Study Protocol

Title: Testing a Low Cost Population- and Theory-Based Outreach Intervention to Engage Ovarian Cancer Survivors and Their Close Relatives to Consider Genetic Services

NCT Number: NCT04927013

Protocol date: October 3, 2022

PROTOCOL TITLE: *Testing a Low Cost Population- and Theory-Based Outreach Intervention to Engage Ovarian Cancer Survivors and their Close Relatives to Consider Genetic Services.*

PRINCIPAL INVESTIGATOR:
Colleen M. McBride, Ph.D.
Grace Crum Rollins Professor and Chair
Behavioral Sciences and Health Education Department
Rollins School of Public Health
Emory University
Phone: 404-727-8226
Email: cmmcbri@emory.edu

EXTERNAL (NON-EMORY) COLLABORATORS N/A ☐:

VERSION: *Version 5, 10/03/2022.*

FUNDING SOURCE: *National Cancer Institute, U01CA240581.*

REVISION HISTORY

Revision #	Version Date	Summary of Changes

Table of Contents

1.0 Study Summary

Study Title	Testing a Low Cost Population- and Theory-Based Outreach Intervention to Engage Ovarian Cancer Survivors and their Close Relatives to Consider Genetic Services
Study Design	randomized intervention trial
Primary Objective	Aim 1: To enlist community partners as citizen scientists to: identify and recruit Georgia residents with a personal/family history of ovarian cancer, generate content, and collaborate on a scalable message-based outreach intervention to reach ovarian cancer survivors and close relatives (i.e., first- and second-degree relatives) to consider genetic service options. Aim 2: In a two-arm randomized intervention trial (RCT), to compare a message-based outreach intervention to standard outreach for effects on: survivor reach, relative reach, and uptake of appropriate cancer genetic services (i.e., genetic counseling and testing for survivors, online genetic risk assessment for relatives) among survivors of ovarian cancer identified via a state cancer registry. We hypothesize that the message-based approach will result in greater reach and uptake of genetic services than standard outreach. Aim 3: To conduct a process evaluation consistent with the RE-AIM framework alongside the RCT to measure: reactions, dose delivered/received, fidelity, acceptability, barriers/facilitators, and alignment with ethical principles.
Secondary Objective(s)	N/A
Research Intervention(s)/Interactions	A message-based outreach intervention
Study Population	Georgia residents with a personal or family history of ovarian cancer
Sample Size	1,240
Study Duration for individual participants	Study duration varies for different participants. **Aim 1 (community working groups):** Eligible participants are: English-speaking, have a personal

	and/or family history of ovarian cancer, 25 years or older, have access to the internet and be available to attend in-person or online focus group discussions. Participants will attend 2 to 3 90-minute in-person meetings and some additional outside "homework". **Aim 2 (message-based intervention (MBI) and waitlist standard outreach approaches):** Eligible survivors are: diagnosed with ovarian, fallopian tube, or peritoneal cancers, lived in Georgia at the time of diagnosis, not deceased, and have a mailing address per the Georgia Cancer Registry (GCR)'s records. Study duration could to up to one year. **Aim 2 & 3 (post-intervention online survey):** Survivors and relatives in both arms who login to the study website will be invited to complete an one-time online survey. Study duration could to up to 30 min. **Aim 3 (mail survey to survivors who did not login to the study website):** GCR will send a brief survey with a $10 incentive to survivors who do not visit the website after the third and final mailing. Study duration could to up to 10 min. **Aim 3 (online discussion forum):** We propose to purposefully sample survivors (~25) and relatives (~25) randomized to the MBI arm to participate in an online discussion forum. Study duration could to up to 1 hour. **Aim 3 (re-engagement of working groups, Year 4):** After data analysis is complete (late Year 4), we will reengage community working groups from Aim 1 for a half-day workshop where we will report findings of the intervention and enlist additional feedback.
Study Specific Abbreviations/ Definitions	Georgia Cancer Registry (GCR); Randomized control trial (RCT); Community advisory boards (CABs)
Funding Source (if any)	National Cancer Institute, pending council review

2.0 Objectives*

2.1 Aim 1: To enlist community partners as citizen scientists to: identify and recruit Georgia residents with a personal/family history of ovarian cancer, generate content, and collaborate on a scalable message-based outreach intervention to reach ovarian cancer survivors and close relatives (i.e., first- and second-degree relatives) to consider genetic service options.

Aim 2: In a two-arm randomized intervention trial (RCT, N~2,918), to compare a message-based outreach intervention to standard outreach for effects on: survivor reach, relative reach, and uptake of appropriate cancer genetic services (i.e., genetic counseling and testing for survivors, online genetic risk assessment for relatives) among survivors of ovarian cancer identified via a state cancer registry.

Aim 3: To conduct a process evaluation consistent with the RE-AIM framework alongside the RCT to measure: reactions, dose delivered/received, fidelity, acceptability, barriers/facilitators, and alignment with ethical principles.

2.2 We hypothesize that the message-based approach will result in greater reach and uptake of genetic services than standard outreach.

3.0 Background*

The majority of women at greatest risk for ovarian cancer due to hereditary factors are unlikely to know about their elevated risk and prevention opportunities. This significant gap in outreach means that most at-risk women will receive a late diagnosis of ovarian cancer with a dramatic negative effect on survival.1 Traceback approaches that leverage state-wide cancer registries' ongoing surveillance activities offer a potentially low cost platform for outreach to ovarian cancer survivors and their close relatives.

Approximately 15-20% of epithelial ovarian cancers are due to inherited mutations in cancer predisposing genes.2 As such, it is now routine in specialty cancer care settings to offer genetic counseling and testing to all patients diagnosed with ovarian cancer.3,4 To promote cascade testing, patients identified with deleterious mutations are generally sent notification letters, and informational materials for specific relatives recommending that relatives seek genetic counseling. The sensitivity of a survivor's mutation status supports the prevailing notion that only the survivor should directly contact close relatives. The few rigorous evaluations of these approaches consistently show limited reach both to survivors and their relatives particularly for rural residents, relatives with low income, and racial minorities.5-7 Current specialty-clinic-centric approaches, despite efforts to expand reach, are not achieving the objective to ensure that all groups benefit from increasing knowledge about hereditary cancer.

An essential function of public health is to ensure the broad reach of prevention programs (e.g., reaching tobacco users to offer cessation programs). However, health professionals have yet to apply much of the three-decades of evidence gained by these programs to promote health among people affected by hereditary cancers. Research shows that multi-component, low cost health communication interventions including foot-in-the-door techniques,8 tailored/targeted communications,9 website support,10,11 and short messages12 expand reach of prevention messages. Moreover, guidance from

theory is critically important to effective cancer communications as fatalistic beliefs about prevention and survival are common.13-15 Health professionals must anticipate the potential for motivated processing of ovarian cancer risk information—denial, counter-arguing or avoidance— that can undermine engagement among those who are reached by traceback programs and the uptake of genetic services. Theory-based interventions offer strategies to counter these responses and suggest that interventionists must develop specific messages in collaboration with affected communities.16-18

The shift from clinic-based promotion of cascade testing to population-level traceback programs introduces a number of ethical questions. The current prevailing notion that the patient must make the initial contact with close relatives warrants reconsideration. Indeed, no systematic efforts have assessed close relatives' preferences regarding direct contact, especially in the circumstances where the patient's mutation status is unknown. Citizen science methods offer a low cost and feasible platform for gaining community wisdom and creativity related to the ethical challenges of population outreach.

With the availability of life-saving prevention options, we need novel approaches to identify, engage and inform ovarian cancer survivors and their close relatives about their risk. State cancer registries are a viable platform to use low cost outreach approaches to contact survivors, offer genetic counseling and testing as well as options for contacting relatives.1,19,20

4.0 Study Endpoints*

4.1 Primary RCT outcomes: 1) Survivor reach: the proportion of the eligible survivors identified and contacted by GCR who log in to the website, 2) Close relative reach: the proportion of close relatives enumerated by survivors who log in to the website, and 3) Uptake of cancer genetic services: the proportion of untested survivors who complete telegenetic counseling and the proportion of relatives enumerated who complete B-RSTTM screening and subsequently access genetic counseling. We will evaluate secondary outcomes: In the MBI arm, we will track survivor' and relatives' patterns of website usage including: duration of time on the website, number of return visits, pages viewed, and the proportion of survivors who select different relative contact options.

5.0 Study Intervention / Design

We propose a multi-component, low cost, message-based communication outreach intervention to engage ovarian cancer survivors and their at-risk relatives in considering cancer genetic services. The intervention includes foot-in-the-door techniques, tailored/targeted print, website support, and short messages to expand reach of prevention messages. An outreach website with content for both survivors and close relatives will be the hub channel in the communication intervention wheel. In turn, we will encourage access to the website using other communication channels as

spokes in the wheel including: 1) Initial print-based contact to survivors sent by the cancer registry, 2) additional briefer reminder postcards and short text message cues (SMS), 3) additional short text message cues sent directly to close relatives (with contact information and permission provided by the survivor).

6.0 Procedures Involved*

6.1 Describe study procedures.

Study Overview: We propose two phases of study activities. Phase 1 (Aim 1) comprises 12 months of collaboration with survivor/family working groups to develop: targeted letters, choice options for relative outreach, and content for an interactive website, and short cueing messages that engage ovarian cancer survivors and their at-risk relatives in considering genetic risk assessment. **All of these study materials will be submitted as an IRB amendment prior to fielding.** Phase 2 (Aims 2-3 – Years 2-4), is an RCT that compares the message-based intervention (MBI) with current standard outreach. We will evaluate the following outcomes: survivor reach, at-risk relative reach, and uptake of appropriate cancer genetic services and conduct a process evaluation based on the RE-AIM framework that includes survivors and relatives (Aim 3).

