Genetic Risk Assessment for Cancer Education and Empowerment Project (GRACE)

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NON-INTERVENTIONAL/METHODOLOGICAL RESEARCH PROTOCOL TEMPLATE

(HRP-503b)

STUDY INFORMATION

Title of Project: **The Genetic Risk Assessment for Cancer Education and Empowerment (GRACE) Project**

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1.0 Research Design

1.1 Purpose/Specific Aims

The primary purpose of this study is to compare the effectiveness of a usual care (UC) vs. targeted generic print (TP) vs. tailored telephone counseling and navigation intervention (TCN) on cancer genetic risk assessment (CGRA) uptake at 6 months for hereditary breast and ovarian cancer (HBOC). Secondary purposes are: 1) to compare the effectiveness of a TP vs. a TCN intervention vs. UC on CGRA uptake at 12 months, after removal of key access barriers; 2) to compare uptake of genetic testing for HBOC across the three study arms at 6 and 12 months; 3) to compare cognitive (beliefs, attitudes, and knowledge) and affective (distress, stress, fear) intermediate endpoints among women in the three study arms and explore potential underlying theoretical mediating and moderating mechanisms that will further specify and elucidate significant intervention effects; and 4) to perform an economic evaluation alongside this randomized controlled trial to estimate the cost effectiveness of the two interventions compared to each other and usual care, for uptake of CGRA services from the societal and payer perspectives.

The New Jersey State Cancer Registry (NJSCR) will collaborate with investigators from the state cancer registries of Colorado and New Mexico (Dr. Anita Kinney = overall Principal Investigator) to identify women recently diagnosed with high-risk breast and ovarian cancer. The NJSCR will (a) recruit and consent New Jersey patients who are eligible to participate in the study, and (b) securely send contact and cancer-related information to the overall PI for women who consent so that they can be enrolled onto study by the overall PI. This application is for case ascertainment using the NJCSR.

A. Objectives

AIM 1: Compare the effectiveness of a TP vs. a TCN intervention vs. UC on CGRA uptake 6 months (primary outcome) after the intervention and at 12 months, after removal of key access barriers.
AIM 2: Compare uptake of genetic testing for HBOC across the three study arms at 6 and 12 months.
AIM 3: Compare cognitive (beliefs, attitudes, and knowledge) and affective (distress, stress, fear) intermediate endpoints among women in the three study arms and explore potential underlying theoretical mediating and moderating mechanisms that will further specify and elucidate significant intervention effects.
AIM 4: Perform an economic evaluation alongside this randomized controlled trial to estimate the cost effectiveness of the two interventions compared to each other and usual care, for uptake of CGRA services from the societal and payer perspectives. This aim provides information about the value of the interventions from both societal and payer perspectives, given a cost per effect measure and the uncertainty surrounding the estimate.

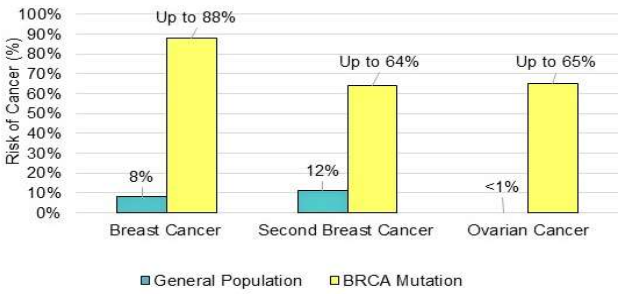
B. Hypotheses / Research Question(s)

Primary Hypothesis: Compared to UC, CGRA (genetic counseling) uptake at 6 months (primary outcome) will be highest among women participating in the TCN arm followed by women participating in the TP arm.

1.2 Research Significance (Briefly describe the following in 500 words or less):

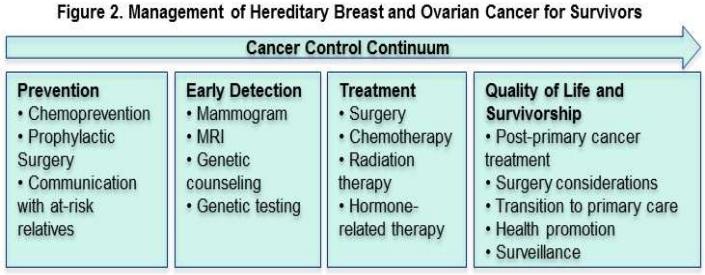
HBOC Cancer Risks and Genetic Risk Prediction. Identification of individuals at increased risk of HBOC is crucial for cancer survivors and their families to benefit from biomedical advances. In 2015, approximately 254,000 new cases of ovarian cancer and female breast cancer were diagnosed in the U.S. Germline mutations in the BRCA1 and BRCA2 genes account for 5-10% of breast cancers and 15% of ovarian cancers.[1-3] This translates to 14,000-27,000 high-risk cancer survivors who may be impacted by HBOC. Women with inherited HBOC gene mutations who have had breast cancer are at higher risk of ovarian cancer and a second breast cancer (Figure 1), and possibly other cancers.[4]
Technological advances in DNA sequencing have now made it possible to test multiple genes simultaneously using multiplex gene panels.[2,5-18]

Figure 1. Cancer Risks in BRCA 1/2 Mutation Carriers



CGRA Personalizes Care and is Recommended for High-Risk Breast and Ovarian Cancer Survivors. CGRA is an evidence-based strategy that informs medical management options that can improve outcomes.[14,17,19] CGRA involves genetic counseling +/- genetic testing. There is evidence that CGRA by genetic professionals improves accuracy of risk perceptions, enables informed decision making, personalizes care, and does not cause adverse psychological outcomes.[14,16,20-22] National organizations have issued guidelines recommending CGRA for breast and ovarian cancer survivors who may be at risk for HBOC.[17,20,23,24] CGRA in HBOC survivors impacts public health (Figure 2).[4,17] If a mutation is identified, testing for the known gene mutation can be offered to relatives to determine if they have the cancer predisposition.[20,25]

Figure 2. Management of Hereditary Breast and Ovarian Cancer for Survivors



Translation of HBOC Discoveries & Guidelines to Practice Has Been Disappointingly Slow. Genetic counseling, guidelines for referral, and testing for HBOC, have been available for >20 years. However, adoption has been slow. It is estimated that ≤50% of high-risk cancer patients receive a CGRA referral from their providers, <35% of these women receive genetic counseling and <10% receive testing.[4,26-33] Many women who receive referrals do not adhere to their provider recommendations.[28,34-44]

1.3 Research Design and Methods

This is a retrospective cohort study of women diagnosed with aggressive breast or ovarian cancer in New Jersey, New Mexico, and Colorado. This application covers the work being completed in New Jersey only. The NJSCR will identify women recently diagnosed breast and ovarian cancer who meet the following inclusion/exclusion criteria. (Table 1)

We will not include any of the following special populations:

- Adults unable to consent
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners

Table 1: Inclusion / Exclusion Criteria for NJSCR recruitment

Cancer Type	Inclusion	Exclusion
Breast Cancer survivors	Hispanic or non-Hispanic Female 21 years of age or older English or Spanish-speaking Breast cancer history = breast cancer at the age or before age 50 OR triple negative breast cancer at or before age 60 OR two or more primary breast cancers Primary Cancer dx'ed prior to breast cancer is OK Primary tumor dx'ed after breast cancer is OK	Have had prior genetic counseling or testing for hereditary breast and/or ovarian cancer Unable to give informed consent (incoherent, dementia) No access to a telephone In hospice care Incarcerated Permanent residence outside of NJ Planning on relocating out of NJ within the next year
Ovarian Cancer Survivors	Hispanic or non-Hispanic Female 21 years of age or older English or Spanish-speaking History of ovarian, fallopian, or peritoneal cancer diagnosed at any age Primary Cancer dx'ed prior to ovarian cancer is OK Primary tumor dx'ed after ovarian cancer is OK	Have had prior genetic counseling or testing for hereditary breast and/or ovarian cancer Unable to give informed consent (incoherent, dementia) No access to a telephone In hospice care Incarcerated Permanent residence outside of NJ Planning on relocating out of NJ within the next year

A. Research procedures:

The NJSCR will conduct patient recruitment following their established Standard Operating Procedures (NJSCR Data Repository #Pro20140000992).

Recently diagnosed cases will be identified by staff at the NJSCR and reviewed by a Certified Tumor Registrar (CTR) for study eligibility (Table 1). We will update address information for the case and the physician of record. Each person will be assigned an arbitrary study ID and imported into the study tracking database "CRIMSoN." NJSCR staff will send a letter to the patient's diagnosing physician of record to notify the physician that his/her patient is eligible for participation in the study. Physicians are asked to notify NJSCR if the patient should not be contacted for participation (i.e., deceased). Two weeks after the physician letter is mailed, NJSCR staff will send the eligible patient a packet of study materials, including:

1. An introductory letter containing a brief description of the study (English or Spanish), a statement of how the patient was determined to be eligible for inclusion into the study, a statement of how the patient was identified via the NJSCR, and a request for the patient's participation;
2. Two copies (one to sign and return, one to keep) of an "agreement to contact" sheet that contains all aspects of informed consent and a location to sign;
3. An information sheet that contains all aspects of HIPAA;
4. An NJSCR Study FAQ brochure which aims to answer common questions about the NJSCR and study participation; and,

5. A postage paid return envelope for the completed Agreement to Contact form.

One week (or five business days) after the initial mailing, staff at the NJSCR will conduct six to eight follow-up phone calls at varying times of the day and different days of the week with at least one evening call made between the hours of 5-8pm and at least one call made on a weekend. Those reached by phone will be given the option to provide a verbal consent to be contacted, which will be recorded in the tracking database. A Spanish-speaking NJSCR staff member will contact individuals who indicated Spanish as a preferred language during patient contact. Additional recruitment packets will be mailed upon patient request or if returned for an incorrect address. NJSCR will track all contact with the patient using the CRIMSoN tracking database.

