

Technology-based Training Tool for an Empirically-Supported Group-Based HIV and STI
Prevention Intervention for Juvenile Offenders

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**University of Illinois at Chicago (UIC) and/or
University of Illinois Hospital & Health Sciences System (UI Health)
Research Information and Consent for Participation in Social, Behavioral, or Educational
Research**

Technology-based Training Tool for an Empirically-Supported Group-Based HIV and
STI Prevention Intervention for Juvenile Offenders

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**Sponsors: National Institute on Minority Health and Health Disparities, Small Business
Innovation Research**

About this research study

You are being asked to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

Taking part in this study is voluntary

Your participation in this research study is voluntary. You may choose to not take part in this study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled.

This consent form will give you information about the research study to help you decide whether you want to participate. Please read this form and ask any questions you have before agreeing to be in the study.

You are being asked to participate in this research study because you work with justice-involved youth or because your employer serves justice-involved youth.

130 - 180 subjects will be enrolled in this research study.

Important Information

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

WHY IS THIS STUDY BEING DONE?	We want to evaluate two different approaches to training facilitators to provide a sexual health program for justice-involved youth. The program is called SYNC and it uses a variety of activities to address HIV/AIDS, STI, healthy relationships, assertive communication, safer sex decision-making, condom use skills, and self-efficacy to reduce risk behavior. The goal of the current study is to determine if people can learn to provide SYNC using only web-based training or if they need additional support.
WHAT WILL I BE ASKED TO DO DURING THE STUDY?	If you agree to participate, you will be randomly assigned to one of two groups: web-based training only OR training + consultation with SYNC expert. Your task first will be to complete a brief questionnaire about yourself, your knowledge of HIV and STI prevention, and confidence talking about sexual health. Second, you will begin the web-based training. Third, if you are in the group that receives consultation, then you will receive reminders that you can contact SYNC experts with any questions you may have. Before completing the web-based training, you will attend at least one group consultation session with the SYNC expert via zoom. If you are not assigned to receive additional support, you will watch a video on an unrelated topic before you complete the web-based training. Fourth, all participants will complete the web-based training. Fifth, you will complete a questionnaire about your knowledge of HIV and STI prevention, confidence talking about sexual health, your experience with the web-based training tool, and beliefs about the SYNC program overall. Sixth, after you complete all of your training activities, you will be asked to demonstrate the delivery of one SYNC session via zoom. Study staff members will act as youth participants during the demonstration session. The demonstration session will be video recorded. Seventh, after you complete the demonstration session you will complete a self-evaluation of how it felt to deliver SYNC material. For more information, please see the “What Procedures Are Involved?” section below.

HOW MUCH TIME WILL I SPEND ON THE STUDY?	The first survey will take approximately 10-15 minutes to complete. The web-based training, including quizzes and post-training survey, will take approximately 12 1/2 hours. If assigned to the additional training group, the consultation session will take no more than 1 hour, otherwise the video will last about 15 minutes. Facilitating the demonstration session will take approximately 2 hours. For more information, please see the “What Procedures are Involved?” section below.
ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?	There is no direct benefit to participation. We hope that your participation in the study may benefit other people in the future by helping us learn more about the best way to train people to implement SYNC and to increase the number of people who use SYNC with their clients.
WHAT ARE THE MAIN RISKS OF THE STUDY?	You may feel uncomfortable in answering questions (such as age, race, STI/HIV knowledge). You may skip any questions that make you feel uncomfortable. Training materials address topics that some people might find sensitive (condom use, sexually transmitted infections). You can stop the training at any time. The primary risks presented by this research study are breaches of privacy (people outside of the study may find out you are a participant) and/or confidentiality (people outside of the study may find out what you did, said, or information that was collected about you during the study). It is possible that other participants who attend the group consultation session will be your co-workers; however, no one at your employment will otherwise be told if you participate or what you say. We will not give out your personally identifiable information to anyone unless: - We have reason to suspect elder or child abuse, neglect or endangerment. The law requires that we report any suspected abuse, neglect, or endangerment. Reports will be made to the Department of Child & Family Services or Adult Protective Services as appropriate; or - We have reason to suspect that anyone is in imminent danger of seriously hurting him or herself or someone else. Such reports will be made to the appropriate authorities.

DO I HAVE OTHER OPTIONS BESIDES TAKING PART IN THE STUDY?	This research study is not designed to provide treatment or therapy, and you have the option to decide not to take part at all or you may stop your participation at any time without any consequences.
QUESTIONS ABOUT THE STUDY?	For questions, concerns, or complaints about the study, please contact Dr. Jodie Barger, SYNC Project Director at 312-996-1014 or jodieb@uic.edu If you have questions about your rights as a study subject; including questions, concerns, complaints, or if you feel you have not been treated according to the description in this form; or to offer input you may call the UIC Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research. Please also feel free to ask the researchers questions at any time.

What procedures are involved?

You can use a desktop computer, tablet, or mobile phone to complete the web-based training, the consultation session, the pre-and post-training surveys, and the demonstration at any location that is convenient or comfortable for you. We ask you to complete the training within 4 weeks.

During this study, the research team will collect information about you for the purposes of this research. The research team will also track your study activities and contact you to remind you of activities to complete if needed.

The following data will be collected after consent is provided:

Contact information, age, ethnic and racial identity, gender identity, education, general information about your work history, HIV and STI knowledge, and your confidence in delivering sexual health-related material.

During the web-based training, the following data will be collected:

Your progress in the web-based activities, when/how often you complete activities, your responses to quizzes after each module, how long it takes for you to complete the training and review information provided in the training, external resources accessed, and how often you log back into the training to review materials after you complete the training.

