MAYO CLINIC

Name and Clinic Number

To be completed by IRB office:
IRB # **09-002265 00**
Consent form approved **April 27, 2012**;
This consent valid through **August 23, 2012**;

1. General Information About The Mitochondrial Disease Biobank

Study Title: "Individualized Medicine Biobank for Mitochondrial Diseases"

Name of Principal Investigator on this Study: Dr. D. Oglesbee and Colleagues

A. Eligibility and Purpose

Researchers at Mayo Clinic are developing a new tool for studying mitochondrial diseases called a biobank. The Mitochondrial Disease Biobank is a place to store blood and tissue samples from people with symptoms of mitochondrial disease. Health information about each donor will be attached to the samples.

The Biobank is like a library for scientists. In the past, in order to study mitochondrial disease, a researcher had to find people to take part in the study. Now he or she can just use samples from the Biobank. It is easier to do research studies when samples and information from hundreds of people are kept in one place. The Biobank is also a place for scientists to share information they collect.

You are being asked to give samples and information to the Mitochondrial Disease Biobank because either you or a family member have symptoms of a mitochondrial disease.

In order to participate in the Biobank, you must:

- fill out a form about your health,
- allow researchers to look at your medical records at Mayo Clinic now and in the future, **and**
- give a blood sample **or** allow researchers to use your tissue that is already stored at Mayo Clinic.

Researchers may contact you in the future to ask you to fill out another health form or give a new blood sample

Do you have to participate?

No. You can choose if you want to donate to the Biobank. Your decision will not affect how you are treated at Mayo Clinic.

As you read this form, ask any questions you have. Feel free to discuss the Biobank with your family, friends, and doctor before you make a decision. If you choose to participate, and then change your mind later, you can ask for your sample to be removed from the Biobank.

If all your questions have been answered, and you wish to take part in this project, please sign this form. You also need to sign this form if you are agreeing for someone else (your child or ward.) Your signature means you have been told about the project and understand the risks.

B. Number of Participants

The plan is to have 1000 people take part in this project at Mayo Clinic.

2. What Will Happen If I Donate To The Biobank?

You will be asked to:

1) Allow researchers to use samples from your body that are stored at Mayo Clinic. Often people with a known or suspected mitochondrial disease have already had small samples (such as urine, blood, skin or muscle tissue) taken for testing. If your doctor no longer needs these samples, we will put them in the Biobank.

2) Provide a sample of blood, if there are not enough samples from you in storage (see #1.)

3) Fill out a short form about yourself and your family. This form will have questions on it about your age, sex, and known or suspected mitochondrial disorder. It will also ask about your family's health. This will probably take you less than 5 minutes to complete.

4) Allow us to get information from your medical record. Once you sign this form, researchers can review your medical records at Mayo Clinic now and in the future. They will gather medical information needed for research. Looking at your records allows researchers to learn information that might be helpful during specific studies. You will not be told if researchers look at your medical records. Details about how we will keep your information private are in section 12.

In the future, you may also be asked to:

1) Complete additional health forms.
   We may send additional forms to your home. You can decide if you want to complete and return them. Each one will probably take you less than 5 minutes to fill out. Biobank staff will not contact you more than twice a year.) Such contact does not mean that anything has been learned about your health.

2) Provide an additional blood sample.
   We may ask for additional samples in order to study changes in your blood over time, or because we used up the first sample you provided. If we ask you for another sample, you may always say no.

Because the genetic tests done on Biobank samples are not used for regular medical care, you will not be told the results of the test(s). The test results will not be put in your medical record.

3. How Long Will I Be In The Biobank?

You will be in the Biobank for many years. The samples you donate to the Mitochondrial Disease Biobank will serve as a research tool until they are used up. By participating, you are agreeing to be a part of ongoing mitochondrial disease research.

You can leave the Mitochondrial Disease Biobank project at any time. There are two ways you can do this:

1) You can decide that you no longer want researchers to contact you, but that they can keep examining your samples and medical information or
2) You can tell researchers to stop contacting you and collecting your stored tissue and medical records. You may also ask them to destroy the samples you have in the Biobank.

If you want to leave the Mitochondrial Disease Biobank project, you can:

1) Write to the following address and tell us what you want researchers to do with your samples and information:

   Mitochondrial Disease Biobank
   Hilton Building, 360-C
   Mayo Clinic, 200 First St. SW, Rochester, MN, 55905, USA
   Tel. 507-293-1386 or 1-877-594-2149, Fax. 507-266-2888
   Email. mitochondrialdb@mayo.edu

2) Or contact us by telephone at 507-293-1386 or 1-877-594-2149 or email at mitochondrialdb@mayo.edu

When leaving the project, please note:

1) We can not take your samples and information out of studies that have already started.
2) Biobank staff cannot get back samples or information that have been shared with other research centers.

