THE FENWAY INSTITUTE

CONSENT TO TAKE PART IN A RESEARCH STUDY

Study Title:	**Integrated behavioral activation and HIV risk reduction counseling for MSM with stimulant use: IMPACT**
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Call us at the number above with concerns, questions, or complaints about the research, study injuries, scheduling, or study visits. If you have questions about your rights as a participant in research, or wish to speak to someone not involved in the conduct of the study, please contact our **Human Research Protection Program** at: 617.927.6031, regulatory@fenwayhealth.org

Introduction

You may be eligible to take part in a research study. This form has important information that will help you decide whether to join.

Ask the study staff any questions you may have and to explain anything that is unclear to you. You can also to talk to others such as your friends, family, or doctors about your possible participation in this study.

If you decide to take part in the study, we will ask you to sign this form. We will give you a copy of the form to take home with you. It has information, including contact information, which you should keep. We will also keep a signed copy of this form in our research records.

Key Information

We are asking you to take part in this research study because you are a man who reports using stimulants (such as meth, cocaine, or crack), you are 18 years of age or older, and you are HIV negative.

Things you should know:

- The purpose of the study is to research a new behavioral treatment for men who use stimulants to improve their sexual health and reduce the risk of getting HIV.
- If you choose to join, we will ask you to complete up to 5 research visits in-person or remotely (via video meeting) and you will be randomly assigned to 1 of 2 study groups:
    - Group A – The Project IMPACT intervention (10 sessions total)
    - Group B – Control/Standard of Care (SOC): 2 sessions of sexual health counseling only.
- This entire research study will take about 12 months. Regardless of which group you are assigned to or if you complete the study remotely (via video chat) or in-person, you will have 4 to 6 research visits: consent visit (this may be combined with the baseline visit if you are doing the study in-person), baseline visit (across 1 or 2 visits) followed by three follow-up visits 4, 8, and 12 months after your baseline. In addition, you will receive either 2 or 10 weekly individual counseling sessions depending on group assignment.
- Risks or discomforts from this research include answering questions relating to depression, anxiety, and stimulant use which can be upsetting. As part of the study you will have access to a licensed clinical psychologist and other qualified counselors who can help you deal with any feelings you have.
- You may not experience any direct benefit from being in this study. You participate in counseling sessions that have been shown to help others cope with and reduce the distress associated with combining sex and stimulant use (such as depression).
- Whether to take part in this study is your choice. You do not have to take part in the study and you are free to stop at any time.
- If you participate at Fenway, you cannot be hired to work at The Fenway Institute until a year after you are done with the study. This is to protect your privacy and the integrity of the research. Being in this study does not impact your eligibility to be hired in other departments of Fenway Health.

Purpose of the Study

The purpose of this study is to help learn what types of treatment programs best help those who use stimulants and may benefit from improving sexual health. To do this we will compare our intervention to 2 other study groups. You will be randomly assigned to 1 of 2 study groups:

1. Group A – The Project IMPACT intervention (10 sessions total): 2 sessions of sexual health counseling, and 8 sessions of Behavioral Activation (BA) therapy with sexual health counseling. BA therapy is a type of therapy that focuses on helping people re-engage in enjoyable and meaningful life activities that do not involve drugs.
2. Group B – Control/Standard of Care (SOC): 2 sessions of sexual risk-reduction counseling only.

You have a 50-50 chance of being in Group A or Group B.

The study is being done at Fenway Health (Fenway), Brown University (Brown), and the University of Miami (U-Miami). The University of California, Los Angeles (UCLA) is a coordinating site and the University of California, San Francisco (UCSF) is a partner site which is providing urine testing kits for PrEP adherence. The study is being paid for by the National Institute on Drug Abuse (NIDA).

Up to 286 people will take part in this study. We plan to enroll up to 143 participants between Fenway and Brown, and up to 143 at the University of Miami.

What will happen in this research study?

Consent visit: Study staff will go over the study details and expectations for participation. You will be able to ask questions and decide if you want to participate or not. If you are doing the study online and you decide you want to participate, we will mail you a package with the study materials needed for the baseline visit.