A. Aim 1: Develop a scalable message-based outreach intervention.

A.1. Overarching Approach: We base our community partnerships on the combined principles and methods of community-based participatory research and citizen science.[21] We propose to bring the issue of increasing reach to the community of ovarian cancer survivors and families and engage their collaboration to develop appealing messages to expand the reach of genetic services to survivors and close relatives. Community members with relevant experience will work with us as citizen scientists using their experiences and skills to help develop messages.[21] We will hone ovarian cancer survivor/family partners' skills as citizen scientists by familiarizing them with theories of information processing, relational autonomy and distributive justice (see below). The overarching objective is to co-create content that has the greatest potential to engage survivors/relatives to thoughtfully consider the tradeoffs of genetic service uptake. Dr. Escoffery, Ms. Paris and Peachtree Solutions have considerable experience working with community advisory boards (CABs) and end users. Dr. McBride has conducted qualitative research to develop genetic risk messages in a variety of settings in the U.S. and abroad.[22-24]

A.2. Study Population and Procedures: Development of the MBI will involve three iterations and the following stakeholders: 1) community members who have a personal and/or family history of ovarian cancer; 2) communication and bioethics experts (Drs. McBride, Shepperd, Guan, Pentz, Emory's Visual Medical Education team); and 3) cancer genetics content experts (Drs. Guan, Bellcross, Meisel). Georgia CORE's CABs will help us identify 35-40 community members via snowball sampling to participate in working groups (see letters of support). We will share eligibility criteria with Georgia CORE (e.g. ovarian cancer survivor/family, access to the internet and being available for in-person or online group discussions). Ms. Paris (Co-I) will oversee these activities with the assistance of an ethics fellow and a research assistant. In assembling the working groups, study staff will conduct additional eligibility screening (e.g., prior experience with cancer genetic services, family size) to increase the diversity of community members for

working group activities. We will subdivide the community members based on their expertise and preference into 3 working groups consistent with a citizen science philosophy. Each group will contain 5-10 survivors and/or close relatives who will work on specific tasks and intervention-related products. Participants will receive $500 for attending 2-3 90-minute in-person meetings and some additional outside "homework". For each in-person working group session, we will prepare an interactive didactic module with lay explanations of theory-based concepts related to the working group's task. The remainder of the session will focus on a specific task (e.g., plans to interview other family members to solicit example experiences, preference for being contacted). We will give working groups ongoing updates as the study progresses and share the study results in a final discussion group half-day meeting described in Aim 3.

A.3. Working Group Procedures: Dr. Guan who has experience working with community groups and evaluating websites that link those with inherited disease to genetic services will oversee working group activities.[25] In *iteration 1*, one community working group will recommend approaches for framing the "large ask" and choice sets for relative contact options. A second and third working group will assist in collecting survivor-family stories using photonovela or other strategies. In *iteration 2*, content experts in communication, genetics and ethics will assemble working group content and develop initial formats for the website and print materials. Communication and bioethics experts will review materials for alignment with communication frameworks and ethical principles. Next, Peachtree Solutions (see letter of support), our web-development partner, will work with Emory's Visual Medical Education team to draft the website and print materials. In *iteration 3*, a third community working group will review initial and revised iterations of intervention content using systematic cognitive interviewing methods.[26] Peachtree Solutions has extensive experience with the latest usability standards and will direct the usability testing. The investigative team and consultants will make revisions based on each round of panel input. We will use the Suitability Assessment of Materials (SAM) and Comprehensibility (CAM) scale to evaluate the readability and comprehensibility of the website with the aim to develop a website that users' rate as "superior", indicating it is easy to use and understand, low in cognitive demand, attention-getting, and motivating.[27]

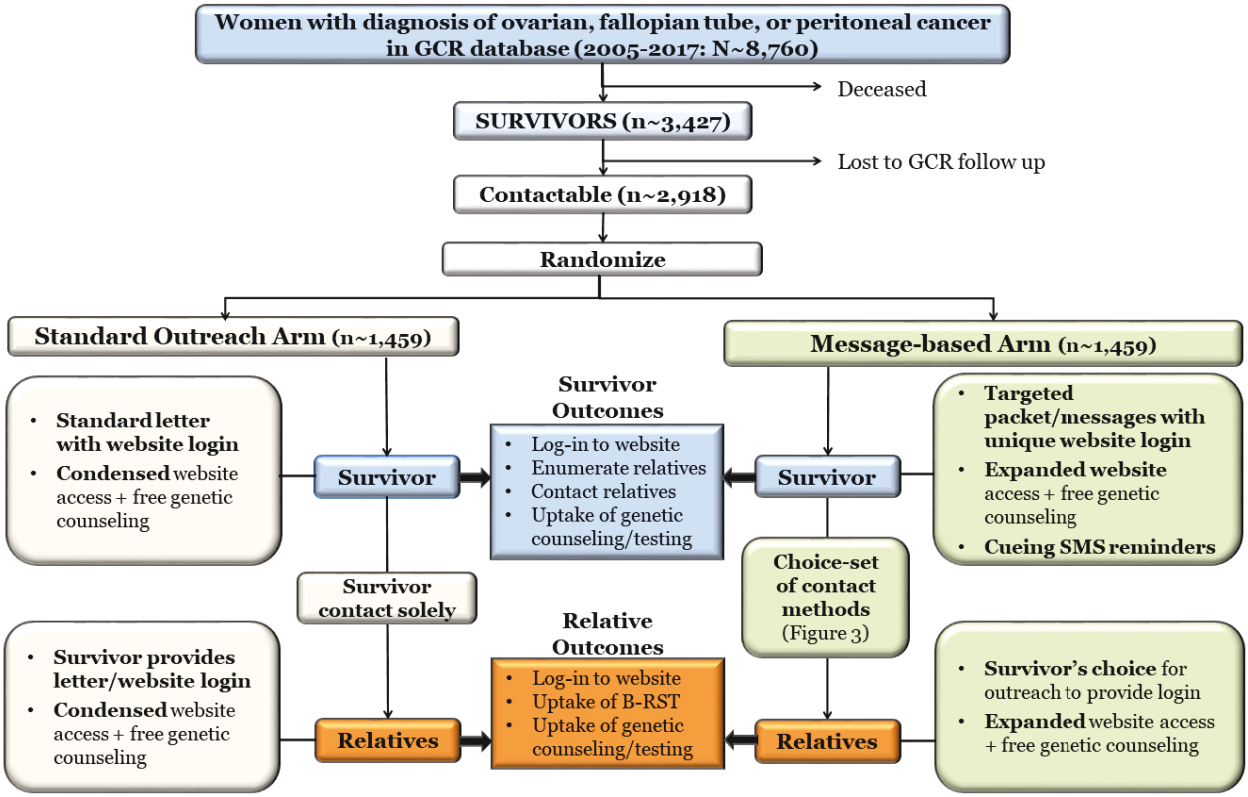
Prior to fielding the trial, we will submit the developed study materials as part of IRB amendment.

B. Aim 2: Conduct a two-arm randomized intervention trial (N~2,918).

B.1. Study Design: We will compare the message-based intervention (MBI) developed in Aim 1 to standard outreach in a two-arm RCT in Years 2 and 3. The MBI comprises a combination of novel intervention components that depart sufficiently from prior research to warrant a comparison arm (with access to the MBI website when the trial period is completed).[28] Figure 2 displays the flow of the intervention.

B.2. Study Population: Study activities will take place in Georgia (GA), where about 615 women are diagnosed with ovarian cancer and about 395 die from the disease each year.[29] We propose a population-wide recruitment approach and will use Georgia Cancer Registry (GCR) to retrospectively identify, screen, and enroll all living ovarian cancer patients in GA, diagnosed between January 2005 and December 2017. GCR contains information on demographic characteristics, condition at time of diagnosis (e.g., stage, histologic types, and other clinical and

Figure 2: Intervention design flow chart



demographic variables), and treatment history of all cancer patients in GA.[29] Since 2001, the database excludes borderline (low malignant potential) neoplasms. We will consider women in GCR for study participation if they meet four criteria: 1) diagnosed with ovarian, fallopian tube, or peritoneal cancers; 2) lived in GA at the time of diagnosis; 3) are not deceased per the registry's records; and 4) have a mailing address. Our review of registry files as of May 2019 revealed: of the 8,760 women with a diagnosis of ovarian, fallopian tube, or peritoneal cancer, excluding those who were deceased or lost to follow as of 2017, we will have addresses for approximately 2,918 survivors during the 16-month recruitment period. GA is the 8th largest state with almost 10.5 million residents; 1.8 million (~17%)[30] residents live in rural areas.[31] The state enjoys substantial racial-ethnic diversity: 32% of the state is Black or African American alone (4th largest African American population in the U.S.), 9.6% is Hispanic or Latino and 4.2% is Asian alone, 15% of the population lives in poverty, and 15% lack health insurance.[30]

The efficient recruitment of survivors presents logistical challenges particularly given the high mortality rate of ovarian cancer. We made the deliberate decision to reach out to ovarian cancer survivors diagnosed back to 2005 based on: 1) our message-based communication traceback approach that targets ovarian cancer survivors with short- and long-term survivorship to include diagnoses that predated changes in testing guidelines[32]; 2) survivors diagnosed more than a decade ago are underrepresented in the majority of case identification trials with self-selected samples in specialty clinical settings; 3) we expect rates of recruitment and enrollment to decline as we trace back; however, we will potentially maximize the total reach and learn about the intervention efficacy across a range of survivor periods; and 4) the cost advantage of using the state-wide cancer registry to identify all of the locatable survivors in GA counterbalances

recruitment drawbacks. Dr. Escoffery has used similar location and outreach strategies in collaboration with GCR to promote mammography and achieved 63% participation rates.[33] Others also have used cancer registries to recruit breast and ovarian cancer survivors into clinical trials for preventive cancer activities; they contacted survivors zero to nine years post-diagnosis, with most reporting response rates between 30-40%.[34-42]

B.3. Randomization: We will randomly assign cancer survivors (N=2,918) in a 1:1 ratio to either the MBI arm (n=1,459) or the waitlist standard outreach arm (n=1,459). Given our access to the entire population of ovarian cancer survivors in GA and characteristics of their cancer and treatment, we will use a covariate adaptive randomization procedure.[43,44] In this procedure, we will randomly assign the first participants to a group, then will assign subsequent participants to a particular group by taking the covariates and previous assignment into account to adapt the probability of group assignment. This approach ensures our randomization is superior to simple randomization that only works perfectly for very large samples.[45] It will result in a covariance balanced allocation and thus avoid potential influence of covariates on the intervention results. We will use the SAS macro developed by Colavincenzo to execute the randomization.[46] We will choose covariates we expect are related to reach from the cancer registry data. Examples are year of diagnosis and age at diagnosis. Registry staff will randomize identified survivors to arm using sequentially numbered and sealed envelopes.

B.4. GCR Recruitment Procedures: The proposed recruitment procedures comply with GCR's current standards. We adapted them from strategies that were effective in other studies using cancer registry for recruitment[34,39,42,47,48] that will allow for sustaining and disseminating the intervention beyond the study. We will classify survivors who log in to the study website as "reached." Recruitment will rely on multiple communications aimed to encourage survivors to log in to the study website with the number of contacts largely identical for both arms (Figure 4).

