Northwestern University
Center for Genetic Medicine
676 N. St. Clair, Suite 1260
Chicago, IL 60611

CONSENT FORM AND AUTHORIZATION FOR RESEARCH

Project Title: NUgene: Gene-Disease Association and Treatment Outcomes

Principal Investigator: Rex L. Chisholm

Funded by: Northwestern University Center for Genetic Medicine

You are being asked to take part in a research project. This document has important information about the reason for this project, what you will do if you choose to be in this project, and the way we (i.e. Northwestern University) would like to use information about you and your health.

What is the reason for doing this project?

Northwestern University has created a genetic bank. A genetic bank is a collection of blood-based samples, such as DNA and RNA, and health information from many people. The genetic samples and health information will be shared with researchers for future research about the role genes play in human diseases.

You are being asked to contribute to this genetic bank because you are a patient at Northwestern Medicine or one of its affiliates.

What you will do if you choose to be in this project?

If you agree to take part in this project, you will be asked to:

1. Give one tablespoon (10ml) of blood
2. Fill out a brief questionnaire
3. Allow us ongoing access to and review of your electronic medical records for any visit to Northwestern Medicine or its affiliates for as long as you remain a participant in this project

What are some of the risks and discomforts that may happen to people who are in this project?

Contributing to this genetic bank may involve the following risks:

1. Potential risks of drawing blood include a bruise at the point where blood is taken, redness and swelling of the vein, and infection. Care will be taken to avoid these complications.

2. Some of the questions we ask may be upsetting or you may feel uncomfortable answering them. You are always free to skip any questions you do not want to answer.

3. Disease testing and genetic research can involve a number of risks. Genetic research results may have the possibility to lead to health or life insurance discrimination as well as job or social discrimination.

4. As with all medical information, there is also a risk in allowing access to your hospital medical records

What steps have been taken to minimize these risks?
This project has taken precautions to decrease these risks in the following ways:

1. The genetic information, research results, and the medical information used in these studies are labeled with a unique number and NOT with any personal identification, so there is little risk that the results can be linked to you.

2. No information about your participation in the NUgene Project will be placed in your medical records.

3. The genetic information, questionnaire information, and health information are kept in a secure database or in our collaborators' secure database, separate from any identifying information (such as your name, date of birth, and social security number).

4. The Principal Investigator of the NUgene Project has obtained a Certificate of Confidentiality from the federal government. This document protects your study records from being subpoenaed (released to the courts at their request), and we will only release your records for a subpoena if you ask us to in writing.

What are some of the benefits that are likely to come from me being a part of this project?
Taking part in this project will not benefit you directly. Joining this genetic bank may help researchers to better understand health problems and/or the role genes play in health, and possibly in the development of new treatments or screening tests as we improve our understanding of what causes many health problems.

Are there any financial costs to being a part of this project?
You will not be charged for any project-related procedures.

You will not be paid for your participation in this project.

The research done with your sample may lead to the development of new products in the future. In some instances, these products may have commercial value and may be developed and owned by the researchers, Northwestern University, and/or others, including companies. No payment will be given to you now or in the future for the use of your sample or data.

If I have questions or concerns about this research project, whom can I call?
You can call us with your questions or concerns. Rex Chisholm, PhD, is the person in charge of this research study. You can call him or a member of the NUgene Project staff at telephone number (312) 695-0700, Monday through Friday, 8:30 am - 4:30 pm.

What are my rights as a research subject?
If you choose to be in this project, you have the right to be treated with respect, including respect for your decision whether or not you wish to continue or stop being a part of the project. You are free to choose to stop being a part of the project at any time.

Choosing not to be in this project or to stop being in this project will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment, your class standing (for students enrolled in a class), or present or future employment to which you are otherwise entitled.

If you want to speak with someone who is not directly involved in this project, or have questions about your rights as a research subject, please contact the Office for the Protection of Research Subjects. You can call them at (312) 503-9338.

What about my confidentiality and privacy rights?

We are committed to respecting your privacy and keeping your personal information confidential.

To create this genetic bank and for you to be in this project, we will need to access your electronic medical records to collect health and treatment information. This information includes your name and date of birth, and we request that you provide us with your social security number or medical record number. You have the right to decide if we can use and share the health information you provide us and the information from your electronic medical records for this project.

