SC CENTRAL CANCER REGISTRY CASE ASCERTAINMENT/RECRUITMENT PROTOCOL

South Carolina Central Cancer Registry
Office of Public Health Statistics and Information Services
Department of Health and Environmental Control
2600 Bull St.
Columbia, SC 29201

Susan Bolick, MSPH, CTR
SCCCR Director

January 2013

Approval Process Summary

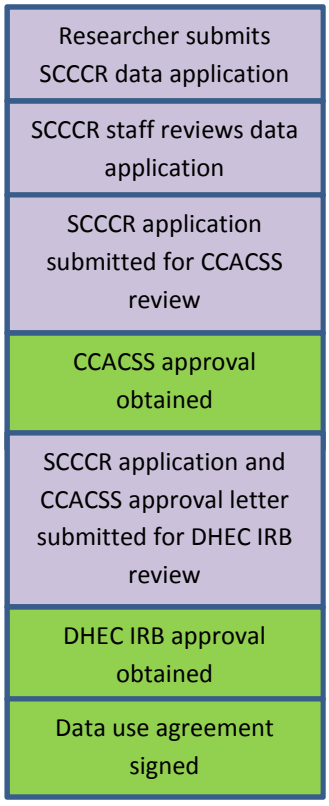
Federal regulations require that all research studies involving human subjects and materials of human origin be reviewed and approved by an Institutional Review Board (IRB) before initiation. In compliance with this federal regulation, study investigators requesting patient identifiable data from the SC Central Cancer Registry (SCCCR) must submit an SCCCR data application and applicable supporting documentation (i.e. study protocol and methodology, sample patient contact forms, sample consent forms, home institution IRB, CVs/biosketches of researchers, proof of human subjects research training, etc.) to the Department of Health and Environmental Control (DHEC) Cancer Control Advisory Committee Surveillance Subcommittee (CCACSS) and the DHEC IRB.

CCACSS and DHEC IRB approval are not obtained concurrently (see Figure 1. SCCCR Approval Diagram). Once a SCCCR data application is submitted, it is reviewed by registry staff and prepared for CCACSS review. Once CCACSS approval is obtained, the SCCCR application, with applicable supporting documentation and CCACSS approval letter are submitted to the DHEC IRB for review.

In addition to obtaining approval from CCACSS and DHEC IRB, a data use agreement (see Attachment 1) must be signed by study investigator(s) and all study personnel who will have access to information that identifies individual cancer patients.

Approvals from the CCACSS and DHEC IRB must be obtained and a data use agreement signed before cancer registry data are prepared and released. Please note that each request for use of patient identifiable data will be processed in a timely fashion. However, applications are placed in a queue for review. If additional work needs to be done to prepare the initial application for presentation to the CCACSS, this could affect the timeliness of review.

Figure 1. SCCCR Summary Approval Diagram.



SCCCR PATIENT CONTACT PROCESS FOR STUDIES REQUIRING CASE ASCERTAINMENT/RECRUITMENT

SCCCR PATIENT CONTACT PROCESS FOR STUDIES REQUIRING CASE ASCERTAINMENT/RECRUITMENT

Case Ascertainment/Recruitment are defined as requests for the use of the SCCCR database for the purpose of patient recruitment for a study (i.e., utilize the SCCCR database to identify cancer patients that may qualify or meet the study's selection criteria for inclusion).

Rapid Case Ascertainment may be required depending on the study aims. Rapid case ascertainment is defined as identification of patients immediately after diagnosis and reported to the SCCCR at that time for a specific study. If required, the SCCCR works with the individual cancer registrars at the reporting facilities to identify patients within a short time period after diagnosis through pathology confirmation. The SCCCR is alerted as patients are identified and information is sent to the SCCCR to confirm eligibility for the study and initiation of the contact process.

SCCCR policy is to perform initial physician and patient consent prior to the release of patient information for investigator contact. A Graduate Assistant, funded through the study and housed within the cancer registry, may be utilized to perform these functions.