Baseline Visit: If you are doing the study in-person, this visit will be at the same time as the consent visit. Study staff will do an assessment with you that will contain psychological, social, and behavioral questions. Some of these questions are about your sexual history and substance use. You will answer some of these on a computer or tablet.

Because you have to be HIV-negative to be in this study, you will be tested for HIV during your baseline visit. As part of the testing process, an HIV test counselor will provide preliminary HIV risk-assessment counseling and will test you for HIV antibodies using the FDA-approved OraQuick® rapid HIV Antibody test, otherwise known as a rapid HIV test. This will be done using a sample of blood (finger prick or blood draw), or oral swab. This test is extremely accurate and provides results in 20 minutes, which will be shared and discussed with you during post-test counseling.

If you have a reactive (preliminary positive) HIV test result, you will not be considered HIV-infected until you get a confirmatory blood test. We will refer you to get confirmatory HIV testing with appropriate medical and psychosocial support services. These test results may take up to 1 week to return from the lab. If you have a reactive (preliminary positive) test result, you will not be able to be in any other part of the study.

All cases of HIV must be reported to your state Department of Health, including name and contact information. We will not report your results. The provider that you see for confirmatory testing will communicate these results to Department of Health.

If you have a negative HIV test result, you will then do a clinician-administered assessment. The clinician will evaluate your answers and decide if you meet all criteria to be in the study. This assessment takes about 90 minutes to complete.

You may have the option of completing the baseline visit across two sessions. However, there are certain assessments that need to be completed in the first baseline session. Once these requirements have been met, you will have the option to finish the rest of the baseline assessments during another visit.

If you are HIV-negative and meet all other study criteria, you will be enrolled in this study.

We will also do a toxicology test by getting an oral swab or urine test (which will be determined by study staff). This tests for methamphetamines, amphetamines, cocaine, opiates, and marijuana. These results are not provided to you and are not shared outside the study.

If you complete research activities online, the study package that was mailed to you will contain an HIV screening test and a urine toxicology test will be sent to you for self-collection during the baseline visit. Research staff will provide detailed instructions to complete these during the baseline visit.

If you are currently using PrEP (a medication to protect you from getting HIV) you will be asked to provide urine (pee on a stick). The result of this test will be used to see if you have been taking PrEP. The PrEP test is optional and you can still participate if you decide not to take the urine test. This pee stick will also be provided to you in the study package we will mail to you.

Sexual health counseling sessions (2 sessions): All enrolled participants will receive 2 sessions of sexual health counseling.

