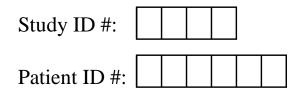
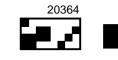
Cancer therapy and side effects in BRCA patients H. Lee Moffitt Cancer Center/ FORCE



For questions or comments, please contact:

Roohi Ismail-Khan, MD Department of Women's Oncology H. Lee Moffitt Cancer Center 12902 Magnolia Drive Tampa, FL 33612, USA Telephone #: 813-745-4933 Email Address: roohi.ismail-khan@moffitt.org





MCC # 16620

IRB # Pro00004774

Moffitt Cancer Center / University of South Florida (USF)

Informed Consent to Participate in Research Information to Consider Before Taking Part in this Research Study

You are being asked to take part in a research study. Please read this information carefully and take your time making your decision.

We are asking you to take part in a research study called: Cancer therapy and side effects in BRCA patients.

The person who is in charge of this research study is **Roohi Ismail-Khan, MD**. This person is called the **Principal Investigator**. However, other research staff may be involved and can act on behalf of the person in charge.

The research will be conducted at Moffitt Cancer Center.

The purpose of this study is to determine if BRCA carriers are at a higher risk for cardiac diseases compared to people without BRCA.

If you decide to take part in this study, you will be asked to complete the following survey. The survey asks questions about your medical history, specifically if you have had cancer or heart disease and if you have any other risk factors for these diseases. If there are questions you do not feel comfortable answering, you do not have to answer them.

You have the option of completing the survey anonymously, without providing any personal information that could identify you. Only the information you provide in the survey will be used in the research. At the end of the survey you are also given the option of providing the research team your contact information so that they can reach you for further information. Our goal is to have 400 people complete the survey.

You do not have to participate in this research study. Completing the survey is completely optional, as is providing information to be contacted later.

You will not personally benefit from being in this study, but what we learn from this study may help people with the BRCA1 mutation in the future.

This research is considered to be minimal risk. That means that the risks associated with this study are the same as what you face every day. There are no known additional risks to those who take part in this study.

Moffitt Cancer Center Injury Statement

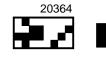
In the event that you sustain an injury as a result of participating in this research, monetary compensation for damages is not automatically available. Damages are only available to the extent specified in Florida law (Florida Statute 768.28). This statue provides that damages are available only to the extent that negligent conduct of an employee caused your injuries and are limited by law. If you believe you are injured as a result of participation in this research and the negligent conduct from one of the staff conducting the study, you may notify the Risk Manager at (813) 745-4219.

You do not give up any of your legal rights by agreeing to participate.

We will not pay you for the time you volunteer while being in this study.

There is no cost to take part in this survey.





[Original Approval Date: MM/DD/YYYY] Version #01 Revision Date 06/17/2011 Adult Minimal Risk Consent Template SUSF Med Rev: 9-3-2010 [MCC Rev: 01-04-2011]



IRB # Pro00004774

Authorization to Use and Disclose Protected Health Information

In this research study, we use and share your health information to the extent authorized (permitted) by you. We know that this information is private. The federal privacy regulations of the Health Insurance Portability & Accountability Act (HIPAA) protect your identifiable health information. If you authorize us to use your information we will protect it as required by the law.

Research at Moffitt Cancer Center is conducted jointly with the University of South Florida. By signing this form, you are permitting Moffitt Cancer Center and the University of South Florida to use personal health information collected about you for research purposes. You are also allowing Moffitt Cancer Center to share your personal health information with individuals or organizations other than Moffitt Cancer Center and USF who are also involved in the research and listed below.

We may publish what we find out from this study. If we do, we will not let anyone know your name. We will not publish anything else that would let people know who you are.

Federal law says we must keep your study records private. Unless you give us your name, the results of your survey will not contain information that would identify you. We will keep the records of this study private by keeping them in a locked area of the Breast Cancer Department at Moffitt Cancer Center. The following people and/or organization(s) will be allowed to disclose, use, and receive your information for the research purposes set forth in this form, but they may only use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law:

Every research site for this study, including the Moffitt Cancer Center and University of South Florida, and each site's study team, research staff and medical staff;

Every member of the Moffitt Cancer Center and University of South Florida workforce who provides services in connection with this study;

Any federal, state or local governmental agency that regulates the study (such as the Food and Drug Administration (FDA) and Florida Department of Health (FDH);

The designated Protocol Review and Monitoring Committees, Institutional Review Boards, Privacy Boards, Data and Safety Monitoring Board and their related staff that have oversight responsibilities for this study;

The National Cancer Institute in evaluating the ongoing research of the Moffitt Cancer Center as a Comprehensive Cancer Center;

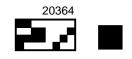
The organizations and people listed above may employ or pay various consultants and companies to help them understand, analyze and conduct this study. All of these people may not be known now, but if you would like to have more specific information about this at any time during the study, you may ask the study doctor and your questions will be answered.