I. PATIENT CONTACT PROCESS

For studies that utilize SCCCR for patient recruitment (see Attachment 2) and, subsequently, patient contact:
Please be advised that the SCCCR will not extract data on those patients with whom we have a death certificate or those who were reported strictly by the VA hospitals or another state.

A. **PULL ELIGIBLE CASES TO CREATE STUDY RECRUITMENT FILE:** SC Central Cancer Registry (SCCCR) staff pulls desired data items for study sample (i.e., African American women with primary invasive breast cancer and no other primary diagnosis of cancer, ages 25-75) from SCCCR database to create Study Recruitment File.

B. **MATCH DATA TO SC DEATH FILE:** SCCCR staff matches Study Recruitment File to SC Vital Records Mortality File to obtain death information. Name, SSN, DOB, race, and sex are utilized for the match.

C. **MATCH DATA TO PHYSICIAN FILE:** SCCCR staff matches Study Recruitment File to physician file to obtain physician name and contact information. NPI number and medical license numbers recorded for each patient are utilized for the match.

D. **SEND PHYSICIAN LETTER:** SCCCR staff/graduate assistant sends Study-approved Physician Letter to physician of record for each patient to inform him/her that he/she has a patient who is eligible for the study and requests a response if he/she knows of any contraindications as to why the patient should not be contacted. Physician Letters are sent out on a weekly basis in batches (20 patients per week).

D1. PHYSICIAN LETTER RETURNED: Updated physician information is requested from the data source (where the case information originated) for more accurate physician contact information.

D2. PHYSICIAN DOES NOT WANT PATIENT CONTACTED: If the physician contacts the SCCCR stating he/she does not want the patient contacted, the patient contact process ends. The patient is given a code indicating the physician does not want patient contacted (including any contraindications indicated) and these codes are recorded in the tracking database. Researchers receive only case information for the patient (no contact information).

D3. PHYSICIAN STATES PATIENT IS DECEASED: If the physician contacts the SCCCR stating the patient is deceased, the patient contact process ends. Patient is recorded as deceased and researchers receive only case information for patient (no contact information). If study requires next of kin contact (NOK), that information is requested from data source (if they are willing to provide it).

E. SEND PATIENT LETTERS: Two weeks from the date that the Physician Letter was mailed, a Patient Letter is mailed for patients who are living and for those whose physician provided no contraindication for contacting. This assumes passive consent from the physician.

E1. PATIENT LETTER RETURNED: Updated patient contact information is requested from data source where information originated. If a current address cannot be found or a Patient Letter is returned a second time, patient is coded as "unable to obtain accurate contact information". Only case information for these patients will be sent to researchers (no contact information).

E2. PATIENT CONTACTS SCCCR TO OPT OUT: Patient calls to say he/she does not want to be contacted by the researcher. The patient is coded "OPT OUT". Only case information for these patients will be sent to researchers (no contact information).

E3. PATIENT CONTACTS SCCCR TO OPT IN: Patient states he/she wants to be contacted by the researcher. Patient is coded "OPT IN". Contact Information is verified with patient and preferred call time for researchers to contact him/her is recorded. Case and contact information for these patients are provided to researchers.

E4. PATIENT LETTER RETURNED STATING PATIENT DECEASED: The patient contact process will end here if patient is deceased. Patient is coded as "Deceased". Researchers receive only case information for patient (no contact information). If study requires next of kin contact (NOK), that information is requested from data source (if they are willing to provide it).

F. CONTACT PATIENT: One week from the date that the patient letter is sent, patients who were successfully sent a patient letter, and did not contact the SCCCR to OPT IN/OUT, are contacted via phone to obtain permission to be contacted by research staff.

F1. INCORRECT/DISCONNECTED NUMBER: Updated telephone number is requested from the data source where patient information originated. If a current phone number cannot be found, patient is coded as "unable to obtain accurate contact information". Only case information for these patients will be sent to researchers (no contact information).

F2. PATIENT OPT OUT: Patient does not agree for contact information to be provided to the researcher. Patient is coded "OPT OUT". Only case information for these patients will be sent to researchers (no contact information).