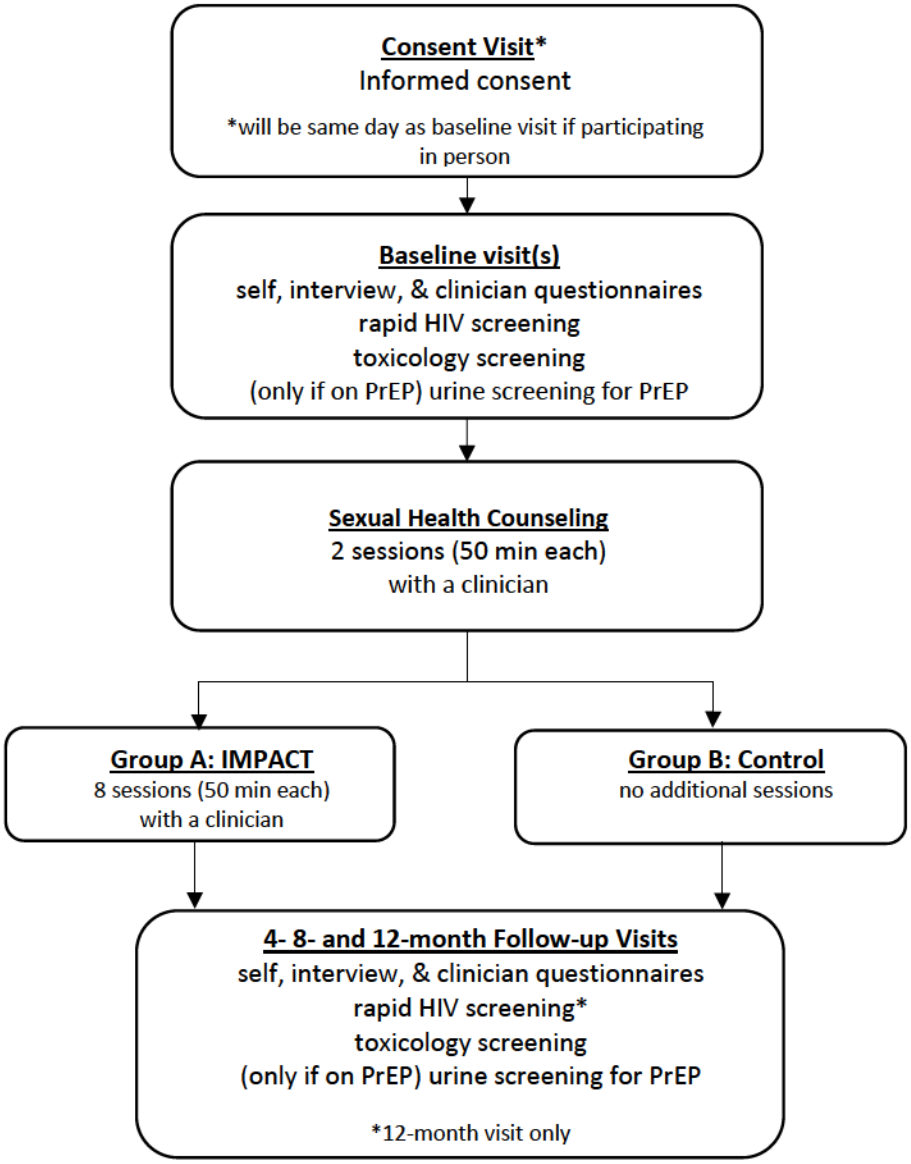
Randomization: At the end of the second session of sexual health counseling, you will be randomly assigned to 1 of the 2 study groups. You do not have the option to choose your group. The odds of being in Group A or Group B are 50-50.

Additional counseling sessions (8 sessions): If you are assigned to Group A, you will get about 8 more sessions with a clinician. Group A participants get the IMPACT intervention, which involves continued discussion of sexual health along with "behavioral activation" to help with mood, helping individuals re-engage in their lives. At each counseling session, you will be asked to complete a brief survey.

Follow-up assessment visits (3 total): 4-, 8-, and 12-months after your baseline visit, you will do the same activities as your baseline visit. You will do a toxicology test, and study staff will determine whether it will be an oral swab or urine. The test method will remain the same for all follow-up visits. You will be tested for HIV at your final 12-month follow-up using the same rapid HIV test as at baseline. If you are currently using PrEP you, we will ask you to do a urine test (pee on a stick) to determine if PrEP is in your system.

All sessions will be audio taped/digitally recorded. To protect your confidentiality, your name will not be on the tapes. All data will be kept confidential and secure at the study

sites. The recorded interview will be password protected and will only be accessible to study staff. We cannot provide copies of these recorded sessions to you.



We may learn new things during the study that you should know about. The research investigators will tell you about new information that could affect your health and whether you want to continue to be in the study. You may be asked to sign a new consent form that shows that you have been told about the new information relating to this research study.

What if I stop the study early or am removed from the study before it is finished?

You can agree to be in the study now, change your mind later, and stop at any time. If you get care at Fenway, Brown, U-Miami (UHealth), or one of our affiliated institutions (e.g., UCLA, UCSF) you can continue to get your regular medical care at there. If you choose not to participate, it will not affect your care now or in the future. There will be no penalty or loss of benefits. Even if you do not join or you leave this study early, you can ask research staff about programs that provide help with HIV/STD testing and other services, such as substance abuse counseling or mental health services.

