



ISSUE 10 SPRING/SUMMER 2014

BioNews

> FOR PARTICIPANTS OF THE MAYO CLINIC BIOBANK

Hello! We are happy to bring to you another issue of *BioNews*. The Mayo Clinic Biobank has been working hard since April 1, 2009 to recruit 50,000 participants. It is exciting to reflect back over the past five years and see how far we have come. We currently have over 40,000 participants in the Biobank and are moving quickly towards our goal of 50,000. We thank you for your commitment to ongoing research. The Biobank continues to be a valuable resource for investigators studying a wide variety of health conditions, with over 110 projects approved to use samples and/or data from the Biobank.



As we are getting closer to reaching our goal of 50,000 participants, we begin to look towards the future of the Biobank. We envision the Biobank will continue to be an integral part of research for years to come. To make this happen, it is important for the Biobank to be a sustainable resource. One way to make the Biobank sustainable while furthering important research and health discovery is to make our samples available to all researchers, not just those at Mayo Clinic. In this issue of *BioNews* we discuss our plan to keep the Biobank running smoothly while continuing to facilitate a wide variety of research across Mayo Clinic and beyond!

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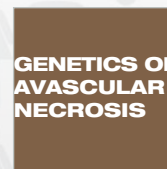
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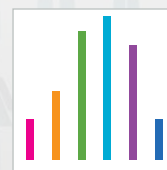
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WHAT DOES IT TAKE TO RUN THE BIOBANK?

IT TAKES A LOT OF TIME AND RESOURCES TO SET UP AND RUN A BIOBANK. ONE OF THE BIGGEST RESOURCES REQUIRED TO RUN THE BIOBANK IS OUR PERSONNEL. WE HAVE A WHOLE TEAM WORKING TIRELESSLY BEHIND THE SCENES TO RECRUIT, CONSENT, AND MAINTAIN THE BIOBANK.



This includes study coordinators, programmers, statisticians, scientists, physicians, ethicists, and genetic counselors. Our study coordinators currently send out 300 recruitment packets per day, receive incoming consents and questionnaires, meet with volunteers, and much more. The statisticians and programmers work to maintain our database and facilitate the retrieval of the appropriate data and samples for researchers. The lab team is responsible for processing all of the blood samples and storing the blood products until they are used by research investigators. We have a team of scientists, physicians, ethicists, and genetics counselors that are responsible for the oversight and governance of the Biobank.

In addition to personnel, there are several ongoing internal services that occur on a daily basis including mailing of patient appreciation incentives and laboratory processing for each sample we receive. All questionnaires we receive need to be reviewed and scanned into our databases so the data can be accessible for researchers.

It has taken a substantial investment from Mayo Clinic to create, build, and maintain the Mayo Clinic Biobank. As we near the completion of our collection, it is important to look for continued funding as we transition to ongoing maintenance and use of our Biobank.

The Center for Individualized Medicine and the Biorepositories Program has created Mayo Clinic Bioservices to coordinate our business efforts. Mayo Clinic Bioservices has four service lines that will be offered to external clients, including Laboratory Services (Biospecimen Processing), Sample Storage Services, Biobanks (we have several biobanks, including the Mayo Clinic Biobank and the Sangre por Salud Biobank), and Bioethics and Genetic Counseling Consultation. The mission of Mayo Clinic Bioservices is to provide world-class Biorepositories and state-of-the-art Biospecimen Processing and Storage with a focus on quality and service. Mayo Clinic Bioservices is a coordinated effort of all of our services in Rochester, MN, Jacksonville, FL, and Scottsdale, AZ.

MAYO CLINIC BIOSERVICES

LABORATORY SERVICES STORAGE SERVICES BIOBANKS BIOETHICS & GENETIC COUNSELING



Why are we creating Mayo Clinic Bioservices?

