BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC

New York University

SUBJECT INFORMATION AND INFORMED CONSENT FORM

Protocol Title: Developing Clinical Translational Tools to Communicate Genetic Risk among Individuals who are at Clinical High Risk for Psychosis
Protocol #: 1 R21 HG010420
Sponsor: NHGRI (National Human Genome Research Institute)
Principal Investigator: Lawrence Yang
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KEY INFORMATION ABOUT THIS RESEARCH STUDY

You are being asked to be a subject in this research study because you are a COPE participant.

The following table is a concise and focused presentation of key information to assist you in understanding why you might or might not want to participate in the research.

Purpose	The purpose of this research study is to understand to what extent a manual works to explain genetic risk for psychosis for people who are identified as at increased risk for psychosis.
Voluntary Participation	Your decision to be in this study is voluntary.
Withdrawal	If you decide to be in this study and then change your mind, you can leave the study at any time without penalty.
Length of Participation	Your participation is expected to last one week. During that time you will have about two study visits. All meetings will be conducted remotely using the telephone or HIPAA-compliant video teleconferencing.
Procedures	The main procedures in the study include: ---Fill out questionnaires (once before and once after individually meeting with a clinician who will administer a manual) --- Individually meet with a clinician who will administer a manual about genetic risk for psychosis. This will be audio recorded with your permission.
Risks	There are not expected to be any physical risks to you as part of this study though some people feel bored or anxious when doing assessments.
Benefit	There is no direct benefit to you from taking part in this study, however the study results may help people in the future.
Confidentiality	There are provisions in place by the study protocol and study site to help protect the privacy and confidentiality of your personal health information and study information.

This overview does not include all of the information you need to know before deciding whether or not to take part. Much additional detail is given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.

INFORMED CONSENT FORM

This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the principal investigator and study staff to explain anything in this form or if you want more information. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends and your mental health counselor. If you agree to take part in this research study, you must sign this consent form.

DISCLOSURE OF FINANCIAL INTERESTS

The National Human Genome Research Institute (NHGRI), the sponsor of this study, is providing funds to New York University for conducting this research study.

PURPOSE OF THE STUDY

The purpose of this study is to understand to what extent a manual works to explain genetic risk for psychosis to people who are identified as at increased risk for psychosis. You will meet individually with a clinician and you'll be asked to share your beliefs about genetics. The cells of your body contain a molecule called deoxyribonucleic acid, or DNA for short. DNA is passed down from your parents and carries a code, in the form of genes, which determines your physical characteristics, such as the color of your hair and eyes; and risk for some diseases. Just as differences in our genetic code help explain why we all look different, these differences can also help to explain why some people develop certain diseases and others do not. We will ask you to complete questionnaires assessing your response to the genetic information once before you begin the educational session and once after you complete the educational session. You are being asked to take part in this study because you are a COPE participant. About 100 people from COPE are expected to be enrolled in this study. This study is funded by The National Human Genome Research Institute (NHGRI).

NUMBER OF SUBJECTS AND LENGTH OF STUDY PARTICIPATION

About 100 subjects are expected to be enrolled in this study at The Center of Prevention and Evaluation at The New York State Psychiatric Institute.

Your participation in this study is expected to last one week, in which you will meet twice with a research assistant and clinician.

STUDY PROCEDURES

You will be asked to meet with a research assistant twice for this study, once before meeting individually with a clinician in which you'll be asked to share your beliefs about genetics and your at-risk state for psychosis, and once after. All meetings will be conducted remotely using the telephone or HIPAA-compliant video teleconferencing. You will be given some questionnaires, including but not limited to, personality characteristics, such as how optimistic you are, stigma related to being identified as at risk for psychosis if genes were related to risk of psychosis development, and treatment and health related behaviors given the make believe situation that genes were related to psychosis development. You will also be shown a website at the end of the interview. In total, the study procedures will take about 2 and ½ hours for each visit.