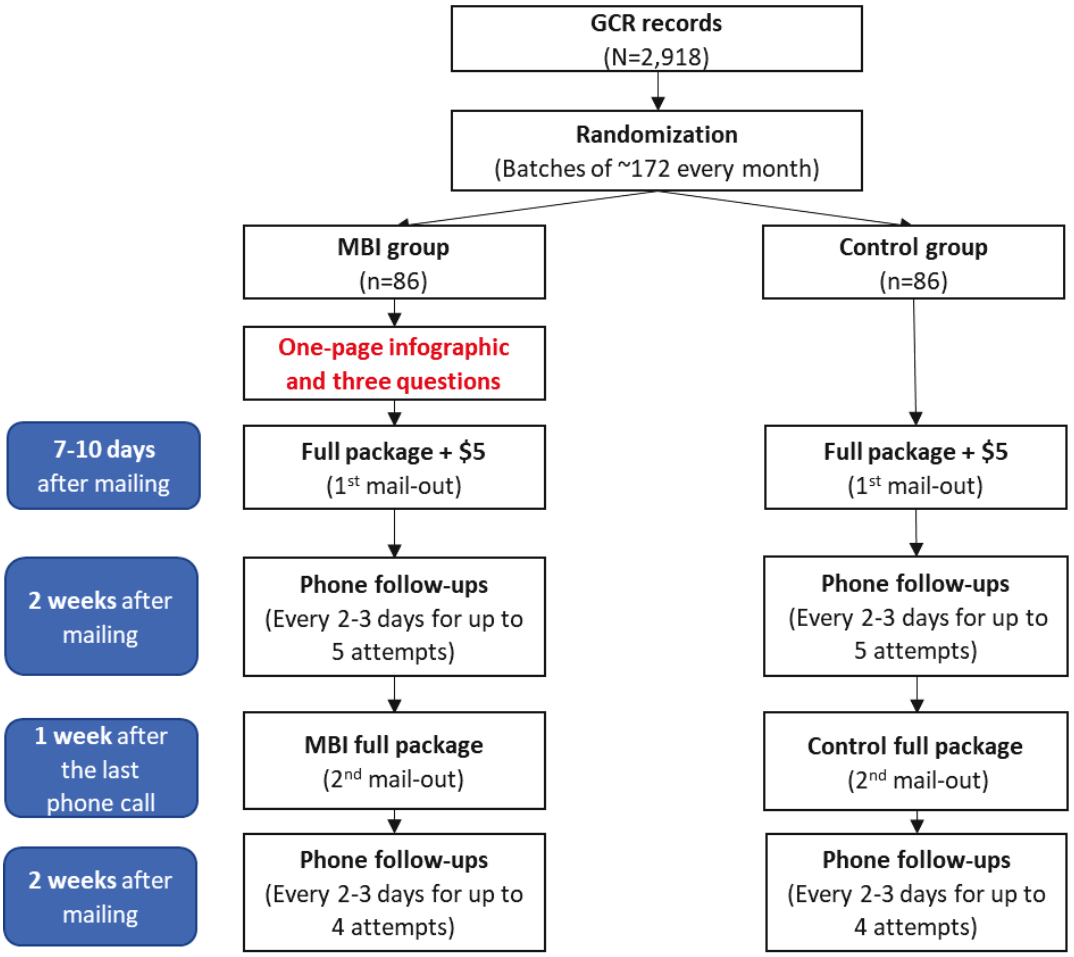
B.4.1. First contact letter (MBI arm only): We will mail survivors in the MBI arm a one-page infographic *(See "U01 MBI infographic draft")* that includes a postage-paid return envelope to return their responses to three questions *(See "U01 MBI three questions draft")*. Responses will help us better understand information needs of families affected by ovarian cancer. Participants may answer the questions online by using a QR code, or write their responses on the enclosed document and return it to GCR. Responses will be anonymous and will not be linked to any personal identifiable information. We will not report participants' responses for research purposes and their responses will be reported on an aggregate level (e.g., number of envelopes returned).

B.4.2. First mail-out: This mailing will be sent approximately 7-10 days after mailing the first contact letter, we will mail to survivors in both arms $5 cash as a token of appreciation for their attention, and a recruitment packet based on their arm assignment: targeted print material in the MBI arm versus standard study invitation letter in the standard outreach arm. GCR staff will mail recruitment materials in batches of about 172 every month. We will use Accurint, a LexisNexis database with coverage across the US, to obtain the most current address for registry survivors in an effort to maximize reach of the mailed material on the initial attempt. The materials will instruct participants to contact the toll-free registry telephone number with questions or concerns. Throughout recruitment, we will perform monthly checks to avoid

initiating contact with a recently deceased woman. To reduce unnecessary contact attempts by GCR, the intervention coordinator will provide GCR with the IDs of survivors who have logged in to the study website on a biweekly basis.

B.4.3. Telephone contacts: Studies show that interpersonal communications, such as a personal phone call, can increase clinical trial accrual when combined with informational handouts.[48-53] Two weeks after mailing each packet, GCR will contact survivors by phone who do not log in to the study website. We will call survivors every 2-3 days for up to 9 attempts, after which we will categorize them as inaccessible. The phone call aims to: 1) check on receipt of the recruitment packet; 2) remind survivors to log in to the study website; and 3) answer questions regarding the study. This schedule is the standard for GCR outreach.

B.4.4. Second mail-outs: Survivors who do not log in to the study website within 2 weeks of the last phone call attempt will receive a second mail-out containing the full recruitment packet.

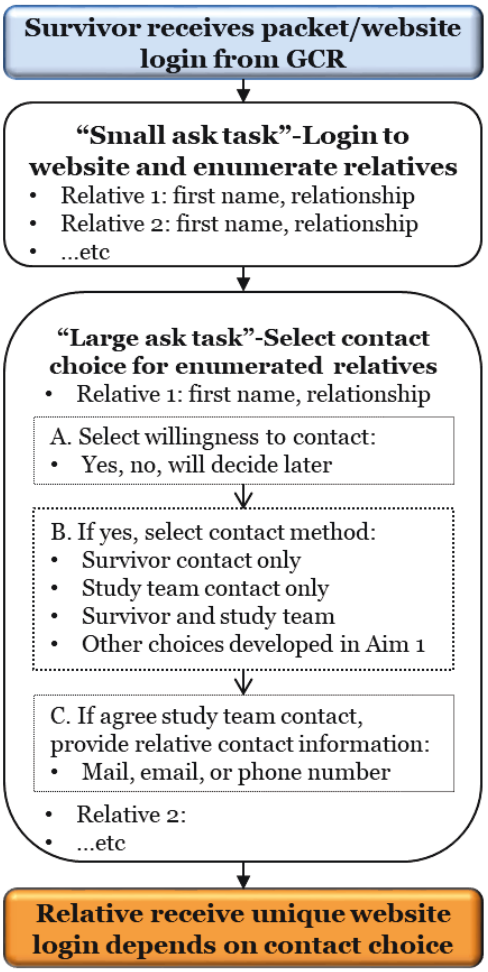


B.5. Message Based Intervention (MBI) Arm: In collaboration with the working groups we will develop messages to increase perceived relevance (e.g., photonovela stories), and prompt website access (e.g., SMS reminders of passwords). Messages will be included in: a website hub, initial print-based contact to survivors sent by the cancer registry, reminder postcards and short text message cues (SMS) for survivors and close relatives (when contact information and permission is provided by the survivor). We will work with Emory's Visual Medical Education team

of certified medical illustrators to design illustrations for these products to increase the accessibility of complex medical concepts.

B.5.1. Survivor components: We will send the initial full recruitment packet to identified survivors randomized to the MBI arm. The packet will contain theory-based targeted messages developed in Aim 1, and a cover letter that explains how we identified the woman, and provide her with a unique login to access the website that we can track and link the survivor to the cancer registry. Figure 3 displays the intervention flow.

Figure 3: MBI flow of survivor-relative contact



B.5.1.a. Website: The study website developed in Aim 1 will be a centralized information delivery portal that contains: graphical depictions of genetic risk, short videos on hereditary cancer risk, photonovelas, structured interactive Q&A choices highlighting pros and cons of seeking genetic services from the perspectives of survivors, and resources for patient navigation programs near them. On entering the website, survivors will see an explanation of the study and the opportunity to continue or to decline. The online consent form ends with the "I agree" checkbox so the participant can decide whether they still want to participate after reading the listed conditions. Dr. McBride successfully used a similar approach with 6,400 enrollees in a managed care organization.[54] Fully 32% of those who received mailed invitations with log-in information visited the website.[55] Results showed high levels of information recall and accurate interpretations of the limits of the genetic susceptibility testing for common diseases suggesting this platform enabled informed consent.[56] The website will ask survivors who log-in to review informed consent information, click the "I agree" button if they want to proceed, and on a separate webpage to complete the requested *"small ask"* task to enumerate their 1st and 2nd-degree relatives (henceforth "close relatives") by first name only and to specify the relationship. Once completed, the survivor will view options for how close relatives might be contacted (we will present 3-4 options that represent graduated involvement of study staff). We will pair each option with personal stories to illustrate pros and cons of the choices. The website will then prompt survivors to complete the *"large ask"* task, which entails selecting an option (e.g., close relatives contacted solely by survivor, share contact of some relatives with study team, study team contact all enumerated relatives, refuse contact, etc.). Survivors who select options that involve the study team reaching out on the survivor's behalf will be prompted to provide contact information (e.g., mailing address, email, phone number) for relatives. Relatives specified for study contact will be sent (via email, mail or text) personal login information linked to the survivor; provide survivors

who opt to contact relatives will be provided with unique log-in information for each of the relatives they list. Relatives that survivors refuse contact will be noted but not contacted.

B.5.1.b. Short messages: Survivors who provide mobile phone numbers will receive two SMS thanking them for accessing the website, and encouraging them to revisit the website to review information and contact relatives. We will time these cues to occur at 3-week intervals over a 6-week time period (two SMS). Additionally, reviews of SMS studies suggest including a substantial pre-testing phase that allows target audiences to provide input on message content as we propose to do in Aim 1.