NJSCR contracted with Salt City Research to design a tracking tool for patient contact studies, particularly mail and phone contact, and participant response status. CRIMSON works with SEER*DMS (NJSCR registry database system) and includes modifiable reports and tracking for mode of contact. Key features of CRIMSON include: (1) enhanced report functions and data collection for key recruitment statistics across all studies; (2) enhanced interoperability with SEER*DMS to reduce manual entry of data and improve data sharing; (3) improved data integrity, quality, consistency, and collection through implementation of validation tools and triggers, elimination of data redundancies, and execution of auto-fill and auto-coding of key variables to remove manual entry of data whenever possible; and (4) implementation of relational structure of the data system allowing for all studies and associated administrative data to be housed within a single data system.

After consent / "Agreement to Participate", NJSCR staff will transfer data securely for consented individuals to the prime site for enrollment and participation in the study.

Briefly, the prime site will randomize the individuals into one of three study arms. NJSCR will not be involved in the intervention. Women will be randomized to one of three study arms: UC, mailed TP, and TCN delivered by a health education specialist. Group assignment will occur at the end of the baseline interview using a computerized randomized list. The interventions will take place ideally within 2 weeks but no more than 30 days upon completion of the baseline survey. Follow-up surveys will be conducted 1 month (to assess mediation), 6 months, and 12 months after randomization for the UC arm, and 1 month, 6 months, and 12 months after the interventions for TP and TCN arms. During the 6 and 12 month surveys, participants will be asked if they'd like to participate in future research. All survey questions will be stored in the REDCap database. The 3 arms will be compared with regard to uptake of CGRA at 6 months (primary outcome) and 12 months, and secondary outcomes including psychosocial and decision-making factors, CGRA preferences, genetic test uptake at 6 and 12 months, and cost outcomes at 6 and 12 months.

B. Recruitment in New Jersey will begin in July 2018 once SRB and IRB approvals are received and continue through July 2020. The tasks include SRB approval, IRB approval, case identification, "Agreement to Contact", data analysis, and publications.
Overall Study Timeline for the Principal Investigator (Dr. Kinney) once the person is enrolled:
- The duration of a woman's participation in the study will be approximately 12-13 months depending on study arm.
- The duration estimated for the investigators to complete the study is approximately 5 years and the estimated time needed to complete primary and secondary analyses that address all the study's aims is about 18 months.

Month 1-7: Start-up, refine data collection and intervention materials, database creation, train health education specialists, IRB approvals
Month 8-32: Recruit and conduct baseline surveys
Months 8-32: Intervention implementation
Months 7-43: Intermediate and final outcome assessments, data cleaning
Months 44-60: Data analysis, presentations, reports, manuscript preparation and publications, and submit competitive renewal

1.4 Preliminary Data

Solutions are Needed to Expand Reach and Access, and Reduce HBOC-related Disparities. Psychoeducational interventions that inform, motivate, and address barriers and facilitators to clinical services are typically more effective in facilitating access to recommended health services.[41,45-49] Evidence shows that patients who are equipped with skills are more likely to follow through with recommended care and have better outcomes at reduced costs.[50,51]

For our diverse target population, both print and telephone have been found to be acceptable ways to communicate CGRA information but tailored counseling and navigation vs. targeted print has not been effectively tested in this context.[39,52-54] The purpose of this randomized trial is to test the efficacy compared to usual care in increasing CGRA for HBOC. Cancer registries are in an ideal position to identify and reach large numbers of high-risk cancer survivors who may benefit from risk information that can help them make informed decisions about their health and/or information pertinent to their biological relatives.[55,56]

Each year NJSCR participates in a variety of research studies to use data collected by the NJSCR. Eligible cases are actively being contacted for 10 patient contact studies and 2 additional patient contact studies are in the start-up phases. All are approved by the SRB and IRB. Over the past three years we successfully completed 7 patient contact studies that resulted in several scientific publications. A complete bibliography of successful NJSCR research can be found on our website:
http://www.state.nj.us/health/ces/documents/njscr_bibliography_seer_1980_2017.pdf

1.5 Sample Size Justification

The overall study will require a sample size of 642 participants, as shown below in Figure 1, CONSORT flow diagram. The 642 (214 per arm) high-risk breast and ovarian cancer survivors will be randomized to one of the 3 study arms. Participants will be recruited from both the NM, NJ, and CO cancer registries. **In New Jersey, we will contact 7,000 breast and ovarian cancer survivors to obtain 700 consents, expecting that 50% of identified individuals sampled and screened for eligibility will fall under our exclusion criteria or will be ineligible for other reasons, 25-28% will consent, and we will retain 80% over the course of the study. Table 2 shows the number of cases available for contact from the NJSCR.**

Based on our experience recruiting through population-based tumor registries there are no anticipated barriers or challenges that will prevent us from reaching our accrual goal and we believe that enrollment will be feasible. Standard methods are used to estimate contact and response rates[113] and these rates are consistent with other studies that used similar population-based sampling and recruitment strategies for health promotion intervention studies in our region (response rates are typically higher for female survivors).[54,57,109,114-116] Based on our calculations and considerable experience recruiting individuals from state cancer registries to epidemiologic and

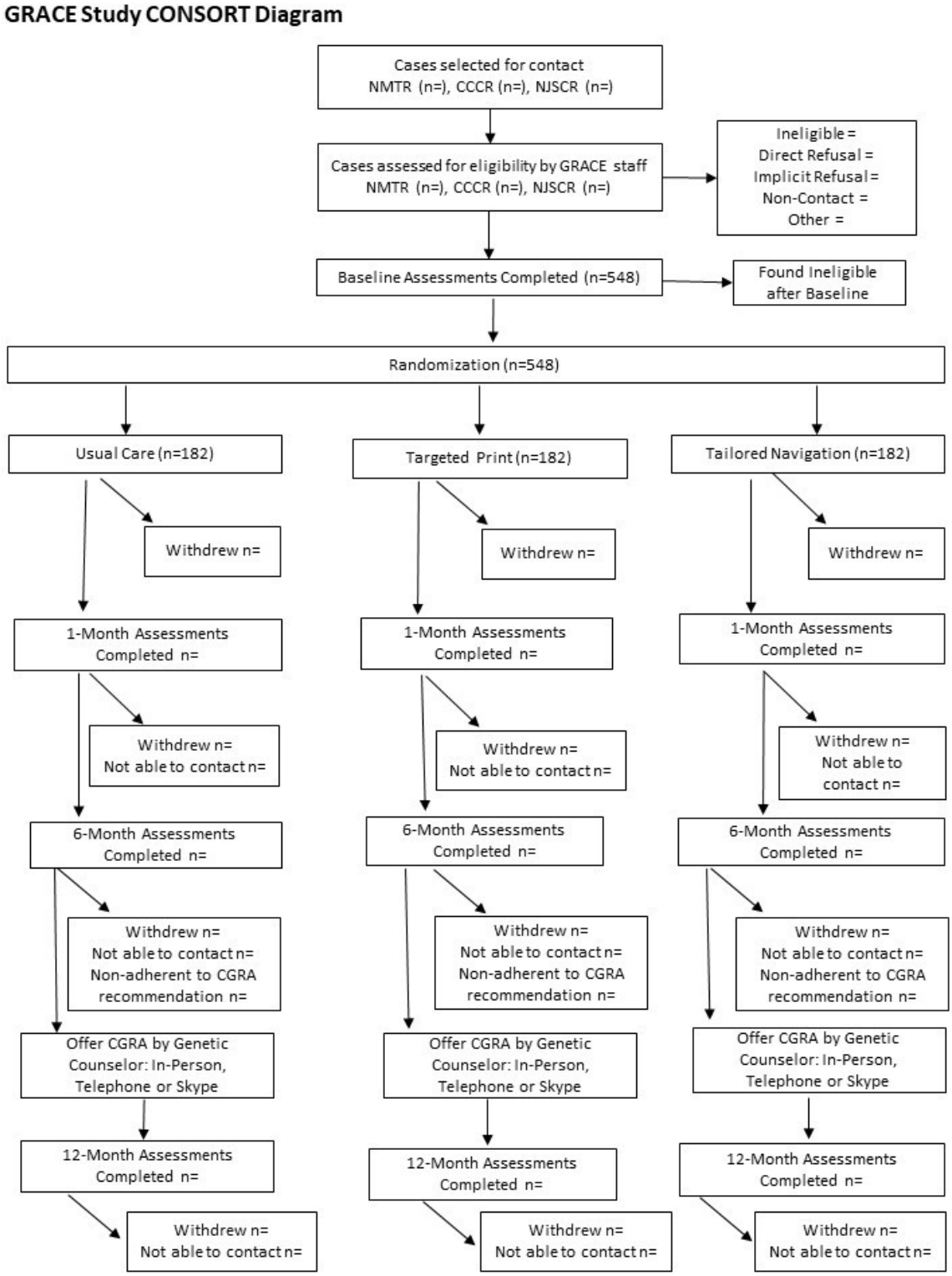
behavioral intervention studies, we are confident that we have a sufficient pool of women who are at increased HBOC risk to recruit into the study. Using data from cancer registries in NJ, NM, and CO, we can estimate the number of potentially eligible living female breast and ovarian cancer survivors who meet the criteria for a referral for CGRA by a credentialed genetic professional.

