

GPC Breast Cancer

PI: Elizabeth Chrischilles

IRB ID #: 201501798

Other Mod and/or Comments

We added a template for sites to mail a letter to participants to inquire about incomplete or ambiguous responses. Similarly, we modified the approved letters for contacting participants about missing medical record or future studies information to allow all sites to use them as needed.

We also revised the approved phone script to allow for contacting participants about missing or ambiguous questionnaire responses (in addition to missing consent information which was previously approved).

These changes are described in VII.E.6

Modifications

VII. Provide a detailed description in sequential order of the study procedures following the E.6 consent process - DO NOT cut and paste from the Consent Document.

Describe study populations separately if they will be participating in different procedures - include CONTROL population if applicable.

DESCRIBE:

- *What subjects will be asked to do/what happens in the study (in sequential order)*
- *The time period over which procedures will occur*
- *The time commitment for the subject for individual visits/procedures*
- *Long-term followup and how it occurs*

Old Value

1) Prospective subjects will be asked to complete a mailed questionnaire. The questionnaire should take about 30 minutes to complete. The questionnaire includes the following standardized questions and scales:

- * Patient-reported outcomes (FACT-B, Quick DASH, neuropathy, heart failure, shoulder diagnoses, fear of recurrence BMI change)
- * Treatments and interventions received including genetic testing, survivorship care plan elements and breast reconstruction
- * Factors considered when making surgery, chemo decisions
- * Shared decision-making question for each treatment type
- * Preferred decision-making role
- * Patient experiences of care (Care coordination and physician communication)
- * Recalled decisional uncertainty and decision support, perceived decision effectiveness
- * Interest in research participation

2) They will also be asked to sign and return the consent document.

3) Both items will be included in one study booklet. The study booklet may be returned in a pre-paid envelope provided. The reply envelope will be addressed to the UI Coordinating Center.

4) The UI Coordinating Center project manager will optically scan the paper questionnaires and may telephone a participant if markings are not legible or ambiguous using contact information provided in the questionnaire by the participant. The CC project manager will detach the consent forms and contact information from the study booklet and store the paper and an electronic copy of each separately from the paper questionnaire pages.

5) The tracking database will be regularly updated with status of the questionnaire and consent.

6) A file containing study ID numbers for consenting individuals will be supplied to the participating sites.

7) Participating sites will generate i2b2 study variables from the electronic medical record for all consented subjects. Information that will be obtained from the medical record to create study variables includes:

- Information about breast cancer diagnosis such as type of breast cancer
- Details of cancer treatments including surgery, radiation, chemotherapy, hormone therapy, and diagnostic tests
- Information about any breast reconstruction procedures
- Information about past medical history such as other health conditions that can affect peoples' experience with cancer care
- Laboratory tests and vital signs

8) Please see the attached SOP for breast cancer cohort study data request, transfer and storage.

9) Please see the attached Major Project Management Tasks and Timeline table.

10) There is no long-term follow-up planned at this time.

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4a) If a participant included one or more pieces of information (i.e., date, printed, name, signature) on the medical record or future study consent documents - but not all 3 pieces of information, AND the participant did not provide their contact information in the booklet, the CC will contact the participating site and request that they contact the participant using the contact information in their mailing list for the associated participant study ID. The CC will provide materials for the sites to use in contacting the participant on a case by case basis. The same process will be implemented in the event that a booklet is received with 1 or more blank booklet pages when other pages were completed and there is no indication that the participation did not intend to complete the blank pages. This is because pages may have been stuck together and inadvertently left blank by the

participant. Up to 3 call attempts will be made to contact the subject.

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Attachments


Old Value




Attachment Name	Category	Ver	Size	Attached
Consent letter 14 May 2015.rtf	Consent & Assent Forms	7	52 k E	05/15/15
Informed consent 14 May 2015.rtf	Consent & Assent Forms	12	187 k E	05/15/15
GPC-PCORI-CDRN-Phase I grant.pdf	Funding Source Grant	1	2 ME	03/05/15
GPC Breast Survey Cover letter 18 May 2015.docx	Recruitment Script: Mail	13	31 k E	05/19/15
GPC Breast Survey Secondary Cover letter changes tracked from Primary Cover Letter.docx	Recruitment Script: Mail	2	31 k E	06/16/15
Relatives.docx	Relative/Proxy Data Collection Instruments	1	14 k E	08/27/14

GPC Breast Cancer Survey Booklet - SAMPLE - 2015-06-05.pdf	Subject Data Collection Instruments	9 806 k E	06/05/15
Breast Cancer Cohort Survey - Site Preparation Questionnaire #1 (3).docx	Miscellaneous	1 24 k E	01/23/15
Breast Cancer Cohort Survey - Survey Implementation Guide 11 March 2015.docx	Miscellaneous	3 20 k E	05/11/15
Cover Sheet Accompanying Participant Copy of the Informed Consent Document 14 May 2015.docx	Miscellaneous	1 21 k E	05/14/15
<p> This is a one page sheet that will accompany the copy of the informed consent document that is inserted into the booklet.</p>			
GPC Missing Consent Letter 26JUN2015.docx	Miscellaneous	1 76 k E	06/26/15
<p> If a partially completed consent document is received and the subject indicates they intended to provide informed consent, this is the letter we will use to mail them a new form to complete.</p>			
GPC Missing Future Studies Consent Letter 26JUN2015.docx	Miscellaneous	1 77 k E	06/26/15
<p> If a consent form is received but the future studies page is partially completed and the subject indicates they want to participate in future studies when we contact them by telephone, this is the cover letter we will use to send them a new form to complete.</p>			
Major Project Management Tasks and Timeline for the Breast Cancer Cohort Study 23 Dec 2014.docx	Miscellaneous	1 26 k E	12/23/14
Noncompliance on GPC Breast Cancer study discussion with U of MN IRB.pdf	Miscellaneous	1 13 k E	05/01/15
SOP for breast cancer cohort study data 4 May 2015.docx	Miscellaneous	4 22 k E	05/11/15
Telephone Script for missing consent information_betsy finalized.docx	Miscellaneous	1 17 k E	06/26/15
<p> When a partially completed consent form is received this is the script we will use to follow up</p>			
Tracking Database Screenshots.docx	Miscellaneous	2 1 ME	03/11/15
<p> This replaces the earlier "Reportable Events Form" and includes the mechanism for all communication and tracking for the project</p>			
URL for sharing study documents among the study team at participating sites.docx	Miscellaneous	1 86 k E	06/26/15
<p> This is the URL at which all approved study documents are readily accessible to the study teams.</p>			
Updated Breast Cancer Cohort Study Teams and POC 26 June 2015.pdf	Miscellaneous	5 151 k E	06/26/15

Assurance document.pdf	Assurance Document	1	57 k E	01/22/15
Cash Handling Email.pdf	Cash Handling Approval	1	125 k E	01/15/15
 Email chain including approval for Cash Handling Policy.				

