Columbia University Medical Center Consent Form

Attached to Protocol: **IRB-AAAN8811**
Principal Investigator: **Ali Gharavi (ag2239)**
Participation Duration: 4 years
Anticipated Number of Subjects: 2400

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study Title: **Cure Glomerulonephritis (Cure GN)**

1.2 Sponsor: **National Institutes of Health (NIH)**

1.3 Name, degrees, and affiliation of the Principal Investigator conducting the study

Contact	Title & Affiliation	Contact Type	Telephone
Ali Gharavi, MD	Asst Professor & Division Chief, Division of Nephrology, Columbia University Medical Center	Principal Investigator	212-851-5556

2. PURPOSE OF THIS STUDY

2.1 Study Purpose

There are several different types of glomerular diseases, such as minimal change disease (MCD), focal segmental glomerulosclerosis (FSGS), membranous nephropathy (MN), and immunoglobulin A nephropathy (IgAN). Over time, these diseases may cause kidney damage. These kidney diseases are rare and because of that, it is difficult for individual researchers to gather a large enough number of people to effectively study underlying mechanisms, identify markers of disease, and identify and evaluate new therapies. The purpose of CureGN is to gather a group of patients with glomerular disease to create a source of information and blood and urine samples, so that researchers can easily and effectively study glomerular disease.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

This consent form is written to address a research subject. If, however, you will be providing permission as the parent or legal guardian of a minor, the words 'you' and 'your' should be read as 'your child'. Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study? Anyone with MCD, FSGS, MN or IgAN, who has had their first kidney biopsy within the last 5 years, is not on dialysis, has not had a kidney transplant, and was not previously enrolled in the NEPTUNE study.

3.2 How many people (subjects) are expected to take part in this study? 2400 people worldwide. We expect to enroll approximately 600 subjects at Columbia.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study? If you decide to take part in this study, you will have an enrollment visit and at least one in person visit per year (see Table A). Two additional 'visits' per year may be done in person, or by phone or email.

The stored kidney biopsy slides, report, and pictures from your first kidney biopsy will be sent to the study pathologist for review to make sure that the biopsy results meet study requirements. These stored slides will be scanned to make a digital copy. These copies will be stored for review by the study pathologists and be available for future research.

Table A: Visit Schedule

Study Year	**Year 1**				**Year 2**			**Year 3**			**Year 4**		
Study Visit	Enroll V0	V1	V2	V3	V1	V2	V3	V1	V2	V3	V1	V2	V3
Study Month	0	1-4	5-8	9-12	13-16	17-20	21-24	25-28	29-32	33-36	37-40	41- 44	45-48

At the first study visit we will gather basic information, such as your name, age, race, contact information and family health history.

At each in-person study visit:

- We will review and record health information from your medical record. Examples include lab test results, medical procedures, and medicines you take.
- We will have you fill out forms about you are feeling and how your kidney disease impacts your life
- We will get a blood sample from you. We will use a needle to draw blood from a vein in your arm. The amount of blood at each visit is listed in the table below:

Table B: Blood Draw Amount

Visit type:		**V0, Baseline**	**V1, Yearly**	**V2 and 3**
CHILDREN:	**<21 pounds**	20 mL (4 teaspoons)	20 mL (4 teaspoons)	20 mL (4 teaspoons)
	21-<52 pounds	45 mL (3 tablespoons)	20 mL (4 teaspoons)	45 mL (3 tablespoons)
	>52 pounds	50 mL (3-1/3 tablespoons)	20 mL (4 teaspoons)	50 mL (3-1/3 tablespoons)
ADULTS:		50 mL (3-1/3 tablespoons)	20 mL (4 teaspoons)	50 mL (3-1/3 tablespoons)

- We will get a urine sample from you:
  - At every study visit we will collect a urine sample in the clinic
  - Once per year we will ask that you bring in a 24 hour urine sample if you are able
  - At all other in-person study visits we will ask you to bring in a first morning urine sample

During the **telephone or email visits**, we will ask you about medications that may have changed, symptoms you are experiencing and if you have had any remissions or relapses since we last saw you.

A lot of the research we do involves looking at your blood and urine. We will look for different substances in the blood or urine, such as levels of different proteins, or cell types that may better inform us about the course of disease.

Stored Specimens and Data:
Your blood and urine samples, along with those from all the other people who take part in CureGN, will be stored in the CureGN Biorepository which includes the NIDDK Central Repository. These repositories, also known as biobanks, are sponsored by the National Institutes of Health/National Institute of Diabetes, Digestive and Kidney Disease (NIH/NIDDK). A repository collects, stores, and distributes biological samples and associated data from people with many kinds of disorders, unaffected family members, and healthy people. The purpose of this collection is to make samples available for use in research for the study of human diseases both during and after this current study is completed. Biobanks are especially useful to learn about diseases and possible treatments. The CureGN study is sponsored (funded) by the National Institutes of Health/National Institute of Diabetes, Digestive and Kidney Disease (NIH/NIDDK).

Digital images from your stored kidney biopsy will be scanned into an electronic database and put into the study data repository.

Study data labeled with your unique study identifier will be stored on a secure computer at the CureGN data repository (Arbor Research Collaborative for Health in Ann Arbor, MI). At the end of the study, coded data will be transferred to the NIH/NIDDK data repository. Information that could directly identify you will never be included. In addition to the data collected as part of the study, information from more detailed analyses of your coded samples will be put into the NIH/NIDDK data repository.

Since the purpose of the CureGN study is to build data and sample collection for future research on glomerular diseases, it is likely that your samples and data may be shared outside of the CureGN study. Researchers from other universities, the government, and drug- or health-related companies can apply to use the materials. Your samples will only be shared with other researchers once they have gone through a review process. Sharing will not occur until it has been confirmed that all of the appropriate regulatory and ethical approvals are in place. Any data or samples that are sent to other researchers will contain only a unique identifying number; they will NOT contain personal identifiers such as your name or address. Data and samples will be kept indefinitely, allowing researchers in the future to ask new questions about kidney diseases.

Optional:
DNA: This study will use a small amount of the blood received to study your genes (also called DNA). We collect DNA to help us understand the genes involved in disease processes. DNA is unique to you, like your fingerprint. Your DNA sample and information obtained from it will be examined for the purpose of understanding processes related to health and disease.

The genetic tests will help to determine whether there are certain genes that make some people more likely to develop kidney diseases, or whether there are genes that are expressed more in patients with certain diseases or symptoms than in people without those diseases or symptoms. Additional measures will be evaluated in laboratories with standard methods for the specific measures of interest.

Cell Line: We would like to use a small amount of the blood and urine specimens to create a cell line so we can continue to study markers of kidney disease. To do this, we will select specific cells from your blood and give them space and nutrients, which will allow your cells to grow and divide forever.

A cell line is a sample of specially processed cells from your blood and urine that will allow the researchers to grow more cells and obtain more research material like protein or DNA as needed for future research projects studying the cause and prevention of glomerular kidney disease and other health conditions.

Consent for Optional Genetic Testing

Instructions: For each question, please check "**Yes**" or "**No**" in each row and enter the date and your initials in the space provided.

I give my permission to:

Yes	No		Initials	Date
_____	_____	Get DNA from my blood, urine and biopsy samples and check my DNA for genes related to kidney disease and other health conditions.	_____	_____
_____	_____	Create a cell line from my blood cells	_____	_____

Genetic Testing Results: In the future, research discoveries may be made about your genes. If something is discovered that is genetically relevant to you, and you would like to learn the results of such research, you may give us permission to contact you. However, such information could have risks. For example it could make you anxious, or if research results are later confirmed via a clinical test and insurance companies or employers find out, it could make it difficult to get insurance or to get a job.