Table 2: Number of Eligible Women, by cancer type, NJ, annual estimates

Cancer Type	NJ Annual* No. of Eligible Cases	% Hispanic
Ovary	269	10
Fallopian Tube	21	<1
Peritoneal	14	<1
Breast Early Onset	1849	18
Breast Triple Negative	425	16
Breast 2+ primaries	1059	10

New Jersey State Cancer Registry October 25, 2016 analytic file. Processed in December 2017.
***Annual averages are based on counts from the five most recent diagnosis years (2011-2015)**

Figure 1: Overall Sample Size and Study Design



1.6 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

Intervention Arms. Following completion of the baseline survey, participants will be randomly assigned to 1 of 3 study arms: 1) a Usual Care (UC) control arm; 2) a mailed Targeted Print arm (TP); and 3) Tailored Counseling & Navigation (TCN) arm. We hypothesize that the TCN intervention will increase CGRA uptake significantly compared to UC and the TP intervention.

Arm 1- Usual Care: A usual care arm is included to assess GGRA uptake in the absence of intervention as well as priming from the surveys for the primary outcome analysis.

Arm 2- Mailed Targeted Print: Participants randomized to this arm will be mailed an educational brochure within two weeks of completing the baseline survey. The brochure will be available in English and Spanish. It addresses important evidence-based theoretical targets: CGRA guideline (knowledge), threat appraisal (to validate or raise risk perceptions, HBOC seriousness), response efficacy (benefits and expectations about CGRA), self-efficacy messages (CGRA resources, insurance reimbursement, assistance for those with financial challenges), and possible actions to take (make an appointment and discuss with provider). As described in Section D.1, both the targeted print and tailored intervention materials (described below) were developed using formative community engaged research methods.[119]

Arm 3 - Telephone Counseling & Navigation: Within one month of the baseline survey, a bilingual health education specialists will conduct a 30-45 minute (depending on participant needs) telephone health education and counseling session with women randomized to this arm. The intervention will be offered in English or Spanish, depending on the participant's preference. Because theoretically-based tailored messages are generally more effective than generic messages in producing behavioral change,[91,120] we will individualize the psycho-education and navigation session according to each participant's perceptions of threat and efficacy as derived from the EPPM,[41,100] and according to personal factors such as HBOC and CGRA awareness, family history, cultural factors (e.g., ethnicity, language preference, familism, fatalism, family history), psychological and logistical concerns, knowledge, and barriers to CGRA that arise during the phone call. Prior to the telephone session, participants will receive the same brochure that the TP arm receives. After the phone call, participants will receive a tailored follow-up letter. It will include images tailored to the individual's age, self-identified ethnicity, and family composition. Health education specialists will enter this into the study database using user-friendly study-specific computer screens similar to our previous work.[41,100] The Michigan Tailoring System (MTS), a publicly available software program, will be used to individually tailor messages and images using demographic, clinical and patient-reported data (http://chcr.umich.edu/mts/) for the letter. This information will be derived from the cancer registry data (age, type of cancer diagnoses) and during the survey or phone call (ethnicity, family history, primary care provider (which may be an oncology specialist), threat and efficacy appraisals, concerns (e.g., family member's risk and/or risk of second cancer, family orientation), top two CGRA facilitators/benefits and top two barriers, and action plan.

Both the health education specialists coaching and tailored letter incorporate evidence-based communication and behavior change approaches designed to raise the participant's perceptions about the threat (to herself and at-risk family members), arouse emotions and manage fear, enhance positive beliefs about CGRA (response efficacy), and increase self-efficacy by addressing barriers, facilitators, and motivation to get CGRA.[39,42,51,121-128] The health education specialist will use a MI style to help participants explore their reasons for getting CGRA, resolve ambivalence/decisional conflict, and develop their own action plans. The outline of the call is summarized in Table 3.

Table 3. Overview of TCN Arm
Step 1: Introduction and Rapport Building.
Step 2: Address HBOC Threat Perceptions. To enhance HBOC risk perception, the health education specialist elicits the women's awareness and thoughts about the CGRA referral guidelines and how these guidelines apply to them. The health education specialist provides information about the participant's personal risk for a HBOC-related second cancer and acknowledges that male and female blood relatives may be at increased cancer risk. Although we anticipate that the vast majority of participants will perceive HBOC as serious, their responses will be used to enhance cognitive processing of information.
Step 3: Address Barriers and Efficacy. The health education specialist elicits the participant's response efficacy beliefs, including risk management options for HBOC. If desired by the participant, the health education specialist describes the CGRA/genetic counseling process; its effectiveness in helping women like them and their blood relatives; and addresses questions, concerns or misconceptions about CGRA (e.g., getting CGRA does not mean one has to have a genetic test). The health education specialist uses the "Importance" Ruler (1 - 10 scale) to elicit participant talk around desire and reasons for CGRA. The health education specialist uses the "Readiness" Ruler (1 - 10 scale) to elicit participant talk around ability, confidence, and commitment to obtain CGRA within the next six months. Throughout the interaction, the health education specialist will utilize a series of open-ended questions to elicit and reinforce the participant's reasons for undergoing CGRA. The health education specialist explores factors that the participant believes would increase priority and/or efficacy to get a CGRA. The health education specialist also elicits and addresses the participant's two most important barriers to getting CGRA and attempts to resolve during the phone call.
Step 4: Construct an Action Plan. Using readiness ruler and action planning visual aids, the health education specialist prompts the participant to create a personalized action plan. The health education specialist applies implementation intention principles by encouraging the participant to formulate a plan to obtain a CGRA, to determine what her first step will be, as well as when and how she will execute the plan.
Step 5: Provide Navigation as Needed. To further bolster self-efficacy and behavior change, the health education specialist offers further assistance (navigation) to help the patient overcome barriers and asks permission to follow-up with them to provide further help as needed. The dose and follow-up navigation activities will be tracked and analyzed as process variables.
Step 6: Summary, Closing and Follow-up. The health education specialist provides a summary of the participant's self-identified primary reasons for getting CGRA, how to overcome the top two barriers as well as the action plan. The health education specialist asks permission to send a letter to the patient's primary provider letting them know that the participant meets the referral criteria for CGRA according to national guidelines and a copy of the participant's tailored letter. For participants who identify barriers, the health education specialist delineates the next steps and schedules a time to follow-up with the patient by phone. A computer generated tailored letter will be mailed immediately after the phone session that includes the women's personalized action plan.

B. Dependent Variables or Outcome Measures

a) Primary Objective: To compare the effectiveness of a usual care (UC) vs. targeted generic print (TP) vs. tailored telephone counseling and navigation intervention (TCN) on cancer genetic risk assessment (CGRA) uptake at 6 months for hereditary breast and ovarian cancer (HBOC).
   - Primary Endpoint: Medical record verified CGRA uptake at 6 months and at 12 months after removal of key access barriers

b) Secondary Objective 1: Compare uptake of genetic testing for HBOC across the three study arms at 6 and 12 months.
   - Secondary Endpoint 1: Medical record verified genetic testing uptake at 6 and 12 months.

c) Secondary Objective 2: Compare cognitive (beliefs, attitudes, and knowledge) and affective (distress, stress, fear) intermediate endpoints among women in the three study arms and explore potential underlying theoretical mediating and moderating mechanisms that will further specify and elucidate significant intervention effects
   - Secondary Endpoint 2: Measures of cognitive and affective psychological constructs at 1 and 6 months.

d) Secondary Objective 3: Perform an economic evaluation alongside this randomized controlled trial to estimate the cost effectiveness of the two interventions compared to each other and usual care, for uptake of CGRA services from the societal and payer perspectives. This aim provides information about the value of the interventions from both societal and payer perspectives, given a cost per effect measure and the uncertainty surrounding the estimate.
   - Secondary Endpoint 3: Cost analysis at 6 and 12 months

1.7 Specimen Collection as a Primary Source

Not Applicable

1.8 Interviews, Focus Groups, Surveys, and/or Observations

A. Administration

NJSCR SITE:

Recently diagnosed cases will be identified by staff at the NJSCR and reviewed by a Certified Tumor Registrar for study eligibility. We will update address information for the case and the physician of record. Each person will be assigned an arbitrary study ID and imported into the study tracking database "CRIMSoN." NJSCR staff will send a letter to the patient's diagnosing physician of record to notify the physician that his/her patient is eligible for participation in the study. Two weeks after the physician letter is mailed, NJSCR staff will send the eligible patient a packet of study materials. One week (or five business days) after the initial mailing, staff at the NJSCR will conduct six to eight follow-up phone calls at varying times of the day and different days of the week. Those reached by phone will be given the option to provide a verbal consent to be contacted, which will be recorded in the tracking database. A Spanish-speaking NJSCR staff member will contact individuals who indicated Spanish as a preferred language during patient contact. NJSCR will track all contact with the patient using the CRIMSoN tracking database. After consent / "Agreement to Participate", NJSCR staff will transfer data securely for consented individuals to the prime site for enrollment and participation in the study.

PRINCIPAL INVESTIGATOR SITE:

All interventions and surveys will be conducted by the Principal Investigator at the prime site. Women will be randomized to one of three study arms: UC, mailed TP, and TCN delivered by a health education specialist. Group assignment will occur at the end of the baseline interview using a computerized randomized list.

