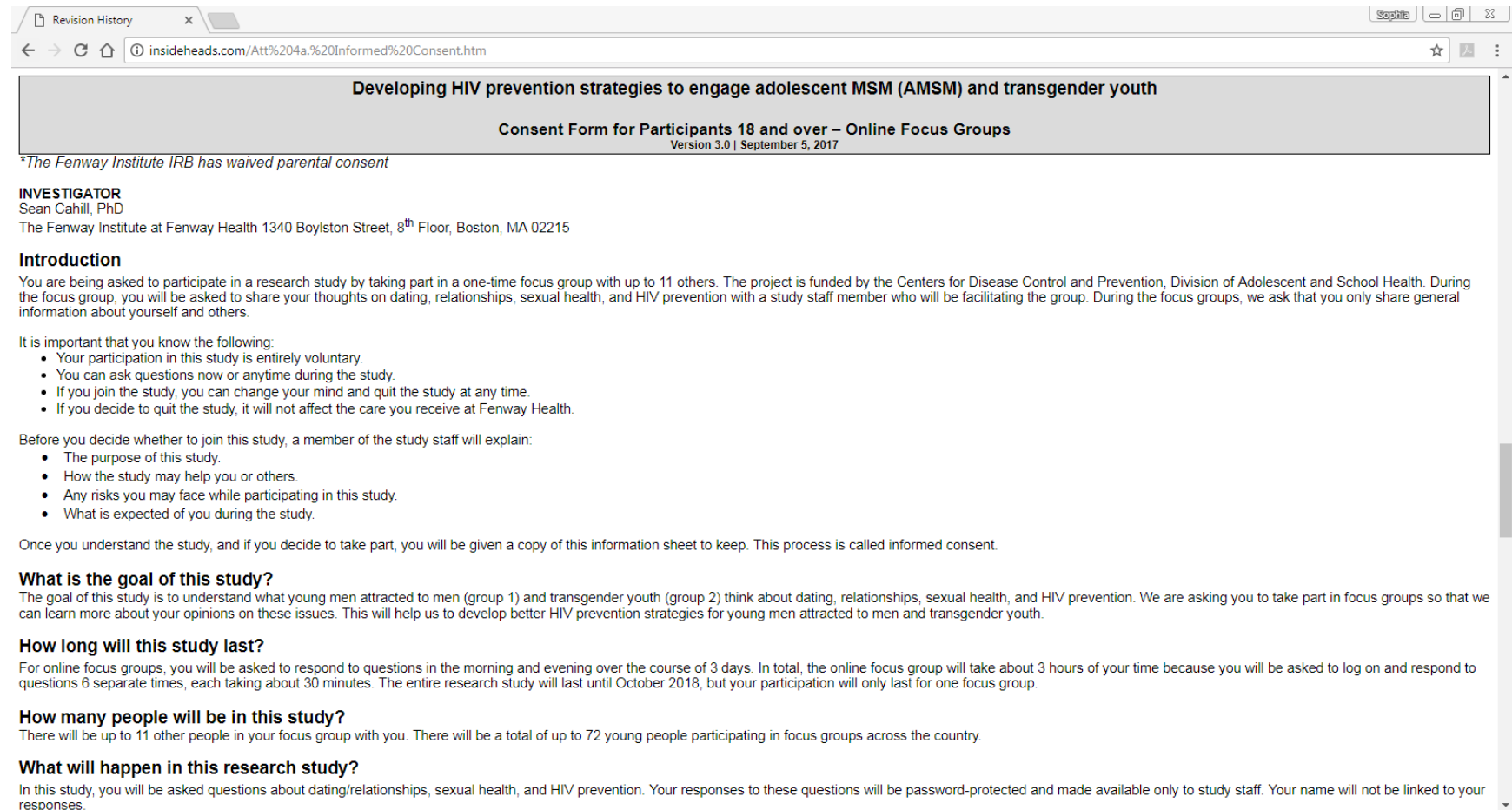


## Online Informed Assent Screenshots Attachments 4a & 4b

### Att 4a. Informed Consent



The screenshot shows a web browser window with the address bar displaying "insideheads.com/Att%204a.%20Informed%20Consent.htm". The page title is "Developing HIV prevention strategies to engage adolescent MSM (AMSM) and transgender youth". Below the title, the text reads "Consent Form for Participants 18 and over – Online Focus Groups" and "Version 3.0 | September 5, 2017". A note states: "\*The Fenway Institute IRB has waived parental consent".