Moffitt Cancer Center and the University of South Florida cannot guarantee the privacy of your information, or block further use or distribution, after the information has left MCC or USF. The sponsor of this study or others listed above may further disclose your information. If disclosed, the information may no longer be covered by federal privacy regulations.

Anyone listed above may use consultants in this research and for the purpose of this study, may share your information with them. Individuals who receive your health information for this research study may not be required by the HIPAA Privacy Rule to protect it and may share your information with others without your permission. They can only do so if permitted by the laws governing them.

By completing the survey, you authorize the use and disclosure of the information you provide in the survey. The purpose for the uses and disclosures you are authorizing is to conduct the study explained to you above and to ensure that the information relating to that study is available to all parties who may need it for research purposes.





[Original Approval Date: MM/DD/YYYY] Version #01 Revision Date 06/17/2011 Adult Minimal Risk Consent Template ^{SUSF} Med Rev: 9-3-2010 [MCC Rev: 01-04-2011]



MCC # 16620

IRB # Pro00004774

By completing the survey, you authorize the use and/or disclosure of your protected health information described above. Your authorization to use your health information will never expire unless and until you expressly revoke it in writing to:

Principal Investigator's name: Roohi Ismail-Khan, MD

Address of the PI:	Moffitt Cancer Center
	12902 Magnolia Drive, Mail Stop: MCC-BR Prog
	Tampa, FL 33612-9497

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to complete the survey. There will be no penalty or loss of benefits you are entitled to receive if you do not complete the survey.

If you have any questions, concerns or complaints about this study, or experience an adverse event or unanticipated problem, call Dr. Roohi Ismail-Khan at 813-745-4933.

If you have questions about your rights as a research patient at Moffitt Cancer Center, call the Division of Research Compliance in the Corporate Compliance Department at The Moffitt Cancer Center at (813) 745-1869.

If you have questions about your rights as a participant in this study, general questions, or have complaints, concerns or issues you want to discuss with someone outside the research, call the USF IRB at (813) 974-5638. By completing the survey you are giving your consent to participate in this research study and authorization to use your anonymous information.

If you do not want to participate, STOP HERE





	- 1		· <u> </u>	
STUDY ID:	PATIENT	ID:		
This is a survey to determine side effect risks for patients with BRC population. By participating in and completing this survey, you are and staff to use the information you provide anonymously for resear be identified in any studies or publications related to this survey. (<u>It the survey</u>).	e giving per arch and p	rmisssion (ublication	to the study purposes. Y	coordinator ou will not
Are you a Moffitt patient? Yes No				
1. Are you Female? Yes No				
2. Date of Birth? (Optional) $\lim_{mm} / \lim_{dd} / \lim_{yyyy}$				
General Cancer History in BRCA				
3. Have you ever tested positive for the BRCA-1 gene mutation?	_			
Yes No I don't know, but I have a strong family history	ry of cancer	•		
 4. Have you ever tested positive for the BRCA-2 gene mutation? Yes No I don't know but I have a strong family histor 	ry of concor			
5. Have you ever been diagnosed with cancer? Yes No 5a. Was it breast? Yes No If yes, Was it lobular? Yes No Was it ductal? Yes No Was it another type? Yes No				
If so, please specify:				
5b.Was it ovarian? 🗌 Yes 🗌 No				
5c.Was it other? Yes No				
If so, please specify:				
6. At diagnosis, what stage were you?				
Stage I Stage II Stage III Stage	IV			
7. When were you first diagnosed?				
Review of Systems mm yyyy				
8. Did you experience any of the following side effects:				
	Yes	No	Don't know	
General:				
Weight loss				
Weight gain				