The researchers may choose to stop your participation in this study at any time.
You may be removed from the study if:

- You fail to follow instructions.
- Continuing in the study would be harmful to you.
- The study is cancelled.

There may be other reasons to take you out of the study that we do not know at this time.

If you withdraw or are removed from the study, any data or samples collected from you before your withdrawal will still be used for this study.

What are the risks of this study? What will the study team do to protect against these risks?

Risks of Surveys

There is some risk of feeling embarrassed or uncomfortable during your participation in this study, such as while talking about personal or sexual issues, or about your behavior related to alcohol and drugs. You can refuse to answer any question and can leave a study session early at any time. You can request that the researcher refer you to a counselor or other means of psychosocial support.

Questions relating to depression, anxiety, and stimulant use can be upsetting. As part of the study you will have access to a licensed clinical psychologist and other qualified counselors who can help you deal with any feelings you have.

Risk of Blood Draw

Some participants may have their blood collected for HIV testing. You may experience some discomfort with these procedures. You may feel a slight pinch when we draw your blood and you may experience bruising from the needle. However, bruising is not likely.

Risks of HIV Testing

HIV may cause you to worry or become anxious. If you test positive for HIV, you will be referred to your provider for treatment and follow-up.

Risks of Loss of Privacy

We will take several steps to protect your personal information. Although the risk is low, it is possible that your personal information may be given to someone who should not have it. If that happens you could face discrimination, stress and embarrassment. We can tell you more about how we will protect your personal information if you would like it.

Additionally, if you present us with a referral code, the Study Ambassador who refers you will receive $20 in compensation if you are randomized to Group A or B. Study Ambassadors are not told who has joined the study and are paid on a monthly basis to minimize the risk that they will be able to figure out who is participating in the study. There is still a chance that the Study Ambassador will have referred a limited number of people in a given month and may assume you are participating in the study upon receiving compensation for their referral.

What happens if I am hurt or become sick because I participated in this research study?

It is highly unlikely that you will be at any risk of physical harm as a result of this study. If you are injured as a direct result of this study, trained research staff will provide immediate treatment for your injuries as necessary. If you are injured as a direct result of the study, Fenway, Brown, UCLA, UCSF, or U-Miami (UHealth) will give you immediate necessary care for your injuries. Study staff will then direct you where to go if you need additional medical care. Each Institution reserves the right to bill your insurance company or other third parties, if appropriate, for the care for the injury. We will try to have these costs paid for, but you may be responsible for some or all of them. For example, if the care is billed to your insurer, you will be responsible for any deductibles or co-payments required by your insurer.

Injuries sometimes happen even when no one is at fault. There are no plans to pay you or otherwise compensate you for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

How might I be helped by participating in this study?

You might receive no direct benefit from being in this study. You will be provided with safer sex kits containing lube and condoms after HIV testing. You will also have counseling sessions that have been shown to help others cope with and reduce the distress associated with sexual risk taking and stimulant use (such as depression). What we learn from this study may help further HIV prevention research, which may help other men who have sex with men who are at risk for HIV in the future.

What kind of information will be collected about me during this study?

The following types of data may be collected from you during this study:

- Survey/Questionnaire/Interview answers
- HIV serostatus
- Biospecimens (Blood & Urine)
- Counseling Sessions

What will happen to my samples and information once this study is over?

As part of this project, Fenway, Brown, UCLA, UCSF, or U-Miami plan to keep your research data/specimens to use for future research. Your name and other information that can be used to identify you will be kept safe and stored separately from the research data collected as part of the project. Access to the data/ specimens will be restricted to the investigators from this study, other approved investigators, and other selected research staff. Your donated data/specimens will be stored using a code that will not contain identifying information. Fenway, Brown, UCLA, UCSF, and U-Miami will store the data/specimens as long as they may be needed or until they are used up. You may request that we destroy your data/specimens that are still linked to your identity at any time. We will not be able to destroy or recall results from any test or analysis already conducted, or take back data or samples that have already been shared. If you want us to destroy your samples, please contact the Principal Investigator.