**INVESTIGATOR**  
Sean Cahill, PhD  
The Fenway Institute at Fenway Health 1340 Boylston Street, 8<sup>th</sup> Floor, Boston, MA 02215

**Introduction**  
You are being asked to participate in a research study by taking part in a one-time focus group with up to 11 others. The project is funded by the Centers for Disease Control and Prevention, Division of Adolescent and School Health. During the focus group, you will be asked to share your thoughts on dating, relationships, sexual health, and HIV prevention with a study staff member who will be facilitating the group. During the focus groups, we ask that you only share general information about yourself and others.

It is important that you know the following:

- Your participation in this study is entirely voluntary.
- You can ask questions now or anytime during the study.
- If you join the study, you can change your mind and quit the study at any time.
- If you decide to quit the study, it will not affect the care you receive at Fenway Health.

Before you decide whether to join this study, a member of the study staff will explain:

- The purpose of this study.
- How the study may help you or others.
- Any risks you may face while participating in this study.
- What is expected of you during the study.

Once you understand the study, and if you decide to take part, you will be given a copy of this information sheet to keep. This process is called informed consent.

**What is the goal of this study?**  
The goal of this study is to understand what young men attracted to men (group 1) and transgender youth (group 2) think about dating, relationships, sexual health, and HIV prevention. We are asking you to take part in focus groups so that we can learn more about your opinions on these issues. This will help us to develop better HIV prevention strategies for young men attracted to men and transgender youth.

**How long will this study last?**  
For online focus groups, you will be asked to respond to questions in the morning and evening over the course of 3 days. In total, the online focus group will take about 3 hours of your time because you will be asked to log on and respond to questions 6 separate times, each taking about 30 minutes. The entire research study will last until October 2018, but your participation will only last for one focus group.

**How many people will be in this study?**  
There will be up to 11 other people in your focus group with you. There will be a total of up to 72 young people participating in focus groups across the country.

**What will happen in this research study?**  
In this study, you will be asked questions about dating/relationships, sexual health, and HIV prevention. Your responses to these questions will be password-protected and made available only to study staff. Your name will not be linked to your responses.



### Are there any other costs associated with taking part in this study?

No.

### Why might I be withdrawn from the study?

You might be asked to leave the study if:

Continuing would be harmful to you.

You fail to follow instructions.

The study is cancelled.

For other reasons that we do not know at this time.

### How will my confidentiality and privacy be protected?

Your confidentiality and privacy is one of our top priorities. All the data we collect will be stored in locked file cabinets and kept in secure computer files. All study visits will be private. We will also create a unique study code for the data we collect about you. Identifying information will not stay with the data and, whenever possible, will be kept apart from your name. The results of this research may be published in a medical book or journal or be used for teaching purposes. However your name or identifying information will not be used.

We will ask you and the other people in the focus group to use only first names or pseudonyms during the group session. For online focus groups, your username will not have any identifying information. We will also ask group members not to tell anyone outside the group what any other person said in the group. However, we cannot guarantee that everyone will keep the discussions private. Only the research team will have access to your study records, audiotapes, and online transcripts. After the group discussion has been transcribed from the tapes, the tapes will be destroyed. No personal identities will be used in any reports or publications that may come from this study.