- > **Because we can.** Through the Center for Individualized Medicine and the Biorepositories Program, Mayo Clinic has the ability and expertise to be a leader in the industry. In addition, our infrastructure facilities have excess capacity that can be utilized by others. We believe Mayo Clinic has valuable services and resources to offer through our laboratories and Biobank collections to advance science and improve health care delivery to all patients.
- > **Because we must.** By commercializing our services, it will allow us to sustain the resource we have built over the years, including the laboratory infrastructure and our specimen collections. It is also critical for the success of our laboratory services in Florida and Arizona. Finally, as large as Mayo Clinic is, we cannot take on every important research project. We recognize that there are important discoveries occurring across the globe to improve healthcare. By making our services available to those outside Mayo Clinic, we are able to facilitate discovery on a much wider scale.

BIOBANK ACCESS

The Mayo Clinic Biobank has always closely reviewed every request for use of participant data and samples. Our Access Committee carefully reviews every protocol using our Access Principles (see box). The health information and samples donated by our participants are extremely valuable and are a precious resource. We want to ensure that projects using these samples are done in an ethical way, address important health issues, and are consistent with the mission of the Biobank and Mayo Clinic.

Although the Mayo Clinic Biobank will begin making samples available to researchers outside of Mayo Clinic, each and every protocol will continue to be closely reviewed. We will continue to require scientific excellence and will assess the use of all Biobank samples to determine that each use has the potential to impact health and improve patient care.

The Mayo Clinic Biobank is charging a project fee from users to help maintain the collection. Investigators have always paid for the sample retrieval from the laboratory storing the samples, but as of January 2014, the Biobank has also begun charging investigators for other study costs such as coordinator and statistician effort.



ACCESS PRINCIPLES FOR USE OF BIOBANK SAMPLES

- All projects require documented review for scientific excellence by an independent group of researchers.
- All projects must be approved by the Mayo Institutional Review Board.
- A Mayo researcher must be included in proposals submitted by external investigators.
- Samples are provided for specific uses and any change in the project must be approved by the Access Committee.
- Data generated from the use of Mayo Clinic Biobank samples will be returned to the Biobank for potential future use; exceptions to this must be justified.

COMMUNITY ADVISORY BOARD UPDATE: **REVIEW OF THE BUSINESS PLAN**

The Mayo Clinic Biobank Community Advisory Board continues to meet every two months to discuss and provide important feedback on issues facing the Biobank. During the November 2013 and January 2014 meetings, Community Advisory Board members learned about the proposed business plan of the Mayo Clinic Biobank. Community Advisory Board members recognized that the business plan was feasible, beneficial to implement, and in line with the overarching mission of advancing science and medicine.

Community Advisory Board members deliberated on a number of important issues, including:

- 1.** **The review process for accessing Biobank samples and data:** Ensure that the scope and goals of each project is consistent with our access principles and mission.
- 2.** **Relationship with outside groups:** Partnerships should be with reputable groups that have a similar mission to the Biobank.
- 3.** **Communication and Education:** Communication and transparency about new uses of Biobank samples is critical to preserving public trust in Mayo Clinic and the Biobank.
- 4.** **Return of research results:** Research outcome from users should be returned to the Biobank whenever possible to increase the value of the Biobank for future investigators. Consistent with our current policies, the Board recommended that clinically actionable results should also be made accessible to patients when appropriate.

We greatly value the advice of our Community Advisory Board. As we continue to refine our business plan and enter into new commercial relationships with external partners, we plan to revisit these discussions with the Board.

NEW RESEARCH PROJECTS USING THE BIOBANK

The purpose of the Biobank is to enable research. We are pleased that the Mayo Clinic Biobank continues to be used for a wide variety of research projects. Overall, we now have 108 approved projects requesting a total of approximately 101,695 samples from Biobank participants. Several new projects have been approved to use samples and information from the Mayo Clinic Biobank since the last issue of *BioNews*. Included are a subset of the recent studies that have been approved for Biobank sample and/or data use. For a complete list of projects, visit our website (<http://www.mayo.edu/research/centers-programs/mayo-clinic-biobank/projects>).