B.5.1.c. Genetic service options: We will offer free pre-test telegenetic counseling to all survivors who log in to the website, regardless of whether they complete the tasks. Two recent trials showed that similar approaches are non-inferior to face-to-face counseling.[57,58] Survivors can opt for phone and/or video counseling via Emory HIPPA approved Zoom links. They can schedule a session (~60 min) on the study website by providing their contact information and preferred appointment date/time. We will ask survivors to review an online genetic counseling consent form and complete a brief intake survey (e.g., prior genetic testing result). Survivors may invite a support person or other family members to participate in the session. Scheduling a telegenetic counseling session indicate that participants agree to receive services provided by means of telemedicine by a genetic counselor intern at Emory University. Genetic counseling interns (supervised by Drs. Guan and Bellcross) will proactively contact consented survivors for the counseling sessions. Interns will be blinded to participant's/relatives study-arm assignment. All interns will have comprehensive training in cancer genetics and use of telemedicine. The intern will be trained in best practices: review personal and family medical history, discuss appropriate genetic tests (e.g., minimum *BRCA* and Lynch syndrome, other genes based on survivors' family history), and discuss the risks/benefits/limitations of recommended tests. Interns also will receive training in how to refer survivors to informational and support resources, including any local patient navigator programs to assist the participant with additional medical care needs. Participants will receive a copy of their pedigree, a medical referral letter summarizing key aspects of the counseling session and recommendations for genetic testing. We will recommend that participants share these letters with their primary care provider (PCP) as follow-up. If participant's prefer, the intern can work with the PCP to arrange genetic testing. We will also offer post-test telegenetic counseling at no cost to all participants. Medicare's covers *BRCA1*/2 genetic testing for people with personal history of ovarian cancer. In addition, the Genetic Testing Fund established by Georgia CORE (Ms. Paris, President and Co-I) provides access to genetic testing for hereditary breast and ovarian cancer for uninsured Georgians.[59] Since 2014, the Fund has supported testing for over 70 underinsured Georgians who would not have otherwise been able to afford it.

B.5.2. Close relative procedures: Relatives eligible to participate must be: 25 years or older (age recommended to initiate preventive behaviors)[60], able to access the internet, a 1st or 2nd degree relative of the survivor, able to read English, and non-incarcerated or institutionalized. Relatives will receive a unique website login linked to the survivor that enables access to the website content and describes pros/cons of family-history-based genetic risk screening for HBOC. Additionally, relatives for whom we have cell phone numbers will receive 3 cueing SMS reminders over 9 weeks (developed during Aim 1). The SMS will thank them for visiting the website and

suggest they return as needed and complete the genetic risk assessment for ovarian cancer family history. We will use the B-RST™ (developed and validated by Dr. Bellcross in 2009),[61,62] which is endorsed by the USPSTF as one of several validated screening tools that is clinically useful for estimating the probability of *BRCA1/2* mutation and identifying women for referral to genetic counseling. This screener assesses personal and family history (1st and 2nd relatives) of breast cancer, bilateral breast cancer, ovarian cancer and male breast cancer, and Ashkenazi Jewish heritage. The intervention website will include a separate portal dedicated to the B-RST™ 3.1 screen. Although all 1st or 2nd degree relatives of ovarian cancer survivors will screen positive on B-RST™, completing the screener will raise participant awareness of the factors that contribute to hereditary risk of ovarian cancer and will reinforce the salience of seeking genetic counseling. We will recommend genetic counseling for all close relatives because of their heightened risk for carrying a *BRCA1/2* mutation. We will direct interested relatives to the same telegenetic counseling services provided to survivors. Ideally, we would recommend testing the survivors first, and only offer genetic testing to close relatives with a confirmed pathogenic variant ala cascade testing. However, we will offer genetic testing to relatives regardless of survivor's testing status.

B.6. Standard Outreach Arm

B.6.1. Survivor components: GCR will mail survivors a standard letter and log-in information. Survivors will have access to a condensed version of the website that includes information on: genetic risk and genetic counseling, patient navigators in their locale, and the importance of conveying information to close relatives. Survivors will be provided with 2 extra letters and login information for 2 close relatives. Survivors can request additional relative letters/logins for any relatives that they would like to involve on the website or the GCR.

B.6.2. Close relative components: The standard family letter shared by the survivor will provide login codes for the relative to visit the condensed website with information about genetic risk and the value of completing the online B-RST™ screener.

All survivors and relatives in the standard arm will have access to the telegenetic counseling services described above. After completion of intervention trial, all survivors in the standard outreach arm regardless of their study participation will have access to the MBI sections of the website.

6.2 Procedures being performed to monitor participants for safety or minimize risks.

We expect the research-related risk to be minimal: the probability & magnitude of harm/discomfort anticipated in the research is no greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations/tests.

There are no anticipated physical risks of participating in this study. However, participants may experience psychological or emotional distress from participating in the study, particularly activities related to the way their family interacts or communicates about ovarian cancer and genetic risks. Survivors may worry about their family members' emotional distress. Participants whose motivations for study

enrollment include histories of ovarian cancer in either themselves or their family members may find it upsetting to re-visit their personal experiences.

There is a small potential risk of outreach to family members of a recently deceased woman. In GCR's past experiences, this event does indeed happen on occasion but the typical response is a family member contacts GCR to inform about the passing of their family member. No adverse event has been reported thus far (e.g., distress, confusion). The proposed research activities present the same outreach risk (which is minimal) as routine contact by the GCR.

Other potential risks to participation include the possibility of a breach of confidentiality or data privacy in which the study participant's involvement in genetic counseling, comments or survey information may become known by individuals not directly involved in the research.

In order to attenuate the likelihood and impact of these potential risks:

Throughout recruitment, GCR will perform monthly checks to minimize the risk of initiating contact with a recently deceased woman. If such contact occurs, GCR's standard protocol is that the registry is the single point of contact for all patient outreach. The GCR's primary goal is to ensure that trained registry staff respond to such calls and work to reduce possible distress and address questions and concerns per their standard protocols.

Participants will be informed that their responses will be described in aggregate and they can skip any questions they do not wish to answer, or withdraw from the study at any time. Additionally, all of those who log in to the study website (restricted or expanded) will be provided with a 24-hour call in line (hosted by the GCR Registry) to request contact from the study team regarding any concerns. Jointly, our research team includes 2 board-certified genetic counselors (Guan, Bellcross), an oncologist (Meisel) and a bioethicist (Pentz) with expertise in areas that may raise concerns for participants. We can arrange call backs to participants who register concerns related to their participation in the study.

Participants who receive tele-genetic counseling will have the opportunity to have their questions/concerns related to genetic screening/testing addressed by the genetic counselors as is standard practice. All of the genetic counselor interns will have to complete at least one cancer rotation at the time of the study and they will receive clinical oversight by senior clinicians including Drs. Bellcross, Guan, and Meisel. Each of these genetic counseling professionals have extensive experience in cancer genetics. During the online discussions (Aim 3), they will also be available to answer questions related to cancer care and genetic counseling via online written responses.

More detail about data security and participant confidentiality are described below in the Data Management and Monitoring and Confidentiality sections of this protocol.

6.3 Describe the source records that will be used to collect data about participants. (Attach all surveys, scripts, and data collection forms in

Smartform on "Study-Related Documents" page under "Other Attachments." If unable to attach data collection instruments due to copyright requirements, include description of the instrument in the protocol document)

Aim 1: User testing procedures will include structured interviews to assess website content and messaging feedback, and the ratings of the website using the Suitability Assessment of Materials (SAM) and Comprehensibility (CAM) scale, facilitated by Peachtree Solutions (the developer of the website).

Aim 2: Primary data sources include: 1) GCR will record all survivor contacts (i.e., mailings, calls, messages left, call-backs), 2) website use reported by Peachtree Solutions on a monthly basis (i.e., website login and user-patterns data), 3) genetic counseling interns' electronic case logbook of appointment scheduling and completion, 4) post-intervention online survey.

Aim 3: Data sources are online survey data and participants' comments on the online discussion forums collected from the study website.

The project is currently in the process of being considered for funding by NCI. NIH requires provisional IRB approval for any project to receive funding. At this time there are no documents that are ready for IRB review. We state this throughout the protocol, that all documents will be submitted prior to interacting with study participants. We are asking that we obtain approval in concept for the project, provisional on review of specific materials if the grant is funded. We used the same approach for our Deliberative Democracy R21 (IRB00114524) that was funded in December, 2019.

6.4 What data, specifically, will be collected during the study and how that data will be obtained.

Primary RCT outcomes: 1) Survivor reach: the proportion of the eligible survivors identified and contacted by GCR who log in to the website, 2) Close relative reach: the proportion of close relatives enumerated by survivors who log in to the website, and 3) Uptake of cancer genetic services: the proportion of untested survivors who complete telegenetic counseling and the proportion of relatives enumerated who complete B-RST™ screening and subsequently access genetic counseling. We will evaluate secondary outcomes: In the MBI arm, we will track survivor' and relatives' patterns of website usage including: duration of time on the website, number of return visits, pages viewed, and the proportion of survivors who select different relative contact options. We can also link survivor and relative patterns of use to evaluate "family" patterns of use. We will assess the proportion of survivors and relatives who self-report in the post-intervention online survey (described below) having completed genetic testing, but we will not have sufficient power to consider uptake of genetic testing as a primary outcome.

Primary data sources include: 1) GCR will record all survivor contacts (i.e., mailings, calls, messages left, call-backs), 2) website use reported by Peachtree Solutions on a monthly basis (i.e., website login and user-patterns data), and 3) genetic counseling interns' electronic case

logbook of appointment scheduling and completion. We will limit website data collection to information regarding survivor's prior genetic counseling/testing, enumeration of relatives, and contact information for relatives with survivors' approval to contact. We will limit data collected from relatives on the website to telephone number, home address, email addresses, and to prior experiences with genetic counseling/testing. We decided against a formal survey prior to or during the intervention to minimize participant burden and to enable a cleaner evaluation of the feasibility of using the proposed intervention to maximize survivor/relative reach.

Table 2. Post-Intervention Online Survey Data Collection

Component	Measures
Ability to process health information	health literacy
Central processing	Breast/ovarian cancer knowledge, accuracy of perceived risk for *BRCA1/2* mutations and ovarian cancer
Defensive processing	Accept information as accurate, cancer fear, cancer risk perception
Prevention efficacy	Endorsing statements that ovarian cancer risk can be reduced
Reactions to the intervention	Acceptability and votes on outreach communication approaches
Other	Family communication style, age, race, education, personal cancer history etc.