New Value

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Breast Cancer Cohort Survey - Survey Implementation Guide 11 March 2015.docx	Miscellaneous	3	20 k E	05/11/15
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 This is a one page sheet that will accompany the copy of the informed consent document that is inserted into the booklet.				
* GPC Missing Consent Letter 17JUL2015.docx	Miscellaneous	3	26 k E	07/22/15
* GPC Missing Future Studies Consent Letter_17JUL2015.docx	Miscellaneous	3	26 k E	07/22/15

* GPC Missing Questionnaire Responses 17JUL2015.docx	Miscellaneous	1	26 k E	07/17/15
Major Project Management Tasks and Timeline for the Breast Cancer Cohort Study 23 Dec 2014.docx	Miscellaneous	1	26 k E	12/23/14
Noncompliance on GPC Breast Cancer study discussion with U of MN IRB.pdf	Miscellaneous	1	13 k E	05/01/15
* SOP for breast cancer cohort study data 17 July 2015.docx	Miscellaneous	5	27 k E	07/17/15
* Telephone Script for Missing Consent Missing Future Studies Missing Questionnaire 17JUL2015.docx	Miscellaneous	3	17 k E	07/22/15
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 Email chain including approval for Cash Handling Policy.				
Asterisk indicates modified attachment.				

Enrollment as Reported on Previous Forms

Type	Approval Date	Total Subjects Approved by IRB	Total Subjects Reported	Enrollment Stopped
Mod	07/21/15	1300		
Mod	07/06/15	1300		
Mod	06/16/15	1300		
Mod	06/08/15	1300		
Mod	05/19/15	1300		
Mod	05/14/15	1300		
New	05/09/15	1300		

Form Content

I. Project Introduction

I.1 *Project to be reviewed by:*
IRB-01

I.2 *Project Title:*
Greater Plains Collaborative Breast Cancer Study

I.3 *Short Title (optional):*
GPC Breast Cancer

I.4 *Provide a short summary of the purpose and procedures of the study proposed in this IRB application.*

- *DO NOT include information on studies not proposed in this application.*
- *Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.*
- *DO NOT cut and paste technical abstracts from funding applications that may not be understood by a general audience.*

This project is part of a major new initiative funded by the Patient-Centered Outcomes Research Institute (PCORI) to create “PCORNet”: The National Patient-Centered Clinical Research Network. U of I is a participating site (Rosenthal PI, IRB# 201401787) in the Greater Plains Collaborative (GPC) and one of 11 Clinical Data Research Networks (CDRNs) participating in PCORNet initiative. The GPC is comprised of leading medical centers in 7 states, and is led by the University of Kansas Medical Center (Russell Waitman, PI). The aim of the GPC is to create an integrated research network of academic institutions dedicated to conducting comparative effectiveness trials. GPC is using NIH-funded open source technology (e.g., i2b2, REDCap) to provide a cost-effective common data model that promotes data transparency and interoperability across the participating centers. The i2b2 warehouse (see Rosenthal IRB 201401787) is fully de-identified with re-identification possible when accompanied by an approved IRB protocol. As part of its application, the GPC selected Breast Cancer as one of three cohorts it will use to demonstrate that the network is capable of collaboration and data sharing across the 9 sites that serve

adult patients. Dr. Chrischilles is the project lead for the Breast Cancer cohort work. PCORI-required milestones include selecting the cohort from electronic healthcare data, characterizing the cohort with electronic health care data, and conducting a survey of all or a sample of the cohort. To demonstrate success it will be important to: (1) develop and validate key measures from electronic health care data including electronic health record (EHR) and hospital tumor registry files; (2) collect patient experiences from a patient questionnaire; (3) attain a high participation rate. Representatives from each of the 9 medical centers have collaborated to prioritize the data elements to collect.

Electronic health care measures and patient-reported measures proposed for cohort characterization:

- Risk factor information: age, race/ethnicity, sex, marital status, family history, genetic markers (BRCA1/BRCA2), Oncotype or Mammoprint recurrence risk, menopausal status, use of hormone replacement therapy, alcohol use, tobacco use, body mass index, prior history of breast cancer, prior radiation treatment, prior diagnosis of breast tissue hyperplasia.
- Baseline information: diagnostic and genetic tests, tumor stage, size, number of positive lymph nodes, grade, histology, laterality, hormone, HER2 and EGFR receptor status, performance status, comorbidity, body mass index, beliefs about breast cancer, priorities and preferences.
- Treatment: chemotherapy, hormonal therapy, molecular targeted therapy, surgical procedures including reconstruction.
- During treatment: laboratory (WBC); psychosocial characteristics including quality of life, positive meaning and vulnerability; adverse effects including lymphedema, fatigue, shoulder function, pain, depression, nausea; experiences of care (coordination, communication, quality).
- Post-treatment/survivorship: cancer surveillance imaging; cancer status (whether disease-free); medications including aromatase inhibitors and hormone modulators; quality of life and symptoms; adverse effects; late effects such as cardiotoxicity, cognitive effects, bone loss; ACoS/IOM survivorship process measures including having a care plan, treatment summary, measure of distress; lifestyle characteristics such as body mass index, exercise, nutrition, alcohol, and smoking.

I.5 ***Specify your research question(s), study aims or hypotheses (do not indicate "see protocol")***

We propose to select and characterize a cohort women with breast cancer using electronic healthcare data in the i2b2 warehouse at each of 9 GPC medical centers and conduct a survey for a random sample of these women of sufficient size to achieve responses from at least 1,000 women. The survey of 1,000 breast cancer patients will generate pilot data for future grant proposals. It will also generate data on other current issues important to breast cancer patients and clinicians such as: patient knowledge about breast reconstruction options, quality of life outcomes of bilateral mastectomy, prevalence and correlates of gene testing, the role of patient preferences and shared decision-making, and correlates of patient experiences of care coordination.

We have the following specific aims:

Aim 1: Select a de-identified cohort of all patients diagnosed with primary breast cancer at a GPC medical center during the study period

Aim 2: Demonstrate the ability to survey a sample of the cohort with high participation.

Aim 3: Generate pilot data for future GPC studies including estimating the prevalence of characteristics including reconstruction, physician-diagnosed shoulder conditions, and out-of-system care (i.e. care received at >1 medical center), the correspondence between treatment measures derived from data in i2b2 and self-reported measures, and tabulation of the item and scale properties, such as item response rates, means and standard deviations for patient-reported outcomes and risk factors

Aim 4: Determine the prevalence of characteristics in the underlying de-identified cohort, and correspondence of EHR-derived study variables with tumor registry gold standard variables, for example comparing the positive predictive value of breast cancer diagnosis codes from EHR encounters with the tumor registry primary site and date of diagnosis fields.