Opt In for Results

Instructions: Please check "**Yes**" or "**No**" and enter the date and your initials in the space provided.

Yes	No		Initials	Date
_____	_____	If something that is medically relevant to me is discovered, I wish to have the results sent to me.	_____	_____

If "Yes," please provide your contact information:

_____

_____

4.2 How much of my time will be needed to take part in this study? The first study visit will take about an hour and a half to two hours of your time. After that, each in person visit will take about 45 minutes and each phone call or email visit will take about 10 minutes.

4.3 When will my participation in the study be over? The initial funding period is for four years, but the study is expected to last beyond that time point. We plan to follow you until death, withdrawal of consent, or until the end of the study.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

Blood draws: The risks of having blood drawn include soreness and bruising at the puncture site, and sometimes there may be discomfort during the procedure. Occasionally people feel lightheaded or faint. There is also a small risk of infection whenever blood is drawn. These risks are minimized by the use of trained personnel to draw your blood. The amount of blood to be taken is not considered to be a significant amount, and is therefore not expected to have any significant risk to you.

Some of the questions asked may make you feel uncomfortable. You do not have to answer any questions that you don't want to.

There is a small risk to your privacy. Some data obtained for research use will be labeled your name; however, this information will stay at Columbia. Information that is put in the study database or that is sent with your samples will be labeled with a study specific identification number and it will not contain any personal identifying information.

If a disclosure of your genetic information does happen, a federal law, called the Genetic Information Nondiscrimination Act (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

1) Health insurance companies and group health plans may not request your genetic information that we get from this research.
2) Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
3) Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when settling the terms of your employment.

However, you should be aware that this law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, taking part in this research study may result in injury or harm to you. In the event of an emergency you should go to an emergency room. If you require immediate medical care and are not a hospitalized patient you should seek immediate medical treatment.

Otherwise, Columbia University will help you get the care you need. You will be sent a bill for whatever medical care you receive. All or part of your bill may be paid by your health insurance. Columbia University and New York Presbyterian Hospital (NYPH) are not offering to pay for the care. Likewise,

Columbia University and NYPH are not offering to pay you for pain, worry, lost income, or non-medical care costs that might occur from taking part in this study.

5.3 If I take part in this study, can I also participate in other studies? You may take part in other studies. Please let your research team know so that they can make sure you are able to participate safely (for example: you don't have too much blood drawn at one time).

5.4 How could I benefit if I take part in this study? How could others benefit? You may not receive any personal benefits from being in this study. Other people with glomerular disease in the future may benefit from new information that results from this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study? Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have? Your other option is to not take part in this study. Your care at Columbia University Medical Center / New York Presbyterian Hospital will not be affected if you decide to not take part in this study.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do? You are free to leave the study at any time. If you decide to leave the study before it is finished, please tell one of the persons listed in the "Contacts" section on page 1 of this consent form.

7.2 Could there be any harm to me if I decide to leave the study before it is finished? No.

7.3 Could the researchers take me out of the study even if I want to continue to participate? Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ The study is suspended or canceled.
- ✓ You become ineligible to participate

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study? The study will pay for research-related items or services that are provided only because you are in the study. You or your health plan will pay for all the things you would have paid for even if you were not in the study. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study? To defray the cost of transportation and parking, you will receive $25 cash for each in-person study visit that you complete.

8.3 Who could profit or financially benefit from the study results? Sometimes, research results in findings or inventions that have value if they are made or sold. These findings or inventions may be patented or licensed, which could give a company the sole right to make and sell products or offer testing

based on the discovery. Some of the profits from this may be paid back to the researchers and the organizations doing this study, but there are no plans for you to receive financial benefits.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy? Only the study team at Columbia will know your identity. Any information that is sent outside of Columbia will be coded with a study number. It will not contain any identifying information about you. The study database is on a secure server at Arbor Research in Ann Arbor, MI.