Post-intervention online survey: We will recruit survivors and relatives who logged on to the website, regardless of their level of participation. We will post a study invitation letter and a one-time 20-minute survey on the study website and send the letter to survivors and relatives with contact information (e.g., mailing address, email, or mobile phone number) about 4 weeks after the intervention phase. Based on our sample size scenarios in Table 3 we estimate recruiting 120 survivors (15% response rate) and 66 relatives (15% response rate) to complete the online survey. We will compensate participants with $35 to complete the online survey. In other research, we used an online survey to evaluate recall of B-RST™ results following a mammogram screening visit; 35% agreed to complete an online survey with a $25 incentive.[63] We will include measures of (Table 2): Ability to process health information ("How confident are you filling out medical forms by yourself?") This item correlates strongly with longer health literacy assessments[142]; We will assess central processing in several domains: a 7-item breast/ovarian cancer genetic knowledge scale[143], recall of the B-RST™ result (correct/incorrect), accuracy of perceived likelihood of carrying a *BRCA1/2* mutation, and accuracy of perceived absolute risk of ovarian cancer ("how likely is that you will develop ovarian cancer in your lifetime?").[63-65] We will assess defensive processing with a 9-item information acceptance scale in which relatives respond to statements such as, "The information I received about my risk for hereditary breast and ovarian cancer seems accurate" (scores range from 0-45, a higher score indicates a high acceptance)[63]. Cancer fear is based on 3-items (e.g., "of all the diseases, I am most afraid of cancer.")[66] We will assess comparative risk perception with a single item "compared to the average woman your age, would you say that you are less likely/as likely/more likely to develop ovarian cancer." Prevention efficacy: We will assess ovarian cancer fatalism with two items (e.g., "If a woman is meant to get ovarian cancer, she will get it no matter what she does?").[66] Other measures: cancer genetic testing (yes/no), extent of family discussions about ovarian cancer, and relevant demographics.[30]

Process Data Collection and Measures: To measure reach (coverage and participation rates) and dosage (intervention delivered and received), we will electronically track the number of mailings/phone calls to each participant, website usage pattern, request for genetic counseling, and the completion of genetic counseling and testing. Fidelity: For quality control purposes, Drs. Guan and Bellcross will evaluate audio-recordings of ~70 sessions (10% of the estimated total) to assess whether the following topics have been discussed: personal/family medical history, inheritance, appropriate genetic tests, and the risks/benefits/limitations of recommended tests. A sum score of 80 (out of 100) will demonstrate good quality of counseling.

All survey instruments used in the study will be developed in the 12-month planning stage. Prior to fielding the study, these instruments and related scripts will be submitted as an IRB amendment.

6.5 If there are plans for long-term follow-up (once all research related procedures are complete), what data will be collected during this period.

- N/A.

6.6 If audio/video-recordings will be generated, describe processes for transcribing audio/video recordings. Will audio-recordings be destroyed after transcription? If so, how long after transcription? If not how will they be kept secure? If video-recordings will be used beyond the current research procedures for educational/presentation purposes.

- The genetic counseling sessions will be held on Zoom and the meetings will be recorded. After each session, all recorded files will be uploaded to Emory password protected, research network drives. The recordings will be deleted from any computers/laptops after transcription. Access will be given to essential team members only. No personal identifiable information will be transcribed or reported.
- For quality control purposes, Drs. Guan and Bellcross will evaluate recordings of ~70 sessions (10% of the estimated total) to assess whether the following topics have been discussed: personal/family medical history, inheritance, appropriate genetic tests, and the risks/benefits/limitations of recommended tests.

6.7 Does the research design require subjects to be deceived?

- No. All study subjects must be alive at the time of recruitment.

6.8 Will the subjects be exposed to any stress?

- No. Other potential psychological or emotional distress is described in detail in section 6.2.

7.0 Data and Specimen Banking*

- N/A.

8.0 Sharing of Results with Participants*

- N/A. This project does not involve investigational diagnostic tests, genetic tests, or incidental findings. We will not share any participant information with the participant's physicians.

9.0 Study Timelines*

9.1 The duration of an individual subject's participation in the study:

Aim 1 (community working groups): Eligible participants are: English-speaking, have a personal and/or family history of ovarian cancer, 25 years or older, have access to the internet and be available to attend in-person or online focus group discussions. Participants will attend 2 to 3 90-minute in-person meetings and some additional outside "homework".

Aim 2 (message-based intervention (MBI) and waitlist standard outreach approaches): Eligible survivors are: diagnosed with ovarian, fallopian tube, or peritoneal cancers, lived in Georgia at the time of diagnosis, not deceased, and have a mailing address per the Georgia Cancer Registry (GCR)'s records. Study duration could to up to one year.

Aim 2 & 3 (post-intervention online survey): Survivors and relatives in both arms who login to the study website will be invited to complete an one-time online survey. Study duration could to up to 30 min.

Aim 3 (mail survey to survivors who did not login to the study website): GCR will send a brief survey with a $10 incentive to survivors in both study arms who have never accessed the website after GCR completes recruitment efforts. Study duration could to up to 10 min.

Aim 3 (online discussion forum): We propose to purposefully sample survivors (~25) and relatives (~25) randomized to the MBI arm to participate in an online discussion forum. Study duration could to up to 1 hour.

Aim 3 (re-engagement of working groups, Year 4): After data analysis is complete (late Year 4), we will reengage community working groups from Aim 1 for a half-day workshop where we will report findings of the intervention and enlist additional feedback.

9.2 Totally duration of overall study: Four years.

10.0 Subject Population*

Aim 1 (community working groups): English-speaking, have a personal and/or family history of ovarian cancer, 25 years or older, have access to the internet and be available to attend in-person or online focus group discussions.

Aim 2 (message-based intervention (MBI) and waitlist standard outreach approaches): Survivors: diagnosed with ovarian, fallopian tube, or peritoneal cancers, lived in Georgia at the time of diagnosis, not deceased, and have a mailing address per the Georgia Cancer Registry (GCR)'s records. Relatives of survivors: able to read English, be 25 years or older, have access to

the internet, be a first- or second-degree relative of the survivor, and not be incarcerated or institutionalized.

Aim 2 & 3 (post-intervention online survey): Survivors and relatives in both arms who login to the study website.

Aim 3 (mail survey to survivors who did not login to the study website): Survivors in both study arms who have never accessed the website after GCR completes recruitment efforts.

Aim 3 (online discussion forum): Survivors and relatives randomized to the MBI arm who login to the study website.

11.0 Vulnerable Populations*

- N/A.

12.0 Local Number of Participants

1240

Planned (Anticipated)

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/Alaska Native	4	1	0	0	5
Asian	35	6	4	1	46
Native Hawaiian or Other Pacific Islander	1	0	0	0	1
Black or African American	302	53	33	7	395
White	591	102	66	11	770
More than One Race	18	3	2	0	23
Total	951	165	105	19	1240

13.0 Recruitment Methods

Aim 1 (community working groups): We will collaborate with local community organizations and use snowball sampling approaches to recruit35-40 individuals to serve in study working groups. To be eligible, individuals must : speak English, have a personal and/or family history of ovarian cancer, be 25 years or older, have access to the internet and be available to attend in-person or online focus group discussions. In assembling the working groups, study staff will conduct additional eligibility screening (e.g., prior experience with cancer genetic services, family size) to increase the diversity of community members for working group activities. Georgia CORE Community Advisory Boards (CAB), the Cancer Patient Navigators of Georgia, and the Survivorship Advisory Board have extensive experiences working with cancer survivors across Georgia and will assist in recruitment for Aim 1 (See letters of support). Ms. Nancy Paris (Co-I) will oversee these activities with a research assistant and an ethics fellow. Two community consultants nominated by Ms. Paris will work with local organizations to recruit working group participants. Additionally, we will approach organizations where members are more likely to have undergone genetic counseling/testing and include male members to increase diversity on these characteristics. Participants will receive $500 for attending 2 to3 90-minute in-person meetings

and some additional outside "homework". Recruitment of community members will take approximately 3 months at the beginning of Year 1.

Aim 2 (message-based intervention (MBI) and waitlist standard outreach approaches): Ovarian cancer survivors in the Georgia Cancer Registry (GCR) database who meet the following criteria will be considered for study participation: 1) diagnosed with ovarian, fallopian tube, or peritoneal cancers; 2) lived in Georgia at the time of diagnosis; 3) currently are alive per the registry's records; and 4) have a mailing address. The proposed recruitment procedures comply with GCR's current standards and are adapted from strategies that were effective in other studies using cancer registry for recruitment.[1-5] We will classify survivors who log in to the study website as recruited. Recruitment will rely on multiple communications aimed to encourage survivors to log in to the study website; the number of contacts will be largely identical for both arms: first mail-out (full packet plus $10 incentive), telephone contact from a trained GCR staff, second mail-out (postcard reminder), and third mail-out (full packet). Our review of registry files as of May 2019 showed that: of the 8,760 women with a diagnosis of ovarian, fallopian tube, or peritoneal cancer (excluding those who were deceased or lost to follow as of 2017), we will have addresses for about 2,918 survivors over the 16-month recruitment period. In a recent study using GCR to recruit breast cancer survivors in Georgia with registry standard mailing and phone contact without financial compensation, 63% agreed to participate.[6] A conservative assumption of reaching (i.e., log in to the study website) 45% in the MBI arm versus 10% in the standard outreach arm, we need to recruit 801 cancer survivors into our study. Relatives of survivors eligible to participate must be: 25 years or older, have access to the internet, be a first- or second-degree relative of the survivor, able to read English, and not be incarcerated or institutionalized. We estimate that 801 cancer survivors will log in to the website and 75% of them (N=601) will enumerate a median of 2 at-risk relatives. We assume the number of at-risk relatives enumerated will not differ between intervention arms. Furthermore, we estimate that 40% of relatives referred by MBI arm participants will log on compared to 20% in the standard outreach arm. We expect that about 438 relatives will participate in the study. Recruitment of survivors and relatives for the intervention will occur in Year 2 and 3.

Aim 2 & 3 (post-intervention online survey): We will recruit survivors and relatives who logged on to the website, regardless of their level of participation. We will post a study invitation letter and a one-time 20-minute survey on the study website and send the letter to survivors and relatives with contact information (e.g., mailing address, email, or mobile phone number) about 4 weeks after the intervention phase. Based on our sample size scenarios we estimate recruiting 120 survivors (15% response rate) and 66 relatives (15% response rate) to complete the online survey. We will compensate participants with $35 to complete the online survey. In other research, we have used an online survey to evaluate recall of B-RST™ results following a mammogram screening visit; 35% agreed to complete an online survey with a $25 incentive.[7] Recruitment of survivors and relatives for the online survey will take approximately 3 months at the beginning of Year 4.

