

BFOR STUDY: IMPORTANT RESEARCH INFORMATION

YOUR RIGHTS

Taking part in this study is your choice. If you do not want to be in the study, or change your decision, there will be no penalty to you. If you decide not to be in this study or leave it, you will not lose medical care or any legal rights, or any benefits you would otherwise be entitled to.

What if I work for one of the study centers participating in the study, or the sponsor? What if I am a family member of someone who works for one of the study centers or sponsor?

Study center/sponsor employees and their family members do not have to be in this study. No one should influence or pressure you to be in this study. An employee's or his/her family member's decision to be in the study, or to leave the study early, will not affect the employee's job or job benefits.

TESTING ACCURACY

There is always a risk of a false test result. The test may be positive when it really is not. This is called a false positive result. The test may be negative when it really is not. This is called a false negative result. We will make every effort to limit the risk of false results. We will use only approved laboratories. We will offer to repeat positive tests to be sure that they are accurate. We will also tell you about options for more testing if needed.

CONFLICT OF INTEREST

The testing lab QUEST has a joint venture with Memorial Sloan Kettering to develop gene tests for tumors. This venture is not related to this study of BRCA mutations. There are no known investigator and/or institutional conflicts of interest for this study. As part of this study, QUEST has agreed to provide the BRCA gene tests at no cost.

IN CASE OF INJURY

It is unlikely that you will be injured as a result of taking part in the study. If you feel an injury is a result of a medical error by your doctor, you keep all your legal rights to receive payment for this even though you are in a study. Your follow-up medical care after this study will be by your doctor or primary care provider. If you do need treatment for an injury while on this study you and/or your health plan will be charged for this treatment. If you think you have been injured by taking part in this study, please contact the study team at the number below, or by email.

Be aware that your health care payer/insurer might not cover the costs of study-related injuries or illnesses.

1-833-600-BFOR

support@BFORstudy.com

OPTIONS FOR TESTING OUTSIDE STUDY

You can choose to have BRCA testing outside of this study. If you would like to learn more about your cancer risk but do not want to join this study, please talk about this with your PCP. You may also explore our website for links to more information. If you are tested outside this study, your insurance may or may not cover it. This will depend largely on your family history,

CONTACT INFORMATION

If you move during the course of the study, or if the best way to contact you changes, please let the study team know. If we do not have a way to contact you it may not be possible for you to receive important medical information, or follow-up.

OPTION TO STOP STUDY

You may decide to stop being in this study at any time. If you stop, you can decide whether you want the study to be able to continue to use the information that you have already provided. Also, if we learn any information that may affect your desire to continue in the study, we will tell you. It is possible you may have to leave the study if you are not able to follow the study instructions. The study may also be stopped by the sponsor (Memorial Sloan Kettering Cancer Center) or by regulatory bodies.

If you leave the study, the study team will still be able to use the information they have already collected.

QUESTIONS ABOUT THE STUDY

You should contact the study team if you have questions or complaints or if you get hurt or sick during the study. You can also contact Quorum Review—a group of people who review studies (including this one) to protect the rights and welfare of participants—if you have questions about your rights as a participant or what it means to be in a study. Quorum's toll-free number is 888-776-9115. Quorum's website is www.QuorumReview.com.

1-833-600-BFOR

support@BFORstudy.com

WHO WILL HAVE ACCESS TO YOUR INFORMATION

If you join the BFOR study, we will limit access to information about you. We will limit who will know personal information about you. Your name and how to contact you will be known only by certain people. This will include your primary care provider (PCP). It will also include those working on the study. People working on the study include genetic counselors and the staff who help get test results to you. It also includes people who maintain the data base and online portal. Only those involved in the study will know your protected information. The information used and shared will include information from your regular medical records and information collected during the study (such as your survey responses and the results of the genetic test).

Your medical information is protected by a federal law called HIPAA. We believe the chance your genetic test results will be used against you is very small, but we cannot promise that this will not occur.

All your study-related information will be stored in a secure manner. It will only be sent to study sites where it is stored on secure computers. These computers have features to protect your information. There is always the chance that someone you do not know will get access to (“hack”) your own computer. If that were to happen, that person could see the information you provide to the BFOR study over the Internet. We strongly suggest you use standard Internet security software. You should be careful giving any information over the Internet.

The people who have access to your personal information in this study will be the leaders and the staff of the study. The leaders and staff are from hospitals that are part of the study. Those hospitals are at Memorial Sloan Kettering (New York), the University of Pennsylvania (Philadelphia), the Dana Farber Cancer Institute (Boston), the Beth Israel Deaconess Medical Center (Boston) and the David Geffen School of Medicine at the University of California Los Angeles (Los Angeles). The study staff also include our partners at QUEST laboratories which is the lab that will test your sample. The staff will include those at LIFELINK which will run the internet access and data system for the study. These people will use your information for the purposes of the study as described previously. Also, some regulatory bodies may have access to data in this study. This includes Institutional Review Boards (IRBs) such as Quorum Review. IRBs oversee research on human subjects and protect your rights and welfare. Federal regulatory bodies may also have access as needed to review the study. Your information will be placed into your medical record. It may be seen by all those authorized to see your medical records. Your test result will also be sent to the person you tell us is your primary care provider.

To maintain the integrity of this research, you might not have access to health information developed as part of this study until it is completed. At that point, you generally would have access to your health information.

After your information is shared with the people and groups described above, privacy laws may no longer protect it.

You can cancel your authorization to use and share your information at any time by writing to the study team. If you cancel your authorization, you will no longer be able to take part in the study. However, any information that has already been collected can still be used to complete the research. You can

cancel your authorization for the optional psychosocial surveys part of the study and remain in the main study.

By selecting below, you authorize the BFOR study team to use your health information as described. You cannot be in the study unless you authorize this use and sharing of your information. You can still be in the main part of the study even if you do not authorize the use and sharing of your information for the optional psychosocial surveys part of the study.

This authorization to use and share your information expires in 50 years.