Consent to Be Included in the Breast Disease Research Repository (BDRR): Tissue and Bodily Fluid and Medical Information Acquisition Protocol (HCC 04-162, Consent Version 7-26-2019)

Program Director: Adam Brufsky MD

DESCRIPTION: As part of your medical care, you may undergo medical procedures that involve the removal or collection of biological specimens (such as blood, urine and other fluids or tissues). We are asking your permission to add your specimens and/or your medical information to the UPMC Breast Disease Research Repository (BDRR). **No additional tissue will be removed surgically or collected for the purpose of including a sample in BDRR.** If you agree to this request, all testing of your specimens that are required for your medical care will be completed before they are deposited into the BDRR. We may also ask for small additional blood samples and/or for additional samples of urine or other fluids. If possible, those would be obtained at a time when you are having specimens collected as part of your clinical care.

Biological specimens placed in this Research Repository will be used for research studies. The specific nature of these research studies will vary and are not fully known at this time, but they may include studies of cells, chemistry of the immune system, proteins and genes. If specimens are being surgically removed or collected because you have a specific disease or condition, it is likely that the research studies that use your specimens will be directed at the same disease or condition.
However, it is possible that your specimens may be used in research studies directed at other diseases or conditions.

These specimens may also be used to produce genetic material (like DNA and RNA) that will be stored for an indefinite period of time for future studies, including those that may be unrelated to your current condition. Some cells may be treated so that they can be studied for many years. These will be destroyed when they are no longer needed.

In order to use your biological specimens effectively for research, it is necessary that your medical information is available for review. Hence, if you agree to participate in the BDRR, you also agree to allow individuals responsible for the BDRR to review and collect past, current, and future identifiable information from your medical records about your diagnosis, age, medical, personal and family history, diagnostic procedures, surgery, treatment, and results of any procedures associated with your medical care. This information will be available in the BDRR for an indefinite period of time, and may also be stored in the UPMC Data Warehouse where that information may be used by researchers studying ways to improve health care.

Your specimens and medical information may be collected several times at different clinical care visits and/or during follow-up medical procedures. They will be stored in the BDRR in a way that will permit the people responsible for the BDRR to connect your identity with your sample. However, **when your specimens, data (genotype and phenotype) derived from your specimens, and medical information are made available for actual use in research studies, they will be provided to the researchers without personal identifiers so they cannot easily connect your identity with the specimens or medical information, unless they have legitimate access to your records, as in the case of your doctor**. **Your de-identified specimens, results (genotype and phenotype) from specimens, and medical information may also be shared with other scientists and researchers at other universities, government, hospitals, health related commercial entities, tissue banks, and shared databases (both unrestricted- or controlled-access repositories), to be used for future research purposes and to be shared broadly**. You will not be contacted when your specimens or information are sent to researchers. Note that these will be released after careful review of the research proposal by oversight committees (e.g. institutional review board and tissue utilization committee).

Because it may not be possible to connect your identity with your tissue/biological specimen when the sample is being used for research, **it may also not be possible to inform you of the results of such research.**

The BDRR is supported in part by funds from UPMC. If you agree to give samples of your biological specimens to the BDRR, they will become the property of the University of Pittsburgh, UPMC HILLMAN CANCER CENTER and UPMC and their use will be under the control of the BDRR Program Directors. **Your medical information and samples will be stored in the BDRR (and/or at other research repositories) until such time that the samples are used up or no longer appropriate for use in research studies**. Your decision to provide these specimens and medical information to the BDRR, or to later withdraw from it, will not affect your current or future medical care at UPMC.

RISKS AND BENEFITS: You will receive no direct benefit by giving samples of your biological specimens to the BDRR. However, the availability of such samples for research use is important for understanding medical diseases and developing new treatments. **There are few risks associated with participation**. For most people, the specimens that we are requesting are materials that which would normally be thrown away after the testing for your medical care is completed, although we may – if needed – obtain additional blood or fluid samples throughout your clinical care. The risk of obtaining blood is similar to risks associated with any blood draw for clinical care. Also, although the BDRR and any other repository that receives specimens and medical information will take all measures to protect your privacy, there is a very small risk that your information could be disclosed outside Pitt/UPMC HILLMAN CANCER CENTER /UPMC.

COSTS and PAYMENTS: There will be no additional costs to you or your insurance company if you agree to include your specimens and medical information in the BDRR, nor will you receive any payment. Research use of your specimens may lead, in the future, to discovery and development of new drugs, tests, cell lines, or commercial products. Even in the event that new products, tests, cell lines or treatments are developed or discovered from the use of the samples that you give to the BDRR, **you will not receive any money.**

COMPENSATION for INJURY: Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. It is possible that UPMC and/or the UPMC Cancer Centers may bill your insurance provider for the costs of this emergency treatment, but none of these costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care unless otherwise specifically stated below. There is no plan for monetary compensation.
You do not, however, waive any legal rights by signing this form.

CONFIDENTIALITY: To protect your privacy, **your samples and information will be stored in the BDRR using a code number**, and only the individuals at UPMC associated with the BDRR will be able to connect this code number with your identity. The information linking this code number with your identity will be kept by these individuals in a secure manner.
Only approved researchers can use your samples and information, and they will only know your code number; they will not be able to contact you nor identify you personally. The BDRR and all other US-based repositories must follow federal rules and laws to protect your privacy. A **federal law called the Genetic Information Nondiscrimination Act helps protect you from being treated unfairly because of the genes you have.** It is possible that authorized officials from the National Institutes of Health, the University of Pittsburgh Research Conduct and Compliance Office, or UPMC may have access to your identifiable information, but only for monitoring the appropriate conduct of this tissue bank program.

NIH Funded Projects: In circumstances when your biospecimen is used for a National Institutes of Health (NIH) funded project, then the research is covered by a Certificate of Confidentiality from the NIH. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state or local law that requires disclosures (such as to report child abuse or communicable diseases but not for federal, state or local civil, criminal administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

RIGHT TO WITHDRAW: You may refuse to allow us to include samples of your biological specimen in the BDRR. Such a decision will not affect the current or future care that you receive at this institution or any other benefits for which you might qualify. **If you agree to give specimens and medical information to the BDRR, you may also withdraw your permission at any time** through a written request. Depending on your wishes, we can either destroy any remaining samples or continue to store your samples in the BDRR but in a totally anonymous manner, so that no one, including the individuals responsible for the BDRR, will be able to connect your name with your samples. Your medical information will also be removed from the BDRR.

Note that it is not possible for us to guarantee that we will be able to destroy any of your samples that may have been previously provided for research use since your identity will not be connected with those samples.

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VOLUNTARY CONSENT:

The above information has been explained to me and all of my questions have been answered. I understand that any future questions I have can be answered by one of the individuals responsible for the BDRR (412.641.7557). The Human Research Subject Advocate of the Institutional Review Board, University of Pittsburgh (1.866.212.2668), will answer any questions that I may have about my rights as a research subject.

By signing this form, I agree to give samples of my biological specimens to the Breast Disease Research Repository for use in research studies directed at any disease or condition, and I agree to allow the use and disclosure of my medical record information, as described above.

_____
Patient/Subject Printed Name

_____ _____
Patient/Subject Signature Date and Time

CERTIFICATE of INFORMED CONSENT:

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____
Signature of Person Obtaining Consent Date and Time

_____ _____
Printed Name of Person Obtaining Consent Role

Contact the BDRR Office: Women's Cancer Research Center, 300 Halket St, I-410, Pittsburgh, PA 15213. Phone: 412.641.6073