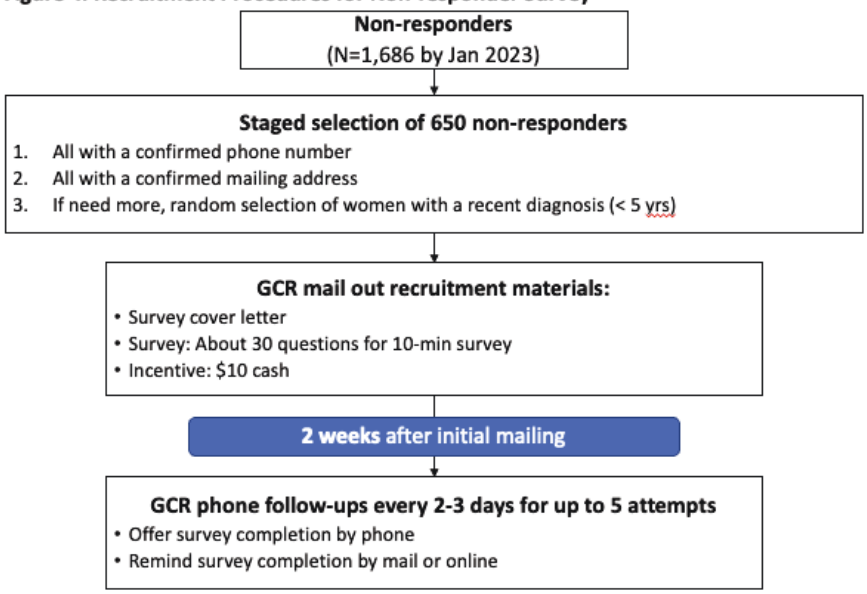
Aim 3 (mail survey to survivors who did not login to the study website): GCR will send a brief survey to survivors in both study arms who have never accessed the website after GCR completes recruitment efforts. Based on our prior recruitment data, about 1,686 survivors will not visit the study website by Jan, 2023 and will be eligible for this survey. We will conduct staged selection

of 650 non-responders over the 8-month recruitment period (Jan – Aug 2023): (1) reach out to all participants with a confirmed phone number (GCR have talked to participants during trial recruitment or their voicemail states their name); 2) reach out to all participants with a confirmed mailing address (GCR confirmed the mailing address through at least two resources (GCR database, ACCUR or voter registration database); and 3) reach out to participants whose ovarian cancer diagnosis is within five years. We aim to recruit 375 survivors for this survey. The proposed recruitment procedures comply with GCR's current standards. Recruitment will rely on two rounds of communications aimed to encourage non-responders in both study arms to complete the survey (Figure 4).

The first mail-out packet will include a survey cover letter (See "non-responder survey cover letter"), $10 cash, a postage-paid return envelope to return completed survey, and a 10-min survey (See "Non-responder survey draft") that asks about participant recall of receiving study materials, perceived importance and relevance of learning ovarian cancer risks, privacy concerns about health website, and trust in university health research. Participants may answer the questions online by using a QR code or write their responses on the enclosed document and return it to GCR.

Two weeks after mailing each packet, GCR will contact survivors by phone who do not complete the survey online or by mail. We will call survivors every 2-3 days for up to 5 attempts, after which we will categorize them as inaccessible. The phone call aims to: 1) check on receipt of the survey packet; 2) offer survey completion by phone; 3) remind survivors to complete the survey by mail or online; and 4) answer questions regarding the study. This schedule is the standard for GCR outreach.

Figure 4. Recruitment Procedures for Non-responder Survey



Aim 3 (online discussion forum): We propose to purposefully sample survivors (~25) and relatives (~25) randomized to the MBI arm to participate. We will conduct cluster analysis based on 2/3rds of the recruited sample to assess patterns of website use and identify sub-groups of users. We will use multinomial regression analysis to understand sociodemographic differences

in cluster members and use the clusters as strata for the recruitment into the online discussion forum. These analyses will allow us to identify "user profiles" and stratify sampling to increase representation of various user patterns based on GCR contact effort, website usage (high/low), and uptake of genetic counseling/testing (yes/no). We will send invitations and identify a back-up individual from the waiting list, should the original invitee decline. Participants will receive information about how to participate in the online discussion forum via email/mail/phone/website postings. Recruitment of survivors and relatives for the online discussion forum will take approximately 3 months at the beginning of Year 4.

All survey instruments used in the study will be developed in the 12-month planning stage. Prior to fielding the study, these instruments and related scripts will be submitted as an IRB amendment.

14.0 Withdrawal of Participants*

Participants will be informed that they can choose not to participate in the study. They can skip any questions they do not wish to answer, or withdraw from the study at any time.

15.0 Risks to Participants*

We expect the research-related risk to be minimal: the probability & magnitude of harm/discomfort anticipated in the research is no greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations/tests.

There are no anticipated physical risks of participating in this study. However, participants may experience psychological or emotional distress from participating in the study, particularly activities related to the way their family interacts or communicates about ovarian cancer and genetic risks. Survivors may worry about their family members' emotional distress. Participants whose motivations for study enrollment include histories of ovarian cancer in either themselves or their family members may find it upsetting to re-visit their personal experiences.

There is a small potential risk of outreach to family members of a recently deceased woman. In GCR's past experiences, this event does indeed happen on occasion but the typical response is a family member contacts GCR to inform about the passing of their family member. No adverse event has been reported thus far (e.g., distress, confusion). The proposed research activities present the same outreach risk (which is minimal) as routine contact by the GCR.

Other potential risks to participation include the possibility of a breach of confidentiality or data privacy in which the study participant's involvement in genetic counseling, comments or survey information may become known by individuals not directly involved in the research.

In order to attenuate the likelihood and impact of these potential risks:

Throughout recruitment, GCR will perform monthly checks to minimize the risk of initiating contact with a recently deceased woman. If such contact occurs, GCR's standard protocol is that the registry is the single point of contact for all patient

outreach. The GCR's primary goal is to ensure that trained registry staff respond to such calls and work to reduce possible distress and address questions and concerns per their standard protocols.

Participants will be informed that their responses will be described in aggregate and they can skip any questions they do not wish to answer, or withdraw from the study at any time. Additionally, all of those who log in to the study website (restricted or expanded) will be provided with a 24-hour call in line (hosted by the GCR Registry) to request contact from the study team regarding any concerns. Jointly, our research team includes 2 board-certified genetic counselors (Guan, Bellcross), an oncologist (Meisel) and a bioethicist (Pentz) with expertise in areas that may raise concerns for participants. We can arrange call backs to participants who register concerns related to their participation in the study.

Participants who receive tele-genetic counseling will have the opportunity to have their questions/concerns related to genetic screening/testing addressed by the genetic counselors as is standard practice. All of the genetic counselor interns will have to complete at least one cancer rotation at the time of the study and they will receive clinical oversight by senior clinicians including Drs. Bellcross, Guan, and Meisel. Each of these genetic counseling professionals have extensive experience in cancer genetics. During the online discussions (Aim 3), they will also be available to answer questions related to cancer care and genetic counseling via online written responses.

More detail about data security and participant confidentiality are described below in the Data Management and Monitoring and Confidentiality sections of this protocol.

16.0 Potential Benefits to Participants*

Participants may or may not benefit directly by taking part in this study. Through reviewing the print- and website-based communication materials and undergoing genetic counseling, participants may develop a broader knowledge base, competence and confidence to interpret and analyze genetic risk information related to hereditary cancers. If participants choose to undergo genetic testing in the future and are found to be a mutation carrier of hereditary cancer syndromes, the information will be useful for their personal health care management and for their family members' health as well.

As any risks of participating are anticipated to be minimal, it is believed that the knowledge gained from participants' responses will provide societal benefits that outweigh any risks to the participants.

Results of this study could inform the adaptation of similar traceback programs for other heritable cancers and in other states to increase the likelihood of fair distribution of precision medicine advances.

17.0 Data Analysis, Management* and Confidentiality

Power analysis for RCT: Our study population is equal to (and thus limited by) the population of ovarian cancer survivors in Georgia. A recent study using GCR to recruit breast cancer survivors in Georgia used registry standard mailing and phone contact without financial compensation, which yielded 63% rate of agreeing to participate (Lipscomb, under review). With a conservative

assumption of reaching (i.e., login to the study website) 45% in the MBI arm versus 10% in the standard outreach arm, we aim to recruit 801 cancer survivors into our study, 656 into the MBI arm and 145 into the control arm. We conducted power calculations using SAS PROC POWER to assess power given these assumptions. Table 3 shows power for the 4 primary outcomes. We will have very good power (β>95%) to detect an intervention effect for each primary outcome. Even if we unexpectedly are less successful in recruiting survivors in the MBI arm, we are still powered to detect a significant intervention effect for 20% reach in the MBI arm with a total sample size of 436. Power analyses for the two primary outcomes for close relatives were conducted assuming a design effect (DEFF) of 1.3 expecting moderate clustering in the outcome. Even with DEFF=2, we are adequately powered to detect an intervention impact in relatives for reach and uptake of B-RSTTM.

Table 3. Power for primary RCT outcomes

Outcome	Sample size		Response rate		Power
	MBI	Control	MBI	Control	
Survivor primary outcomes:					
Survivor reach	1459	1459	45%	10%	>.99
Survivor uptake of genetic counseling	656	145	70%	30%	>.99
Relative primary outcomes:					DEFF=1.3
Relative reach	985	219	40%	20%	>.99
Relative uptake of B-RST	394	44	70%	30%	>.99

Data analysis for primary RCT outcomes: We will conduct all analyses in SAS 9.4. Because our sample is identical with the study population, there will be no missing data for the main outcome. We will code people who do not engage in primary study outcomes (e.g., visiting website) as '0', and all others as '1'. Among participants interacting with the website, we will calculate dose of web use as the number of sessions and time spent on the website as indicators of central processing. For the main trial outcomes, we will first examine distributions (frequencies and means/standard deviations) for all relevant variables. To analyze *survivor outcomes*, we will use logistic regression to analyze arm assignment as a predictor of: 1) reach and 2) uptake of genetic counseling yielding an odds ratio and 95% confidence interval for the intervention effect. For *close relatives outcomes*: 1) reach, 2) uptake of B-RST™, and 3) uptake of genetic counseling, we will conduct a logistic multilevel analysis accounting for clustering of close relatives in cancer survivors (i.e. close relatives are level-1 who are nested in level-2). Given the binary nature of the outcomes, we will assess dispersion and adjust for over- or under-dispersion in our analyses. Subsequently, we will conduct moderator analyses to see for whom the intervention worked best. These analyses will entail expanding the described logistic regression/logistic mixed models to include direct effects of a proposed moderator (e.g. age at diagnosis) and an interaction effect between the moderator and arm assignment. Although the main outcomes will have no missing data, our covariates might have missing data. We will assess patterns of missingness and use appropriate methods (i.e. full-information maximum likelihood estimation or multiple imputations) to account for missing data.