Aim 5: Demonstrate the ability to link i2b2-derived study variables with complementary patient-reported survey data from a sample of consenting patients with breast cancer in 9 medical centers within GPC.

I.6 ***Background and significance and/or Preliminary studies related to this project.
(do not indicate "see protocol")***

The idea of gathering data from real-world clinical experiences of patients within their system is very appealing to both clinicians and researchers. In spite of the strong skills of researchers and interest from clinicians, and the rich clinical data contained in electronic health records (EHR), there are multiple barriers impeding the ability to conduct this research. For example, the available sample size of persons exposed to each treatment is often inadequate within a single healthcare system. Capture of many key outcomes can be incomplete if some patients obtain some of their care outside the system. Patient-reported outcomes, often important in comparative effectiveness research, are almost entirely missing. If the research question requires randomization, recruitment of patients is costly and inefficient, and obtaining IRB approval often cumbersome.

Eager to have an answer that could benefit so many individuals, all parties involved wonder if there are better ways to leverage existing electronic healthcare data within and across systems; other methods for collecting data and engaging patients, such as social media and modern digital technologies; and opportunities for interested, activated patients and clinicians to participate in and facilitate the efficient conduct of important comparative effectiveness research and the rapid clinical implementation of effective treatment strategies.

Every day, patients and their caregivers are faced with crucial healthcare decisions while lacking key information that they need. The Patient-Centered Outcomes Research Institute (PCORI) was created to conduct research to provide information about the best available evidence to help patients and their providers make more informed decisions. PCORI's research is intended to give patients and their caregivers a better understanding of the prevention, treatment, and care options available and the science that supports those options. However, the nation's capacity to conduct patient-centered comparative effectiveness research (CER) quickly and efficiently remains extremely limited.

The goal of PCORI's National Patient-Centered Clinical Research Network Program is to improve the nation's capacity to conduct CER efficiently, by creating a large, highly representative, national patient-centered clinical research network for conducting clinical outcomes research. Specifically, this program will promote a more comprehensive, complete, longitudinal data infrastructure; broader participation of patients, clinicians, health systems, and payers in the research process; and improvements in analytic methods for both

observational and experimental CER. The creation of a national patient-centered clinical research network could empower the United States to become a learning healthcare system, which would allow for large-scale research to be conducted with enhanced accuracy and efficiency. The core component of this network will be Clinical Data Research Networks (CDRNs), which are system-based networks (such as hospital systems) that have the potential to become an ideal electronic network, without structural impediments.

PCORI envisions that the CDRNs that will develop the capacity to conduct observational studies and randomized comparative effectiveness studies using data from clinical practice in a large, defined population. Characteristics of an ideal CDRN will include:

1. Coverage of large, diverse, defined populations unselected for a particular disease, condition, or procedure; ability to capture complete clinical information on this population over time, including longitudinal information on clinical care, changes in clinical characteristics and conditions, and the occurrence of clinical care or outcomes, within or outside the system.
2. Involvement of multiple (two or more) health systems, with data interoperability and data standardization to allow efficient, valid sharing of individual or aggregate data across systems for purposes of data analysis.
3. The ability to efficiently contact patients for the purposes of efficient recruitment; collecting patient-reported information; and maintaining consistently high levels of participation in research studies, including sustained randomization, participation, and follow-up over time.
4. Demonstrated ability to engage substantial patient populations with selected conditions, both within and outside their systems, for purposes of generating research questions, participating in network governance, or in appropriate research studies.
5. Involvement of the healthcare system leadership in governance and use of the network to enhance network efficiency, utility, and sustainability.
6. Willingness to serve as a national data infrastructure resource for the conduct of CER by researchers outside the network.

7. Capacity to support large-scale comparative effectiveness trials, as well as observational studies of multiple research questions, including prevention and treatment, at low marginal cost, with substantive patient involvement throughout, including formulation of research questions and essential study characteristics, study participation, and dissemination of study findings.

8. Capacity to embed research activity within functioning healthcare systems without disrupting the business of providing health care; alignment of human subjects oversight, IRB review and approval, and informed consent procedures with the level of risk in proposed comparative effectiveness studies, including plans to obtain buy-in from all organizations to accept review of specific projects under auspices of a central IRB.

9. Clear, proven policies to maintain data security, patient privacy, and confidentiality; ability to collect, store, retrieve, process, or ship biological specimens for research purposes, with appropriate consent, for use by qualified researchers.

10. Ability to streamline subcontracting processes for research involving multiple sites.

I.7 ***Literature cited / references (if attaching a grant or protocol enter N/A).***

1. Selby JV, Krumholz HM, Kuntz RE, Collins FS. Network News: Powering Clinical Research. *Sci. Transl. Med.* 5, 182fs13 (2013).
2. Selby JV. The Patient-Centered Outcomes Research Institute: A 2013 Agenda for “Research Done Differently.” *Population Health Management.* April 2013, 16(2): 69-70.
3. Califf RM, Platt R. Embedding cardiovascular research into practice. *JAMA.* 2013 Nov 20;310(19):2037-8.
4. Califf RM. Large simple trials: really, it can't be that simple! *Eur Heart J.* 2014 Jan 9. [Epub ahead of print].
5. Reith C, Landray M, Devereaux PJ, Bosch J, Granger CB, Baigent C, Califf RM, Collins R, Yusuf S. Randomize clinical trials—removing unnecessary obstacles. *N Engl J Med.* 2013 Sep 12;369(11):1061-5.

III.5 *What is the current status of this funding source?*

Source	Status	Other Status Description
Patient-Centered Outcomes Research Institute	Awarded	

IV. Project Type

IV.1 *Do you want the IRB to give this project*
Regular (expedited or full board) review

IV.2 *Enter the date you will be ready to begin screening subjects/collecting*
data for this project.
3/2/2015

IV.3 *Are you requesting a waiver of informed consent/authorization*
(subjects will not be given any oral or written information about the
study)?
No

V. Other Committee Review

V.1 *Does this project involve any substance ingested, injected, or applied to the*
body?

- *Do not answer yes, if the involvement includes a device, wire, or instrument*

No

V.2 *Are any contrast agents used for any purpose in this study?*
No

V.9 *Will any subject be asked to undergo a diagnostic radiation procedure*
(including radiographic, nuclear medicine, DEXA)?
No

V.14 *Will any subject be asked to undergo a radiation therapy procedure*
(including external beam therapy, brachytherapy, or nuclear medicine

therapy)?

