Biobank Survey 2_ E-Consent Form

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

Title: Decentralized Biobanking *"de-bi"*
An App for Patient Feedback from Biobank Research Donation

PI: Mylynda Massart, MD, PhD; email: massartmb@upmc.edu; 412-641-7521 204 Craft Avenue, B406, Pittsburgh, PA 15213 Funding Sources: University of Pittsburgh Institute for Precision Medicine; University of Pittsburgh Chancellor's Gap Fund

Explore DE-BI: a new patient-centered biobanking app

This study is developing an app for patients to track and learn about biosamples they've donated for research.

We hope to learn about what patients want to know about research on their tumors/tissues, blood, and other biosamples.

We are also looking at when and how patients would like to be updated about how their specimens are being used in research. Using this information, we are developing educational content and designing tools for patient engagement and participation in research. We aim to enroll 10,000 people.

You are invited to take a brief (10 min) survey. If you are also a participant in the study Breast Disease Research Repository (STUDY19060196), we will obtain identifiable information collected as a part of that study. We will use research data from the Breast Disease Research Repository to provide you with personalized information about biosamples you may have donated to the UPMC breast research biobank.

Who is eligible:
Anyone who can read English & is aged 18-118. If you have had breast surgery, biopsies, related lab tests, breast screening, breast cancer treatment, or preventative breast care at UPMC, you may also be eligible to receive personalized information about your research donations. This info will be provided as part of your participation in this study. It's okay if you don't know if you're enrolled in the Breast Disease Research Repository; a member of the study team will check for you.

If you are not currently eligible to receive this personalized info, you may join our waitlist.

What's involved:

You will be sent a personalized link to access either a website or mobile application (called de-bi), for download on your personal device. The mobile application has its own terms and conditions, separate from the research study. Any information input into the app will be held to the confidentiality agreements of the app, as well as the research study. The study team cannot guarantee the confidentiality of any data input into the app nor control how data within the app is used.

The survey will include education about biobanking, including definitions of terms and information and statistics about the samples that have been collected for the entire BDRR. We will ask about your illness, disease progression and treatment as well as your interest in learning about what happened to your own biosamples. A member of the study team with authorized access to identifiable records of the Breast Disease Research Repository (STUDY19060196) will verify if you are also enrolled in the Breast Disease Research Repository. If you are, you will receive personalized feedback. This means that information about tissue and/or bodily fluids that you have donated to the biobank will be obtained, such as the number/status of any biosamples that have been collected for research. Due to current policy, you will not know the specific project(s) that your tissue or bodily fluids are being used for. A copy of this information will be included in your follow up materials, which you will receive after the survey for your records (no action is required).

If you are currently not enrolled in the Breast Disease Research Repository (STUDY19060196), you may still download the app and complete the survey related to your interest in learning about what happens to biospecimens you may have donated in the past or samples that you may donate in the future. However, you will not receive personalized feedback about specimens that may have previously been donated. Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information for the purpose of ensuring the appropriate conduct of this research study. Information will not be collected from your medical records.

You will also have an opportunity to connect with your donor community.

You will have an opportunity to join a waitlist for further updates on tissue and/or bodily fluids that you have donated to the biobank. If you are not enrolled in the Breast Disease Research Repository, you will have the opportunity to do so. You will have the option to sign up for updates and receive notifications as your biosamples are added to our system over time as we onboard different biobank collections within and beyond Pitt/UPMC. At the end of this study, we will also send you the latest version of the biobank education materials we are developing as a token of appreciation for your participation. There is no monetary compensation for participation in this study.

Risks and Benefits

Participation in this project is voluntary and will not affect your medical care, your involvement in the Breast Disease Research Repository and/or research use of your biosamples. You will not directly benefit from this research, except by receiving personalized information that may be of interest to you. Initially, we can only provide you data about breast tissues and other samples that were preserved specifically for research use by the breast cancer biobank. Many patients also have tissues/samples stored at other biobanks at Pitt or in the UPMC clinical archive. Data about these other samples will not be included in your initial biobank report, but we are working to expand patient access to all biosample data at our institution in the future.

You may find it uncomfortable or upsetting to think about research on your tumor/tissue as it relates to cancer diagnosis or treatment. If you are uncomfortable with any of the questions, you can skip them or stop participating at any time. There is also a small chance that someone might accidentally become aware of your participation in this research, your survey responses, or information related to this survey (a breach of confidentiality), but we have a system in place to prevent that from happening, which includes storing your survey responses on a password protected server accessible only to authorized team members, and storing your identifying information separately from other data.

Disclosures

One or more of the investigators conducting this research has a financial interest in Heny, Inc. This means it is possible that results of this study could lead to personal profit for the individual investigator(s) and/or the University of Pittsburgh. Any questions you might have about this will be answered fully the Human Subject Protection Advocate of the University of Pittsburgh at (866) 212-2668, or by the Principal Investigator, Mylynda Massart, MD, PhD; email: massartmb@upmc.edu; who has no financial conflict of interest with this research. Your doctor may be involved as an investigator in this research study.

Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not obligated to be a part of any research study offered by your doctor. At some point, your identifiers might be removed from the private information. This de-identified information may be used by other researchers for future research studies. If this happens, we will not contact you for additional consent. Your data used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

Per University of Pittsburgh policy, all research records must be maintained for at least seven years following final report or publication of a project. You can withdraw from this research study at any time. Any identifiable research information obtained as part of this study prior to the date that you withdrew your consent will continue to be used by the investigators for the purposes described above. If you want to withdraw, notify the study team. Your decision to withdraw will

have no effect on your current or future relationship with the University of Pittsburgh or the hospitals of UPMC. Withdrawal from this study will not not impact your participation in the Breast Disease Research Repository (BDRR).

Sign up and next steps

If you would like to participate in this study, please provide your name, date of birth, answer to a security question, phone number and email address below. We will verify your eligibility, prepare a personalized report and/or survey (if also enrolled in the Breast Disease Research Registry, and contact you about the next steps.

If you have any questions, feel free to contact us at:
mendozacervantesdc@upmc.edu

The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during this study. Any future questions, concerns or complaints will be answered by a qualified individual or by the investigator listed above. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the Human Research Protection office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. By completing the fields below, I consent to participate in this research study. A copy of this consent form will be emailed to me.

End of Block: INTRO