As part of your participation in a research study we would like you to give permission to audio tape the meeting between you and the clinician who will administer a manual about genetic risk

for psychosis. The purpose of the audio taping is for the research personnel to analyze this meeting in-depth. If you refuse to allow the research team member to audio tape the interviews you can still participate in the research project. If anytime during or after the audiotape session, you wish the tape to be erased, this will be done.

PERMISSION FOR AUDIOTAPING

You are being asked for your permission to collect an audio recording of your voice and the answers your provide during your meeting with the clinician.

Please initial yes or no for the statement below:

I give permission to Dr. Girgis, Dr. Yang and the research team to audio record my interview.

_____YES _____NO

RISKS AND DISCOMFORTS

It is possible that some of the questions may lead to anxiety. It is possible that you could feel upset, tired, or anxious during the study procedures. You can decide at any time to end the interview or decline to answer specific questions. Furthermore, we will follow up with you to talk about your thoughts and feelings from participating in this study two weeks and three months after the study is completed.

A risk of taking part in this study is the possibility of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your confidentiality both during the sessions and by keeping the information from sessions securely stored. Their plans for keeping your information private are described in the 'confidentiality' section of this consent form.

NEW INFORMATION

You will be notified in a timely way if important new findings become known that may affect your willingness to continue in the study.

Clinically Relevant Research Results

If results of study procedures, including individual research results and clinical information that may be important to your health care become available, then you will be told about those results by your clinician.

BENEFITS

You will not receive personal (direct) benefit from taking part in this study. However, the information collected from this research may help others with similar symptoms to yours in the future.

REIMBURSEMENT

You will receive $50 after each study visit for the time required for your participation ($100 total for completing both study sessions). This may be paid in cash or check, mailed to your home address.

COMPENSATION FOR INJURY

For medical emergencies please call 911.

No other compensation will be offered by New York University or the sponsor or the Biomedical Research Alliance of New York.

You are not waiving any legal right to seek additional compensation through the courts by signing this form.

CONFIDENTIALITY

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor. Medical records, which identify you and the consent form signed by you, will be looked at by the sponsor or the sponsor's representatives and may be looked at by other regulatory agencies, The National Human Genome Research Institute (NHGRI), the Institutional Review Board, and the Biomedical Research Alliance of New York. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Please understand that the researchers of this study will notify your clinician if any information during the interview that indicates that you may be at risk for harming yourself or other people.

Since this research is funded by The National Human Genome Research Institute (NHGRI) this means this study is covered by a certificate of confidentiality. A certificate of confidentiality protects the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations.

Collection of Identifiable Private Information:

- Identifiers might be removed from your identifiable private information. After such removal, the information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent (or consent from your legally authorized representative).

When conducting remote visits, we will use telephone or HIPAA compliant video conferencing.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may stop your participation at any time, without penalty or loss of benefits or medical care to which you are otherwise entitled. If you decide to leave the study, please tell the principal investigator and research assistant.

Your participation in this study may be stopped without your consent at any time and for any

reason by the principal investigator, treating clinician, the sponsor, and other regulatory authorities. Reasons you may be withdrawn from the study include being at risk for harming yourself or others, your clinical symptoms worsen significantly, or the study is stopped. If you leave the study early, you may be asked to return to the COPE clinic for a final study visit for your safety.

CONTACTS FOR QUESTIONS, COMPLAINTS, CONCERNS

If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Dr. Lawrence Yang at 212-992-6334 or Dr. Ragy Girgis at 646-774-5553.

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

STATEMENT OF CONSENT

By signing this form, I confirm the following:

- I have read all of this consent form.
- All of my questions have been answered to my satisfaction.
- I can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, sharing and analysis of my personal health information and study information collected as part of this study by the sponsor and other authorized persons and regulatory agencies as described in this form.
- I will be given a copy of this signed and dated consent form to keep.
- I do not give up any legal rights that I would otherwise have if I were not in this study.

I voluntarily agree to participate in this study.

Subject: Name (Print)	Signature	Date
Person Obtaining Consent: Name (Print)	Signature	Date