No

V.20 *Does this project involve the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participant?*

No

V.21 *Will any portion of this project be conducted in the CRU, or does it use any CRU resources?*

No

V.22 *Will this project use any resource/patients of the HCCC?*

No

V.23 *Will any part of this project be conducted on VAMC premises?*

No

V.24 *Does this project involve VAMC patients or records?*

No

V.25.a *Will the study involve any of the following activity at UI Health Care, even if subjects or their insurance will not be billed for the item or service, and regardless of the study funding source (including studies with departmental or no funding)?
(for studies conducted entirely at the VAMC, the answer to this question is "no")*

- *Procedures, tests, examinations, hospitalizations, use of Pathology services, use of clinic facilities or clinical equipment, or any patient care services, including services conducted in the Clinical Research Unit; or*
- *Physician services or services provided by non-physicians who are credentialed to bill (ARNPs, Physician Assistants, etc.)*

No

V.26 *The study involves nursing, nursing resources or evaluates nursing practices.*

No

VI. Subjects

VI.1 *How many adult subjects do you expect to consent or enroll for this project?*

1300

VI.2 *What is the age of the youngest adult subject?*

18.0

VI.3 *What is the age of the oldest adult subject?*

100.0

VI.4 *What is the percentage of adult male subjects?*

0

VI.5 *What is the percentage of adult female subjects?*

100

VI.6 *How many minor subjects do you expect to consent or enroll for this project?*

0

VI.13 *Describe EACH of your subject populations*

- *Include description of any control group(s)*
- *Specify the Inclusion/Exclusion criteria for EACH group*
- *Studies under IRB-03 enrolling non veterans as part of the subject population must present a compelling argument to the IRB for the inclusion of non-Veterans (e.g., insufficient number of Veterans; survey of VA employees; study of active duty military; study involving Veterans' family members), and the research is relevant to the care of Veterans or active duty military personnel.*

There is an underlying de-identified cohort and there is a survey sample. Only the survey sample will participate in the research. The de-identified cohort is the sampling frame and it is described because these data will be preliminarily reviewed for quality assurance prior to proceeding to select the survey sample.

Inclusion criteria for the UNDERLYING de-identified cohort are:

- a. any sex
- b. age 18 or older at the time of breast cancer diagnosis

- c. diagnosed during 5/1/2013-5/1/2014 (If there are insufficient patients diagnosed during, we may extend the window. Also, if tumor registry data have not been refreshed recently, it may be necessary to revisit the date span.)
- d. primary breast cancer
- e. any mode of diagnostic confirmation
- f. in situ or invasive
- g. any stage
- h. Case is "Analytic" to a GPC medical center (i.e. NAACCR Class of Case codes 00-22)

For the SURVEY sample, a medical center-stratified random sample will be selected from the underlying cohort as described above but with the following ADDITIONAL EXCLUSIONS:

Exclude from SURVEY sample if:

- a. Sex not equal to female
- b. women less than 18 years of age
- c. prior cancer diagnosis
- d. breast cancer was not microscopically confirmed
- e. only tumor morphology was lobular carcinoma in situ
- e. stage IV breast cancer
- f. known to be deceased

From individuals in the UNDERLYING cohort (all people diagnosed with primary breast cancer (SEER Site Recode=Breast) diagnosed during 5/1/2013 – 5/1/2014 (except at UI and U Nebraska where the start date of the period is 1/1/2013) who are age 18+ at the time of diagnosis), Honest Brokers submit the following variables needed for case selection: primary site (should be only breast), class of case (should be only Analytical cases), cancer identification (masked date of diagnosis, grade, diagnostic confirmation, morphology, sequence number, AJCC-7 stage, SEER Summary Stage 2000), and demographics (masked date of birth, sex, vital status, race, Spanish/Hispanic origin).

VI.14

Provide an estimate of the total number of subjects that would be eligible for inclusion in each of your study populations (include your control population if applicable)

4,500 newly diagnosed patients across all 9 medical centers; 220 newly diagnosed patients at UIHC

VI.15 *Describe how you will have access to each of your study populations in sufficient number to meet your recruitment goals.*

Tumor registry data will be used for case ascertainment. Although tumor registry data will not be imported into i2b2 until a case is complete, cases diagnosed by 5/1/2014 should have a high rate of completion by the end of 2014. We will request a pre-consent partial HIPAA waiver for the University of Minnesota which is the only site that does not have an IRB-approved i2b2 warehouse. Annually, there are approximately 4,500 newly diagnosed cases of breast cancer in the 9 GPC medical centers that serve adult patients. There are approximately 220 new diagnoses of breast cancer per year at UIHC. Assuming a 50% response rate, we will invite 2,000 patients to achieve completed questionnaires from 1,000 patients.

VI.16 *Do you plan to recruit/enroll non-English speaking people?*

No

VI.18 *Do you propose to enroll any of the following in this study as subjects?*

- *Employee of the PI or employee of a research team member*
- *Individual supervised by PI or supervised by member of research team*
- *Individual subordinate to the PI or subordinate to any member of the research team*
- *Student or trainee under the direction of the PI or under the direction of a member of the research team*

No

VI.20 *Will subjects provide any information about their relatives?*

Yes

VI.21 *Describe in detail how this information will be obtained. NOTE: The collection of identified data about family members makes the family member a subject in the study. This would require a consent process with the family member or a request for waiver of consent to collect these data. See the Research Guide for more information.*

A single item on the study questionnaire. No identified data will be collected on family members.

VI.22 *List the data to be collected about subject relatives including the names of any surveys, questionnaires etc. to be used. Attach data collection tools under the Relative/Proxy Data Collection Instruments*

category.

One item on the study questionnaire asks about family history of breast cancer:

G1. Which of the following members of your family had been diagnosed with breast cancer at the time of your recent breast cancer diagnosis? Please include only family members who are related by blood.

Please mark ALL that apply

Mother

Sister

Daughter

Grandmother

Aunt

No family members had been diagnosed with breast cancer

VI.23 *Will anyone (other than the subject) provide you with information about the subject (e.g. proxy interviews)?*

No

VI.26 *Is this project about pregnant women?*

No

VI.27 *Will this project involve fetuses?*

No

VI.28 *Does this project involve adult subjects who may be incompetent or have limited decision-making capacity on initial enrollment into the study?*

No

VI.32 *Does this project involve subjects whose capacity to consent may change over the course of the study?*

No

VI.37 *Does this project involve prisoners as subjects?*

No

VII.A. Project Description (A)

VII.A.1 *Where will project procedures take place (check all that apply)?*

- Other UI campus site - S424 CPHB, 2126 WL

VII.A.2 *Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?*

Yes

VII.A.3 *What is the UI site's role(s) for this project (check all that apply)?*

- Clinical/participating site
- Coordinating Center

VII.A.4 *Provide specific and detailed information describing how the UI investigator will coordinate all aspects of the study, such as:*

- *Name, location, and IRB of record for each site,*
- *Verification of IRB approval and continuing review for all sites*
- *Managing variation in requirements from the IRBs or institutional policies of the different sites.*
- *Outline all activities that will occur at each participating site*

In their role as the Coordinating Center (CC) UI staff will: 1) coordinate IRB approvals, make modifications to protocol documents, and update sites with modifications to the protocol, 2) ensure each site is provided with approved study documents, 3) produce the study booklet and cover letter and distribute these to the sites, 4) train each site on what it should be doing according to the approved IRB protocol, 5) provide a link to the UI section of the Investigator's Guide describing the IRB policy on adverse event reporting, 6) review sites' mailing protocols, 7) maintain the study database, 8) manage unanticipated problems, and 9) prepare the final report. The UI is likely to be the lead IRB for all sites of sites: Marshfield Clinic, Medical College of Wisconsin, University of Kansas - Kansas City, University of Minnesota, University of Nebraska, University of Texas Southwestern, and University of Wisconsin.