Data analysis for post-intervention online survey: To evaluate factors suggested by information processing theories that are associated with the intervention, we will conduct quantitative

analyses of survey data to characterize participants' processing and demographics. We will apply linear or logistic regression to compare differences on knowledge, comprehension, between the intervention and standard outreach arms. For example, in these analyses we will evaluate whether participants in the MBI arm show higher cancer genetic knowledge than relatives in the standard outreach arm. Overall, we will adjust these analyses for health literacy and age.

User Pattern Analysis: To assess patterns of website use and identify sub-groups of users, we will use traditional web tool user data (e.g. time of access after invite to use, frequency of use) and programmatic user data (e.g. types of viewed content, types of completed tasks). These analyses will be conducted approximately 2/3 of the way through recruitment when we have adequate numbers for characterizing user patterns. We will identify the sub-groups through descriptive analysis and if meaningful using cluster analysis.[70] Subsequently, we will use multinomial regression analysis to understand sociodemographic differences in cluster members and use the clusters as strata for the recruitment into the online discussion forum described above.

Process Outcome Measures: Implementation reach, dosage, and fidelity is based on proportions and means/standard deviations for relevant quantitative variables (e.g., website access, number of visits/length, counseling session evaluation scores). Outreach approach's acceptability, barriers, facilitators, and perceived alignment with ethical principles will be based on descriptive analyses of *quantitative* survey responses (mail and online – e.g., the proportion of participants who vote "yes or no" and rate outreach as protecting autonomy and respecting family relationship (relational autonomy). For *qualitative* responses on the online discussion forum, we will conduct qualitative content analysis using MaxQDA. We will identify distinct themes and categories related to each discussion topic, such as acceptability, and alternative contact strategies and best methods of supporting relational autonomy. Two study team members (led by Dr. Pentz) will independently code five responses per discussion topic to ensure agreement of coding. Using a final codebook, a bioethics fellow and graduate assistants will conduct coding. We will systematically review all responses for the most commonly occurring themes and will identify representative quotes. The recorded counseling sessions (~70) will also be qualitatively coded to compare 4 measures by study arm: 1) session length in minutes, 2) verbal dominance (ratio of counselor to participant statements), 3) patient activation (number of patient medical, psychosocial, and lifestyle statements and questions), and 4) nonverbal affect assessed by a 6-point scale[71,72] (low to high) reflecting both positive (interest, warmth, engagement, empathy, respectfulness and interaction) and negative affect (dominance and hurried for the genetic counselor, anxiety and distress for the patient).

As described in detail in section 19.0, confidentiality safeguards are in place during the following activities: recruitment, informed consent process, participation in study website, survey and online forum, data transportation, data analysis, and study finding reporting. Only the study ID number will be attached to data. In terms of reporting of study results, only basic sociodemographic identifiers (e.g., age, income, education) will be reported in aggregate.

18.0 Provisions to Monitor the Data to Ensure the Safety of Participants*

- N/A. Our project involves no more than minimal risk to participants.

19.0 Provisions to Protect the Privacy Interests of Participants and Confidentiality of Participants' identifiable data

To protect participants' privacy, the community working groups will take place in private settings (e.g., conference rooms). Participants in the telegenetic counseling sessions will be asked to schedule a time when they can speak privately. The online survey and discussion forum will be hosted by the study website and access will be password controlled. We will advise participants to use a pseudonym to maintain their anonymity. Participants can share their responses to the research team only, or make the responses available for other participants to view.

Based on existing best practices for security and privacy in health information technology, we have employed the technologies and features needed to ensure privacy and security of personal information. These features address identity and access management, secure storage, secure messaging, encryption, and other security technologies and approaches. The GCR logistical survivor contact records on mail-outs and phone calls (i.e., messages left, call-backs) will be managed in accordance with HIPAA Privacy Rule, 45 CFR Parts 160 and 164. All other data (i.e., website login and user-pattern data, telegenetic counseling logbook, online survey and discussion forums) will be collected via HIPAA compliant online platforms developed and managed by Peachtree Solutions. All of the data will then be downloaded to Emory password protected, research network drives.

Peachtree solutions has three levels of safeguards built into their business approach: administrative, technical and physical to insure the security and privacy of sensitive data. Administrative safeguards include annual risk assessments of the hosting environment and coding practices. Employees are trained annually on the proper handling of sensitive client data and secure coding techniques. Policies and procedures are reviewed on an annual basis and reviewed by an outside security department on a regular basis as a normal course of business. All employees are background checked at the time of hire. Technical safeguards include quarterly external vulnerability scanning, and access controls (e.g., unique user identification; emergency access procedures, automatic logoff, authentification, and encryption/decryption). Physical safeguards include contingency procedures for facility access in support of data restoration under the disaster recovery and emergency operations plan. All data is stored in an ISO 9001 certified facility that requires badge and biometric confirmation to gain access to the data center floor. All data is stored in a locked server cabinet that only datacenter employees can access. Access is logged. Policies and procedures are implemented toward final disposition of PHI that is stored. All data is backed up every 3 hours and stored both locally and in a remote data center using hard encryption.

Strict confidentiality of the completed data will be maintained. A unique random identification number will be generated and assigned to each participants. These identification numbers will be used for all data analysis and kept separately from identifying information and accessible only by the study team. Identifying information collected for participant recruitment (patient contact

lists, phone numbers) will be transferred and stored using secure, encrypted file transfer protocols. Encryption will be used for all data in transit between the web browser and the server, all identifiable data at rest in the database, and all backups of the data. Access to decrypted identifiable data will be limited to a need-to-know basis for study team members. Any data collected for research will have identifiable data removed from the data set. All administrative accounts will have their own unique login (no shared logins). All data will be secured in password-protected computer files and reported at the group or aggregate level. Names will not be identified in any reports resulting from the research, and no individual information will be released to anyone outside of the project. Study personnel will be required to have IRB authorization which requires ongoing credentialing regarding procedures to maintain confidentiality. Research staff will also sign statements of confidentiality. Only necessary study personnel will have access to any of these files. Identifying information (phone numbers) will be deleted from all files at the end of the study period.Names will not be identified in any reports resulting from the research, and no individual information will be released to anyone outside of the project. Study personnel will be trained regarding procedures to maintain confidentiality. Research staff will also sign statements of confidentiality. Access to subject personal identifiers will be restricted to the PI, recruitment staff, and upon written request, to the Institutional Review Board or other appropriate regulatory agencies. Identifying information (phone numbers) will be deleted from all files at the end of the study period.

The data and safety monitoring will be conducted annually by an independent data safety monitoring committee. The data will be reviewed include: adverse events, enrollment numbers, raw data, and outcomes. Safety monitoring results will be reported to the IRB of the Rollins School of Public Health of Emory University.

All study team members have current CITI certifications through Emory University. Study team members' preparedness will be enhanced and accomplished by pretrial and ongoing training on basic breast cancer and hereditary cancer risk information, study protocol, and ethical conduct. In addition, the study team will also receive training in how to refer participants to informational and support resources, including patient navigator programs in the survivor's locale that can assist in additional medical care needs.

20.0 Compensation for Research-Related Injury

- N/A. Our project involves no more than minimal risk to participants.

21.0 Economic Burden to Participants

- N/A.

22.0 Consent Process

We request "Waiver of Documentation/Signature only", given that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. More details are included in the "Combined_Waiver_Consent_HIPAA_Elements" document.

All consent materials used in the study will be developed in the 12-month planning stage. Prior to fielding the study, these materials will be submitted as an IRB amendment.

Aim 1 (community working groups): The study team will collaborate with Community Advisory Boards (CAB) to identify 35-40 individuals using snowball sampling approaches and provide them with information about the study, describe working group procedures, the stipend provided for their participation, and obtain permission to provide research staff with their contact information. Study staff will then contact referred individuals and complete a brief screener to determine eligibility for the working group, discuss the details of the working groups, explain that participation is voluntary, safety of privacy and confidentiality of protected health information, and confirm availability. Study research assistants will provide those who agree with a printed consent form and discuss any questions. Verbal consent will be obtained from participants. Those who participate in the working groups will receive $500 for attending 2-3 90-minute in-person meetings and some additional outside "homework".

Aim 2 (message-based intervention and waitlist standard outreach approaches): The GCR will identify eligible cancer survivors and provide them with website access information. Upon entry to the study website, we will provide survivors with an explanation of the study and the opportunity to continue or to decline. The online consent form ends with the "I agree" checkbox so the participant can decide whether they still want to participate after reading the listed conditions. Those who agree to participate and include their mobile phone number will receive cueing SMS reminders from the study team. Survivors who select choice options that involve the study team doing outreach on the survivor's behalf will receive an additional prompt to provide consent and contact information (e.g., mailing address, email, phone number) of first and second degree relatives. Relatives, contacted by the survivor or permitted to be contacted by the study team will receive a unique website login that is linked to the survivor and enables access to a consent form on the study website that describes the study procedures, potential benefit and risks, privacy and confidentiality of protected health information. Same as survivors, relatives who click the "I agree" button on the informed consent webpage would indicate consent. Relatives in the MBI arm who log in to the website and are willing to provide a mobile phone number also will receive cueing SMS reminders from the study team. All relatives who consent to participate will be directed to complete B-RST™ and the same tele-genetic counseling services.

All survivors and relatives who log in to the website, regardless of whether they complete the tasks, will have access to the same pre-test telegenetic counseling. Survivors can opt for phone and/or video counseling via Emory HIPPA approved Zoom links. Participants will be asked to review online a genetic counseling consent form. The consent form will include information about the procedures of genetic counseling, potential benefits and risks, privacy and confidentiality of protected health information, and contact information for the Emory IRB and study team. Verbal consent will be obtained by the genetic counselor intern from the participant prior to the counseling session.

Aim 2 & 3 (post-intervention online survey): We will recruit survivors and relatives who log on to the study website regardless of their level of participation. We will post a study invitation letter and a one-time 20-minute survey on the study website and send the letter to survivors

and relatives with contact information (e.g., mailing address, email, or mobile phone number) about 4 weeks after the intervention phase. The invitation letter will contain information about how to access the one-time online 20-minute survey. After participants click the "I agree" checkbox at the end of the online consent form, they will be directed to the online survey link.

Aim 3 (mail survey to survivors who did not login to the study website): GCR will mail survivors a mail-out packet, which will include a survey cover letter (See "non-responder survey cover letter"), $10 cash, a postage-paid return envelope to return completed survey, and a 10-min survey (See "Non-responder survey draft"). Participants will be asked to review the cover letter that explains study procedures, voluntary nature of participation, and actions to protect their confidentiality. Participants may answer the questions online by using a QR code or write their responses on the enclosed document and return it to GCR.