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. For example, the following people might see information about you:

- Research staff at Fenway Health involved in this study
- Other researchers that are a part of the study
- People at Fenway Health who oversee research and care. This includes the Fenway Health Institutional Review Board.
- People from agencies that provide accreditation and oversight of research.
- People that oversee the study information such as data safety monitoring boards, clinical research organizations, and others.
- Sponsors or others who fund the research, including the government or private sponsors, and their contractors.
- Federal and state agencies that oversee or review research information, such as, 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 Health, such as laboratories
- Public health and safety officials (for instance, if we learn information that could mean harm to you or others, we may need to report this, as required by law.

The main reasons why we may share this information include:

- To conduct the study as described to you in this informed consent.
- To make sure the study meets all legal and organizational requirements.
- To ensure 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 Health who get 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 when we will destroy this data. Researchers continue to use data for many years so it is not possible to know when they will be done.

The main reasons why we may share this information include:

- To conduct the study as described to you in this informed consent.
- To make sure the study meets all legal and organizational requirements.
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Because research is ongoing we cannot give you an exact time when we will destroy this data. Researchers continue to use data for many years so it is not possible to know when they will be done.

### Your privacy rights

If you do not want to take part in this study, you do not have to. If you do want to take part, you must verbally consent. If you are an online participant, you must confirm your consent at the bottom of this page.

If you do not consent, it will not affect your care at Fenway Health now or in the future. There will be no penalty or loss of benefits. You can leave the study and end your permission for Fenway Health to use or share the protected 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 private health information will be collected. If you wish to withdraw your health information you will need to do so in writing.

You may have the right to get some of the information that was shared with others for research, treatment or payment. This information is available after the study analysis is done. To learn more about your privacy rights, please contact the Manager of Research Compliance at 617-927-6031.

### Who do I contact if I have questions or problems?

If you have any questions or concerns, please contact the study staff:  
Sean Cahill at (617) 927-6016  
Sophia Geffen at (857) 313-6670

If you are distressed during or after the focus group, you can also call the Trevor Lifeline at 1-866-488-7386.

If you have questions about your rights as a participant in a research study and want to talk with someone not involved with the study, then you may call the Manager of Research Compliance at (617) 927-6400. They will get you in contact with the Fenway Health Institutional Review Board (IRB).

The Fenway Health IRB is a committee of volunteers who protect the rights and welfare of research participants. The investigators and Manager of Research Compliance may also be contacted at the following address:  
Fenway Health  
1340 Boylston Street  
Boston, MA 02215

### Participant Consent

- I consent to participate in the focus group.
  - I understand the information on this form. I understand the risks and potential benefits of my participation in this focus group. I understand that my participation is completely voluntary and that I may leave the focus group at any time. I understand that if I have questions or concerns I may contact the study team at any time.
- I do not consent to participate in the focus group.

## Att 4b. Informed Assent



### Developing HIV prevention strategies to engage adolescent MSM (AMSM) and transgender youth

#### Assent Form for Participants under 18 – Online Focus Groups

Version 3.0 | September 5, 2017

*\*The Fenway Community Health IRB has waived parental consent*

#### INVESTIGATOR

Sean Cahill, PhD

The Fenway Institute at Fenway Health 1340 Boylston Street, 8<sup>th</sup> Floor, Boston, MA 02215

#### Introduction

You are being asked to participate in a research study by taking part in a one-time focus group with up to 11 others. The project is funded by the Centers for Disease Control and Prevention, Division of Adolescent and School Health. During the focus group, you will be asked to share your thoughts on dating, relationships, sexual health, and HIV prevention with a study staff member who will be facilitating the group. During the focus groups, we ask that you only share general information about yourself and others.

It is important that you know the following:

- Your participation in this study is entirely voluntary.
- You can ask questions now or anytime during the study.
- If you join the study, you can change your mind and quit the study at any time.
- If you decide to quit the study, it will not affect the care you receive at Fenway Health.

Before you decide whether to join this study, a member of the study staff will explain:

- The purpose of this study.
- How the study may help you or others.
- Any risks you may face while participating in this study.
- What is expected of you during the study.

