# Consent Documents Cover Page

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| **Official title of study:** | Innovative Approaches for Minor Consent: Consent 2.0 - A Multi-Center Study of the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) |
| **NCT number:** | NCT03242954 |
| **Secondary ID:** | 5U24HD089880-02 [U.S. NIH Grant/Contract Award Number] |
| **Document Date:** | 12 March 2018 |

**SIS Adolescents**

This is an information sheet about the Consent 2.0 Study. The full title of the study is *"Innovative Approaches to Minor Consent to Biomedical HIV Prevention Research."* This sheet contains important information about the study that you may want to refer back to at a later time. It also contains contact information for the study staff. Please save this information sheet in case you want to refer to it later.

**The researcher in charge of this study is Dr. Amy Knopf. You may call her at 317-274-2285 between the hours of 9 am and 5 pm Eastern, Monday through Friday, if you ever have questions about this study.**

**Local Investigator (Site's city): [Insert local investigator's name and phone number]**

## STUDY INTRODUCTION

You are being asked to participate in this study because you are a young person who has sex with men. In this study we will ask you questions to better understand your interest and willingness to participate in two different kinds of HIV prevention studies. We are **not** asking you to sign up for one of these studies—instead, we will be asking you to imagine how you would feel if you were asked to join a similar study. We will use the information you provide to improve the research process for other young people who sign up for studies like the ones we discuss today.

This study is funded by the National Institutes of Health through the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN).

## PARTICIPATION IS VOLUNTARY

Your participation in this study is completely voluntary. You do not have to be in this study. Refusing to join the study will not change your usual health care. You will not lose any benefits that you otherwise could get. You may also stop being in the study at any time without any negative effects.

## STUDY PROCEDURES

If you decide to participate in this study, you will:

- Be assigned a study ID number that will be used to identify you, instead of your real name.
- Privately answer some questions on an electronic tablet. Your answers will be linked to your study ID number, only. This means that the researchers who review the data at a later date will not know your identity. The questions cover a few different topics, for

example: your current living situation, your sexual orientation, your gender identity, the extent to which you worry about becoming infected with HIV, the number of sexual partners you have had so far in your life, and your relationship to your parent(s)/guardian(s).

- Listen to the researcher explain two different HIV prevention studies that have involved young people like you. **We are not asking you to be in one of these studies; we are just using them as examples for our discussion today.**
- Privately answer questions on the electronic tablet about your willingness to be part of a study like the ones we describe to you.
- Verbally answer questions about the studies we tell you about. Your answers to the questions will tell us how easy or difficult it was for you to understand the consent form.
- You may choose not to answer any questions that you do not want to answer. You may decide to stop the survey at any time. Skipping questions or stopping the survey may mean that you cannot finish the study visit. The researchers hope that you will answer all the questions because they can learn much more if all the questions are completed.
- Some or all of your study visit will be audio-recorded for research and quality assurance purposes. The audio recording will not have your name or any identifying information attached. A script of the recording will be made at a later date. Your unique survey code will be attached to the script. The audio recording and the script will be stored on a secure server at Indiana University that only Dr. Knopf has access to. Once the script has been confirmed to be correct, the audio recording will be destroyed.
- You may be asked if you are willing to participate in an additional interview that takes about 45 minutes to complete. If you want to be part of the additional interview, here is what will happen:
    - The study staff will ask you questions that are similar to the questions you answer on the tablet, but allow us to understand your answers better.
    - The entire interview with the researcher will be audio-recorded. Your real name and contact information will not be associated with the recording.
    - A script of your answers will be made after the interview is finished. Your unique survey code will be attached to the script. The audio recording and the script will be stored on a secure server at Indiana University that only Dr. Knopf has access to. Once the script has been confirmed to be correct, the audio recording will be destroyed.

## CONFIDENTIALITY (PRIVACY)

Your participation in this study will be kept confidential (private) as allowed by law. Your study ID will be used to link your survey answers to the interview script(s). Your name or any other personal information that may identify you as a study participant will not be used on the study-related survey, interview, or forms.

Information about the study may be published in a scientific magazine, presented at a scientific meeting, or used by other researchers, but your identity will not be revealed.

All data will be stored on secure password-protected computers. During the study, only the ATN 150: Consent 2.0 study team and the ATN Coordinating Center will have access to this information. In the future, other researchers can request permission to review and analyze the data from this study. Future researchers will not be able to connect your data to you. We do not know how long the information from this study will be stored.

Every effort will be made to keep your participation and the personal information of your research record private and confidential, but absolute privacy cannot be guaranteed.

## RISKS AND BENEFITS OF THE STUDY

The possible risks or discomfort of this study are minimal (small). Some of the questions asked in the online survey and interview may make you feel uncomfortable or upset. Remember that you can choose to stop the survey or interview at any time, for any reason.

There are no direct benefits to you for participating in this study. However, the information you give us may help improve the research process for other young people who may participate in future studies.

## COMPENSATION FOR STUDY PARTICIPATION

If you decide to be in this study, as a way of thanking you for your time, you will receive compensation. [Each site enter compensation amount for participant and indicate if transportation costs will be provided].

## CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study or a research-related injury, contact the researcher, Dr. Amy Knopf, at 317-274-2285, between the hours of 9 am and 5 pm Eastern, Monday through Friday or you may contact [Sites to insert local investigator's name and phone number] For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or offer input, contact the IU Human Subjects Office at 317-278-3458 or 800-696-2949 between the hours of 9 am and 5 pm Eastern, Monday through Friday.

**SIS Parents**

This is an information sheet about the Consent 2.0 Study. The full title of the study is *"Innovative Approaches to Minor Consent to Biomedical HIV Prevention Research."* This sheet contains important information about the study that you may want to refer back to at a later time. It also contains contact information for the study staff. Please save this information sheet in case you want to refer to it later.

**The researcher in charge of this study is Dr. Amy Knopf. You may call her at 317-274-2285 between the hours of 9 am and 5 pm Eastern, Monday through Friday, if you ever have questions about this study.**

**Local Investigator (Site's city): [sites to insert local investigator's name and phone number].**

## STUDY INTRODUCTION

You are being asked to participate in this study because you are the parent of a teen between the ages of 14 and 17 years. In this study we will ask you questions to better understand how you would feel about your teen participating in two different kinds of HIV prevention studies. We are **not** asking you to allow your teen to sign up for one of these studies—instead, we will be asking you to imagine how you would feel if your teen were asked to join a similar study. We will use the information you provide to improve the research process for young people who sign up for studies like the ones we discuss today.

This study is funded by the National Institutes of Health through the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN).

## PARTICIPATION IS VOLUNTARY

Your participation in this study is completely voluntary. You do not have to be in this study. Refusing to join the study will not change your usual health care. You will not lose any benefits that you otherwise could get. You may also stop being in the study at any time without any negative effects.

## STUDY PROCEDURES

If you decide to participate in this study, you will:

- Be assigned a study ID number that will be used to identify you, instead of your real name.
- Privately answer some questions on an electronic tablet. Your answers will be linked to your study ID number, only. This means that the researchers who review the data at a

later date will not know your identity. The questions cover a few different topics, for example: the structure of your household (number of family members, annual income), your education level, the extent to which you worry about your teen becoming infected with HIV, and your relationship to your teen.

- Listen to the researcher explain two different HIV prevention studies that have involved young people about your teen's age. **We are not asking your teen to be in one of these studies; we are just using them as examples for our discussion today.**
- After you hear about the study, you will be asked to read the consent form from the study.
- Privately answer questions on the electronic tablet about your opinion of different options for consent, or informing teens about and signing them up for research studies.
- Verbally answer questions about the studies we tell you about. Your answers to the questions will tell us how easy or difficult it was for you to understand the consent form.
- You may choose not to answer any question for any reason. You may decide to stop the survey at any time. Skipping questions or stopping the survey may mean that you cannot finish the study visit. The researchers hope that you will answer all the questions because they can learn much more if all the questions are completed.
- Some or all of your study visit will be audio-recorded for research and quality assurance purposes. The audio recording will not have your name or any identifying information attached. A script of the recording will be made at a later date. Your unique survey code will be attached to the script. The audio recording and the script will be stored on a secure server at Indiana University that only Dr. Knopf has access to. Once the script has been confirmed to be correct, the audio recording will be destroyed.
- You may be asked if you are willing to participate in an additional interview that takes about 45 minutes to complete. If you want to be part of the additional interview, here is what will happen:
    - The study staff will ask you questions that are similar to the questions you answer on the tablet, but allow us to understand your answers better.
    - The entire interview with the researcher will be audio-recorded. Your real name and contact information will not be associated with the recording.
    - A script of your answers will be made after the interview is finished. Your unique survey code will be attached to the script. The audio recording and the script will be stored on a secure server at Indiana University that only Dr. Knopf has access to. Once the script has been confirmed to be correct, the audio recording will be destroyed.

## CONFIDENTIALITY (PRIVACY)

Your participation in this study will be kept confidential (private) as allowed by law. Your study ID number will be used to link your survey answers to the interview script(s). Your name or any other personal information that may identify you as a study participant will not be used on the study-related survey, interview, or forms.

Information about the study may be published in a scientific magazine, presented at a scientific meeting, or used by other researchers, but your identity will not be revealed.

All data will be stored on secure password-protected computers. During the study, only the ATN 150: Consent 2.0 study team and the ATN Coordinating Center will have access to this information. In the future, other researchers can request permission to review and analyze the data from this study. Future researchers will not be able to connect your data to you. We do not know how long the information from this study will be stored.

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There are no direct benefits to you for participating in this study. However, the information you give us may help improve the research process for young people who may participate in future studies.

## COMPENSATION FOR STUDY PARTICIPATION

If you decide to be in this study, as a way of thanking you for your time, you will receive compensation. [Each site enter the compensation for participant and indicate if transportation costs will be provided].

## CONTACTS FOR QUESTIONS OR PROBLEMS

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