Form Approved
OMB No: 0920-XXXX
Exp. Date: xx/xx/20xx

Project NICE: Navigating Insurance Coverage Expansion

Attachment 6: Informed Consent Form

The UNIVERSITY OF CHICAGO
The Division of the Biological Sciences • The University of Chicago Medical Center

CONSENT/AUTHORIZATION BY SUBJECT FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: IRB16-1260
Name of Subject: _____

STUDY TITLE: Navigating Insurance Coverage Expansion (NICE): A collaboration to increase access to care for black and Hispanic men who have sex with men and transgender persons

Doctor Directing Research: Dr. John Schneider

Address: 5841 South Maryland Ave.

MC 5100
Chicago, IL 60637

Telephone Number: **(773) 702-8349**

You are being asked to participate in a research study. A member of the research team will explain what is involved in this study and how it will affect you. This consent form describes the study procedures, the risks and benefits of participation, as well as how your privacy will be maintained. Please take your time to ask questions and feel comfortable making a decision whether to participate or not. This process is called informed consent. If you decide to participate in this study, you will be asked to sign this form.

WHY IS THIS STUDY BEING DONE?

You are being asked to participate in this study because you are part of a group of black or Hispanic men who have sex with men (MSM), or transgender persons. The purpose of this research is to determine if health outcomes are improved by enrolling in healthcare insurance coverage sooner.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 800 people will take part in this study at the Chicago area.

WHAT IS INVOLVED IN THE STUDY?

If you agree to participate in this study you will be asked to read this consent form and sign it before any study procedures take place. This consent form will be discussed with you and you will be able to ask any questions you might have.

After you sign this form, you will fill out a questionnaire about your housing situation, substance abuse, opinions, feelings and health insurance coverage. The questionnaire will take approximately 45 minutes.

If you are eligible for this study, you will be randomly (like flipping a coin) assigned to one of two groups: the intervention group or the control group. You have an equal chance of being assigned to each group.

If you are assigned to the intervention group, you will be offered assistance in enrolling in healthcare coverage and provided assistance on where to go for care immediately. You will be asked your thought about the help that was given to you.

If you are assigned to the control group, you will be offered a booklet on how to enroll in healthcare coverage through the state's health insurance marketplace. You will be asked your thoughts about the help that was given to you.

All visits you make to a doctor or health clinic will be standard of care. No matter what group you are assigned to, the researchers will collect information about you for a year including laboratory test results as well as your insurance coverage status and clinic visit dates. This information will be gathered from your medical records at your health clinic.

Data that is collected as part of this study will be shared with the Centers for Disease Control and Prevention (CDC) for analysis. The information that is sent to the CDC will be labeled with a unique study number and not your name, initials and birth date.

During this study, Dr. Schneider and his research team will collect information about you for the purposes of this research. This includes your name, birthdate, dates of study interviews, answers given during the interview and questionnaire, the results from the tests, and recording of interview (if applicable).

HOW LONG WILL I BE IN THE STUDY?

You will be in this study for 1 year. You will not be contacted after today.

Dr. Schneider may decide to take you off of the study without your consent if:

- You are unable to meet the requirements of the study;
- If the study is stopped.

WHAT ARE THE RISKS OF THE STUDY?

Loss of Privacy

Any time information is collected about you there is a potential risk for loss of privacy. However, the researchers will make every effort to keep your information private.

Information collected as part of this study may be viewed as reportable offenses and the proper authorities may be contacted as a result of any disclosures.

During the interview you may choose to not answer any questions that makes you uncomfortable.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct medical benefit to you.

WHAT OTHER OPTIONS ARE THERE?

You may choose not to participate.

The decision whether or not you wish to participate in this study will <u>not</u> affect your care at the University of Chicago Medical Center, Howard Brown Health Center or Chicago House Social Service Agency, Inc.

WHAT ARE THE COSTS?

There will be no costs to you or your insurance company resulting from your participation in this research study. However, you or your insurance company will be responsible for costs related to your usual medical care.

WILL I RECEIVE A TOKEN OF APPRECIATION?

For your participation in this study you will receive $25 in cash as a token of appreciation at the end of your visit today.

WHAT ABOUT PRIVACY?

Study records that identify you will be kept private to the extent allowable by law. Data will be stored in a locked office, or in password protected computers at the University of Chicago. Only research staff involved in the study will have access to the data except as specified below. The data collected in this study will be used for the purpose described in this form. By signing this form, you are allowing the team access to your medical records which include Protected Health Information. Protected Health Information (PHI) consists of any health information that is collected about you, which could include your medical history and new information collected as a result of this study. The research team includes all of the individuals indicated on this consent form, as well as personnel at the University of Chicago.

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including the Office of Human Research Protections (OHRP). In addition, representatives of the University of Chicago, including the Institutional Review Board, a committee that oversees the research at the University of Chicago, may also view the records of the research.

If health information is shared outside the University of Chicago, the same laws that the University of Chicago must obey may not protect your health information.

During your participation in this study, you will have access to your medical record. Dr. Schneider is not required to release to you research information that is not part of your medical record.

This consent form will be kept by the research team for at least 6 years. The study results will be kept in your research record and be used by the research team indefinitely. At the time of study

completion, either the research information not already in your medical record will be destroyed or information identifying you will be removed from study results. Any research information in your medical record will be kept indefinitely.

Data from this study may be used in medical publications or presentations. Your name and other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. If you choose not to participate in this study, your care at the University of Chicago/University of Chicago Medical Center will not be affected. You may choose not to participate at any time during the study. Leaving the study will not affect your care at the University of Chicago/University of Chicago Medical Center.

If you choose to no longer be in the study and you do not want any of your future information or samples to be used, you must inform Dr. Schneider in writing at the address on the first page. Dr. Schneider may still use your information that was collected prior to your written notice.

You will be given a signed and dated copy of this document. This consent form document does not have an expiration date.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You have talked with research staff at the University of Chicago about this study and you had the opportunity to ask questions concerning any and all aspects of the research. Dr. Schneider or his study staff will continue to be available to answer any questions you have about this research study or your participation in the study.

If you have further questions about the study, you may call Dr. Schneider 773-702-8349.

If you have any questions concerning your rights as a research study participant, you may contact the Institutional Review Board (IRB), which is concerned with the protection of subjects in research projects. You can contact the IRB in writing at Institutional Review Board (IRB), University of Chicago, 5841 S. Maryland Ave, MC7132, I-625, Chicago, Illinois 60637 or by phone at (773) 702-6505, office hours are 8:30 am - 5:00 pm, Monday through Friday.

CONSENT

SUBJECT

The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

I agree to participate in this study. My participation is voluntary and I do not have to sign this form if I do not want to be part of this research study.

_____ Date: _____
Signature of Subject Time: _____ AM/PM (*circle*)

PERSON OBTAINING CONSENT

I have explained to _____ the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject.

_____ Date: _____
Signature of Person Obtaining Consent Time: _____ AM/PM (*circle*)

INVESTIGATOR/PHYSICIAN

_____ Date: _____
Signature of Investigator/Physician Time: _____ AM/PM (*circle*)