Fatigue Fever

Loss of appetite

Fever Night sweats







 \Box

5

STUDY ID: PATI	ENT ID:		
	Yes	No	Don't know
Skin: Rash Itching Hair Loss Nail changes			
Breast: Breast tenderness Breast swelling Nipple discharge			
HEENT: Headaches Vertigo Lightheadedness Vision changes Nose bleeding/drainage Frequent colds Dental difficulties Mouth pain Trouble swallowing			
Cardiac: Chest pain Irregular rhythm Palpitations/racing heart Trouble breathing/shortness of breath? If so, was it worse with exertion? Leg swelling Prior heart attack Heart failure History of high blood pressure History of heart surgery			
Lungs: Wheezing Cough Any sputum? Any blood?			
GI: Abdominal pain Heartburn Nausea Vomiting Constipation Diarrhea			



STUDY ID: PATI	IENT ID:		
	Yes	No	Don't know
GU: Trouble urinating Loss of libido Change in menstruation			
Musculoskeletal: Pain in muscles Arthritis/ joint pain			
Neuro: Stroke Weakness in extremities Tremor Numbness or tingling in extremities			
Psych: Anxiety Depression			
Hematologic: Anemia Bleeding tendency Easy bruising			
GYN (FEMALES ONLY) 9. What age did you start having periods?			
 10. Are you: Pre-menopausal (I still have regular menses) Peri-menopausal (I am going through the process) Post-menopausal (My menses have stopped) Surgical menopausal (both ovaries were removed by surgery) Status post hysterectomy (ovaries have not been removed but uterus was removed but	ved)		
11. Were you ever on oral birth control? Yes No			
11a. If yes, how many years?			
12. Were you ever on hormonal therapy such as estrogen or progesterone replacement 12a. If yes, Was it pills? Yes No Was it cream? Yes No UNIVERSITY OF SOUTH FLORIDA	ts? 📙 Ye	s 🗌 No 7	20364

Study ID:Pro00004774 Date Approved: 6/20/2011 Expiration Date: 6/20/2012

STUDY ID:	PATIE					
13. How many times have you been pregnant?						
14. How many live births have you had?						
Social History						
15. Did you smoke cigarettes at the time of diagnosis? Yes No						
16. Do you smoke now?						
17. Do you/did you drink alcohol? Yes No						
17a. If yes, how often:	5 drinks per	week	more tl	nan 15 dri	nks p	er week
18. How much did you weigh at the time of diagnosis? lbs						
19. How much do you weigh now? lbs						
20. How tall are you?ft inches						
21. How often do you exercise? less than 3 times per week 3-5 times per week more the	an 5 times p	ber week				
22. Do you work ? Part time Full time Unemployed	Retired	1				
23. Are you disabled? Yes No						
Cardiac Risk Factors/ Cardiac History						
25. Was your heart function normal before starting treatment?	Yes	No No	I d	on't knov	1	
26. Is your heart function normal now?	Yes	🗌 No	I d	on't knov	1	
27. Did you have an echocardiogram?	Yes	No No	I d	on't knov	1	
28. Did you have a multi-gated acquistion (MUGA) scan?	Yes	No No	Id	on't knov	1	
29. Was your LDL cholesterol greater than 130 at the time of diagnosis?	Yes	No No	I d	on't knov	1	
30. Is your LDL cholesterol greater than 130 now?	Yes	No No	I d	on't knov	1	
31. Was your HDL cholesterol less than 40 at the time of diagnosis?	Yes	🗌 No	I d	on't knov	1	
32. Is your HDL cholesterol less than 40 now?	Yes	🗌 No	I d	on't knov	1	
33. Were you on cholesterol medications at the time of diagnosis?	Yes	🗌 No	I d	on't knov 2	v 20364	



Study ID:Pro00004774 Date Approved:	6/20/2011 Expiration Date: 6/20/2012
STUDY ID:	PATIENT ID:
34. Have you had cardiac surgery? Yes No 34a. If yes:	
What type?	
 35. Have you had cardiac catheterization? ☐ Yes ☐ No 35a. If yes: Was it: ☐ Normal ☐ Abnormal 	$\begin{array}{ccc} mm & dd & yyyy \\ \\ Date \prod_{mm} / \prod_{dd} / \prod_{yyyy} \end{array}$
36. Are you on cholesterol medications now? Yes No	
37. Was your blood pressure consistently greater than 140/90 at th	he time of diagnosis? 🗌 Yes 📄 No 📄 I don't know
38. Is your blood pressure consistently greater than 140/90 now?	Yes No I don't know
39. Were you on blood pressure medications at the time of diagnos	osis? 🗌 Yes 🗌 No 📄 I don't know
40. Are you on blood pressure medications now?	No I don't know
41. Were you ever diagnosed with diabetes? ☐ Yes ☐ No If yes, Was it Type 1? ☐ Yes ☐ No Was it Type 2? ☐ Yes ☐ No	I don't know
Was it Gestational? Yes No	
b. a heart attack?YesNoI domc. a heart failure?YesNoI dom	n't know n't know n't know n't know
43 Has your father ever been diagnosed with a heart attack?	Yes No I don't know
a. Was he diagnosed before the age of 65?	Yes No I don't know
44. Has your mother ever been diagnosed with a heart attack?	Yes No I don't know
a. Was she diagnosed before the age of 65?	Yes No I don't know
45. Have any of your grandparents ever been diagnosed with a heat	eart attack? Yes No I don't know
a. Were any of your grandmothers diagnosed before t	the age of 65? Yes No I don't know
b. Were any of your grandfathers diagnosed before th	he age of 55? Yes No I don't know
46. Has anyone else been diagnosed with a heart attack? Yes	s 🗌 No
46a. If yes, who?	20364
UNIVERSI SOUTH FL	