Additionally, as a participating site, UI researchers will: 1) verify the mailing list provided by the UI honest broker, 2) mail study booklet and cover letter to UI patients, 3) maintain tracking database, and 3) conduct one re-mailing to non-respondents.

VII.A.5 *Describe in detail the procedures that will be used to identify and report unanticipated problems from participating sites to the lead institution.*

The study mailing will include a cover letter on letterhead of the participating site signed by the lead investigator at the site and including his/her contact information for questions. An online reporting interface will be provided to the sites for reporting problems (see attached screenshots for this online tracking database). The KUMC study team has programmed the online tool and will train the participating study teams to use it. CC staff will respond to all problems within 2 business days. Sites will be required to communicate events to the CC within 5 business days and the CC will report them to the lead site PI upon notification. The lead site PI will determine whether the event is reportable and, if so, events will be communicated to the UI IRB within 5 additional business days. Reportable events include: unanticipated problems involving risks to subjects or others, noncompliance, and receipt of new information that would change the risk/benefit balance of participation. Adverse drug or device events, while reportable, are not applicable to this protocol.

VII.A.6 *Describe in detail the procedures that will be used to identify and report unanticipated problems from the lead institution to participating sites.*

The consent documents will include contact information for the Coordinating Center. The CC will contact the study manager at a site within 5 business days of learning about a problem from or about a participant. The CC will also communicate as needed with the study manager at a site for unanticipated technical problems with data transfer. Site study managers will notify the lead site researcher about a problem within 2 business days.

VII.A.7 *Describe in detail the procedures that will be used to communicate protocol modifications from the lead institution to the participating sites.*

Only the lead site is authorized to make modifications to the protocol documents. The CC will inform the lead researcher and study manager at each participating site about any protocol changes and provide approved documents to the study project managers.

VII.A.8 *Describe in detail the procedures that will be used to communicate interim results from the lead institution to the participating sites.*

No interim results for this one-time cross-sectional survey study

VII.A.9 *Describe in detail the procedures that will be used to communicate other new information which may impact a subject's willingness to participate, or continue participating from the lead institution to the participating sites.*

The study PI will contact the lead site researcher and will communicate any new or revised procedures, if applicable, within 5 business days of learning new information, such as a breach of confidentiality, that may impact a subject's willingness to participate.

VII.A.10 *What are collaborating site roles for this project?*

- Clinical/participating site - 8

VII.B. Project Description (B)

VII.B.1 *Does this project involve any of the following:*

- *clinical intervention*
- *pharmacologic intervention*
- *therapeutic intervention*
- *physiology studies (e.g. studying the functions of organs, tissues, or cells)*

No

VII.B.11 *Is there a separate, written protocol that will be submitted in addition to this IRB New Project form? (Note: a grant application is not considered to be a protocol)*

No

VII.B.18 *Does this project involve testing the safety and/or efficacy of a medical device?*

No

VII.C. Project Description (C)

VII.C.1 *Does this project involve any research on genes or genetic testing/research?*

No

VII.D. Project Description (D)

VII.D.1 *Check all materials/methods that will be used in recruiting subjects (you will need to attach copies of all materials at the end of the application):*

- Letter -
- Use of any information available to the researchers or their colleagues because this person is a patient OR use of any information considered to be Protected Health Information (PHI) OR review of patient/clinic records - Data to identify eligible patients for the survey for all sites except UMN will be from the i2b2 warehouse which draws data from the electronic health record and the hospital tumor registry and de-identifies it. Because UMN instead will extract this information directly from the EMR, a partial HIPAA waiver has been requested for UMN.
- Existing Registry/database - Each GPC center maintains a warehouse of data from its EHR and hospital tumor registry. This will be the way patients with breast cancer are identified for recruitment. Please see the attached SOP for breast cancer cohort study data request, transfer and storage.

VII.D.2 *List the individual data elements you will need to access/use from the patient or clinic records to identify potential subjects for recruitment*

Patient sex; date of birth; breast cancer diagnosis including stage, histology, diagnosis date, tumor sequence number, and method of diagnostic confirmation; vital status, Spanish/Hispanic origin and language

VII.D.3 *Describe why you could not practicably recruit subjects without access to and use of the information described above*

This study is about breast cancer. Patients will receive a questionnaire about recent breast cancer diagnoses if they do not have metastatic cancer, this is their first breast cancer, they are female, English-speaking, and not known to be deceased. It is especially important to exclude people who have not had a recent breast cancer. This cannot be

done without access to medical data.

VII.D.4 *Describe why you could not practicably obtain authorization from potential subjects to review their patient or clinic records for recruitment purposes.*

It is not possible to know who to approach to obtain authorization without first knowing that they have breast cancer and other aspects about their eligibility. It would be impracticable to approach people who present to clinic and ask if their medical record could be reviewed to determine whether they are eligible to participate in the research because potential subjects are being ascertained 12 to 30 months after their diagnosis.

VII.D.5 *Describe plans to protect the identifiers from improper use or disclosure*

Please see the attached SOP for data request, transfer and storage. Honest Brokers as each site will create and retain a password protected electronic file containing MRN, study ID number and the necessary data elements for selecting eligible patients. The lead investigator at each site will verify the accuracy of the list prior to recruitment. Honest Brokers will assist in supplying a mailing list file to the lead investigator at the site containing:

- a. Patient first and last name
- b. Address, city, state, zip
- c. study ID number

Identifiers will be kept on a password protected folder. Only the site lead investigator or their delegated project manager will have access to this folder.

VII.D.6 *Describe plans to destroy identifiers at the earliest opportunity consistent with conduct of the research*

Identifiers for eligible patients will be retained until the end of the recruitment period (September 30, 2015). At that time, identifiers will be destroyed for patients who have not enrolled.

