UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Project Positive Attitudes Towards Health, Survey Interviews
Principal Investigator: Sunghee Lee, Ph.D., Institute for Social Research
Co-Investigator(s): James Wagner, Ph.D., Institute for Social Research
Michael Elliott, Ph.D., Department of Biostatistics
Erin Bonar, Ph.D., Department of Psychiatry
Sarah Stoddard, Ph.D., School of Nursing
Study Sponsor: National Institutes of Health

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study.

1.1 Key Information

Things you should know:

- The purpose of the study is to improve research design for injection drug user communities.
- If you choose to participate, you will be asked to complete a survey that will last 20 to 30 minutes.
- The risks include answering sensitive questions and a breach of confidentiality.
- You may not receive any personal benefit for being in this study.

Taking part in this research project is voluntary. You do not have to participate, and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

The purpose of the study is to understand ways to improve research design targeting injection drug users in order to improve the health and the quality of life of user communities.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study? To be eligible to participate in this study, you must be

- invited by your peer or our research team by presenting a valid invitation coupon;
- ages 18 years old or older;
- living in the greater Detroit area;
- have injected drugs in the last 6 months; and
- able to show a physical injection mark.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

- We will start with a short screener to check your eligibility.

- If our assessment indicates that you may experience difficulties in completing the questionnaire, we will encourage you to reschedule for another time.
- Once you are ascertained eligible, we will provide a URL over text/email that will direct you a survey questionnaire that you will complete.
- Once completing the survey, we will provide invitation cards/coupons to recruit your user peers. The number and type of invitations will be determined randomly, and we will observe how the participants respond to the invitations.
- You will be invited to take a follow-up survey in 2 to 3 weeks from today.

4.2 How much of my time will be needed to take part in this study?
The interview today will take place once you consent to participate by completing this form. The screener will take about 5 minutes and then the main survey will last 20 minutes. The follow-up survey will take about 5 minutes.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
There is a potential risk of breach of confidentiality. We will collect your name and telephone numbers for issuing incentives and scheduling the follow-up survey. To guard against this breach, all of this information will be kept separately from the answers you provide to this survey in the secure server maintained at the University of Michigan. However, answering questions about your health and life situations can be difficult. You do not have to answer any questions you do not want to answer and may stop your participation in the interview at any time. We have a list of local agencies that can provide you with additional information or support on our website if you are interested.

5.2 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. We hope that this study will contribute to the improvement of ways to study the topic of substance use and health.

6. ENDING THE STUDY

6.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9. “Contact Information”. If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information. For the survey administration, interview staff will assess whether there may be drug-use-related cognitive issues that may prevent you from operating the questionnaire at the time of in-person or virtual visits. If such cases arise, you will be encouraged to reschedule at another time.

7. FINANCIAL INFORMATION

7.1 Will I be paid or given anything for taking part in this study? You will receive $40 for completing the survey. You may also be given invitation notes that you can give to your peers so that they can also participate. If they participate, you will be given an additional $20 per peer who completes the survey. The criteria of those who are eligible for the study will be provided at the end of the survey. Within 2-3 weeks, we will contact you to schedule a return visit for the additional payment for the recruitment and ask about how your invitation worked. This follow-up survey will take about 5 minutes, and we will provide an additional $10 for the follow-up survey. We will provide the incentives through Amazon.com. If you are not eligible, there will be no payment provided.

7.1.1 Will I need to pay anything to be part of the study?
There is no cost associated with your participation.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my information? We will record your name and contact information to send you invitation coupons, reminders and payment. This information will be maintained separately from your survey answers and with password protection. Only authorized research staff will have an access to this information.

8.1.1 Special Protections
This research holds a Certificate of Confidentiality (CoC) from the National Institutes of Health.

This means that we cannot be forced to disclose any research information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. In general, we will use the Certificate to resist any demands for information that would identify you, except as described below.

We will disclose your information for any purpose to which you have consented, as described in this informed consent document.

Please note that a CoC does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research, including your sharing the invitation card/coupon with others. If an insurer, employer, or other person obtains your written consent to receive research information, then we will not use the Certificate to withhold that information.

More detailed information about Certificates can be found at the NIH CoC webpage**:**
https://humansubjects.nih.gov/coc/index

8.2 Who will have access to my research records?
There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.

8.3 What will happen to the information collected in this study?
We will keep the information we collect about you during the research for future research projects and for study recordkeeping. Your name and other information that can directly identify you will be stored securely and separately from the research information we collected from you.

We plan to make the data set from this study available to other researchers including via Interuniversity Consortium for Political and Social Research (ICPSR), a data repository system at the University of Michigan. Also, the results of this study could be published in an article or presentation. The data set or publications from this study will not include any information that would let others know who you are.

8.4 Will my information be used for future research or shared with others?
We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

9. CONTACT INFORMATION

Who can I contact about this study?
Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Project Coordinator: Karen Gates
Email: kgates@umich.edu
Phone: 734-764-7177

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road

Building 520, Room 1169Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

10. YOUR CONSENT

Consent to Participate in the Research Study
By marking "Yes, I agree to take part in the study" below, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. We will make this document URL available for your records and we will also keep the keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

_____ Yes, I agree to the take part in this study.
_____ No, I do not agree to the take part in this study.

Date (mm/dd/yy): _____

11. OPTIONAL CONSENT

Consent to be contacted for participation in future research
Researchers may wish to keep your contact information to invite you to be in future research projects that may be similar to or completely different from this research project. If you agree to this, we'll ask for additional contact information at the end of the survey, including Facebook contact information. This is voluntary and not required to participate today's survey.

_____ Yes, I agree for the researchers to contact me for future research projects.
_____ No, I do not agree for the researchers to contact me for future research projects.

Date (mm/dd/yy): _____