If you move, please contact the Biobank team with your new address so we can continue to involve you in the Biobank:

Mayo Clinic
Section of Registration
200 First Street Southwest
Rochester, MN 55905
mitochondrialdb@mayo.edu

4. Why Would I Want To Donate To The Biobank?

The Mitochondrial Disease Biobank is a place that researchers can get samples needed for research studies. They may learn new information after examining the samples and information in the Biobank. When that happens, they will share the information with other scientists and doctors. As a result, medical care for patients with mitochondrial diseases may improve.

There is no guarantee that anyone will benefit from this research, and even if someone does, it may be many years before that happens. However, you might get a good feeling from knowing that you gave to a Biobank that supports research into mitochondrial disease.

Donating to the Biobank will not make your health better.

5. What Are the Risks?

1) Blood Draw:
   The risks of drawing blood include pain, bruising, or rarely, infection at the site of the needle stick.

2) Genetic Testing:
   There is a small chance that your personal medical information could accidentally be spread to unauthorized people. We cannot guarantee that your information will not be released. In this case, information could potentially be used to discriminate against you. A federal law, the Genetic Information Nondiscrimination Act (GINA), makes it illegal for employers and insurers to use certain kinds of information about your genes to discriminate against you.

3) Questionnaire:
   You will be asked to answer some questions about your health. These questions may make you feel uncomfortable.

6. Will I Need To Pay For Any Of The Tests And Procedures?

You will not need to pay for tests and procedures which are done just for the Biobank, including having your blood drawn.

However, you and/or your health plan will need to pay for all other tests and procedures that you would normally have as part of your regular clinical care.

If you have project related questions regarding billing, insurance or reimbursement, stop by: Admission and Business Services office, or call Patient Account Services at (507) 266-5670.

7. Will I Be Paid For Participating?

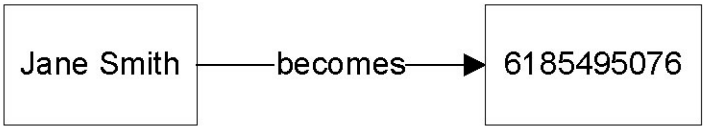
No. You will not be paid for taking part in this project.

8. What About My Privacy?

Protecting Your Privacy

In general, the samples sent out from the Mitochondrial Disease Biobank will NOT have your name, address, Mayo Clinic number, birth date, or social security number on them. There is one exception to this rule. If you decide to enroll in the North American Mitochondrial Disease Consortium (NAMDC), you can give us permission to share your sample and information with NAMDC. The rest of the samples will be assigned a one-of-a-kind code. No one will know which sample is yours just by looking at the label. Only certain members of the Mitochondrial Disease Biobank staff and the Biospecimen Trust Oversight Group (BTOG- the group that manages the Biobank) will know what name goes with what code.

For example:



The Mitochondrial Disease Biobank will be used for many years, so we cannot predict all the ways that your samples and personal medical information might be used. Your genetic information is one-of-a-kind, like your fingerprint, so it is impossible for us to fully hide your identity. Since a lot of people at many places will have access to the Biobank, we cannot guarantee that your information will be kept private. However, Mayo Clinic will take all reasonable measures to protect your privacy.

The Biobank has received a Certificate of Confidentiality from the federal government. The Certificate of Confidentiality allows Mayo Clinic to refuse to release your personal medical information or samples even if a court orders Mayo Clinic to do so. You can still give permission for your personal information to be released.

Authorization to Use and Disclose Protected Health Information

When you sign this form, you give researchers at Mayo Clinic permission to use and share all the information in the Mitochondrial Disease Biobank from your samples, forms, and medical record. Sometimes samples and information will be given to researchers outside Mayo Clinic who want to do their own studies. These researchers must have their studies reviewed and approved by the Mitochondrial Disease Biobank Managing Group before they will have access to the samples and information in the biobank. No easily identifiable personal information, such as your name, address, or telephone number, will be given out.

Samples and information in the biobank will only be given out for certain reasons:

1. For medical research,
2. For an oversight group to make sure that researchers using the biobank are following the rules

This authorization lasts forever, or until you decide you would not like to participate any longer. Please see section 3 for information on how to leave the project.

9. Additional Information About Your Privacy

Additional Protection of Your Confidential Information

The Mayo Clinic has received a Certificate of Confidentiality from the federal government that will help protect the privacy of your study information. With the Certificate the investigators cannot be forced (for example, by court subpoena) to disclose your identity or any information about you collected in this study for use in any legal proceeding at the federal, state or local level including criminal, administrative, legislative or civil hearings. However, the Certificate does not stop you or your authorized agent from giving consent to voluntarily release this information. The Certificate also does not stop the investigator from making required reports for child abuse or other violence or reporting communicable diseases such as HIV or hepatitis to authorities, and does not prevent the investigator from using or disclosing the information as described in the previous section.