VII.D.7 *Does the research team agree that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the study, or for other research for which the use or disclosure of the requested information would be permitted by the HIPAA Privacy Rule*

Yes

- VII.D.8** *Will a member of the research team discuss the study with the subject in person prior to the subject agreeing to participate?*
No
- VII.D.10** *Will a member of the research team discuss the study with the subject by phone prior to the subject agreeing to participate?*
No
- VII.D.15** *Check all materials that will be used to obtain/document informed consent:*
- Consent Document
 - Letter or Information sheet containing elements of consent
- VII.D.16** *Are you requesting a waiver of documentation of consent (either no subject signature or no written document)?*
No
- VII.D.19** *Before the subject gives consent to participate are there any screening questions that you need to directly ask the potential subject to determine eligibility for the study?*
No
- VII.D.25** *After the subject agrees to participate (signs consent), are there any screening procedures, tests, or studies that need to be done to determine if the subject is eligible to continue participating?*
No
- VII.D.27** *Discuss how much time a potential subject will have to agree to consider participation and whether or not they will be able to discuss the study with family/friends before deciding on participation.*
Until the closure of the recruitment/enrollment period. Subjects may discuss the study with anyone they would like before participating.
- VII.D.28** *How long after the subject agrees to participate do study procedures begin?*
Immediately through completion of a one-time questionnaire
- VII.D.29** *Provide a description of the enrollment and consent process for adult subjects*
- Describe each study population separately including control

population

- ***Include when recruitment and consent materials are used***
- ***Use 3rd person active voice “The Principal Investigator will identify subjects. For example, the principal investigator will identify potential subjects, the study coordinator will discuss the study with subjects over the telephone and schedule the first study visit, etc...”***
- ***Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process***

1. The Honest Broker at each participating site will query its Research Repository for all breast cancers diagnosed during the study date range. The dataset will be submitted to the GPC Honest Broker for quality checking and, after survey eligibility criteria have been applied, the GPC Honest Broker will select a random sample of survey eligible people and return the corresponding de-identified patient numbers to the participating site Honest Brokers. The participating Honest Brokers will add a study ID number to each individual on their list, match this list to actual medical record number so that survey responses can later be linked to medical record data for consenting respondents, and create a mailing list that includes name, address, and study ID number.
2. To account for an anticipated 50% response rate, a total of 2,000 potential subjects will be selected. Each site will maintain a file that will include name, address, and study ID number.
3. Sites will send out a packet of information to potential subjects inviting them to enroll in the study. The packet will include, (a) a signed cover letter from the participating site on site appropriate letterhead, (b) the study questionnaire which will include an information sheet containing elements of consent on the inside front cover; (c) a consent document for obtaining medical record data at the end of the study booklet; (d) a copy of the consent document to retain for their records; (e) \$10 cash or gift card and f) a business reply envelope in which to return the study booklet.
4. The address on the business reply envelope will be the CC address.
5. Return of a questionnaire will indicate a willingness to participate in that portion of the study.
6. Return of the consent documents will be required for potential subject to be included in the i2b2 medical information part of the study. Subjects who return a signed and dated consent form but do not return a completed survey will be sent a replacement survey.
7. Return of blank questionnaire will indicate a potential subject has declined to participate.
8. If a subject does not respond at all to the first mailing, one repeat mailing of the invitation packet will occur.

Please see the attached SOP for breast cancer cohort study data request, transfer and storage.

Please see the attached Major Project Management Tasks and Timeline table.

VII.D.37 *Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?*

Examples:

- *Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.*
- *Participants will be provided with false information regarding the particular behaviors of interest in the research.*
- *Procedures include a confederate pretending to be another participant in the study.*
- *Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.*
- *Study is designed to introduce a new procedure (or task) that participants are not initially told about.*
- *If yes, a waiver of informed consent must be requested under question IV.3.*

No

VII.E. Project Description (E)

VII.E.1 *Will subjects be randomized?*

No

VII.E.3 *Will any questionnaires, surveys, or written assessments be used to obtain data directly from subjects in this study?*

Yes

VII.E.4 *List all questionnaires, surveys, written assessments and ATTACH each one to the application. (NOTE: You are NOT prohibited from attaching copyrighted materials to this application)*

Share Thoughts on Breast Cancer Study Questionnaire

VII.E.5 *Does this project involve creating any audiotapes, videotapes, or photographs?*

No

VII.E.6 *Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.*

Describe study populations separately if they will be participating in different procedures - include CONTROL population if applicable.

DESCRIBE:

- *What subjects will be asked to do/what happens in the study (in sequential order)*
- *The time period over which procedures will occur*
- *The time commitment for the subject for individual visits/procedures*
- *Long-term followup and how it occurs*

1) Prospective subjects will be asked to complete a mailed questionnaire. The questionnaire should take about 30 minutes to complete. The questionnaire includes the following standardized questions and scales:

- * Patient-reported outcomes (FACT-B, Quick DASH, neuropathy, heart failure, shoulder diagnoses, fear of recurrence BMI change)
- * Treatments and interventions received including genetic testing, survivorship care plan elements and breast reconstruction
- * Factors considered when making surgery, chemo decisions
- * Shared decision-making question for each treatment type
- * Preferred decision-making role
- * Patient experiences of care (Care coordination and physician communication)
- * Recalled decisional uncertainty and decision support, perceived decision effectiveness
- * Interest in research participation

2) They will also be asked to sign and return the consent document.

3) Both items will be included in one study booklet. The study booklet may be returned in a pre-paid envelope provided. The reply envelope will be addressed to the UI Coordinating Center.

4) The UI Coordinating Center project manager will optically scan the paper questionnaires and may telephone a participant if markings are not legible or ambiguous using contact information provided in the questionnaire by the

participant. The CC project manager will detach the consent forms and contact information from the study booklet and store the paper and an electronic copy of each separately from the paper questionnaire pages.

4a) If a participant included one or more pieces of information (i.e., date, printed, name, signature) on the medical record or future study consent documents - but not all 3 pieces of information, AND the participant did not provide their contact information in the booklet, the CC will contact the participating site and request that they contact the participant using the contact information in their mailing list for the associated participant study ID. The CC will provide materials for the sites to use in contacting the participant on a case by case basis. The same process will be implemented in the event that a booklet is received with 1 or more blank booklet pages when other pages were completed and there is no indication that the participant did not intend to complete the blank pages. This is because pages may have been stuck together and inadvertently left blank by the participant. Up to 3 call attempts will be made to contact the subject.

5) The tracking database will be regularly updated with status of the questionnaire and consent.

6) A file containing study ID numbers for consenting individuals will be supplied to the participating sites.