Once this study is complete, we may remove any information that could directly identify you from study data and samples, and use them for future research at Fenway Health, U-Miami, UCLA, and UCSF; share them with other researchers; or include them in a collection of samples and/or health information from many different studies that researchers from all over could use. We will not ask for additional permission to do this.

Will I get my research results?

We do not plan to return your individual research results to you or your doctor. Your research results are a stepping stone in learning about health and disease. Most of what we learn in this study will not be relevant to your personal health. There is a small chance that researchers could find something that might be important to your health. If this happens, we may try to contact you to find out if you would like to learn more.

How will you protect my privacy?

Your privacy is a top priority. If you agree to take part in this research study, your personal information will not be given to anyone unless we receive your permission or the law requires it. In order to maintain your confidentiality, all your study records will be

kept in locked file cabinets or in secure computer files under a unique code number rather than your name. The secure video chat used for remote visits is conducted on a HIPAA compliant telehealth platform to ensure user security. None of this study information will become part of your medical record at Fenway, Brown, UCLA, UCSF, or U-Miami. Your name will not be publicly disclosed at any time and your records will be strictly maintained according to current legal requirements. This applies to any written study records, survey assessments, and test results.

This research is covered by a Certificate of Confidentiality (Certificate) from the National Institutes of Health (NIH). This means we may not share or give out study information that may identify you if there is a court subpoena, unless you agree. We may still report your medical information if you need medical help, or if there is a risk of harm to yourself or others, as the law requires. A Certificate does not mean the government approves of our project. You should understand that a Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

We will not use the Certificate to avoid releasing information about you for any purpose you have agreed to in this informed consent document or any later agreement.

A description of this study will be posted on a public website, http://ClinicalTrials.gov, and summary results of this study will be posted on this website at the conclusion of the research. No information that can identify you will be posted.

Privacy and Information Sharing Authorization

You may have the right to find out if information collected for this study was shared with others for research, treatment, or payment. You may not be allowed to review the information, including information recorded in your medical record, until after the study is completed. When the study is over, you will have the right to access the information again.

You can withdraw from the study and end your permission for Fenway, Brown, UCLA, UCSF, or U-Miami to use or share the information that was collected as part of the research; however, you cannot get back information that was already shared with others. Once you remove your permission, no more identifiable information about your health ("health information") will be collected. If you wish to withdraw your health information, please contact the research team.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research visits, tests, interviews, and questions.

Your health information is protected by a law called the Health Information Portability and Accountability Act (HIPAA). In general, anyone who is involved in this research, including those funding and regulating the study, may see the data, including

information about you. The following people may see, use, and share your research health information:

- Research staff at Fenway, Brown, UCLA, UCSF, and U-Miami involved in this study;
- Medical staff at Fenway, Brown, UCLA, UCSF, and U-Miami (UHealth) directly involved in your care;
- Other research investigators and centers that are a part of this study, including people who oversee the research;
- People at Fenway Health, Brown, UCLA, UCSF, and U-Miami who oversee, advise, and evaluate research and care, including the Fenway Health Institutional Review Board;
- Non-research staff within Fenway, Brown, UCLA, UCSF, and U-Miami who need this information to do their jobs (such as for treatment, payments, or health care operations);
- People from agencies and organizations that provide accreditation and oversight of research;
- People that oversee the study information such as data safety monitoring boards, clinical research organizations, data coordinating centers, and others;
- Sponsors or others who fund the research, including the government or private sponsors;
- Companies that manufacture drugs or devices use in this research;
- Federal and state agencies that oversee or review research information, such as the FDA, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities;
- People or groups that are hired to provide services related to this research or research at Fenway, Brown, UCLA, UCSF, and U-Miami such as laboratories;
- Your health insurer, only for portions of the research and related care that are considered billable;
- Public health and safety officials (for instance, if we learn information that could mean that harm could come to you or others we may need to report this, as required by law);
- Your state Department of Health, if we learn that you have HIV, as state law requires;

The main reasons why we may share this information include:

- To conduct the study;
- To make sure the study meets all legal and organizational requirements;
- To monitor the safety of participants in the study.