🗌 No

STUDY ID:			
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PATIENT ID:



Treatment

47. Were you initially treated with chemotherapy? \Box Yes

I don't know

47a. Do you know what chemotherapy was used?

ſ	Did you receive	Date	How many
		mm dd yyyy	cycles
	Adriamycin/doxorubicin		
	Cytoxan		
	AC		
	Taxol/Paclitaxel		
	Taxotere/docetaxel		
	5-Fu/Fluorouracil		
	Epirubicin		
	FEC		
	Methotrexate		
	CMF		
	Other		
4 8.	Did you receive hormonal therapy?	Yes No I don't know	1
-	48a. Do you know which hormonal therap	by was used?	
	Did you receive	Date mm dd yyyy	How many years

	illii dd yyyy	jears
Tamoxifen		
Arimidex (Anastrozole)		
Femara (Letrozole)		
Faslodex		
Aromasin (Exemestane)		
Other		

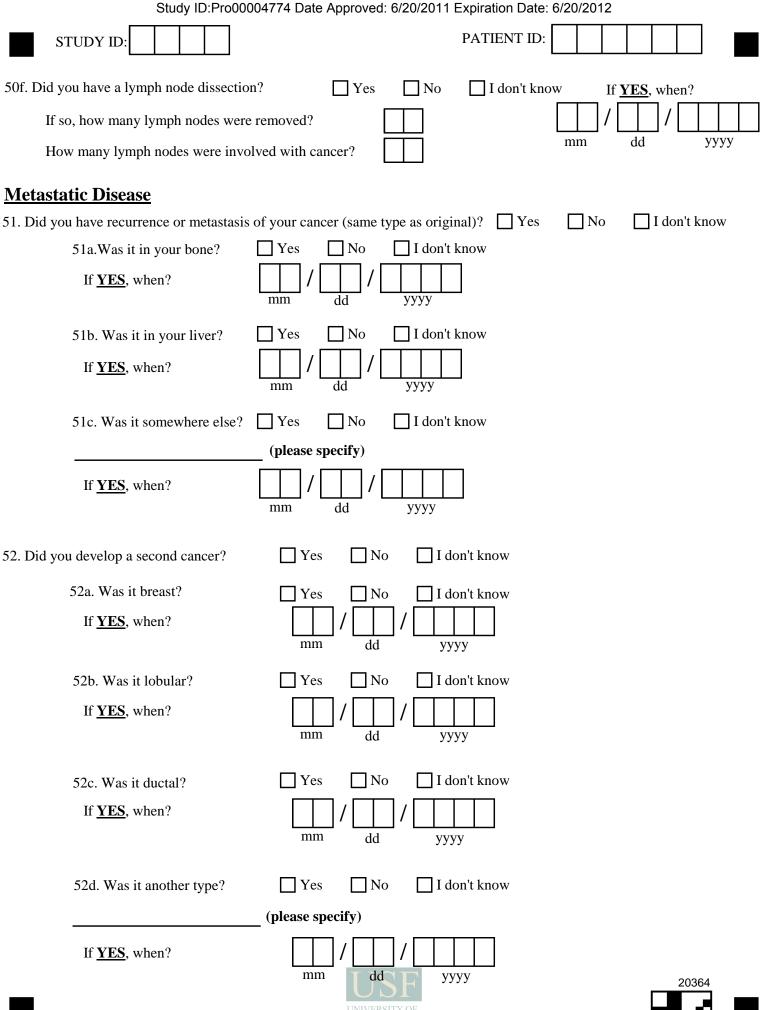


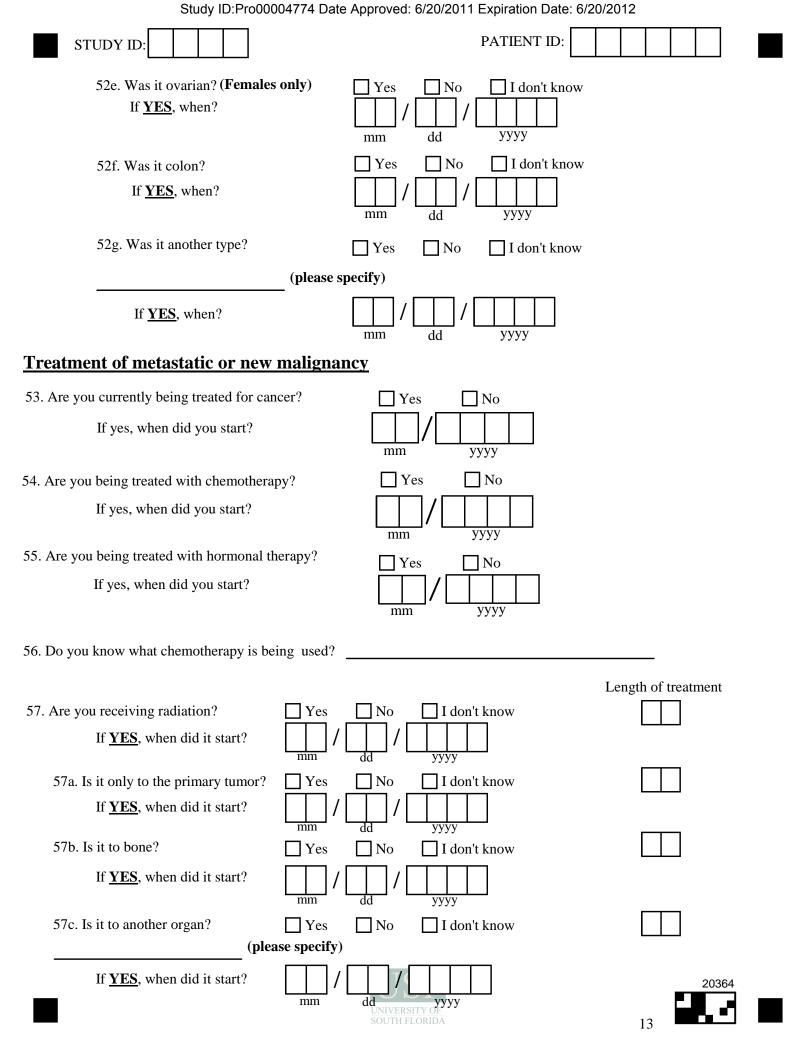


STUDY ID:	PATIENT ID:
49. Did you receive radiation? Yes	No I don't know
49a. Was it only to the primary tumor?	Yes No I don't know Length of Treatment
If <u>YES</u> , when?	mm / dd / yyyy
49b. Was it to the bone?	Yes No I don't know Length of Treatment
If <u>YES</u> , when?	mm / dd / yyyy
49c. Was it to another organ?	Yes No I don't know Length of Treatment years