7) Participating sites will generate i2b2 study variables from the electronic medical record for all consented subjects. Information that will be obtained from the medical record to create study variables includes:

- Information about breast cancer diagnosis such as type of breast cancer
- Details of cancer treatments including surgery, radiation, chemotherapy, hormone therapy, and diagnostic tests
- Information about any breast reconstruction procedures
- Information about past medical history such as other health conditions that can affect peoples' experience with cancer care
- Laboratory tests and vital signs

8) Please see the attached SOP for breast cancer cohort study data request, transfer and storage.

9) Please see the attached Major Project Management Tasks and Timeline table.

10) There is no long-term follow-up planned at this time.

VII.E.7 *Will you attempt to recontact subjects who are lost to follow-up?*

No - followup is not required in this study

VII.E.9 *Will subjects be provided any compensation for participating in this study?*

Yes

VII.E.10 *Cash*

No

VII.E.11 *Gift Card*

Yes

VII.E.12 *Check*

No

VII.E.16 *Other*

No

VII.E.18 *If you plan to compensate subjects using cash, checks or cash equivalent does your unit have a [Cash Handling Procedure](#) in place that has been approved by Accounting Services?*

Yes

VII.E.19 *Describe the compensation plan including*

- *Compensation amount and type per visit*
- *Total compensation*
- *Pro-rating for early withdrawal from study*

Patients will receive the study incentive by mail. \$10 in cash or gift card will be included in the mailing with the study booklet. Each site will purchase the cash/gift cards for their study sample. Potential subjects may keep this whether or not they decide to participate.

VIII. Risks**VIII.1** *What are the risks to subjects including*

- *emotional or psychological*
- *financial*
- *legal or social*
- *physical?*

Potential risks include discomfort from being asked questions about their health condition and loss of confidentiality

VIII.2 *What have you done to minimize the risks?*

- ***If applicable to this study ALSO include:***
 - ***How you (members of your research team at Iowa) will monitor the safety of individual subjects.***
 - ***Include a description of the availability of medical or psychological resources that subjects might require as a consequence of participating in this research and how referral will occur if necessary (e.g. availability of emergency medical care, psychological counseling, etc.)***

If staff become aware of a subject that might need medical or psychological counseling, the lead researcher at the site will be contacted immediately. The sites will provide an institution-specific resource list to provide to a subject in the event one may be identified needing counseling information from their location. Data will be stored using study-assigned ID number instead of names on a password protected computer to which only members of the research team have access.

IX. Benefits

IX.1 ***What are the direct benefits to the subject (do not include compensation or hypothesized results)?***

No direct benefits

IX.2 ***What are the potential benefits to society in terms of knowledge to be gained as a result of this project?***

The study will generate new information about breast cancer care and how that relates to how patients feel and function after treatment is over.

X. Privacy & Confidentiality

X.1 ***What are you doing to protect the privacy interests of the subjects?***

We are collecting the minimum information necessary to meet the aims of this study. Patients will review the study material in the privacy of their own homes. We will not attempt follow up with patients who return the blank questionnaire in the pre-paid envelope to indicate refusal to participate in the study. Please see the attached SOP for breast cancer cohort study data request, transfer and storage.

X.2 ***Are you collecting the Social Security Number of any subjects for any purpose?***

No

X.4 *How will information/data be collected and stored for this study (check all that apply):*

- Paper/hard copy records (hard copy surveys, questionnaires, case report forms, pictures, etc.) - Paper questionnaires will be optically scanned upon receipt. Original paper questionnaires will be stored in locked file cabinets in the locked data security office of the Health Effectiveness Research Center in the Westlawn building. Consent forms will contain the study id and will be stored in a separate locked file cabinet and office from the questionnaires.
- Electronic records (computer files, electronic databases, etc.) - The electronic survey database, the scanned questionnaires, and electronic copies of the consent documents will be stored in password-protected folders on the password-protected study database server which will reside in the UI College of Public Health server cluster. Access to the server is password protected. At the end of the study the research team will be able to access the complete study database for analysis. This complete dataset will include questionnaire data variables and variables from the electronic medical record for consented patients. Work Plan 4 in the attached "SOP for breast cancer cohort study data" describes this process. Briefly, the Breast Cancer Cohort Study project manager will provide the study ID numbers to the GPC Honest Broker who will aggregate the survey and medical record variables for consented subjects into the final study dataset. This dataset will be hosted on the GPC Hosted services. Only research team members will have access to this dataset. With respect to storage of de-identified survey data at the participating site for future use: At the end of the study the Breast Cancer Cohort Study project manager will submit each participating site's survey dataset for subjects who consent to future use to the GPC Honest Broker. This will be a limited dataset containing only those subjects who have signed consent for future use. It will not contain name, address, email address, or names and addresses of service providers. It will contain dates. It will also contain study ID number. If a participating site wishes to add the survey dataset to their i2b2 Research Repository for future use they may download their site's consented subjects survey dataset for transformation, deidentification, and loading to the site's i2b2 repository. Please see Work Plan 3 regarding future use in the attached final "SOP for breast cancer cohort study data"
 - Name - Timothy Shie
 - Title - IT Director/Public Health Admin
 - University/VA Job Classification - Info Tech Management IV

X.5 *Do the confidentiality protections indicated above allow only members of the research team to access the data/specimens?*

No

X.6 *Describe*

Non-research team members may access de-identified survey data stored at the participating site for subjects who consent to future use. If a participating site wishes to add the survey dataset to their i2b2 Research Repository for future use they may download their site's consented subjects survey dataset for transformation, deidentification, and loading to the site's i2b2 repository. Please see Work Plan 3 in the attached "SOP for breast cancer cohort study data"

XI. Data Analysis

XI.1 *Describe the analysis methods you will use, including, if applicable, the variables you will analyze*

The focus of the analysis is on estimating 1) the prevalence of characteristics; 2) the correlation of i2b2-derived measures based on diagnosis and procedure codes with self-reported measures and tumor registry measures; and 3) describing patient experiences and characteristics not captured by the i2b2 warehouse. We will tabulate prevalence and 95% confidence intervals, the positive predictive value of the i2b2 definitions vs. self-reported measures and tumor registry measures, and present frequency distributions of individual items and summary statistics (mean, median, standard deviation, Cronbach's alpha) for all scores in the questionnaire. We will describe the i2b2 and survey variables by demographic and tumor characteristics obtained from i2b2. We plan to conduct analyses to support the following paper topics:

- * The role of patient preferences and shared decision-making in management decisions associated with high inter-institutional variability
- * Patient experiences of care and decisional conflict
- * What do patients know about their breast reconstruction options?
- * Which patients receive autologous fat grafting?
- * Prevalence and correlates of long-term effects including upper limb morbidity, neuropathy, heart failure, fatigue
- * Outcomes of bilateral mastectomy
- * Prevalence and correlates of gene testing

XI.2

Provide the rationale or power analysis to support the number of subjects proposed to complete this study.