After the web-based training, you will complete a questionnaire about your knowledge of HIV and STI prevention, degree of confidence talking about sexual health, a survey about your experience with the web-based training tool, and a survey about the SYNC program overall. This

information will help us understand whether your knowledge of HIV/STI prevention and confidence changed after completing the web-based training and will help us determine if the web-based training needs to be changed.

During the consultation sessions, you will provide the following information:

You will ask any questions that you have about material from the web-based training. You will discuss SYNC content, potential barriers to delivering sessions, and potential solutions to barriers. You can attend as many consultation sessions as you would like. Attendance will be taken, and study staff will document questions asked and topics discussed during the session. Consultation sessions will not be video recorded.

During the demonstration session, the following data will be collected:

During the demonstration session, researchers will assess whether you followed the SYNC training manual. Demonstration sessions will be completed via zoom with study staff members playing the roles of youth participants. The demonstration sessions will video recorded. After the demonstration session, you will complete a short survey about how it felt to deliver SYNC content. This information will help us determine if web-based training is an effective way to teach people how to use SYNC.

What will happen with my information used in this study?

The information collected for this study may be used for future research studies and/or shared with other researchers in the future. If this happens, information which could identify you will be removed before any information is shared. Once the identifying information is removed, the information cannot be withdrawn from further use. You will not be asked for additional consent.

Will I receive the results from the study?

When you complete the web-based training, you will receive quiz results and certification of completion.

What about privacy and confidentiality?

Efforts will be made to keep your personal information confidential; however, we cannot guarantee absolute confidentiality. In general, information about you, or provided by you, during the research study, will not be disclosed to others without your written permission. However, laws and state university rules might require us to tell certain people about you. For example, study information which identifies you and the consent form signed by you may be looked at and/or copied for quality assurance and data analysis by:

- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.

- Government Regulatory Agencies, such as the Office for Human Research Protections (OHRP).
- The National Institutes of Health, Institute on Minority Health and Health Disparities.
- Small Business Innovation Research Agency

A possible risk of the study is that your participation in the study or information about you might become known to individuals outside the study. Both UIC and Influents will use secure servers, password protection, and/or encryption to store your personally identifying information. Influents will have access to the same data as UIC except for videos of demonstration sessions. In addition, Influents will have information necessary to administer incentive payments. When UIC and Influents share data with each other, we will use secure servers to do so.

Your individual data will be stripped of all direct or indirect identifiers after data analysis is complete. All videos will be deleted within five years of the end of data collection.

When the results of the study are published or discussed in conferences, no one will know that you were in the study.

Please remember that there is an exception to protecting subject privacy and confidentiality if child, elder, and/or disabled adult abuse or neglect of an identifiable individual, or the threat of imminent self-harm or harm to others is disclosed. If such information is disclosed, the researchers may be obligated to inform the appropriate authorities.

To help us protect you and the information we will be collecting from you, this research has been given a Certificate of Confidentiality by the National Institutes of Health (NIH). This Certificate means that researchers cannot be forced, even by courts or the police, to disclose information, documents, that may identify you. However, your information may be given to personnel of the United States Government to audit or evaluate projects that are federally funded or to meet other regulatory requirements.

The Certificate does not stop you from disclosing, or agreeing in writing to allow researchers to disclose, information, documents, about you, including your participation in this research. For example, if you would like an employer or insurer to know something about you that is documented in this research, you can write and sign a statement telling the researchers it is okay to give your employer or insurance company information.

Even though the research has a Certificate, the research or any member of the study staff must report (even if it is without your consent) evidence of harm to self or others, including actual or suspected abuse, neglect, or exploitation of a child, or disabled or elderly adult.

A description of this study will be available on <http://www.ClinicalTrials.gov>, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time using the following study identification number: NCT05339412.

What are the costs for participating in this research?

There are no costs to you for participating in this research. If you complete study activities via an app on your mobile phone, you may incur data usage charges.

Will I be reimbursed for any of my expenses or paid for my participation in this research?

Each agency will decide whether staff members who participate in this study may receive incentive payments. If your agency permits incentive payments, then you will receive incentive payments (money order, or check) after completing key participation milestones. Specifically, the first payment of \$25.00 will be provided after completing the following tasks: the study enrollment, pre-training survey, and 2nd module of the web-based training. The second payment of \$25.00 will be provided after attending the consultation session (training + consultation group) or viewing the unrelated video (training only group). The third payment of \$50.00 will be provided after completing the web-based training. The fourth payment of \$50.00 will be provided after completing the post-training survey. The fifth payment of \$100.00 will be provided after completing the demonstration session. **If you reach all five milestones then you will receive a total of \$250.00. If you do not meet every milestone then you will be compensated for only the milestones you reach.** You will receive your payment via US mail within approximately 30 days of completing each milestone. Influent will process the incentive payments. The address that you provide for payment purposes will be shared with Influent and their staff members who process payments.

Can I withdraw or be removed from the study?

If you decide to participate, you have the right to withdraw your consent and leave the study at any time without penalty. You can withdraw from the study by contacting SYNC Principal Investigator, Ashley Kendall (akendall@uic.edu) .

The researchers [and/or funder] also have the right to stop your participation in this study without your consent if they believe it is in your best interests.

What if I am a UIC student?

You may choose not to participate or to stop your participation in this research at any time. This will not affect your class standing or grades at UIC. The investigator may also end your participation in the research. If this happens, your class standing or grades will not be affected. You will not be offered or receive any special consideration if you participate in this research.

Remember:

Your participation in this research is voluntary. Your decision whether to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Consent of Subject

I have read the above information. I have been given an opportunity to contact the researchers and ask questions, and my questions have been answered to my satisfaction. I agree to participate

in this research. **PLEASE PRINT OUT A COPY OF THIS DOCUMENT FOR YOUR RECORDS.**