F3. PATIENT OPT IN: Patient agrees for contact information to be provided to researcher. Patient is coded "OPT IN". Contact Information is verified with patient and preferred call time for researchers to contact them is recorded. Case and contact information for these patients are provided to researchers.

F4. PASSIVE REFUSAL: After 15 attempts to contact patient via phone, spanning different times of the day and days of the week, the patient will be coded "PASSIVE REFUSAL". Only case information for these patients will be sent to researchers (no contact information).

F5. PATIENT FOUND TO BE DECEASED: If call is made and patient has recently expired, the patient contact process will end here. Patient is coded "Deceased" and researchers receive only case information for patient (no contact information). If study requires next of kin contact (NOK), that information is requested from data source (if they are willing to provide it).

EXPORT DATA: An EXCEL file (or preferred file format) of patients who have completed the contact process is provided to the research team on a weekly basis. Researchers may indicate shorter or longer export time interval.

If a patient is found to be deceased at any time throughout the contact process, the patient is coded "Deceased" in the tracking database and only the patients' case information will be sent to researchers (no contact information).

II. CONTACT LETTERS AND TELEPHONE SCRIPT

A *Sample Physician Letter* (Attachment 3), *Patient Contact Letter* (Attachment 4), and *SCCCR Telephone Script* (Attachment 5) are provided for the study investigator's reference. In addition to the study investigator's description of the study, the physician and patient contact letter must include:

- Language furnished by the SCCCR regarding State cancer reporting
- Assurance of voluntary nature of participation

- Assurance that participation or non-participation will not affect medical care

III. Investigators must remember:

- Patients can always refuse to participate, even after having agreed to participate.
- Study investigator should avoid disclosing that the patient is being contacted for a study specific to cancer on the cover of mailings.
- Efforts to recruit a patient should stop immediately when the patient clearly indicates he or she does not wish to participate.
- During the patient recruitment phase of the study, problems may arise with individual patients. Any patient who appears to be upset when contacted about consenting to be contacted by researcher for any study will be removed from researchers' list of eligible cases.
- **Any patient who states that he/she does not wish to be contacted again must be reported promptly to the SCCCR**; this fact will be recorded in the SCCCR databases. That person will not be re-contacted for any study.
- Patient Contact Information (name, address, phone number) will be provided to the researcher only on patients actively consenting to be contacted.

ATTACHMENT 1. SCCCR DATA USE AGREEMENT

Department of Health and Environmental Control
Public Health Statistics and Information Services (PHSIS)
South Carolina Central Cancer Registry

Data Use Agreement

Project Title:

The right to privacy is a basic right of every South Carolinian and the confidentiality of the patient is of utmost concern to the Department of Health and Environmental Control (DHEC) and South Carolina Central Cancer Registry (SCCCR). The release of data, in raw or aggregate form, that can be reasonably expected to reveal the identity of an individual patient will be made only when strict established protocols are approved and the researcher consents to the confidentiality requirements.

The Cancer Control Advisory Committee Surveillance Subcommittee (CCACSS), SCCCR and DHEC IRB have approved the release of restricted/confidential and unrestricted data items, to you the Researcher, for the purposes of the project entitled above. Please refer to your CCACSS approval letter and the attached final approved variable list: *(name of approved variable list here).*

The SCCCR has classified the release of data collected under Section 44-35-30, SC Code of Laws, 1996. This classification scheme aims to promote the use of accurate cancer data, provide equal treatment of data requesters and data providers, expedite the release and process, and encourage the release of the broad spectrum of data elements without compromising confidentiality.

In order for the South Carolina Central Cancer Registry to provide you, the Researcher, a file including the above restricted/confidential and unrestricted data elements, you, the Researcher must agree to the following terms of this agreement.