Smoking Cessation

Steven C. Ames, Ph.D. is using the Biobank to recruit up to 20 participants who may consent to participate in a new research study. Dr. Ames is recruiting participants who are smokers that are interested in receiving medication and counseling to quit smoking. Biobank participants who agree to be part of this study will receive smoking cessation treatment lasting 3 months followed by an additional 3 months of follow up. His goal is to evaluate the effectiveness of a new smoking cessation medication.

Inborn Errors of Metabolism

Devin Oglesbee, Ph.D. is researching Inborn Errors of Metabolism (IEMs), rare genetic disorders caused by defects in specific proteins that help break down (metabolize) parts of food. He has requested samples and whole exome sequencing data from 40 deceased Biobank participants. He is researching genetic testing technology capabilities. His goal is to better understand Whole Exome Sequencing technology to improve clinical testing for rare diseases.

Genetics of Kidney Stone Formation

William E. Haley, M.D. is researching kidney stones. He has requested samples from 400 Biobank participants without a history of kidney stones to compare to patients who have kidney stones of unknown cause that he has recruited through a separate study. He is studying the frequency of genetic variants that are thought to be involved in kidney stone formation. His goal is to identify genetic variants that predispose individuals to kidney stone formation, leading to improved diagnosis, prevention, and treatment options for kidney stones.

Biomarkers for Diagnosis of Inflammatory Bowel Disease

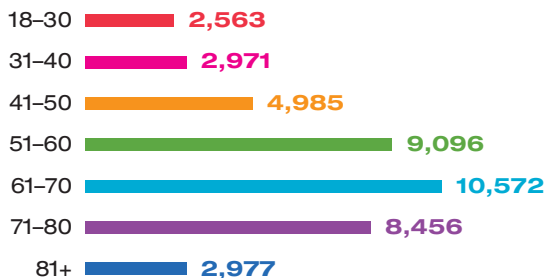
Shabana F. Pasha, M.D. is researching inflammatory bowel disease, including Ulcerative Colitis and Crohn's Disease. She has requested samples from 20 Biobank participants without a history of inflammatory bowel disease (Ulcerative Colitis, Crohn's Disease, Celiac Disease, or Inflammatory Bowel Syndrome) to compare to patients who have Ulcerative Colitis or Crohn's Disease that she has recruited through a separate study. She is researching antibodies against microbial and human proteins in patients with inflammatory bowel disease. Her goal is to identify unique biomarker profiles of inflammatory bowel diseases that can be used to correctly diagnose Ulcerative Colitis and Crohn's Disease.

Genetics of Avascular Necrosis

Rafael J. Sierra, M.D. is researching the genetics of avascular necrosis. He has requested samples from 600 Biobank participants, 150 participants with a history of avascular necrosis to compare with 450 participants without a history of avascular necrosis. Avascular necrosis is the death of bone tissue due to a lack of blood supply. Also called osteonecrosis, avascular necrosis can lead to tiny breaks in the bone and the bone's eventual collapse. He is researching the genetic basis of avascular necrosis. His goal is to identify genetic risk factors for avascular necrosis, allowing for preventative screening and medical treatment before the onset of disease.

UPDATES ON RECRUITMENT STATS

AGE

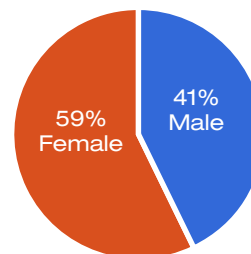


DEMOGRAPHICS

Olmsted County: **13,634**
SE MN: **5,530**
Rest of MN: **6,305**
Iowa: **2,470**
Wisconsin: **3,053**
Dakotas: **718**
Florida: **3,268**
Other US: **6,607**
Missing: **35**

GENDER

Total: **41,620**
Female: **24,355**
Male: **17,265**



VISIT US ON THE WEB

mayoresearch.mayo.edu/biobank

As always, if you have any suggestions or feedback on our website, please contact us!



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If you have questions or need information about the Mayo Clinic Biobank, please contact us at:

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