Your health information we may collect or share for this project includes all information contained in your electronic medical record such as:

- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- HIV results; including diagnoses, treatment, response and laboratory testing
- Mental health information; including diagnoses, treatment, response and laboratory testing

If you sign this document, you are allowing the following groups of people to give information about you (described above) to the researchers of this project: All current and previous health care providers affiliated with Northwestern Medicine and Ann & Robert L. Lurie Children's Hospital of Chicago.

When your sample is collected, the sample and your health information will be identified by a unique number and not by your name or any identifying information (also called de-identified). In all cases where information relating to your sample and health information is shared with any of the people or groups listed below, you will be identified by a unique number and not by name, social security number, address, telephone number, or any direct identifier unless required by law or you specifically give permission.

To do more powerful research, it is helpful for researchers to share information they may get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Once we have your health information, we may share the de-identified information with:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office of Research, and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of this project)

- Other University research centers and University contractors who are also working on the project

- Study monitors and auditors who make sure that the project is being done properly

- Other researchers whose studies have been approved to access the information described above

- Commercial research and drug companies whose studies have been approved to access the information described above

- Government agencies and public health authorities, such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHSS), and the National Institutes of Health (NIH).

- Other academic research center(s)

Access to these scientific databases is restricted and can only be used by approved researchers. Although your information is de-identified, because genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small. Researchers will always have a duty to protect your privacy and to keep your information confidential.

The results from this project may also be used for teaching, research, publications, or presentations at scientific meetings.

Please note that:

- You do not have to sign this consent form. If you do not, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits. However, you will not be allowed to take part in this research study.

- You may change your mind and “take back” (revoke) this consent at any time. Even if you revoke this consent, the Principal Investigator may still use or share health information that was obtained about you before you revoked your consent as needed for the purpose of this study. To revoke your consent for the use of your health information, you must do so in writing to: Rex Chisholm, 676 N. St. Clair Street, Suite 1260, Chicago, IL 60611.

- Unless you revoke your consent, it will not expire.

- If you revoke your consent to use any blood or tissue taken for the study, the Principal Investigator will make sure your genetic sample is destroyed and no further medical information will be collected from your electronic medical records.

Future Contact Options:

Additional Research

I agree that someone may contact me in the future to ask me questions about my health or to ask me to participate in more research. I will not be obligated to participate further, but given the option to decide at that time. Agreeing to be contacted increases the risk to my privacy. It will be my responsibility to notify the NUgene Project if my contact information changes. _____
(initials)

I do not agree to be contacted in the future to ask me questions about my health or to ask me to participate in more research. _____
(initials)

Newsletter

I agree that someone may contact me in the future to send me periodic newsletters on current research or other general updates about the NUgene Project. _____
(initials)

I do not agree to receive newsletters on current research or other general updates about the NUgene Project. _____
(initials)

Consent Summary:
I have read this consent form and the project has been explained to me. I have been given time to ask questions, and have been told whom to contact if I have more questions. I agree to be in the project described above.

A copy of this consent form will be provided to me after I sign it.

_____	_____	_____
Subject's Name (printed)	Subject Signature	Date

_____	_____
Name (printed) and Signature of Person Obtaining Consent	Date

For subjects unable to give consent, permission to participate is given by the following authorized subject representative:

_____	_____	_____
Authorized subject representative (print)	Representative Signature	Date

My authority to sign as the subject's authorized representative:

- ☐ **Parent**
- ☐ **Spouse**
- ☐ **Legal Guardian**
- ☐ **Authorized Agent (e.g., Health Care Power of Attorney)**

Signature Block for Children

Your signature documents your permission for the named child to take part in this research.

All children will be contacted at age 18 to obtain their consent, which would allow them to continue to participate in The NUgene Project.

Signature of child	Date
Printed name of child	
Signature of parent or individual legally authorized to consent to the child's general medical care	Date
Printed name of parent or individual legally authorized to consent to the child's general medical care	❑ Parent ❑ Individual legally authorized to consent to the child's general medical care (See note below)

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Signature of parent	Date
Printed name of parent	

If signature of second parent not obtained, indicate why: (select one)

- ☐ The IRB determined that the permission of one parent is sufficient
- ☐ Second parent is deceased
- ☐ Second parent is unknown
- ☐ Second parent is incompetent
- ☐ Second parent is not reasonably available
- ☐ Only one parent has legal responsibility for the care and custody of the child

Assent

- ☐ Obtained verbally without signature.
- ☐ Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.

Signature of person obtaining consent and assent	Date
Printed name of person obtaining consent	