10. What Will Happen to My Samples?

Your sample (blood, tissue, etc.) will be kept at Mayo Clinic as part of the Mitochondrial Disease Biobank. Researchers at Mayo Clinic and elsewhere who are not involved with this project may ask to use your sample for more research.

Who will use your sample?
If you agree to give your sample, it will be the property of Mayo and may be used for research about mitochondrial disease.

How do researchers from other institutions get the sample?
The Mitochondrial Disease Biobank will only share biobank samples after a strict application and review process. Mayo Clinic will <u>not</u> provide your name, address, phone number, social security number, or any other common identifying information with your sample.

Exceptions when your samples may be used without your permission:
1) When the use of your sample is not considered human subject research.

11. Who Can Answer My Questions?

You can call …	At …	If you have questions or concerns about …
Principal Investigator: Dr. Devin Oglesbee	**Phone:** (507) 284-1970	**Questions about Biobank procedures**
Other Contacts: Leah Eisenberg Jennifer Hesemann Claire Anderson	**Phone:** (507) 293-1386 (local) (877) 594-2149 (toll free)	**Research-related injuries or emergencies** **Any research-related concerns or complaints**
Mayo Clinic IRB **Research Subject Advocate**	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	**Rights of a research subject** **Use of Protected Health Information** **Any research-related concerns or complaints**
Research Billing	**Rochester:** (507) 266-5670	**Billing / Insurance Questions**

North American Mitochondrial Disease Consortium
The Mitochondrial Disease Biobank has a partnership with the North American Mitochondrial Disease Consortium (NAMDC) housed in Columbia University Medical Center in New York, New York. While these are two different projects, our groups have agreed to work together so participants can enroll in Biobank and send information to NAMDC without having to give two blood samples.

NAMDC helps connect organizations running clinical research studies (those that test potential treatments for mitochondrial disease) with eligible participants. They are putting together a registry of people affected by mitochondrial disease that can be used to identify and recruit potential subjects for clinical trials. NAMDC also promises to provide participants with an NAMDC-certified diagnosis.

Will you allow us to share your specimens with NAMDC?

☐ Yes, I will allow the North American Mitochondrial Disease Consortium (NAMDC) to know that I have enrolled in the Mayo Clinic Biobank. I give you my permission to share my sample and information with the NAMDC team. I understand that they may contact me directly.

☐ No, I do not wish to share samples or personal information with the North American Mitochondrial Disease Consortium. I understand that I can still enroll in the Mitochondrial Disease Biobank.

Research Results

You should not expect to receive any results from the Mitochondrial Disease Biobank. If we discover something of general interest to the mitochondrial disease community, we will make those results available to physicians and researchers through scientific publications.

New genetic technology makes it possible for us to learn detailed information about you. If we discover something that our physician advisors think might be useful for you and your doctor to know, we are willing to share that information with you. You may choose if you would like to receive results.

Since there is a lot we still do not know about genetics and mitochondrial disease, we might not know what all the results we find mean. We will only give you the option to learn results that might be needed to treat you now or in the future.

Would you like us to share important findings with you?

- ☐ Yes, please contact me about all results you think are important (this may include results not related to mitochondrial disease, such as results for other genetic conditions or diseases unrelated to mitochondrial disease).
- ☐ Yes, please contact me about results, but only if they are related to mitochondrial disease.
- ☐ No, please do not contact me with any results.

12. Summary and Enrollment Signatures

You have been asked to donate to the Mitochondrial Disease Biobank at Mayo Clinic. This information has been provided to you to inform you about the Biobank. If the statements below are true, please sign and date this consent form.

- I have read the whole consent form, and all of my questions have been answered to my satisfaction.
- I am satisfied that I have been given enough information about the purpose, methods, risks, and possible benefits of the study to decide if I want to join.
- I know that joining the Biobank is voluntary and I agree to join.
- I know that I can call the investigator and research staff at any time with any questions.
- I know that I may leave the project at any time.
- I know that a copy of this completed form will be given to me.

Please do not sign unless you have read this entire consent form. If you do not want to sign, you don't have to, but your signature is required in order to participate in the Mitochondrial Disease Biobank.

______________	________________________________	______________
(Date / Time)	(Printed Name of Participant)	(Clinic Number)

____

(Signature of Participant)

Please sign and date on these lines if you are providing consent for your child/relative/principal/ward.

______________	________________________________
(Date / Time)	(Printed Name of Representative Signing for Participant, if applicable)

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(Signature of Representative Signing for Participant, if applicable)

For Mayo Clinic staff use only:

______________	________________________________
(Date / Time)	(Printed Name of Individual Obtaining Consent)

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(Signature of Individual Obtaining Consent)

______________	________________________________
(Date / Time)	(Printed Name of Individual in Receipt of Consent)

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(Signature of Individual in Receipt of Consent)