To help us protect your privacy, the Data Coordinating Center (DCC) will maintain a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. In the event that information regarding intent to harm yourself or others, including child abuse, becomes known to us, we are required by law to divulge this information even without your consent. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it? Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. This may include medical health information that may be considered sensitive, including HIV status and Hepatitis B or C status.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. For example, Study sponsors or safety monitors may need the information to (a) Make sure the study is done safely and properly, and/or (b) Analyze the results of the study.

The following individuals and/or agencies will be able to look at and copy your research records:

- The investigator, study staff and other medical professionals who may be evaluating the study
- The Data Coordinating Center located at the University of Michigan Health System and Arbor Research Collaborative for Health
- Authorities from Columbia University and New York Presbyterian Hospital, including the Institutional Review Board ('IRB')

- The Office of Human Research Protections ('OHRP')
- The sponsor of this study, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the National Institutes of Health (NIH), including persons or organizations working with or owned by the sponsor
- Other government regulatory agencies (including agencies in other countries) if the sponsor is seeking marketing approval for new products resulting from this research.

Information made available for inspection will be handled in strictest confidence and in accordance with local data protection laws. Once your information has been shared with a third party, federal privacy laws may no longer protect it from further disclosure.

We may contact you in the future with offers to take part in other research. There will be a new consent process just for those studies.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission? When the study is over, information and specimens collected from the study will continue to be used for research.

If you agree to be in this study your samples will be stored in the Repository. You can change your mind up until the end of the CureGN study. If you decide to stop being in the study, we ask that you allow ongoing use of the already collected specimens and information. If you choose to withdraw your specimens and data from the study, we ask that you give written instructions to destroy specimens stored in the study Biorepository and information that identifies you. After the CureGN study ends, you will not be able to withdraw your samples because the Repository will not know which ones are yours. Samples and information that have already been sent out of the Biorepository for approved research studies will not be destroyed as they are no longer under the control of the study investigators and these specimens do not have information that identifies you. If you do not withdraw permission, the sample will stay in the Repository indefinitely.

9.4 When does my permission expire? Your permission does not have an expiration (ending) date. You may change your mind and revoke (take back) your permission at any time and for any reason by writing to Privacy Officer, Columbia University, 630 West 168th Street, Box 159, New York, NY 10032. However, if you revoke your permission, you will not be allowed to continue taking part in the Research. Also, even if you revoke your permission, the Researchers and the Sponsor may continue to use and disclose the information they have already collected as described in this consent form.

10. CONTACT INFORMATION

10.1 Who can I contact about this study? If you have any questions or are hurt while taking part in this research study, you should contact the Principal Investigator, Dr. Ali Gharavi, at 212-851-5556.

If you have any questions about your rights as a research subject, you should contact the Columbia University Institutional Review Board by phone at (212) 305-5883 or by email at irboffice@columbia.edu. More information about taking part in a research study can be found on the Columbia University IRB website at: http://www.cumc.columbia.edu/dept/irb. An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research.

12. SIGNATURES

Statement of Consent/Assent to Participate in the Research Study

I have read the consent form and talked about this research study, including the purpose, procedures, risks, benefits and alternatives with the researcher. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent form to keep for my records.

Study Subject

Print Legal Name: _____

Signature: _____ Date: _____
(mm/dd/yy)

Parental Permission

Print Legal Name: _____

Signature: _____ Date: _____
(mm/dd/yy)

Address: _____

Relationship to subject: ☐ Parent ☐ Legal guardian

Person Obtaining Consent (Principal Investigator or Designee)

I have provided this participant and/or his/her parent/legal guardian with information about this study that I believe to be accurate and complete. The participant and/or his/her parent/legal guardian indicated that he or she understands the nature of the study, including risks and benefits of participating.

Print Legal Name: _____

Title: _____

Signature: _____ Date: _____
(mm/dd/yy)