Timing and Frequency

The overall order of events for the study are in Table 4. NJSCR is responsible for recruiting cases.

Table 4: Study Timeline

Who	Task	Timeline		
NJSCR	**Recruitment and Consenting**	**Start - Up Phase August 2018**		
PI	Enrollment, Baseline Survey & Randomization	Baseline		
PI	Intervention	14-30 days post-baseline		
PI	Follow up surveys	Arm 1: Usual Care (UC)	Arm 2: Targeted Mailed Print (TP)	Arm 3: Telephone Counseling & Navigation (TCN)
PI	1 month	30 d > randomization	30 d > intervention	30 d > intervention
PI	6 months	180 d > randomization	180 d > intervention	180 d > intervention
PI	12 months	360 d > randomization	360 d > intervention	360 d > intervention

- **Location**

Case recruitment using the New Jersey State Cancer Registry will occur at the NJSCR Trenton Office (135 East State Street, Trenton, NJ) and the New Brunswick office (120 Albany Street, New Brunswick, NJ)

- **Procedures For Audio And Visual Recording**

Not applicable

- **Person Identifiers**

Staff at the New Jersey State Cancer Registry will identify and contact eligible breast and ovarian cancer survivors following their established Standard Operating Procedures (NJSCR Data Repository #Pro20140000992). If a woman would like to participate in the research study, she will be required to sign an informed consent form / "Agreement to Contact" which will describe all aspects of informed consent, contain information about the HIPAA Privacy Rule, and fully describe study participation. If the woman chooses not to participate, she does not have to return the consent form and if she chooses to participate she can withdraw at any time.

On the consent form / "Agreement to Contact" a woman can give the NJSCR staff permission to release private identifiable information (PII) to the Principal Investigator. The variables that will be needed are: name, all elements of the address at diagnosis and current address, telephone number, demographic variables (i.e., gender, race, age, date of birth, etc.) and cancer-related variables (i.e., date of diagnosis, cancer type, etc.). NJSCR will need to provide these variables to the Principal Investigator so that the woman can be contacted for enrollment, baseline survey, randomization, and interventions.

To protect personal identifiers, each woman will be assigned an arbitrary identification number and this will be used for communication between research staff. Any PII will be transferred in a secure, encrypted manner. All electronic data will be backed up regularly on a secure server. As aforementioned, the biostatisticians who analyze the data will be blinded to participant's study arm. Data for this study, including PIII, will be stored by NJSCR for 6 years after study completion as required by the Rutgers IRB.

B. Study Instruments

All recruitment materials, surveys, and intervention materials will be available to participants in English or Spanish, depending on their preference. The TCN session will be conducted in English or Spanish, depending on the participant's preference. Spanish materials will be submitted to the IRB after the English materials have been approved. To further facilitate communication, Spanish speaking participants and study staff may use over the phone translation services.

There will be 4 surveys over the course of the study period (baseline, 1 m, 6m, 12 m) and will include different components as described below. These are developed at the prime site.

CGRA Decision and Genetic Test Uptake: Participants who have CGRA within 6 months of the intervention (or baseline survey for UC arm) will be considered "completers" of CGRA for the primary outcome. The primary outcome is medical record verified CGRA delivered by the 6-month follow-up. Those reporting that they had CGRA will be asked to sign a medical release form so that we may verify their self-reported CGRA. This approach is extremely feasible and has been successful in ours'[41,134] and others'[135,136] prior work. We will track the type of provider (e.g., physician, genetic counselor, etc.) who provided CGRA and document their genetics training via the documentation form. Using the same strategy, we will assess CGRA utilization at 12 months. Through the medical record release signed by patients, self-reported genetic testing (including type of test and test result) will also be medical record verified at 6 and 12 months.

Sociocultural Factors and Cues to Action: 1) Sociodemographics: age, gender, education, household income, financial status, marital status, rural-urban community area code,[137] living biological children, and health insurance status, country of origin, years lived in the U.S; 2) Medical history: personal/family history of cancer, cancer stage, heath status, co-morbidity index; 3) Acculturation: Short Acculturation Scale;[138] 4) Family and friends social support and encouragement to obtain CGRA;[41,139,140] 5) Family orientation: The Familism Scale;[141] 6) Brief Fatalism Scale;[142,143] 7) Health System Distrust;[144] 8) Receipt of a physician/provider recommendation for CGRA; and 9) Primary health care provider received tailored letter in the TPN arm.

Cognitions/Beliefs: 1) Perceived risk: Distinct items with established predictive validity will assess absolute and comparative risk perceptions about risk of carrying a HBOC gene mutation and family members' risk of HBOC;[39,41,54,145,146] 2) Self-efficacy: items assess women's confidence in their ability to locate CGRA services and obtain such services;[39,100] 3) Response efficacy: beliefs about benefits of CGRA in helping prevent HBOC, managing personal cancer risks, providing important information for family, helping make decisions about genetic testing, and helping cope with risks; [42,126] 4) Subjective Numeracy: validated items from the Subjective Numeracy Scale to assess self-reported numeracy skills;[147,148] 5) Genetic Self Efficacy: items assess women's confidence in their ability to understand genetic information and how it applies to their own health;[149-151] 6) Genetic Information Non-Discrimination Act (GINA) Law Confidence: belief that the GINA law would adequately protect against genetic based discrimination;[152] 7) Decisional conflict associated with the CGRA and gene test decisions will be measured with the SURE Scale;[153,154] 8) Decisional satisfaction about CGRA and gene test decisions will be measured with a 4-item scale[155-157] and 3 additional items that assess how they feel about their

CGRA/testing decision in relation to their family; 9) Decision Regret Scale will assess regret related to their decision to have or not have CGRA;[54,158] and 10) Several items will assess CGRA and testing intentions.[126]

Knowledge: Items from the National Center for Human Genome Research Knowledge Scale and additional items specific to breast and ovarian cancer survivors and misconceptions concerning CGRA and genetic testing will be used.[159,160] We will also ask participants if they heard about or were referred for CGRA and HBOC genetic testing (e.g., BRCA1/2) prior to being contacted for this study.

Facilitators and Barriers Regarding CGRA: Items will be drawn from prior research, including our own work.[39,42,122,126] Barriers at the individual, interpersonal, structural, and system-level will be assessed.[39,42,122] Facilitators include but are not limited to: help from family, desire to reduce risk, and referrals from medical professionals. We will also document the most important barriers and facilitators.

Health Literacy: Psychometrically validated items[161,162] from the Short Test of Functional Health Literacy in Adults.

Emotions: 1) Fear of HBOC risk (self, family): Affect in Risk Scale;[145,163,164] 2) Cancer Worry Scale; [165,166] 3) Psychological distress: anxiety and depression subscales of the Brief Symptom Inventory,[167-169] Short Perceived Stress Scale;[170,171] 4) Defensive Avoidance[172,173]

CGRA Mode Preferences: At the 6-month follow-up, we will elicit their preferred mode of CGRA delivery (telephone, internet (Skype), or in-person) and reason for this preference.

Reactance to Intervention Materials: At the 1-month survey, participants will be asked if they received and read the print intervention materials (e.g., brochure, tailored letter, reminder action plan) and had telephone coaching.[53] For those who respond "yes," [53,174-176] open-ended questions will also be included regarding what participants liked and did not like about the materials.

Future Research: At the 6 and 12 month surveys, participants will be asked if they are interested in participating in future research.

Cost Data Collection: For the economic assessment, we will collect data on: 1) cost of print materials and mailings; 2) health education specialist time to deliver the intervention and follow-up navigation; 3) participant out-of-pocket and time costs; 4) costs associated with the CGRA and genetic test (BRCA1/2 or gene panel test); and 5) overhead related to the intervention (space, etc.). Time will be valued at US wages rates using data from the US Bureau of Labor Statistics.[177] Some costs will obviously differ by study arm (e.g., telephone/internet charges and time), but other differences may be less obvious. Since we are interested in future replication costs, we will focus on intervention delivery costs, including events and health care use. Briefly, health education specialists will record time and resources used delivering the interventions on participant encounter forms; these forms will be compiled to calculate averages. Participants will asked questions regarding how much time they spent, how much childcare they paid for, and how many miles they traveled for each preventive measure, cancer genetic risk assessment, or genetic test they report getting. We have successfully used these methods previously.[54,178,179]

Table 5. Concordance Table of Measures					
Measure	**Base-line**	**1mo**	**6mo**	**12mo**	**Description**
General Health and Clinical Information	x				Heath status, co-morbidity index, information on cancer diagnosis(es)
Prophylactic Measures	x		x	x	Assess uptake of and intention to get mastectomy, mammography, breast MRI, oophorectomy, CA 125, and pelvic ultrasound. Participants will also report on how much time they spent getting each procedure, how much childcare they paid for, and how many miles they had to drive.
Psychological Distress[167,168]: BSI anxiety (α = 0.79-0.81); BSI depression (α = 0.84-.085); Short PSS[170,171] (α = 0.84-0.86)	x	x	x	x	Psychological distress will be assessed using the following: anxiety and depression subscales of the Brief Symptom Inventory;[167,168] Short Perceived Stress Scale.[170,171]
Cancer Worry: The McCaul Brief Worry Scale[165,166] (α = 0.78)	x	x	x	x	Three items will assess cancer worry using the McCaul Brief Worry Scale[165,166]
Fear of HBOC: Affect in Risk Scale[145,164] (α = 0.94)	x	x	x		Fear of HBOC will be assessed using 6 items in the Affect in Risk Scale.[145,164]
Defensive Avoidance	x	x	x		Four items assess avoidance in thinking about personal and familial inherited cancer risk.[172,173]
Perceived HBOC risk for self and family[146,180,181]. Perceived threat and efficacy regarding HBOC: Risk Behavior Diagnosis Scale (RBDS)[182,183] (α = 0.76-0.92)	x	x	x		Four items assess perceived HBOC risk for self and family[146,180,181]. Threat and efficacy related to HBOC is assessed using the RBDS which assesses cancer-focused EPPM constructs (perceived risk, response efficacy, self-efficacy, cancer severity).[182,183]
HBOC Knowledge: National Center for Human Genome Research Knowledge Scale[160] (α = 0.74)	x	x			HBOC knowledge will be assessed using items from the National Center for Human Genome Research Knowledge Scale.[160] Additional items specific to breast and ovarian cancer survivors[159] have been added, as well as items to assess misconceptions concerning hereditary cancer, CGRA, and genetic testing

