

CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

Title: Project among African Americans to Explore Risks for Schizophrenia
PAARTNERS

Investigators: Rodney C. P. Go, Ph.D., Jacqueline Feldman, M.D., Robert Savage, Ph.D., Paul Lyons M.D., Ph.D., Charlie Swanson, M.D., Laura Barefield, M.D., Roberta May, M.A., Clifton R. Tennison, Jr., M.D.

Sponsor: National Institute of Mental Health

SELECTION OF SUBJECTS

You are invited to participate in a research study conducted by Dr. Rodney Go. Our study is dedicated to the study of mental illness in families of those mentally ill. We evaluate individuals and their family members in order to get comprehensive information. With your permission, our researchers will only contact those relatives whose name and number you provide on the "Family Information Sheet."

You were selected because you are a subject with a mental illness or a family member of a subject and you are willing to participate in research on brain processes and behavior and you have met other inclusion criteria. These inclusion criteria are based on medical and study design requirements.

PURPOSE

The National Institute of Mental Health (NIMH) would like to help scientists learn more about how genes effect the development of schizophrenia. We are gathering medical information and genetic material, or DNA, from persons who seem to have schizophrenia and their family members, in order to make this research possible. NIMH will store the medical information and DNA in a central place in New Jersey, called a repository. We will also store a small amount in Dr. Go's lab here at UAB. NIMH will make the medical information and DNA available to other scientists who want to do research on schizophrenia. Any use of these materials would first need to be reviewed and approved by NIMH. Since you or a family member appears to have schizophrenia, we are contacting you to see if you would be willing to contribute your medical information and a blood specimen to the repository for use in future research on schizophrenia. The specific purpose of this study is to carefully examine DNA of individuals within African American families where schizophrenia seems to be present. Because previous infections or illnesses are also factors that may increase a person's chance of developing a mood or anxiety disorder, investigators will examine antibodies that are present in your blood sample. Antibodies are particles that are made by your blood in response to an infection.

PROJECT DESCRIPTION

If you decide to be in this study, your part in the research will involve a clinical interview about yourself and your family. You will then take a series of tests that assess your ability to think clearly. These interviews and tests will take from 2 to 4 hours. A specially trained interviewer will ask you questions that address a broad range of personal life experiences involving social, occupational, family, and other behaviors. We may contact you later on for further information, or ask you to complete another interview in the next few years. You may be asked to be videotaped during one of these interviews. The videotapes will be used to train research staff or to help the UAB doctors to better understand your psychological status.

If you agree to participate, we will also draw from you a small sample of blood (approximately 3 tablespoons). We may need to contact you again regarding getting another blood sample. The blood sample you give will be used to create a cell line, which is living tissue. The blood sample, without your name, will be sent to the repository in New Jersey. Here, DNA will be taken from the cell line and used for scientific research now and in the future.

DNA and medical information collected from you will be stored at the repository. Your DNA and medical information will be stored there in a coded way to keep your identity a secret. Your DNA and medical information will be stored as a national resource. NIMH will provide them to qualified scientists around the world to study how genes cause schizophrenia. These scientists may not be currently working on this research right now.

RISKS ASSOCIATED WITH THE STUDY

There are no more than minimal medical or psychological risks associated with this study. If you feel fatigued, tired, uncomfortable, or in any way upset during any of the sessions, you may ask to stop for a rest break or have interviewing discontinued.

You may experience discomfort when having blood drawn; this may be a source of mild pain, and some swelling may occur at the site of the blood draw. Although it is uncommon, this may also cause you to feel faint, to bleed slightly, or to develop an infection at the site of the blood draw. Direct pressure will be applied to site of the blood draw. Procedures will be done to minimize risk of infection, swelling and bleeding.

The interview you are being given is not, and does not take the place of, a full psychiatric evaluation. You may experience some emotional discomfort when answering some questions. If any particular question makes you feel uncomfortable, you may discuss its importance with the specially trained interviewer. You may choose not to answer any question with which you still feel uncomfortable.

If you tell your family doctor that you have participated in this study, or if you tell your doctor about any specific aspects details relating to your participation, this information may then become part of your medical record with this doctor. Insurance companies routinely have access to such records. An insurance company might consider participation in a family study an indication of higher risk because it implies that there is a family history of a genetic condition. This might then hurt your access to health or other insurance.

We will not release information about you or your family to your doctor unless you authorize us to do so.

NEW FINDINGS

If new findings that would affect your safety develop during your participation in the study, you will be told as soon as possible so you can decide whether to continue or withdraw from the study.

BENEFITS

Although the results of this evaluation and participation in genetic studies will not benefit you directly, individuals who might develop schizophrenia in the future, their family members, and future generations may benefit if we can locate genes that lead to such disorders. That can lead to the development of methods for

prevention and new treatments. We do not expect to discover information which will directly benefit your condition during the next few years. If later on, diagnostic tests or new ways to treat your condition are discovered, this information should be obtained from properly licensed clinical labs or clinics, and will not come from the research team.

ALTERNATIVES

The only alternative is not to participate.

COSTS AND COMPENSATION

There are no costs to participants in this research project. Neither you, nor your insurance carrier will be billed for any evaluation.

Many research groups include investigators from private companies. Scientists who get your DNA and medical information and biological materials may work with a private company. Such companies have a financial interest in using information found from studying DNA. This includes developing commercial products that may later help others by improving the diagnosis and treatment of various medical problems. These companies may patent products or sell discoveries based on this research. Some of the scientists who study your DNA and medical information may get some financial benefit from this work. There are no plans to provide any compensation to you or your heirs should this occur.

RESEARCH RELATED INJURY

Neither the University of Alabama at Birmingham (UAB), the Helen Ross McNabb Center, nor the National Institute of Mental Health, has made provisions for monetary compensation in the event of injury resulting from the research and in the event of such injury, treatment is provided, but is not provided free of charge.