Once you understand the study, and if you decide to take part, you will be given a copy of this information sheet to keep. This process is called informed consent.

#### What is the goal of this study?

The goal of this study is to understand what young men attracted to men (group 1) and transgender youth (group 2) think about dating, relationships, sexual health, and HIV prevention. We are asking you to take part in focus groups so that we can learn more about your opinions on these issues. This will help us to develop better HIV prevention strategies for young men attracted to men and transgender youth.

#### How long will this study last?

For online focus groups, you will be asked to respond to questions in the morning and evening over the course of 3 days. In total, the online focus group will take about 3 hours of your time because you will be asked to log on and respond to questions 6 separate times, each taking about 30 minutes. The entire research study will last until October 2018, but your participation will only last for one focus group.

#### How many people will be in this study?

There will be up to 11 other people in your focus group with you. There will be a total of up to 72 young people participating in focus groups across the country.

#### What will happen in this research study?

In this study, you will be asked questions about dating/relationships, sexual health, and HIV prevention. Your responses to these questions will be password-protected and made available only to study staff. Your name will not be linked to your responses.

### **Can I change my mind about being in this study?**

Yes. Your participation is completely voluntary and you do not have to participate in this study. If you agree to be in the study now, you can change your mind later and leave the study. You may skip any of the questions you don't want to answer. If you refuse to participate or leave the study early, it will not impact any care you may receive at Fenway Health. If you leave the study early, Fenway Health may use or give your health information that it already has if the information is needed for this study or any follow-up activities.

### **What are the risks associated with this study?**

It is unlikely that you will be at any risk of physical harm from being in this study. If you are injured from being in this study, you will receive immediate, short-term treatment as determined by Fenway Health. The cost of the treatment will be charged to you or your insurance company, as would normally be done for your medical care. You will then be told where you could receive further treatment for injuries. Your insurance may or may not pay for treatments for injuries that are caused by taking part in this study. No payment to you or other forms of compensation for such injuries will be provided by Fenway Health or the sponsoring agency.

There is some risk of feeling embarrassed and/or uncomfortable while taking part in this study, especially while talking about personal or sexual issues. Any information you give to the researcher will remain private and secure. You do not have to answer any question you do not want to. You can leave the study at any time. If you become upset during the study and want to talk with a professional, there are Fenway staff members licensed in mental health services that are available on-call. We can help connect you with one of these mental health professionals or other means of support.

Every effort will be made to keep your participation and your personal information private, but absolute confidentiality cannot be guaranteed. If we learn something that would immediately put you or others in danger, the study staff is required by law to take steps to keep you and others safe. This means that we have to report to the authorities (hospital, police, or social services) anything you tell us that suggests that you might be in danger. This includes things like if you tell us that you plan to hurt or kill yourself or hurt or kill someone else. Health care professionals are required by state laws to report suspected cases of abuse or neglect. While we do not ask you direct questions about abuse or neglect, if you are under the age of 18 and were to report an incident to us, we would need to do additional assessments and/or report the incident to the authorities.

Each focus group has up to 12 people. In-person focus groups are for young men attracted to men (ages 14 to 17). Taking part in a focus group means there is a chance that participants could share information about you or make you feel uncomfortable based on what you choose to share about yourself. If you are not "out" to family or friends, there is the chance that someone may find out about your sexual orientation or gender identity because you were in this study. At the start of the group, the study staff members who are leading the group will discuss the importance of respecting everyone's opinion and experiences, as well as keeping one another's information confidential. However, **we cannot promise** that other participants will keep your information confidential. You do not have to share any personal information about yourself during the focus group sessions that you do not want to share. You may end participation in the group at any time.

The in-person focus group will be audio recorded. For online focus groups, a transcript will be extracted from the online platform. To ensure that your responses are maintained in a secure manner to protect privacy, your full name will not be recorded. You may refuse to share any identifiable information and still take part in the study. You also have the option of using a different name during the focus groups. Please do not share any information about another participant with someone outside of the group. Also, please do not share any identifying information (such as their last name) about someone else (such as a partner) at any point during the group.