(please specify) If <u>YES</u> , when?	$\lim_{mm} / \prod_{dd} / \prod_{yyyy}$
50. Did you receive surgery? Yes N If yes:	No I don't know
50a. Was it a lumpectomy?	Yes No I don't know
If <u>YES</u> , when?	mm dd yyyy
50b. Was it mastectomy?	Yes No I don't know
If <u>YES</u> , when?	mm dd yyyy
50c. Was it another type? (please specify) If <u>YES</u> , when?	$ \begin{array}{c c c c c c c c c c c c c c c c c c c $
50d. Did you have an excisional biopsy? If <u>YES</u> , when?	$ \begin{array}{c c} Yes & \square No & \square I don't know \\ \hline \\ mm & dd & & yyyy \end{array} $
50e. Did you have a sentinal lymph node If <u>YES</u> , when?	biopsy? \Box Yes \Box No \Box I don't know \Box dd / \Box $yyyy$









Study ID:Pro00004774 Date Appr	oved: 6/20/2011 Expiration Date: 6/20/2012
STUDY ID:	PATIENT ID:
	the following contact information so we can reach you for further omplete this section, our study will not identify you by name but by

study number. All of your information will be kept confidential.

Name:						
Phone Number:	-] - 🔲				
Email address:						
Best time to be contac (Please circle one)		Late Morning	Afternoon	Evening	Night time	