Family Cancer History	x				Family history of cancer: relative, cancer type, age at diagnosis, etc.
Prior Access to CGRA and Genetic Testing	x				Will assess whether participants had heard about CGRA and/or were referred for CGRA and HBOC genetic testing (e.g., BRCA1/2) prior to being contacted for this study
Physician/Health Care Provider Recommendation and Communication	x	x	x	x	Will assess whether healthcare providers have discussed participant's risk of HBOC and CGRA, and how participants feel discussing CGRA and genetic testing with health care provider.
Cancer Genetic Risk Assessment (Genetic Counseling)		x	x	x	Participants will be asked whether they have had CGRA, the provider who conducted the CGRA, and the provider's genetics training. CGRA will be medical record verified.
Cancer Genetic Risk Assessment Intention	x	x	x	x	One item will measure future intention to get cancer genetic risk assessment. In follow up surveys, this will only be asked if participant does not report uptake of CGRA
HBOC Genetic Testing Uptake		x	x	x	Participants will be asked whether they have had HBOC genetic testing, what type of genetic test they had, and the facility where the testing was done. Genetic testing will be medical record verified.
HBOC Genetic Testing Intention	x	x	x	x	One item will measure future intention to get genetic testing for HBOC. In follow up surveys, this will only be asked if participant does not report uptake of genetic testing.
Decisional conflict for CGRA: SURE Scale[153,154] (α = 0.86)		x	x	x	Decisional conflict associated with the CGRA decision will be measured separately with 4 items using the SURE Scale[153,154]
Decisional conflict for HBOC genetic testing: Low Literacy Decisional Conflict Scale (DCS)SURE Scale[153,154] (α = 0.86)			x	x	Decisional conflict associated with the HBOC gene test decision will be measured separately with 4 items using the SURE SCALE[153,154]
Decisional satisfaction with CGRA: Satisfaction with Decision Instrument[155,156] (α = 0.90).			x	x	Decisional satisfaction will be assessed using the Satisfaction with Decision Instrument.[155,156] Four questions assess their personal satisfaction with their decision and three additional items assess

					how they feel about their CGRA decision in relation to their family.
Decision Regret Scale[158] (α = 0.81-0.92)			x	x	Five items will ask about regret regarding the decision to have or not have CGRA.[158]
CGRA and HBOC Genetic Testing Facilitators[42,126]	x	x	x	x	Facilitators include but are not limited to: help from family, desire to reduce risk of second cancers, and help/referrals from medical professionals.
CGRA and HBOC Genetic Testing Barriers[39,42,122]	x	x	x	x	Barriers include but are not limited to: low perceived importance, competing demands, family members' lack of support, travel time, lack of insurance reimbursement.
Fatalism (fatalismo) and destiny (destino)[142,143]	x	x			Fatalism (fatalismo) and destiny (destino) beliefs will be evaluated with three items.[142,143]
Competing Life Concerns[126]	x	x			Competing life concerns will be evaluated with three items.[126]
GINA Confidence	x	x			Assess belief that the Genetic Information Non-Discrimination Act (GINA) law would adequately protect against genetic based discrimination.
Health System Distrust Scale[144]	x				Nine items measure one's distrust of the Health Care System. This measure has been psychometrically validated.[144]
Health Literacy Screen[161,162]	x				Psychometrically validated items used to asses health literacy in adults.[161,162]
Genetic Self Efficacy[151]	x	x	x		Five items used to assess confidence in ability to understand genetic information and how it applies to personal health and disease risk.[151]
Subjective Numeracy[147,148] (α=0.78)	x				Three items used to assess self-reported numeracy skills and preferences.
Acculturation: Short Acculturation Scale[138] (α = 0.90)	x				Acculturation is assessed by country of origin, time in the U.S., and language preference (five items from the Short Acculturation Scale).[138]

Social support and encouragement to get CGRA[41,139,140]		x	x		Six items assess the extent to which family and friends impact one's intention or ability to get a CGRA for HBOC. The measure was expanded from the 2-item measure of family support[139,140] to assess more aspects of family influence; tangible support, emotional support, and normative influence.
Family Orientation: The Familism Scale[141] (α = 0.87)	x				Family orientation (Familism) assess the relative imporance of self and family where the needs of family are more important and take precedence over the needs of any of the family members. The Familism Scale has been used in several Latino samples.[141,184,185]
Sociodemographic	x				Age, gender, ethnicity, education, household income, financial status, marital status, rural-urban community area code,[137] living biological children, employment status.
Health Insurance Information	x		x	x	Health insurance status and changes in insurance
CGRA Mode Preferences			x		At the 6-month follow-up, for those who have not had genetic counseling but desire it, we will elicit their preferred mode of CGRA delivery: telephone, internet (Skype), and in-person along with the reason underlying their preference.
Reactance to Intervention Evaluation Items adapted from previous work[41,53,173-175]		x			At the one month survey, participants will be asked if they received the print intervention materials and telephone health education specialist coaching from the GRACE Project.[53] For those who responded "yes" to specific materials, a set of [174,175] participants will be asked open-ended questions regarding the materials. Participants will also report how much time they spent reviewing materials and speaking to a cancer education specialist.
Cancer Education Specialist Follow Up			x	x	Participants will report how long they spoke on the phone during follow up calls with the cancer education specialist.

Future online adaptations		x			Following intervention, internet usage and willingness to search for genetic service information will be assessed.
Cost Data			x	x	Several items will be used to conduct a cost analysis

2.0 Project Management

2.1 Research Staff and Qualifications

New Jersey State Cancer Registry Staff

Antoinette Stroup, PhD, NJSCR Site-Principal Investigator

Dr. Stroup is the Director of the New Jersey State Cancer Registry. As such she will be responsible for oversight of this project at the NJSCR, including sample selection, participant recruitment, data collection and quality control. She will lend her expertise in cancer surveillance, population-based survey research and participate in manuscript writing and presentation of study findings at scientific meetings. As the Director of Cancer Epidemiology Services (CES) and the New Jersey State Cancer Registry (NJSCR) and Principal Investigator of the New Jersey SEER contract, she oversees all administrative and operational aspects of the NJSCR, and manage and oversee all research-related activities (e.g., protocol development, institutional review board compliance, patient contact) through the CES Cancer Research Program. She has over 15 years of experience in population-based cancer surveillance methods and research including prior work at two of the highest performing state cancer registries in the SEER Program.

Lisa E. Paddock, MPH, PhD – Program Manager

Dr. Paddock is the Deputy Director of the Cancer Surveillance Research Program, which operates under the direction of the NJSCR Director (Dr. Stroup). Dr. Paddock has nearly 20 years of experience in epidemiologic research and patient contact studies, 15 years of which were spent doing research with the NJSCR data. Dr. Paddock's experience is in outcomes research, with specific training in cancer epidemiology, survey research, and health-related quality of life and she is currently a co-investigator in six patient contact studies where NJSCR-CSRP is recruiting and surveying cases. Dr. Paddock has experience in contacting breast and ovarian cancer survivors for case-control studies that are similar to the work proposed in this application.

Jie Li, MPH – Team Lead

Ms. Li is a Masters trained epidemiologist and data analyst who is a Research Scientist in the New Jersey State Cancer Registry – Cancer Surveillance Research Program. In this role, Ms. Li conducts registry-based analytics using data from the New Jersey State Cancer Registry database (SEER*DMS), and other state and national cancer registry data sources available through SEER*Stat. She is a member of the Patient Contact Studies Team and the Data Linkage Team and assists in linking cohorts with NJSCR data. Additionally, she assists researchers who would like to use NJSCR data in preparing linkage cohort study protocols and IRB applications, analyzes NJSCR data and develops data reports. Ms. Li has several years of experience successfully leading patient contact studies for the NJSCR, including the CEASAR Study and SEER Willingness to Participate.

Natalia L. Herman, MPH - Coordinator

Ms. Herman holds a Master's Degree in Public Health with supplemental training in project management and eight years of experience administering, coordinating, and managing survey research projects. Ms. Herman's expertise is in conducting patient contact studies and surveying patients and studies of various aspects of NJSCR data such as rapid case

ascertainment and medical record abstraction. Ms. Herman is the Project Manager for the CRIMSON database, providing operational and functional guidance to staff utilizing the database as well as acting as point of contact for the outside consultant, and internal database administrator in the creation of a web-based version. She will coordinate the day-to-day operations of the patient contact staff and provide training to those who are

Cynthia G. Nunez, BS – Spanish Interviewer

Ms. Nunez is a Research Teaching Specialist III with the NJSCR-Cancer Surveillance Research Program and is the staff member who can translate and speak Spanish to eligible patients. Ms. Nunez has more than 10 years of experience working with patients and sensitive populations prior to her work at NJSCR-CSRP. Ms. Nunez's primary responsibility is maintaining Scientific Review Board and Institutional Review Board approvals for research studies, coordinating patient contact mailings and patient phone calls, and provides training and mentoring for new staff members.