1. I will not allow others nor will I myself use the data elements for purposes other than the study protocol and the purposes specified in the SCCCR's Research Data Request application and any limitations described in my CCACSS Approval Letter. Use of confidential data elements for a research project other than the one described in the SCCCR application will not be undertaken until a separate application form for that project has been submitted and approved under the procedures established in the DHEC SCCCR Data Release Protocol.
2. I will not allow others to nor will I myself release, furnish, disclose, publish or otherwise disseminate these data in any manner other than those approved and specified in this application.
3. I will not allow others to nor will I myself use these data to attempt to learn the identity of any person whose data is contained in the file, nor release the

identity or any information which may disclose the identity of any patient without prior legal authority.

4. I will not allow others to nor will I myself use these data to identify any health care facility and/or professional without prior SCCCR approval.
5. I will not allow others to nor will I myself publish, disseminate, communicate or otherwise re-release health care facility and/or professional identifiable data without prior approval by the SCCCR and review and comment by the affected facilities.
6. I will not allow nor will I myself match these data set(s) to other patient level data sets by use of patient, health care facility and/or professional level characteristics without prior approval by the SCCCR.
7. I will not allow others nor will I myself release data in a report or disseminate data with a cell size of less than 5 without prior approval by the SCCCR.
8. I will remain as the sole holder of the data and ensure access to the data is limited to persons under my supervision and whose names are in the SCCCR's Research Data Request application. A new application will be submitted in the event of a proposed change of the lead entity for the project.
9. I will submit a final report of the data to the SCCCR.
10. All data released for this project by the SCCCR will either be returned to the SCCCR or destroyed upon completion of the project.

This data use agreement is by and between DHEC South Carolina Central Cancer Registry and *(the research institution listed here)* and its effective date is *(date listed here).*

The following individuals with *(the research institution listed here)* are authorized to use these data and agree to comply with the above statements. The data holder (PI) assumes all responsibility for any additional individuals not specifically listed on this agreement that will be accessing or using the data (e.g., graduate assistants, etc.). Failure to comply with the Confidentiality Contract may result in legal action as specified in Section 44-35-30 SC Code of Laws.