A good case example for evaluating power and the rationale for our sample size is one of the data elements we are interested in - autologous fat grafting (AFG). The prevalence of the procedure is unknown, though suspected to occur very often among women who have reconstruction after breast cancer. The validity of diagnosis codes and procedure codes in electronic data for identifying this procedure is unknown.

Questionnaire data are required to estimate prevalence of AFG and frequency of out-of-system reconstruction and out-of-system AFG, and to evaluate the sensitivity and positive predictive value of the codes in i2b2.

- If 10% of 1,000 survey respondents have AFG, the 95% confidence interval would be $\pm 1.83\%$
- If 20% of an estimated 240 reconstruction patients have out-of-system reconstruction, the prevalence $\pm 95\%$ confidence interval for out-of-system reconstruction would be $20\% \pm 5.06\%$
- If 20% of an estimated 100 AFG recipients have out-of-system AFG procedures, the prevalence of out-of-system AFG (among AFG recipients) would be $20\% \pm 7.84\%$
- If i2b2 data indicate 100 questionnaire respondents had an AFG and only 90 of them self-report, the positive predictive value of the i2b2 algorithm is estimated with a precision of $\pm 5.88\%$
- If the questionnaire indicates that 110 questionnaire respondents had an AFG and only 90 of them have an indication of AFG in the medical record, the sensitivity of the medical record definition is estimated as $81.8\% \pm 7.21\%$

For analyses involving only the de-identified i2b2 cohort, power to estimate prevalence of procedures and events, correspondence with tumor registry data, and sensitivity and positive predictive values of EHR- derived variables compared with tumor registry variables will be considerably higher due to the larger sample size of the underlying cohort (~4,500 patients).

XII. Future Research

XII.1

Do you wish to keep any information about subjects involved with this research project so that members of the current research team may contact them in the future for your own research projects?

Yes

XII.2 *Do you wish to keep any information about subjects involved with this research project so that other researchers may contact them for future research?*

No

XII.3 *List the data or information you will keep:*

XII.3 pertains to contact information and the use of this contact information in the recruitment process for future studies.

As participating site we will keep name, address, phone number, e-mail for UI patients.

As Coordinating Center we will keep the name, address, phone number, e-mail if subjects provide it.

The study tracking database does not contain name, address, contact information thus as Coordinating Center we will only have access to this information for all UI study subjects and for survey respondents from other sites who provide this information when they complete these optional items at the end of the survey.

XII.4 *Does this project involve storing any data, tissues or specimens for future research?*

Yes – contribution for future use is optional

XII.5 *Describe how you will keep track of those who consent to future use and those who do not and how you will prevent future use for those who do not consent.*

The survey data will be provided to the sites only if the subject has consented to future use. Otherwise, if the subject has provided signed consent only for this study, the survey data will remain in the study database and only the study ID will be provided to the sites to obtain medical record data. The tracking database is updated whenever a change in subject status takes place. Included in the tracking database is an indicator for whether the subject has provided signed informed consent for use of their medical record data for the study and separate indicators for whether the subject has agreed to future use. Screenshots (attached) of the tracking database show how consent to future use is tracked.

XIII. Other Mod and/or Comments

XIII.1 *Most modifications should be made in the appropriate section (see Index) of the project itself. If you need to describe other changes, or wish to add comments about something you changed, please do so here.*





We added a template for sites to mail a letter to participants to inquire about incomplete or ambiguous responses. Similarly, we modified the approved letters for contacting participants about missing medical record or future studies information to allow all sites to use them as needed.

We also revised the approved phone script to allow for contacting participants about missing or ambiguous questionnaire responses (in addition to missing consent information which was previously approved).

These changes are described in VII.E.6

Project Modification Attachments

Attachment Name	Category	Ver	Size	Attached
Consent letter 14 May 2015.rtf	Consent & Assent Forms	7	52 k E	05/15/15
Informed consent 14 May 2015.rtf	Consent & Assent Forms	12	187 k E	05/15/15
GPC-PCORI-CDRN-Phase I grant.pdf	Funding Source Grant	1	2 M E	03/05/15
GPC Breast Survey Cover letter 18 May 2015.docx	Recruitment Script: Mail	13	31 k E	05/19/15
GPC Breast Survey Secondary Cover letter changes tracked from Primary Cover Letter.docx	Recruitment Script: Mail	2	31 k E	06/16/15
Relatives.docx	Relative/Proxy Data Collection Instruments	1	14 k E	08/27/14
GPC Breast Cancer Survey Booklet - SAMPLE - 2015-06-05.pdf	Subject Data Collection Instruments	9	806 k E	06/05/15
Breast Cancer Cohort Survey - Site Preparation Questionnaire #1 (3).docx	Miscellaneous	1	24 k E	01/23/15
Breast Cancer Cohort Survey - Survey Implementation Guide 11 March 2015.docx	Miscellaneous	3	20 k E	05/11/15

Cover Sheet Accompanying Participant Copy of the Informed Consent Document 14 May 2015.docx	Miscellaneous	1	21 k E	05/14/15
 This is a one page sheet that will accompany the copy of the informed consent document that is inserted into the booklet.				
GPC Missing Consent Letter 17JUL2015.docx	Miscellaneous	3	26 k E	07/22/15
GPC Missing Future Studies Consent Letter_17JUL2015.docx	Miscellaneous	3	26 k E	07/22/15
GPC Missing Questionnaire Responses 17JUL2015.docx	Miscellaneous	1	26 k E	07/17/15
Major Project Management Tasks and Timeline for the Breast Cancer Cohort Study 23 Dec 2014.docx	Miscellaneous	1	26 k E	12/23/14
Noncompliance on GPC Breast Cancer study discussion with U of MN IRB.pdf	Miscellaneous	1	13 k E	05/01/15
SOP for breast cancer cohort study data 17 July 2015.docx	Miscellaneous	5	27 k E	07/17/15
Telephone Script for Missing Consent Missing Future Studies Missing Questionnaire 17JUL2015.docx	Miscellaneous	3	17 k E	07/22/15
Tracking Database Screenshots.docx	Miscellaneous	2	1 ME	03/11/15
 This replaces the earlier "Reportable Events Form" and includes the mechanism for all communication and tracking for the project				
URL for sharing study documents among the study team at participating sites.docx	Miscellaneous	1	86 k E	06/26/15
 This is the URL at which all approved study documents are readily accessible to the study teams.				
Updated Breast Cancer Cohort Study Teams and POC 26 June 2015.pdf	Miscellaneous	5	151 k E	06/26/15
Assurance document.pdf	Assurance Document	1	57 k E	01/22/15
Cash Handling Email.pdf	Cash Handling Approval	1	125 k E	01/15/15
 Email chain including approval for Cash Handling Policy.				