Overall Principal Investigator

Anita Y. Kinney, PhD, RN, Principal Investigator - Dr. Kinney holds the Carolyn R. Surface Endowed Chair in Population Sciences and is Professor of Epidemiology in the Department of Internal Medicine at the University of New Mexico (UNM) School of Medicine. She is also the Associate Director for Cancer Control and Population Sciences at the UNM Cancer Center. Dr. Kinney has primary responsibility for directing all scientific and administrative activities associated with this project. She works closely with the Senior Program Manager and Project Coordinator, who ensures staff are adequately trained and are meeting study progress benchmarks and day-to-day oversight of study staff data collection activities, recruitment, and retention of participants. Dr. Kinney leads the intervention design and implementation strategy, and works closely with the Senior Program Manager and Project Coordinator to ensure adherence to the study's timeline. She will oversee data analysis and dissemination of the study findings and submission of the competitive grant renewal application.

2.2 Resources Available

A. Facilities

Cancer cases diagnosed in New Jersey will be obtained from the New Jersey State Cancer Registry (NJSCR), located within the Cancer Epidemiology Services (CES) program at the New Jersey Department of Health (NJDOH). The NJSCR is managed and supported by Rutgers Cancer Institute of New Jersey (CINJ) through a Memorandum of Agreement between the NJ Department of Health and Rutgers, The State University of NJ. NJSCR receives funding from the National Cancer Institute, the Centers for Disease Control, and other state and federal programs. The NJSCR is a population-based cancer registry dedicated to tracking the occurrence of cancer in the state of New Jersey since 1978. The NJSCR contains information on all cancer cases including the type of cancer, race, gender, age residence at diagnosis, first course of treatment, and survival and, has received recognition for its high quality and timely data. The CRP collaborates on and conducts cancer research studies, publishes findings in scientific journals, analyzes data from the NJSCR and produces statewide cancer incidence, mortality and other specialty reports that inform cancer prevention and control efforts.

The NJSCR employs a full complement of experienced cancer registration, research, and information systems personnel to successfully meet its goals for statewide cancer surveillance and research support. Research and data use are primarily managed and conducted by research scientists in the Cancer Surveillance Research Program (CSRP), under the leadership of the Director (Dr. Stroup) and Deputy Director (Dr. Paddock). The senior Research Scientists manage several research studies and participate in cancer control and prevention initiatives using NJSCR data. Investigators are required to work collaboratively with CSRP staff when developing a research protocol using NJSCR data. Staff members at NJSCR and CSRP are well trained in cancer registration and surveillance research

including patient contact studies. CES will support this project by providing key technical and research support for patient contact and provide critical content expertise to the research team in regards to cancer surveillance data and interpretation of results.

The physical location of NJSCR: 135 East State Street, 1st Floor, Trenton, NJ 08625 and 120 Albany Street, Tower 2, 8th Floor, New Brunswick, NJ 08903. Location of Data (Hosted by NCI contractors, remotely): Information Management System (IMS), Inc., TierPoint Baltimore Data Center 1401 Russell Street, Baltimore, MD 21230.

Primary registry operations are located at the NJDOH, 135 East State Street, Trenton, NJ 08625 where key card access to the building and registry space on the 1st floor is required. All visitors must be registered with building security. Per state policies, all cancer registry staff must display their state-issued ID at all times while on the premises. (Note: all employees hired through CINJ are issued state IDs upon employment.) Paper-based documents with identifiable data for cancer cases and employees are stored daily at the close of business in locked filing cabinets and drawers. Employees are also required to log- off or lock desktop computers when they step away from their workspace. The registry has staff working at the Rutgers-New Brunswick Campus in CINJ, 120 Albany Street, Tower 2, 8th Floor, where key card access is also required and who follow the same procedures for securing paper-based documents with identifiable information and securing workstations as described above.

B. Medical Or Psychological Resources

Not Applicable

C. Research Staff Training

NJSCR staff involved in this study have been with CSRP for up to 5 years, and the majority possess a college or graduate degree. They attend regular trainings for phone interviewing and speaking with cancer survivors regarding NJSCR and study participation. All staff are trained on Confidentiality Procedures and are required to sign a confidentiality agreement annually. Study specific training will include:

1. The purpose and scope of the study;
2. Review of roles and responsibilities of each staff and NJSCR;
3. Review of the questionnaire;
4. Review of frequently asking questions.

2.3 Research Sites

The NJSCR will facilitate enrollment of New Jersey patients who consent to participate in the study and provide contact information for these consented women to the Principal Investigator so that they can be contacted for study activities. Recruitment of the NJ cases will be performed at the New Jersey State Cancer Registry offices:

- 135 East State Street, 1st Floor, Trenton, NJ 08625
- 120 Albany Street, Tower 2, 8th Floor, New Brunswick, NJ 08903

Recruitment will also occur at the state cancer registries of Colorado and New Mexico, upon IRB approval at the respective site.

3.0 Multi-Site Research Communication & Coordination

Not Applicable

3.1 Non-Rutgers Site Research

Not Applicable

RUTGERS
THE STATE UNIVERSITY OF NEW JERSEY

4.0 Research Data Source/s

4.1 Primary Data: Subjects and Specimens

4.2 Subject Selection and Enrollment Considerations

A. Recruitment Details – New Jersey State Cancer Registry – Cancer Surveillance Research Program (NJSCR-CSRP)

Subjects are recruited through contact by the NJSCR-CSRP, following their established Standard Operating Procedures (NJSCR Data Repository #Pro20140000992).

Recently diagnosed cases will be identified by staff at the NJSCR and reviewed by a Certified Tumor Registrar (CTR) for study eligibility (Table 1). We will update address information for the case and the physician of record. Each person will be assigned an arbitrary study ID and imported into the study tracking database "CRIMSoN." NJSCR staff will send a letter to the patient's diagnosing physician of record to notify the physician that his/her patient is eligible for participation in the study. Physicians are asked to notify NJSCR if the patient should not be contacted for participation (i.e., deceased). Two weeks after the physician letter is mailed, NJSCR staff will send the eligible patient a packet of study materials.

One week (or five business days) after the initial mailing, staff at the NJSCR will conduct six to eight follow-up phone calls at varying times of the day and different days of the week with at least one evening call made between the hours of 5-8pm and at least one call made on a weekend. Those reached by phone will be given the option to provide a verbal consent to be contacted, which will be recorded in the tracking database. A Spanish-speaking NJSCR staff member will contact individuals who indicated Spanish as a preferred language during patient contact. Additional recruitment packets will be mailed upon patient request or if returned for an incorrect address. NJSCR will track all contact with the patient using the CRIMSoN tracking database.

B. Source of Subjects

Eligible subjects are sourced directly through the New Jersey State Cancer Registry.

C. Method to Identify Potential Subjects

Subjects will be identified from the New Jersey State Cancer Registry using established methods, by a highly trained Research Scientist using the study inclusion criteria below.

D. Subject Screening

The NJSCR will identify women recently diagnosed breast and ovarian cancer who meet the inclusion/exclusion criteria in Table 1.

- **Inclusion Criteria –** Breast or Ovarian Cancer diagnosis as defined in Table 1.

- **Exclusion Criteria -** Exclusion criteria include not being able to speak or read English, not a resident of New Jersey at the time of diagnosis, or currently enrolled in an active patient contact study with NJSCR-CSRP. See Table 1.

E. Recruitment Materials

The eligible patient will be sent a packet of study materials, including:

1. An introductory letter containing a brief description of the study (English or Spanish), a statement of how the patient was determined to be eligible for inclusion into the study, a statement of how the patient was identified via the NJSCR, and a request for the patient's participation;
2. Two copies (one to sign and return, one to keep) of an "agreement to contact" sheet that contains all aspects of informed consent and a location to sign;

3. An information sheet that contains all aspects of HIPAA;
4. An NJSCR Study FAQ brochure which aims to answer common questions about the NJSCR and study participation; and,
5. A postage paid return envelope for the completed Agreement to Contact form.

Materials will be translated to Spanish after English materials are approved.

- **Lead Site Recruitment Methods –** Not Applicable

4.3 Subject Randomization

NJSCR will not be involved in the randomization process. Briefly, the Principal Investigator (Dr. Kinney) will randomize consenting women to one of 3 intervention arms using block randomization – (1) Usual care, (2) Mailed Targeted Print, and (3) Telephone Counseling and Navigation. Randomization will be single blinded. Research team members who are assessing the outcomes will be blinded to study arm assignment. Research staff who are conducting follow-up interviews will be blinded to group assignment as much as possible. At the beginning of the follow-up interviews, the interviewer will request that the participant does not reveal the study arm they were assigned to.

4.4 Secondary Subjects

Not Applicable

4.5 Number of Subjects

A. Total Number of Subjects

In New Jersey, we will contact 7,000 breast and ovarian cancer survivors to obtain 700 consents, expecting that 50% of identified individuals sampled and screened for eligibility will fall under our exclusion criteria or will be ineligible for other reasons, 25-28% will consent, and we will retain 80% over the course of the study.