Name: _____

Signature

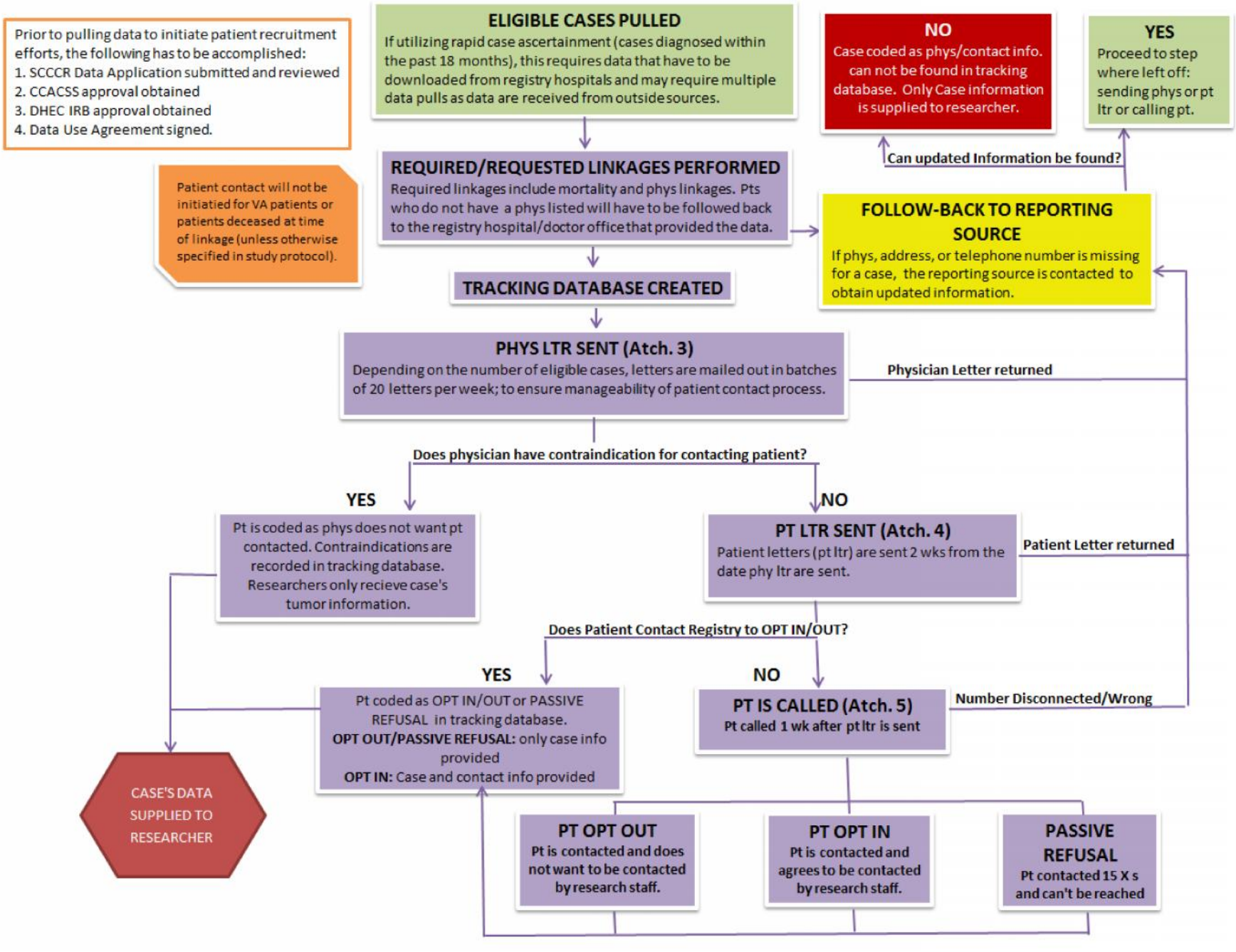
Name: _____

Signature

Name: _____

Signature

ATTACHMENT 2. PATIENT TRACKING FLOW



ATTACHMENT 3. SAMPLE PHYSICIAN LETTER

<Current date>

Dr. <first name> <last name>
< address line 1>
< address line 2>

Dear Dr. <last name>:

I am contacting you regarding the study entitled, "_____" which is currently funded by the _____. The study has been approved by the SC DHEC Institutional Review Board (IRB) and DHEC Cancer Control Advisory Committee Surveillance Subcommittee (the oversight committee for release of SC Central Cancer Registry (SCCCR) data used for research).

The purpose of this study is to identify _____ who are identified through the rapid case ascertainment system used by the SCCCR. All participants will complete a web-based or telephone questionnaire which assesses _____ risk factors. After completion of the questionnaire, participants will be mailed a kit and instructions for the collection of DNA from saliva. Participants will then mail the sample back using a pre-paid envelope. The study will be introduced to the patients as the "_____" study. All participant information and samples obtained will be kept strictly confidential.

Your patient**,** **_____,** is eligible for this study. Prior to patient contact by the registry, the SCCCR affords the opportunity for the patient's physician to provide any contraindication for contacting his/her patients for the research study. If there is any reason why this patient should not be contacted, please contact the Director of the SCCCR, Susan Bolick, within two weeks. You may contact the SCCCR by phone at 1-800-817-4774, or by e-mail, bolicks@dhec.sc.gov. Otherwise, the SCCCR will proceed by sending the patient a letter explaining that she is eligible for this study; what she can expect by participating in the study; and requesting her permission to be contacted by the researcher. This is an extra step the SCCCR takes to make sure the patient is willing to be contacted. If the patient does not respond to the letter, the SCCCR will call her to follow up on the letter and to ask permission to be contacted. If permission is granted, her contact information will be sent to the researcher who will contact her. If she does not give permission, no further contact is made.

No reference to the patient's former or current physician will be made in the letter. Finally, if this patient agrees to be contacted, in three weeks, research staff will contact this individual to seek participation.

Due to a large number of eligible cases, you may be contacted multiple times through staggered mailings. Thank you very much for your assistance.