CONFIDENTIALITY

We will keep confidential your name and any other personal information we learn about you. **This information will not be given out to the repository or to anyone else.** We will take the following steps to ensure confidentiality. A research number will be assigned to you and your name will not be used. The only people who will have access to your individual identity are Dr. Go and his staff. The results from the analysis of your DNA will not be released or shared in any way with your relatives, with insurance companies, or any third party not involved in research unless you request that we do so. When results of this study are published, your name will not be used.

The researchers have obtained a Certificate of Confidentiality from the Federal Government which will help them protect your privacy, unless you consent in writing to the release of research information. However, if they learn that you or someone else is in serious danger of harm [such as in cases of child abuse] they may make disclosures to protect you and/or the other persons.

The UAB Institutional Review Board may review the research records for auditing purposes.

WITHDRAWAL

You do not have to be in this study if you don't want to be.

You have the right to leave the study at any time without giving any reason, and without penalty. If you wish to leave the study, contact Dr. Rodney Go, Dr. Jacqueline Feldman, Dr. Robert Savage, Dr. Charlie Swanson, Dr. Laura Barefield, Dr. Clifton Tennison, or Ms. Roberta May. We will tell the repository to remove your medical information and genetic material. We will keep your identity a secret by using a code number. The repository can use this code number to remove your medical information and genetic material, without ever knowing your name or other personal information. By using this code number, the repository will tell scientists to not include your data in their research. These scientists will not know your name or other personal information we learn about you.

RIGHT TO ASK QUESTIONS

If you have any questions about the study, you may contact Dr. Rodney Go at (205) 934-6107, Dr. Jacqueline Feldman or Dr. Robert Savage at (205) 934-4108, Dr. Clifton Tennison at (865) 637-9711 or Ms. Roberta May at (205) 934-2484.

If you have any questions about your rights as a research subject, you may contact Ms. Sheila Moore, Director of the Office of the Institutional Review Board for Human Use (IRB). Ms. Moore may be reached at (205) 934-3789 or 1 (800) 822-8816 press the option for an operator/attendant and ask for extension 4-3789 between the hours of 8:00 a.m. and 5:00 p.m. CT, Monday through Friday.

You will get a copy of this consent form to keep.

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a participant in this study. If you are of minor status, we must have your parent(s) or legal guardian sign on your behalf.

FUTURE SPECIMEN RESEARCH

_____ I agree to allow my samples preserved for future research other than schizophrenia.

_____ I **do not** agree to allow my samples preserved for future research other than schizophrenia.

LEGAL RIGHTS

Your are not waiving any legal rights by signing this consent form.

SIGNATURE OF PARTICIPANT

Date

SIGNATURE OF PHYSICIAN/INVESTIGATOR

Date

SIGNATURE OF WITNESS

Date

CONSENT FORM FOR RESEARCH INVOLVING CHILDREN/MINORS

You are making a decision whether or not to have our child participate in this study. Your signature indicates that you have decided to allow your child to participate, that you have read (or been read) the information provided above and that you have received a copy of this consent form.

SIGNATURE OF PARENT
OR Legally Authorized Representative

Date

SIGNATURE OF PARENT

Date

SIGNATURE OF PHYSICIAN/INVESTIGATOR

Date

SIGNATURE OF WITNESS

Date

ASSENT OF CHILD

_____ (name of child) has agreed to participate in research

| Project among African Americans to Explore Risks for Schizophrenia

Deleted: among African Americans

SIGNATURE OF CHILD

Date

OR

WAIVER OF ASSENT

The assent of _____ (name of child) was waived because of

_____ Age

_____ Maturity

_____ Psychological state of the child

SIGNATURE OF PARENT OR

Date

SIGNATURE OF PARENT

Date



**University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION
FOR RESEARCH**

You are being asked to sign this form to serve as authorization for UAB to use and release your health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your health information may be used for the research. Once this information has been disclosed, it may be subject to redisclosure and no longer be protected by federal privacy regulations.

Participant Name: _____
Research Protocol: Project among African Americans to Explore Risks for Schizophrenia

UAB IRB Protocol Number: F01113002
Principal Investigators: Rodney Go, Ph.D., Jacqueline Feldman, M.D., Paul Lyons, M.D., Ph.D., Robert Savage, Ph.D.

Sponsor: National Institute of Mental Health

Persons/organizations providing the information (check all that apply):

- University Hospital**
- UAB Clinics: Community Psychiatry Program**
- Kirklin Clinic/Health Services Foundation (“HSF”)**
- Callahan Eye Foundation Hospital (“CEFH”)**
- The Children’s Hospital of Alabama**
- Jefferson County Department of Public Health**
- Other:** _____

Description of health information to be provided: **All medical information and personal identifiers including past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind related to or collected for use in the research protocol.**

Persons/organizations receiving the information: The physicians, nurses and staff working on the research protocol (whether at UAB or elsewhere); other operating units of UAB, HSF, Children’s, CEFH and the Department of Public Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees; and outside regulatory agencies such as the Food and Drug Administration.

Authorization Expiration: **Completion of Research Protocol**

Authorization Revocation: **You or your legally authorized representative must read and initial the following:**

Initials: _____ **I understand that I may revoke this Authorization at any time by notifying the Director of the IRB, in writing, referencing the Research Protocol and IRB Protocol Number. If I revoke this Authorization, it will not have any effect to the extent UAB took action in reliance on the Authorization and any research data generated prior to revocation may still be used by the researcher.**

Signature of participant:

OR

Signature of legally authorized representative:

Printed name of participant's representative:

Relationship to the participant:

Date:

Date: