



Welcome to BioNews

It is with great enthusiasm that we greet you with our first issue of BioNews, the newsletter for participants in the Mayo Clinic Biobank. We truly thank you for enrolling in the Biobank. We are off to a great start and, thanks to feedback from many participants, we have identified and implemented new and better approaches to recruiting and contacting participants. To date, over 2,500 people have participated, so we are on our way to a target of 20,000. We also have over four projects already approved to begin using Biobank samples and data. With the launch of this newsletter, we hope to keep you informed of ongoing activities of the Biobank. As with all parts of our Biobank, your input is important to us, and so we would love to hear your ideas for the newsletter, website, or any other aspects of the Biobank. We hope you find this newsletter of interest.

*Sincerely,
The Biobanking Team*

Goal of the Mayo Clinic Biobank

The Mayo Clinic Biobank is a collection of samples (such as blood) and health information donated by volunteers. Unlike many biobanks already in existence at Mayo Clinic and elsewhere, the Mayo Clinic Biobank is NOT focused on any particular disease. Rather, this biobank will collect samples and health information on patients and volunteers regardless of their health history. Once you became a participant in the Biobank, you became part of ongoing health research conducted at Mayo Clinic indefinitely.

The Biobank was established at Mayo Clinic's Rochester Campus and recruitment began in April of 2009. The goal of this project is to enroll 20,000 Mayo Clinic patients over a three-year period in an effort to support a wide array of health-related research studies throughout the Institution.

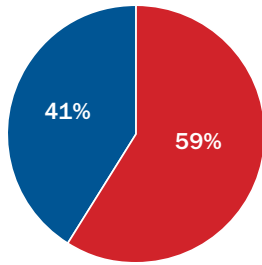
Enrollment Criteria

Are you wondering who is eligible for the Mayo Clinic Biobank? Do you know someone who might be interested?

Anyone who meets the following criteria would be eligible to be a participant in the Biobank:

- ▶ Mayo Clinic patient (has a Mayo ID)
- ▶ Age 18 years or older
- ▶ Able to provide informed consent
- ▶ Legal resident of the United States

Current Participant Statistics

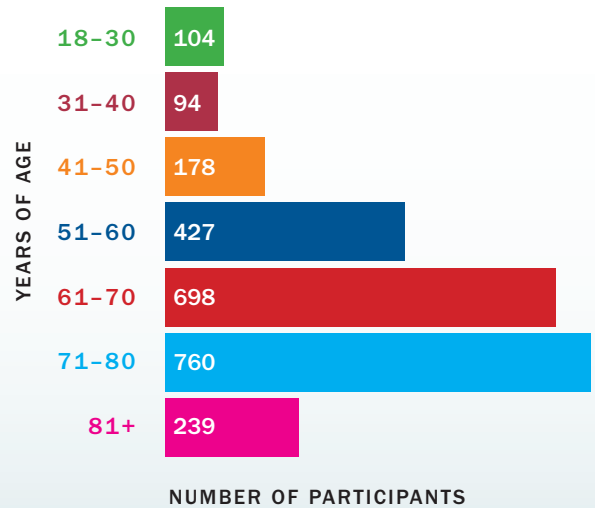


GENDER OF PARTICIPANTS

The current total enrolled biobank participant count is 2,500. 1,487 are female and 1,013 are male.

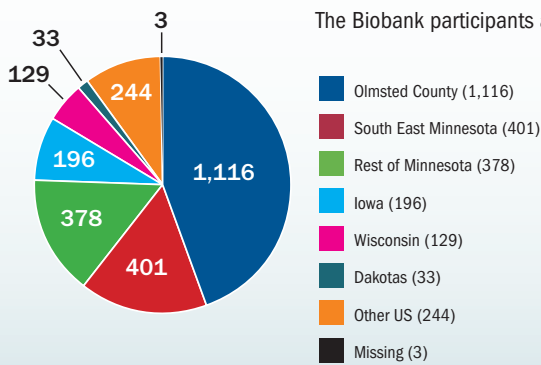
AGE OF PARTICIPANTS

This graph represents the different age ranges of all participants of the Mayo Clinic Biobank.



DEMOGRAPHIC OF PARTICIPANTS

The Biobank participants are from these areas.



Current Studies Approved for Use of Biobank Samples

Several researchers have asked to use the samples and information from the Mayo Clinic Biobank. These are some of the current projects approved to use Biobank samples:

CARDIOVASCULAR

Suzette Bielinski, Ph.D. is researching patients during the development of a heart attack (myocardial infarction). She has requested samples from 200 Biobank participants without a history of heart attack to compare to patients who have had a heart attack that she has recruited through a separate study. She is researching

several biomarkers that are found in human blood and may help to predict which patients may be at an increased risk of having a heart attack. She



heart attack, as well as which of the biomarkers may be associated with a heart attack.

is trying to determine the best time that these markers should be measured in patients having a

BREAST CANCER

Fergus Couch, Ph.D. is researching genetic risk factors for breast cancer. He has requested samples from 1,000 Biobank participants without a history of breast cancer to compare to patients who have had breast cancer that he has recruited through



a separate study. He is looking for subtle changes in the DNA sequence that might prove to increase risk for breast cancer. He is also working to identify genes, other than those

Visit Our Web Site

We have recently designed a Web site for our current or prospective participants. Please visit the site to learn more about the following topics:

- ▶ **General information about biobanking**
- ▶ **Planning the Biobank**
- ▶ **Governing the Biobank**
- ▶ **Frequently asked questions about the Biobank**
- ▶ **Expectations of you as a participant now and in the future**
- ▶ **Updates on the studies using the Biobank**
- ▶ **Issues of this newsletter (printer friendly)**
- ▶ **Our contact information**



FEEL FREE TO E-MAIL US WITH
SUGGESTIONS FOR THE CONTINUOUS
IMPROVEMENT OF OUR WEB SITE AT:
BIOBANK@MAYO.EDU

[HTTP://MAYORESEARCH.MAYO.EDU/BIOBANK](http://MAYORESEARCH.MAYO.EDU/BIOBANK)

currently known (BRCA1 and BRCA2), that may increase risk for the development of breast cancer.

COLON CANCER

Lisa Boardman, M.D. is studying a possible risk factor for colon cancer. She has requested samples from 500 Biobank participants without a history of cancer to compare to patients who have had colon cancer that she has recruited through a separate study. She is studying whether telomere length is correlated to colon cancer risk. Telomeres are located at the end of chromosomes and are known to shorten with

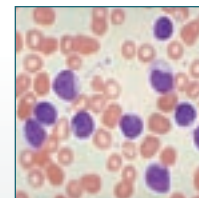
age. Our chromosomes are the structures in which all of our DNA (genes) are packaged. We have 46 total chromosomes and inherit half



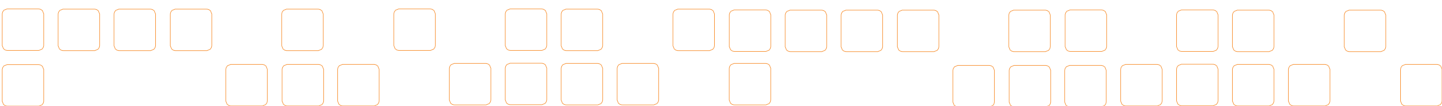
from each of our parents. Lisa Boardman, M.D. is also trying to determine if the genes that are involved in telomere shortening over one's lifetime might also play a role in risk for colon cancer.

CHRONIC LYMPHOCYTIC LEUKEMIA (CLL)

Susan Slager, Ph.D. is researching genetic risk factors for CLL. She has requested samples from 500 Biobank participants without a history of CLL to compare to patients who have had



CLL that she has recruited through a separate study. She is looking to confirm subtle changes in the DNA sequence that she has identified in prior studies, which may prove to be risk factors for developing CLL.



Deliberative democracy as a framework to inform biobank policy

In September of 2007, the Bioethics Research Program at Mayo Clinic Rochester invited 21 people from Olmsted County to come together over four days of discussion to identify the values that ought to inform the development of the Mayo Clinic Biobank.

We applied a political theory called “deliberative democracy” to structure our discussions about the Biobank. It argues that policies are legitimate and accountable only if they reflect the attitudes and opinions of the citizens who are affected by them, so we wanted to bring together people with different cultural backgrounds and personal histories to address the issues that they considered to be important in setting up policy for the Mayo Clinic Biobank.

Participants discussed a wide range of topics, including: the value of emerging science; the structure and content of the informed consent process; donor payment; sharing samples and health information with research institutions outside Mayo Clinic; privacy and security of donor samples and health information.

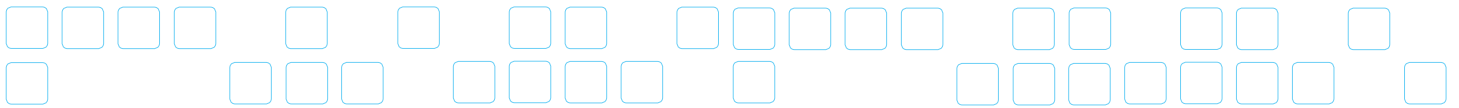
Our goal was not for participants to agree on every issue, but rather to rank values, make trade-offs between different issues, and be able to state areas of disagreement. We sampled a diverse group of participants to bring together individuals who could share different experiences and whose values would differ. For example, while our participants trusted Mayo Clinic and the research that would be carried out using their samples, they recognized that not all donors would be so trusting. Given this, participants agreed that Biobank participants should be able to forbid the use of their samples for future studies and to find out what studies are being carried out using samples donated to the Biobank.

The Community Advisory Board

Participants thought the Biobank needed ongoing community guidance and involvement in Biobank governance, so Mayo Clinic established a Community Advisory Board (CAB) to ensure that the voice of the community continues to be heard. The CAB reports directly to the Biospecimen Trust Oversight Group (BTOG), the board that oversees operation of all biobanks at Mayo Clinic. Nine participants from the community engagement event agreed to serve as members of the Community Advisory Board. During the summer of 2008, Board members met with Mayo Clinic Biobank liaisons, including Biobank director Stephen Thibodeau and Bioethics Research Program Director Barbara Koenig, for three work sessions. They worked hard on revising the Biobank’s informed consent documents and reviewing recruitment materials and methods. Many of the improvements and suggestions generated by the CAB were adopted by the Mayo Clinic Biobank before it began operations in April 2009.

The CAB now has 21 members, the nine initial members and 12 new members chosen to reflect the diversity of community interests and backgrounds. New members will attend an education session before the first meeting of the CAB, planned for later this year. The CAB will meet three times each year to ensure that the community’s voice is heard. Members will elect a community representative to co-chair the Board along with a member of the Bioethics Program staff. The Mayo Clinic Co-chair will attend all CAB meetings and update BTOG on the Board’s progress and recommendations. The community member Co-chair will attend BTOG meetings when appropriate.

The CAB’s agenda includes reviewing and recommending policies and procedures on new issues in Biobank research, such as: 1) return of research results, 2) data sharing with other researchers, and 3) procedures used to recruit Biobank donors.



Frequently Asked Questions

Many of your questions about the Mayo Clinic Biobank may have already been answered prior to your enrollment in the Biobank. We have found that there have been a few questions commonly asked by you, our participants, which are addressed below.

GENERAL

What is the Biobank studying?

The Biobank is not focused on studying any particular disease. Samples and health information will be collected from 20,000 adult patients. Participants must be at least 18 years or older, but there are no other limitations on participation.

Do I have to pay for anything involved in the Biobank?

You will not need to pay for a blood draw done just for the Biobank. However, you or your health insurance will need to pay for

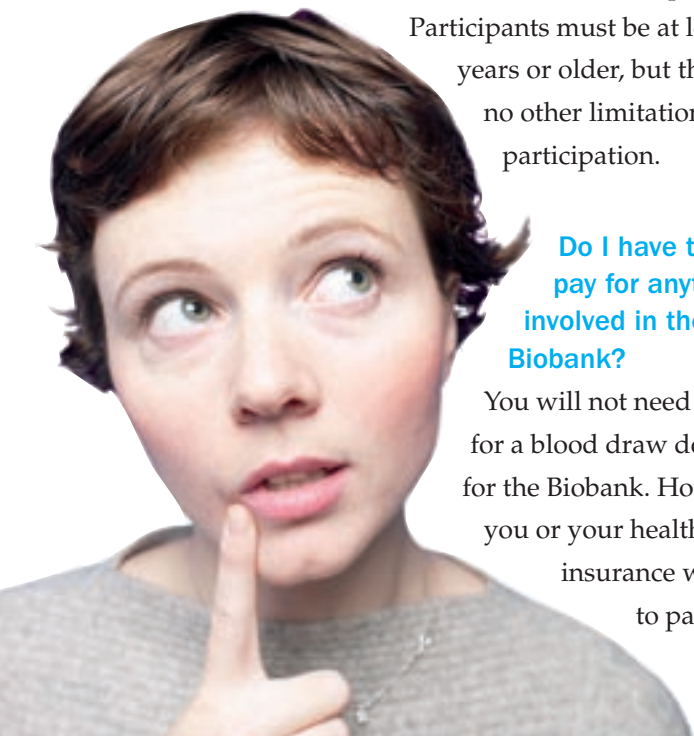
all tests and procedures that you have as part of your medical care.

Will there be any additional appointments or tests required for participation in the Biobank? How often will I need to come back and provide information or samples?

You only need to have blood drawn and fill out our questionnaire to participate in the Biobank. You may be contacted someday for more blood or for another questionnaire, but not more than twice a year. These contacts will come directly from our Biobank staff. Contacts requesting an additional blood sample will be much less frequent. If we re-contact you, you may always say no.

If I have consented to participate in the Biobank, is it necessary for me to have my blood drawn and/or fill out the questionnaire?

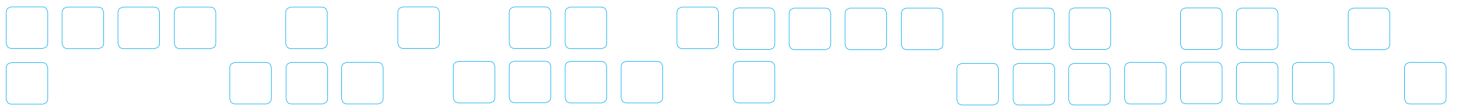
Yes. It is critical to the success of the Biobank that we have an adequate blood sample and a complete questionnaire for all participants. Without this information and your sample, there would be little use for the Biobank. Please do complete the blood draw and fill out your questionnaire. If you have questions about doing so please contact us at: 1-866-613-2386 or biobank@mayo.edu.



Quotes From Willing Participants

“The more family and other people we can get this word out to, the better. This is where we are going to make the biggest difference. The biggest reason I donated is because my dad had Parkinson’s disease and rheumatoid arthritis. And mom has a family history of heart disease. It’s in the interest of my son and future generations.”

“I would do whatever I can to help research. I have participated in many studies at Mayo Clinic, and if I can help someone live longer because of it, I am all for it!”



How was my name chosen?

We chose your name from people who had appointments in General Internal Medicine, Primary Care Internal Medicine, or Family Medicine. Other Mayo Clinic patients (18 years of age or older) may also volunteer for the Biobank, if interested.

RESULTS

Will I find out any research results?

Generally we will not be returning research results. Many research studies will be performed using samples from the Biobank. During individual research studies, researchers could find out important information about your health. They might discover something about your health right now or about your risk of getting sick in the future. Researchers will not discover something about every donor, so you may not receive results.

However, for some studies, research results may become available. Since decisions about health and disease are very personal, no one can predict which results participants will want to receive. Therefore, we have set up the Biospecimen Trust Oversight Group, which includes members of the community, to help us decide which results may be helpful to participants and how those results may be given to them. Names will not be mentioned during this process. It may be necessary for you to meet with a healthcare professional to get test results.



Will research results be placed in my Mayo Clinic medical record?

Should medically relevant results come from studies using the Biobank, you will be contacted and given the opportunity to learn those results. Should you choose to learn these results, you may be required to meet with a healthcare provider to discuss the results and their implications. The results will be placed in your medical record only if you learn these results and meet with a provider. You will not be required to learn results.

How will I be contacted about results?

You may be contacted by phone or letter if results are available.

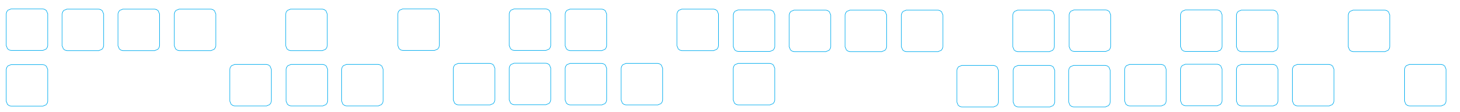
Will I know for which studies my information is being used?

No. You will not be told exactly which research studies are using your samples and information. Information from only some participants will be used for each research study. You will be able to get general information about all research studies that use the Biobank through newsletters such as this one or on our Web site.

PRIVACY

How could my information be “accidentally spread”?

Although investigators will not have access to information commonly used to identify you, you could be identified through your samples. Your DNA is unique like your fingerprint. So even if your DNA doesn't have your name attached, people could still use it to identify you. In order to link de-identified DNA to you, a sample of your DNA with your name on it must be available for comparison. Although it is unlikely



that this will happen, it is possible. For example, if your DNA is stored somewhere with your name attached and those samples are matched with the samples you donate to Mayo Clinic, you could be identified. Although both Mayo Clinic and its research partners try hard to protect the privacy of research samples, there will always be a chance that you could be identified through your sample.

Will my name be placed on anything (forms, blood, records)?

Yes. Your name will be placed on your forms and the blood sample until they reach the laboratory. Once the sample reaches the laboratory and before the sample is ever used in any study the blood sample label and your identifying information will be removed. A separate code will be attached to your sample.

How will Mayo keep my sample and information confidential?

Your medical information will be de-identified before given to a researcher. This means that your name, address, Mayo Clinic number, social security number, and anything else commonly used to identify you will be taken off your health records. So, when a researcher looks at your medical records, they will not be able to tell whose records they are by looking at them.

Your samples will be given a unique code that very few people will know. No one will be able to identify you just by looking at your sample. For example, Joe Smith will become sample #5096739651. Researchers will not be able to connect the code to your name unless they have been given special access. For example, Biobank staff may need to contact you about your sample or information in



order to perform a research study. They will try to make sure that no one connects your name to your samples unless it is necessary.

Can my DNA be patented and can Mayo or other companies benefit from this financially?

Your DNA cannot be patented. However, the technology that is used to isolate a specific gene or DNA sequence could be patented. If this were to happen, it is possible that Mayo Clinic or another company involved in a particular research project may benefit financially. You would not be offered a share in the profits.

Contact Us

If you have questions or need more information about the Mayo Clinic Biobank, please contact one of our staff members at:

507-293-0203 (local)

1-866-613-2386 (toll free)

biobank@mayo.edu (e-mail)

<http://mayoresearch.mayo.edu/biobank>



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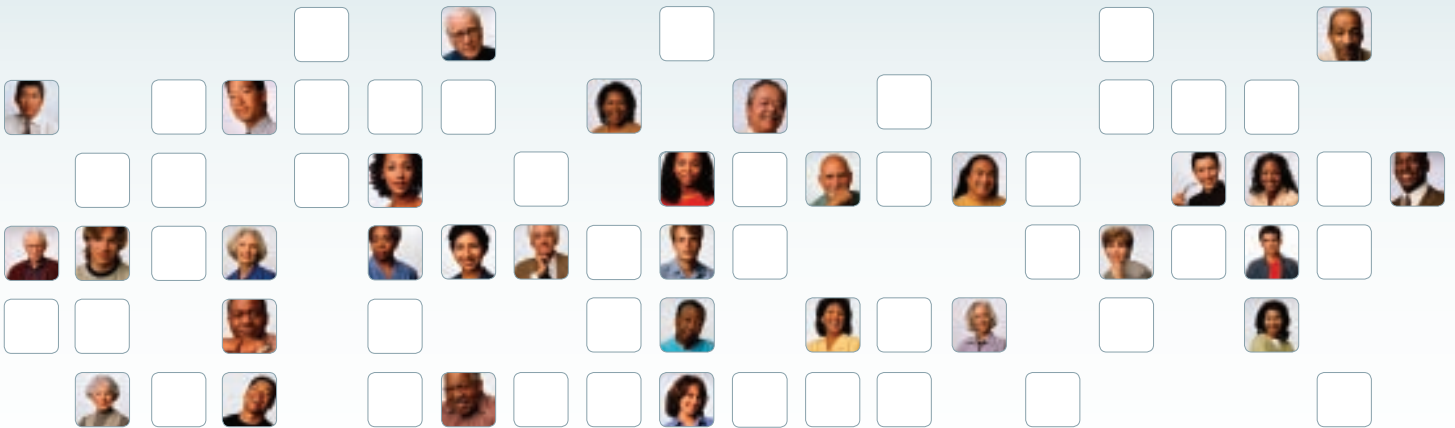
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