Sincerely,

Susan Bolick, MSPH, CTR
Director, SC Central Cancer Registry

ATTACHMENT 4. SAMPLE PATIENT LETTER

<Current date>

Mr./Ms. <first name> <last name>
<patient address line 1>
<patient address line 2>

Dear Mr./Ms. <last name>

I am writing to let you know you may be eligible to take part in an important study, called the "_____." It is being conducted by Dr. _____, a researcher at _____.

The overall study goal is to find out whether _____. Hopefully, the information learned from this study can be used to help future generations _____.

You were identified through the South Carolina Central Cancer Registry (SCCCR) at the Department of Health and Environmental Control (DHEC) in Columbia, SC. This registry is used to examine where and how often cancers occur, and cancer survival rates. It also helps prevent cancer by assisting researchers to understand causes of cancer.

Staff from the SCCCR will be contacting you by telephone within the next week. At that time, we will briefly explain the "_____", and ask if you would like to learn more about it. If you agree, your contact information will be sent to the study staff at _____, and they will contact you to provide additional information and to ask if you would like to participate in the study.

If you agree to participate when you are called by study staff at _____, you will be asked to complete a short survey over the telephone. No sensitive questions will be asked. You will also be asked to _____. This information will be used for research only. It will not affect the clinical care that you receive, or your privacy.

Deciding to take part is up to you. Whether you participate or not will have no effect on your medical care. Taking part offers you an exciting chance to play an important role in the discovery of new information. This information could lead to improvements in breast cancer prevention and treatment. The attached Fact Sheet may answer your questions about genetic research, and why it is so important to take part in this study.

You may contact the SCCCR at any time if you have questions. You can do this by calling 1-800-817-4774, or e-mail me at bolicks@dhec.sc.gov. Thank you for your consideration.

Sincerely,

Susan Bolick, MSPH, CTR
Director, SC Central Cancer Registry

ATTACHMENT 5. SAMPLE SCCCR RECRUITMENT SCRIPT FOR INITIAL PATIENT PHONE CALL

Hello, may I please speak with Mr./Ms./Mrs. _____,

My name is _____ and I am calling from DHEC in Columbia with the South Carolina Central Cancer Registry. We sent you a letter about a week ago to tell you about a study of _____ cancer being conducted by researchers at _____in __. I am calling now to follow up with you about the study. Do you have a few minutes?

<table>
<tr><td>If no:</td><td colspan="2">If yes:</td></tr>
<tr><td>When would be a better time that I could call back and talk to you?</td><td colspan="2">Great, thank you very much. First of all, how are you doing?

This study is called the _____. We hope that what we learn from the study can help future generations of women.

There are different parts to the study. One part is being interviewed by telephone, and the other part includes _____.

If you are interested in learning more about the study, I am asking your permission to give your name, your contact information and confirmation of your cancer to the ___ study team. You would then receive a study information letter and a ___ gift card in the mail. A member of the ____ research team would then call you to tell you more about the study, and you could decide then if you want to participate. Your participation is voluntary and your decision will not affect your medical care in any way. Would it be ok for us to give your information to the ____ study team so that they may contact you?</td></tr>
<tr><td rowspan="2"></td><td>If no:</td><td>If yes:</td></tr>
<tr><td>Thank you, I understand. Thank you very much for taking the time to speak with me. We wish you the best.</td><td>Thank you so much, Mr./Ms./Mrs. _____.

We sent your study letter to: _____.

Is this the best address for the _____ research team to mail your study packet?

If No, confirm best address:
_____

What is the best phone number for ___ staff to call you? (__ __ __) __ __ __ -__ __ __ __

Do you have a second phone number as a backup? (__ __ __) __ __ __ -__ __ __ __

Be aware that the call from the study team will be coming from the (___) area code, in case you screen your calls and don’t recognize that area code.

I’ll send your information on to the _____ research team and they will be in touch soon. Do you have any questions?

Thank you, and have a great day!</td></tr>
</table>