B. Total Number of Subjects If Multicenter Study – Not applicable

4.6 Consent Procedures

A. Consent

- **Documenting Consent**
  NJSCR will obtain consent for contact and document consent using a form and tracking the information in CRIMSoN patient tracking database.
- **Waiver of <u>Documentation</u> Of Consent -** Consent will be taken over the telephone by Rutgers Cancer Institute of New Jersey study staff. The subjects will be asked to sign the HIPAA and return it to the CINJ staff members. During COVID 19 they will return the consent form to a staff member with the address included on the return envelope. These HIPAA consent forms will be stored in a locked safe and transferred back to Rutgers CINJ following the COVID 19 pandemic.
- **Waiver or Alteration of Consent <u>Process -</u>** Not Applicable
- **Destruction of Identifiers -** Not Applicable
- **Use of Deception/Concealment -** Not Applicable

B. Consent Process

- **Location of Consent Process**
  The consent process will begin by mail for all participants. Participants will receive a recruitment letter announcing the study and inviting participation. The consent to contact contains a brief description of the study. The process will continue at the start of the survey. A consent script will be read to the subject over the phone. All options contain the appropriate contact information if the

subject has any questions. If the woman prefers to provide a verbal consent at the time of follow-up, NJSCR will document the verbal consent.

- **Roles for Individuals Involved in Consent**
  Consent will be obtained by NJSCR staff. The staff has extensive training, supervision, and experience in obtaining consent.

- **Coercion or Undue Influence**
  All potential subjects are informed that their participation is voluntary. They are also told that any current or future health care will not be affected if they choose not to participate.

4.7 Special Consent/Populations

A. Minors-Subjects Who Are Not Yet Adults - Not Applicable

- **Criteria for Consent of Minors-** Not Applicable
- **Wards of the State -** Not Applicable
- **Parental/Guardian Permission -** Not Applicable
- **Assent Process -** Not Applicable

B. Non-English Speaking Subjects

- All recruitment materials, surveys, and intervention materials will be available to participants in English or Spanish, depending on their preference. The TCN session will be conducted in English or Spanish, depending on the participant's preference. Spanish materials will be submitted to the IRB after the English materials have been approved. To facilitate communicate between Spanish speaking participants and study staff, participants and study staff may also use over the phone translation services.
- .**Process for Non-English Speaking Subjects**
  The New Jersey State Cancer Registry database indicated Hispanic ethnicity. If a person is Hispanic, then they will receive English and Spanish materials. NJSCR has a Spanish-speaker on staff (Ms. Nunez) who is available to speak with Spanish-speaking subjects for the consent / Agreement to Contact.

C. Economic Burden and/or Compensation for Subjects

- **Expenses**
  There is no cost for participation in the study.
- **Compensation/Incentives**
  Compensation will be offered in consideration of the time spent participating in each phase and is estimated to be 45-60 minutes per survey. Participating women will receive a $50 gift card for each survey that they complete, totaling 4 surveys or $250.

D. Risks and Benefits to Subjects

- **Description of Subject Risk**
  This study is expected to be of minimal risk to participants. The study involves consent to participate in research studies. The greatest risk involved is the loss of confidentiality. See Provisions to Protect the Privacy Interests of Subjects section below.

- **Risks to Non-Subjects -** Not Applicable

- **Minimizing Risks**

The greatest risk in the study is the loss of privacy. This is minimized using de-identified data (see Provisions to Protect the Privacy Interests of Subjects below).

- **Certificate of Confidentiality (CoC) –**
  To help us protect privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for identifying information. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of harm to self or others.

- **Potential Benefits to Subjects**
  Although the risks to participants are minimal, the personal and familial benefits are that all participants will be provided with education via print material and those in the TPN arm, will receive behavior change counseling and patient navigation. At 6-months, the study will offer to cover the costs of CGRA for all enrolled women across all study arms, should they desire these services.

- **Provisions to Protect the Privacy Interests of Subjects**
  The NJSCR has established policies and procedures governing the use of cancer surveillance data for research including physical access controls, data access controls, and confidentiality and CITI training. On occasion, a cancer patient that has been contacted by the NJSCR for participation in such observational research studies will express concern about his/her cancer diagnosis information being included in the statewide cancer registry. All NJSCR staff are trained in the proper procedures to discuss the state-mandated collection of cancer diagnosis information. If the cancer patient expresses discontent over being contacted for inclusion in research studies, the NJSCR staff member will offer the option for the patient to be placed on a "Do Not Contact for Research" list. The patient will no longer be contacted for any research studies.

- **Research Team Access To Subject Data**
  The NJSCR will obtain consent to be contacted prior to transferring identifiers to the investigators. The NJSCR will extract selected independent variables from the cancer registry for participants that consent to NJSCR. All computers are password protected and in a secure office. The database holding PII is password protected also and is restricted to NJSCR-CSRP research staff. All electronic files are saved on a secure, encrypted server. Paper files are secured in locked file cabinets in the locked office.

4.8 Secondary Data - Not Applicable

A. Chart/Record Review Selection - Not Applicable

B. Secondary Specimen Collection - Not Applicable

5.0 Special Considerations

5.1 Health Insurance Portability and Accountability Act (HIPAA)

NJSCR is a non-HIPAA covered entity.

5.2 Family Educational Rights and Privacy Act (FERPA) - Not Applicable

5.3 NJ Access to Medical Research Act - Not Applicable

5.4 Code of Federal Regulations Title 45 Part 46 (Vulnerable Populations) - Not Applicable

6.0 Research Data Protection and Reporting

6.1 Data Management and Confidentiality

A. Data Analysis Plan

Participants will be randomized into the 3 arms using block randomization. Analyses will be conducted with SAS 9.4 and R 3.2 or updated versions. Outcome variables, along with baseline and follow-up (as applicable) demographic, clinical and psychosocial factors described above, will be summarized by study arm using standard descriptive statistics such as means (standard deviations) for continuous variables and tabulations for categorical variables. Although we do not anticipate baseline differences in the distribution of measured factors between the randomly assigned arms, we will assess for statistical differences using appropriate parametric and non-parametric tests. While the specific aims along with the analyses are described below, some of the analytical strategies across the aims are described as follows: 1) The key study outcomes will be reported that account for missing data using multiple imputation and intent-to-treat (ITT) approaches. Multiple imputation under the Missing at Random assumption will be applied using a Markov Chain Monte Carlo method[186] via PROC MI in SAS, given the expected pattern of non-monotonic missing data. A post hoc approach will address the influence of missing not at random (MNAR) and the effect of attrition on outcomes of interest. Sensitivity analyses will be performed to assess alternative multiple imputation techniques upon the extent of MNAR influences. 2) Multiplicity will be adjusted for the primary outcome analysis using the Holm's adjustment procedure, which guarantees strong error control.[187] The SAS MULTTEST procedure will be used with the marginal p-values. For secondary endpoints, no multiplicity adjustment is considered. All tests will be two-sided. The effect sizes and 95% confidence intervals (CIs) of all outcomes using both ITT, per protocol, and multiple imputed data will be reported regardless of statistical significances.

Analytic Plan for Addressing Specific Aims: Aim 1 is to test the hypothesis that compared to UC, medical record verified CGRA uptake at 6 months, as the primary outcome, will be highest among women participating in the TCN arm followed by women participating in the TP arm. The proportion and its 95% confidence interval (CI) of CGRA uptake for each arm will be calculated using Wilson score interval or the exact binomial CI of Clopper and Pearson method, depending on the data skewness or sample sizes at each time and ethnic and geographic subgroups. For the primary outcome analysis, logistic regression modeling will be employed with the main covariate of arm to estimate an odds ratio (OR) along with a 95% CI. As needed, we will report an adjusted OR, controlling for confounding factors. Potential confounds include age in years, cancer diagnosis site (breast, ovarian or both), family cancer history (yes vs. no), at-risk first-degree relatives (yes vs. no), education level (< high school, high school diploma, >= college), household income (low: below the median income vs. high or as appropriate), time since diagnosis (≤5 years, 6-10 years, > 10 years), health insurance (yes vs. no), geographic residence (rural vs. urban), state (NM vs. CO), health literacy (continuous or categorical levels), ethnicity (Hispanic vs. Non-Hispanic), primary language (English vs. Spanish); other psychological, sociocultural and demographic factors will be adjusted as needed. We will also compare the 3 study arms with regard to medical record verified CGRA uptake by 12 months (secondary outcome) after offering to cover the costs of CGRA following the 6-month survey for those

who desire but did not access CGRA. Evaluation of the incremental effect will be assessed by comparing the difference of the primary outcome between changed intervention arms (UC to TP/TCN; TP to TCN). For those that availed themselves of "free" CGRA provided through the study, we will describe patient preferences by study arm and other factors (e.g., age, ethnicity, residence area, education, income, literacy, psychosocial factors, and language preference). Model selection with multiple variables will be conducted using AIC and BIC approximation criteria, while including theoretically and practically relevant variables. **Aim 2** tests whether there are differences across the 3 study arms with regard to uptake of genetic testing for HBOC at 6 and 12 months. Similar to Aim 1, multivariable regression modeling approach will be performed for the binary outcome (genetic testing yes vs. no) with the main covariate of arm and other confounding variables at each time point. Then, generalized linear mixed effects model (GLMM) will be employed for the two time point outcomes, using binomial distribution with logit link function and adjusting for the correlation within the same subjects to estimate the behavior trend over time. **Aim 3** compares cognitive and affective intermediate endpoints among women in the 3 study arms and explores potential underlying theoretical mediating and moderating mechanisms that will further specify and elucidate significant 6-month and 12-month intervention effects, if such effects are observed. The study arms will be compared with regard to beliefs (threat and efficacy), informed decision making indicators (knowledge, decisional conflict, and decision regret) and emotional factors (cancer worry and fear). Arm comparisons will be based on differences in least-square mean changes from baseline to 6 months (including values from the 1-month survey) from an analysis of covariance model containing terms for study arm with baseline scores for as a covariate. Structural equation modeling (SEM) for the hypothesized meditational pathways will be conducted with the procedure of CALIS in SAS and the 'sem' package in R. Before the SEM, all variables in the modeling will be centered with means zero. The SEM will focus on (1) specifying structural equation models; (2) interpreting the model fit statistics and estimation results; (3) testing model with the arms; and (4) analyzing direct and indirect effects. Mediators of intervention effects include threat appraisals, response efficacy, self-efficacy, knowledge, recommendation about CGRA measured at one-month post intervention. Several indices will be used to assess the adequacy of overall model fit: Comparative Fit Index, Standardized Root Mean-Square Residual, and Root-mean Square Error-of Approximation.[188] The interventions may not be beneficial for all study participants. Thus, sensitivity/moderation analysis will be done to identify subgroups for which the intervention has or does not have an effect (e.g., age, diagnosis, time since diagnosis, rural/urban, education level, literacy, acculturation, language preference, close at-risk relative, household income, familism, family support of CGRA, provider recommendation, and cost, travel and time barriers). This will provide important information about subgroups who are particularly receptive or resistant to the effect of each intervention.

Economic Analysis: Aim 4 will measure the incremental cost of implementing the interventions from a payer and societal perspective. The payer in this case would be the entity responsible for funding the cancer registry considering patient ascertainment and intervention implementation; therefore, we will estimate recruitment costs, intervention development and delivery costs and downstream costs up to 1-year post intervention. The societal perspective in theory includes all goods and services consumed as a result of the intervention, including the payer costs and patient costs: deductibles, copayments, and cost-sharing for direct medical goods and services in addition to direct non-medical goods and services such as transportation to appointments, and indirect, or opportunity costs incurred as part of the intervention.[189] We will use micro-costing techniques as recommended by the US Panel on Cost-Effectiveness in Health and Medicine[190] and utilized in our past research on the costs of behavioral interventions.[54,178,179] Implementation costs will include labor (e.g., registry and study staff, MI trainer, health education specialists) and non-labor (e.g., printing, mailing, costs of CGRA and genetic tests, telephone

charges, patient-related travel time). Costs will be grouped as variable and fixed costs. We focus on costs of replicating delivery of the intervention and the immediate down-stream consequences (e.g., obtaining CGRA and genetic testing). Costs will be estimated via direct elicitation from participants and medical records to assign fixed price weights. We consider the following outcomes based on *a priori* trial specifications: 1) average cost per patient for ascertainment, scheduling, health education specialist-participant interaction time; 2) average cost per CGRA and genetic testing; and 3) average time spent with health education specialist. We will also examine overall health care use (including, visits to genetic professionals and other providers, and genetic testing) by study arm (and covariates as needed) at 6 months and 12 months. The incremental cost-effectiveness of one method over another is derived from using the following formula: $Incremental\ cost\text{-}effectiveness_{A} = (C_A - C_B)/(E_A - E_B)$ where C_A and C_B refer to average total costs of each alternative and E_A and E_B refer to average total effectiveness for each alternative. The resulting incremental cost effectiveness ratio (ICER) calculated for each combination of comparators, TCN, TP, and UC, can be used to assess the value provided by alternative A when compared to alternative B, as it represents the investment required for each additional unit of effect gained. All analyses of cost and effectiveness will be completed on an intent-to-treat basis. Uncertainty in estimates will be tested using probabilistic modeling and sensitivity analysis to assess key drivers of results such as rural/urban residence, cancer type, ethnicity, language preference, age, education, household income and family composition (have at least one living at risk first-degree relative).[191] Uncertainty in the ICER will be evaluated using cost-effectiveness acceptability curve plots.[192]

Additional analysis: We will apply the RE-AIM framework to assess reach and effectiveness, implementation and adoption issues overall and by ethnic and geographic subgroup, as well as socioeconomic status and cultural variables (e.g., language, medical mistrust).[193-195] We will describe adherence to the theoretical aspects of the intervention and brief MI using MITI global scores.[133] We will also explore whether process variables (dose and timing of health education specialist-participant interactions, intervention fidelity and intervention reactance measures) influence CGRA uptake at 6 and 12 months. Additionally, implementation issues will be assessed, including health education specialist learning needs and challenges related to counseling and navigation. Content and thematic analysis will be employed to evaluate responses to open-ended questions about barriers and facilitators to CGRA and genetic testing, preferences regarding CGRA and perceptions about the interventions and overall study experience.[196] Two coders (AK & KF) code data and inter-rater reliability will be reported.

B. Power Analysis

The sample size and power evaluation for the proposed study was based on the primary outcome analysis. Given the study's hypothesis that the TCN intervention will have greater effects over both the UC and TP arm, we believe a minimum 12% difference on CGRA uptake 6 months between any intervention arm would be significant from a public health perspective.[197] We expect no greater than 7% CGRA uptake by 6 months in UC, with at least 12% increments for TP and TCN, respectively. With the adjusted significance level of 0.017 (alpha) for the multiple comparisons using

Holm's correction, 182 participants per study arm will provide 95.7% power to detect a 15% difference in the CGRA uptake 6 months between the UC and TP arms. For the comparison between TP and TCN, 182 patients per arm will provide 84.5% power to detect a 15% difference (19% vs. 34%) at the adjusted 0.025 alpha level using the two-sided Likelihood Ratio test. For the secondary analysis, we expect at least 80% power to assess the interventions' effects on ~10-12% change to 15% differences in genetic testing uptake, and small to medium effect sizes of psychosocial targets between the study arms given the measures' standard deviations since our final

sample size per arm of 182 exceeds the planned final sample size of 164. Randomizing 548 participants based on 1:1:1 relative sizes ensures > 80% power for all contrasts. Assuming up to 20% attrition after baseline assessment, we will recruit 182 individuals for each arm. The sample size and power was evaluated using PASS13 software.[198] A total of 548 individuals will be required (182 per arm x 3 arms). **NJSCR will recruit 700 individuals and the remaining sample size will be obtained from other participating registries.**

C. Securing the Data

All computers are password protected and in a secure office. The database holding PII is password protected also and is restricted to NJSCR-CSRP research staff. To protect personal identifiers, each woman will be assigned an arbitrary identification number and this will be used for communication between research staff. Any PII that is consented to be released will be transferred in a secure, encrypted manner.

All electronic data are saved on a secure, encrypted server and backed up regularly on a secure server. Paper files are secured in locked file cabinets in the locked office.

At the Prime Site, the Principal Investigator (Dr. Kinney) will provide each study participant with a Registry Identifier and Participant Identifier. Data will be linked by these two keys. Names and birthdates (and other PHI) that could be used to identify individuals will not be entered into the main study database. These data will be stored in an excel file which will be kept separate from research data. As aforementioned, the biostatisticians who analyze the data will be blinded to participant's study arm.

Data for this study, including PIII, will be stored by NJSCR for 6 years after study completion as required by the Rutgers IRB.

D. Data Quality Control

Quality Control – The CRIMSoN patient tracking database will reviewed regularly to assure quality.

E. Data Handling

At the New Jersey State Cancer Registry, the Site Principal Investigator (Dr. Stroup) will be responsible for data protection and handling. All data will be stored indefinitely. Only authorized and trained research staff will have access to the data and will be responsible for the transmission of the data. Any PII for consented cases will be shared with the Principal Investigator using Rutgers LiFT, or another large file encryption mechanism.

6.2 Data Security

The workflow has been designed to limit access to the link between identifiers and the study ID (see Research Design, section h). Access to data will be limited to study personnel. All computers on which analyses will be conducted will be password protected and will be further protected by the Rutgers firewall and malware protection. All data will be transferred using a secure file transfer system (encrypted file, encrypted email, or secure file transfer protocol). Paper copies of raw data will not be produced. Only aggregate results will be published.

6.3 Data and Safety Monitoring – Not Applicable

6.4 Reporting Results

A. Sharing of Results with Subjects – Not Applicable

B. Individual Results – Not Applicable

C. Aggregate Results

Aggregate results will be published in scientific journals and abstracts will be presented at scientific meetings. Abstracts will be posted on the NJSCR website for the public and participants to read. Participants who request copies of scientific findings will be sent any published journal articles.

D. Professional Reporting

Investigators will also comply with policies and procedures governing the publication of finding from research utilizing NJSCR data, as well, Dr. Stroup and all co-authors will be given opportunity review any abstract/manuscript prior to its submission or use.

Significant contributions to the field of genetics screening will be reported through:

- Poster and/or oral presentations submitted for professional meetings
- Summarized tables described in manuscripts for submission to professional journals such as Cancer

7.0 Data and/or Specimen Banking

A. Storage Methods – Not Applicable

B. Storage Data – Not Applicable

C. Releasing Data/Specimens – Not Applicable

8.0 Other Approvals/Authorizations

This study has approval by the University of New Mexico Comprehensive Cancer Center and the Colorado Central Cancer Registry as collaborating sites.

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