The information you provide will be kept secure and stored in locked cabinets in a secure area at Fenway. The digital file will be transcribed (writing down what you said) after the focus group so that researchers have a written copy of the interview. Your name will not appear in these written copies of the interview.

### **What are the benefits to participating in this study?**

There are no direct benefits to taking part in this study. However, you may have the chance to increase your own knowledge about topics such as HIV prevention and PrEP.

### **What are the alternative treatments available in lieu of participating in this study?**

You do not have to join this study. If you receive care at Fenway Health, leaving the study will not affect your care in any way.

### **Will I be told of any new findings while I am participating in this study?**

The data we gather will help to create tools for HIV prevention for young men attracted to men and transgender youth. These findings will be made available to the public at the end of the study in October 2018 or later.

### **Will I be paid to participate in this study?**

You will be given a gift card valued at \$30 for your participation in the focus group. The focus group will take place over 3 days for online focus groups. You will receive this payment at the conclusion of the focus group by email within 2 business days.

### **Are there any other costs associated with taking part in this study?**

No.

### **Why might I be withdrawn from the study?**

You might be asked to leave the study if:

Continuing would be harmful to you.

You fail to follow instructions.

The study is cancelled.

For other reasons that we do not know at this time.

### **How will my confidentiality and privacy be protected?**

Your confidentiality and privacy is one of our top priorities. All the data we collect will be stored in locked file cabinets and kept in secure computer files. All study visits will be private. We will also create a unique study code for the data we collect about you. Identifying information will not stay with the data and, whenever possible, will be kept apart from your name. The results of this research may be published in a medical book or journal or be used for teaching purposes. However your name or identifying information will not be used.

We will ask you and the other people in the focus group to use only first names or pseudonyms during the group session. For online focus groups, your username will not have any identifying information. We will also ask group members not to tell anyone outside the group what any other person said in the group. However, we cannot guarantee that everyone will keep the discussions private. Only the research team will have access to your study records, audiotapes, and online transcripts. After the group discussion has been transcribed from the tapes, the tapes will be destroyed. No personal identities will be used in any reports or publications that may come from this study.

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. For example, the following people might see information about you:

- Research staff at Fenway Health involved in this study
- Other researchers that are a part of the study
- People at Fenway Health who oversee research and care. This includes the Fenway Health Institutional Review Board.
- People from agencies that provide accreditation and oversight of research.
- People that oversee the study information such as data safety monitoring boards, clinical research organizations, and others.
- Sponsors or others who fund the research, including the government or private sponsors, and their contractors.
- Federal and state agencies that oversee or review research information, such as, 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 Health, such as laboratories
- Public health and safety officials (for instance, if we learn information that could mean harm to you or others, we may need to report this, as required by law.

The main reasons why we may share this information include:

- To conduct the study as described to you in this informed consent.
- To make sure the study meets all legal and organizational requirements.
- To ensure 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 Health who get 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 when we will destroy this data. Researchers continue to use data for many years so it is not possible to know when they will be done.

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

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If you do not consent, it will not affect your care at Fenway Health now or in the future. There will be no penalty or loss of benefits. You can leave the study and end your permission for Fenway Health to use or share the protected 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 private health information will be collected. If you wish to withdraw your health information you will need to do so in writing.

You may have the right to get some the information that was shared with others for research, treatment or payment. This information is available after the study analysis is done. To learn more about your privacy rights, please contact the Manager of Research Compliance at 617-927-6031.

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Sophia Geffen at (857) 313-6670

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1340 Boylston Street  
Boston, MA 02215

### Participant Assent

- I assent to participate in the focus group.
  - I understand the information on this form. I understand the risks and potential benefits of my participation in this focus group. I understand that my participation is completely voluntary and that I may leave the focus group at any time. I understand that if I have questions or concerns I may contact the study team at any time.
- I do not assent to participate in the focus group.