We will use and disclose your protected information only as described in this form; however, people outside Fenway, Brown, UCLA, UCSF, and U-Miami who receive your information may not be covered by this promise. We will try to ensure that everyone who needs to see your information keeps it confidential, but we cannot guarantee this.

Because research is ongoing, we cannot give you an exact time of when we will destroy this information. Researchers may continue to use your data for many years.

Will I be paid for taking part in this study?

You will receive up to $350 for your participation in this study.

- $50 for each assessment visit (baseline, 4-, 8-, and 12-months).
    - If you choose to complete the baseline across 2 sessions, you will be paid $25 after completing the first part of the baseline visit and $25 after completing the second part of the baseline visit.
    - For remote visits, participants will receive $30 for completing the survey and up to $20 for toxicology screening (4-, 8-, and 12-months) and HIV testing (baseline & 12-month only) (see remote procedures below).
- $15 for each individual counseling session (either 2 or 10 sessions depending on your randomly selected group).

It is possible the samples or information we collect for this study may be used for commercial profit. There is no plan for you to receive any money or other benefits if this happens.

What will I have to pay for if I take part in this research study?

There is no cost to you related to taking part in this research project.

STUDY OPTIONS

This page includes tests, procedures, and study choices that are not required in order to take part in this study. You can say yes or no and still participate.

Urine Test for PrEP Adherence Testing

If you are currently using PrEP (a medication to protect you from getting HIV) you will be asked to complete a urine test (pee on a stick). Your results will be used to see if PrEP is in your system.

This is optional, and you can still participate if you don't want to provide urine/take the test

INITIAL one of the following:

_____ I **AGREE** to provide my urine to test PrEP adherence.

_____ I **DO NOT AGREE** to provide my urine to test PrEP adherence.

Remote Research Participation

As part of your participation in this study some people will complete research visits remotely. A “remote visit” means that you will be able to complete your research questionnaires and interviews by computer and secure video chat (this means you will be able to see and talk to the study staff from a computer) or by telephone.

If you choose to consent (say yes) to participate in remote visits, study visits may take place on the computer and through a secure video chat with study staff. This means you will be completing surveys online or by interview. If you choose to participate, you will access the survey through a secure, private web address/hyperlink that only study staff and you have access to. If, for any reason, you are unable to complete the survey online, a staff member will arrange for you to complete the survey by phone. Since part of the study requires a rapid HIV screening test and urine collection, we will mail you a package with all the materials you would need to complete these. Detailed instructions will be provided, and you will complete these procedures with study over while over video chat.

Remote visits take about the same time as if you were doing the visit in-person. All participants may choose to participate in person at any time. Enrollment sites are located in Boston MA, Providence RI, and Miami FL. Individuals who enroll remotely may not be able to participate in-person due to distance from the enrollment site or other restrictions (e.g., COVID-19). These individuals may complete all study activities remotely.

We ask that you find a private location to complete the remote visit. Please be sure that you have access to a strong internet connection. Please plan to complete the survey in a single sitting (not doing it in pieces at different times) from the same device. If you have to exit out of the survey, your answers may not save and we will ask you to do the survey again.

INITIAL one of the following:

_____ I **AGREE** to participate in this research remotely.

_____ I **DO NOT AGREE** to participate in this research remotely.

Informed Consent and Authorization

Person Obtaining Consent

- I have explained the research to the study participant.
- I have answered all questions about this research study to the best of my ability.

_____ _____

Person Obtaining Consent (Signature) **Date/Time**

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- I have been informed about the purpose of the research study, the procedures that I will undergo, and the possible risks, discomforts, and benefits I may experience.
- I have had the opportunity to ask questions and my questions have been answered.
- I understand that this is a choice, and know the alternatives to my participation.

I give my consent to take part in this research study. I give permission to Fenway Health and its collaborators to use and disclose my protected health information as described above.

_____

Subject's Name (Printed)

_____ _____

Subject (Signature) **Date/Time**

STUDY STAFF USE ONLY:

_____ _____

QC Initials **QC Date**