties Were Selected

The KIU! team used two primary criteria in selecting counties. First, using estimates of county-level MSM populations developed by Grey et al.\(^2\), we identified those counties with more than 1,500 YMSM. Second, because the burden of new HIV infections is disproportionately borne by YMSM from communities of color, we made final selections based on those counties with the highest proportions of young men of color.

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