Aim 3 (online discussion forum): We propose to purposefully sample survivors (~25) and relatives (~25) randomized to the MBI arm to participate. We will send invitations and identify a back-up individual from the waiting list, should the original invitee decline. Participants will receive information about how to participate in the online discussion forum via email/mail/phone/website postings. Participants will be asked to review the informed consent posted on the discussion forum. If they agree to participate, they will click the "I agree" button and be directed to the discussion forum.

Aim 3 (re-engagement of working groups): After data analysis is complete (late Year 4), we will reengage community working groups from Aim 1 for a half-day workshop where we will report findings of the intervention and enlist additional feedback. Participants will receive $50 for this meeting. Verbal consent will be obtained from participants.

Non-English-Speaking Participants ☐N/A

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception) ☐

- Please review our submitted Combined_Waiver_Consent_HIPAA_Elements document.

Participants who are not yet adults (infants, children, teenagers) ☐N/A

Cognitively Impaired Adults ☐N/A

Adults Unable to Consent ☐N/A

23.0 Process to Document Consent in Writing

- N/A. Please review our submitted Combined_Waiver_Consent_HIPAA_Elements document.

24.0 Setting

Emory University is the ideal setting for the proposed study, as several key resources are uniquely poised to support the research outlined in this study. Below we provide an overview of the setting and several key resources and how they will contribute to, facilitate, or support the study**.**

Emory Rollins School of Public Health

The Rollins School of Public (RSPH) Health has six academic departments: Behavioral Sciences and Health Education, Biostatistics and Bioinformatics, Environmental Health, Epidemiology, Health Policy and Management, and Global Health, and hosts over 20 interdisciplinary centers. More than 160 full-time, doctoral-level faculty members teach and conduct research in areas such as developing behavioral interventions and identifying the social determinants of health. RSPH also draws strength from several unique local resources, including the Centers for Disease Control and Prevention (CDC, located next door) and the Carter Center. RSPH has a large and comprehensive research portfolio (over $90,000,000 in FY2015), with faculty receiving funding from a wide range of federal and non-federal sources. The Office of Research is available to facilitate faculty research, help identify funding opportunities, enhance the quality of applications for extramural research support, stimulate inter-departmental research, and provide resources and support for faculty research programs. RSPH faculty members provide a rich resource for consultation on analytic, medical, and epidemiologic issues that may arise in the course of the proposed research.

In 2010, RSPH more than doubled its physical size with the opening of the 190,000 square foot Claudia Nance Rollins building. The nine-story building was designed to achieve Silver Leadership in Energy and Environmental Design (LEED) certification. The GCR building, which opened in 1994, underwent a major renovation in 2010 to upgrade classrooms, computer rooms, and technology. The two buildings combined encompass 330,000 square feet total, providing ample office space to house study investigators and staff.

<u>Behavioral Sciences and Health Education Department</u>

The mission of the Department of Behavioral Sciences and Health Education (BSHE) is to better the health of all people by advancing knowledge and training tomorrow's leaders in how to change behavior and social conditions that influence health. BSHE offers a Master of Public Health (MPH) degree and a PhD. The MPH degree is geared toward students with an interest in multi-level behavior change interventions, social determinants of health and community engagement to enhance dissemination and implementation of effective interventions. BSHE's PhD program is offered through Laney Graduate School, and trains students to identify, analyze, and intervene in today's most pressing health issues.

Major areas of faculty expertise are: (1) the social determinants of health; (2) behavioral risk factor trajectories; (3) health education and behavioral interventions; and (4) implementation science. Our research is funded by federal government organizations such as the National Institutes of Health (e.g. NCI, NIEHS, NIAAA, NIDA, NIMH), the Centers for Disease Control and Prevention, Health Resources and Services Administration, Association of Schools of Public Health, and private foundations such as the American Legacy Foundation and Robert Wood

Johnson Foundation. We also work with the Georgia Division of Public Health and local health departments in Georgia and across the nation.

Our faculty work in diverse areas that involve social-ecological determinants of health and diseases. BSHE faculty's research spans major disease problems (HIV/AIDS, cancer, and heart disease) and areas of health promotion (mental health, physical activity, healthy eating), specific populations (adolescents, women, minority groups, rural communities), multiple health promotion settings (schools, communities, churches, the Internet) and specific behavioral and social problems (substance abuse, tobacco control, nutrition, physical activity, injury prevention, health communication). Students have many opportunities to work with faculty on these research projects.
Laboratory: Not applicable to this project.

Clinical: Not applicable to this project.

Animal: Not applicable to this project.

Computer/Technological
The Information Technology (IT) Department of the Rollins School of Public Health offers a state-of-the-art desktop and server infrastructure that supports over 2,500 users. From the ground up, it was designed to be modular and expandable in order to give Rollins the greatest computing capability, flexibility, and growth potential.

Server Environment
The school's server environment is based on a combination of UNIX and Windows and can be divided into a number of service areas:

Computer Services: The core of our compute services is provided by a high-performance computing cluster composed of 18 nodes with an aggregate of 354 processors and 3 TB of RAM. Storage is provided through our storage area network (SAN) and the central Isilon storage with 200 terabytes of RAID-protected HIPAA-compliant storage local on the cluster. The server hosts analysis and programming tools including: SAS, SPlus, gFortran, C, C++, Java, R, and MATLAB. The application environments are 64 bit and parallel computing enabled when the product supports the capability. Services are provided to the desktop using the X Windows and Univa Grid Engine interfaces.

Internet/Web Services: Our email services are provided by a central campus resource through Office 365, and we have access through a browser or direct interface such as Outlook. We provide secure and open access web services. The secure web areas can be restricted to the Emory network or an account. There are a number of services that support various CMS, JAVA environments, and other web services. We also take advantage of a central IT CMS service called Cascade for our main school website. All Rollins web content is served through our local web servers, which also support center, program, and personal faculty research websites. We

have a number of application environments to support research endeavors such as a Cold Fusion development server, RedCap, and Feedback server survey tools.

Database Services: We provide both secure and academic database services utilizing Microsoft SQL Server 2008 and MySQL instance. These databases are used to services a number of application systems across our administrative and research needs. Database accounts are available for any faculty member upon request.

File and Print Services: Based on Windows NT, seven servers work together to provide file and print service to the School's desktop network. These state-of-the-art systems provide the latest in general use programs, including statistical and mathematical modeling software, database management, graphics and office support tools.

Network Environment

Rollins' network consists of Fast Ethernet hardware running TCP/IP. Ten Gigabit Ethernet provides high-speed transmission to the Rollins campus buildings and all other buildings across campus. Ethernet provides high-speed (100 Mbps) access to most desktop computers and peripheral devices. The network terminates at over 2,500 locations.

The Rollins network is connected to the Emory Campus backbone via a 10 Gigabit Ethernet connection, making campus services and wide area network services readily available. We also have an extensive wireless network providing "N" class connections and speeds that cover all of our buildings and the nearby external areas. This network has guest services as well as secure services for our faculty and staff.

Our voice communications are connected into a Unified Communications system that provides phones through VOIP and are integrated with our email systems for VMail access. All of the secured services inside our firewalls including network storage and other services can be access through the Emory VPN.

Desktop Computers

Currently, the analytical computers are at least a I7 CPU configuration with 8GB of RAM memory, and have CD/DVD-RW and 20" or higher flat panel monitors standard with 500 gigs local disk space and 64 bit Windows. Our Apple Mac environments are generally iMac configurations or MacBook laptops with at least 4 gigs of memory. All of our desktop and laptop systems are connected to our network storage that provides both highly secure and open storage areas.

Our student computing environments are provided through our RSPHDesktop environment. This is a Citrix-based virtual desktop environment that provides more than 40 applications to our students and is accessible from any place they can get on a network and open a browser. Faculty and staff can also request access to the Citrix environment to access these applications when working remotely.

Information Security

The Rollins School of Public Health information technology environment is a HIPAA-covered entity and complies with HIPAA and Emory information security and privacy policies and practices. In compliance with these policies and practices, Rollins aligns with the National Institute of Standards and Technology (NIST) special publications (800 series) for identifying, assessing, and managing information security risk within a technology environment.

Drawing on federal and industry best practices, Rollins has implemented a series of multi-layered security controls to protect the integrity, reliability, and confidentiality of data. A sample of the key security controls includes:

- An annual risk assessment of all Rollins information technology assets with their level of risk, potential impact, probability, and controls evaluated based on NIST SP 800-30 Risk Management Guide for Information Technology Systems.
- Rollins and Emory networks are protected by firewalls and intrusion detection devices. Rules on these devices are set to deny all traffic by default and "allows" are written as exceptions. These devices are updated as appropriate through Emory University's change management process and evaluated to ensure they provide the appropriate level of protection based on the sensitivity level of the data.
- Servers are housed within a secured network operating center (NOC). The NOC has environmental controls (fire, water, temperature), is accessible only through a two-factor authorization system (key card and passcode), and is accessible only by authorized information technology personnel. In the event of a power outage, the NOC devices will draw UPS power from a backup generator.
- All servers are configured based on Rollins and Emory University best practices. Only authorized, trained system administrators have administrative privileges on the servers. System administrators monitor security mailing lists and sites and patch/update systems based on priority of the patch. All servers are periodically scanned for vulnerabilities and any identified vulnerabilities are assessed and managed.
- All information technology personnel go through background checks before gaining access to administrative privileges. At the point of termination with Emory, all information technology personnel's administrative privileges are removed.
- Protected health information (PHI) data and the services that manage them are stored on a separate network and server infrastructure with limited access and additional security controls.
- Data is backed up daily. Backups are stored in a tiered structure for disaster recovery purposes and include local, off-site, and out-of-state storage. Data stored off-site is encrypted to prevent compromise and can only be retrieved by authorized personnel.
- Data written to any Rollins file servers is checked with server-based anti-virus software. Access to data is verified with a local single point of contact within each department before any access control is granted. Principal investigators are required to review access control lists each year to ensure continued accuracy.
- All Rollins desktops are configured based on best practices in the industry as well as those outlined in NIST SP 800-69 Guidance for Securing Microsoft Windows XP Systems for IT Professionals: A NIST Security Configuration Checklist. All Windows machines have

anti-virus software installed with updated virus signatures as well as the latest Microsoft XP Professional updates. Desktops require authentication from the Emory Active Directory to gain access to network services.

- Security policies are created and reviewed through the Woodruff Health Sciences Center HIPAA committee, the Emory University Technology Infrastructure and Policy committee, and local policies through the Rollins Information Technology Advisory committee.

Conference rooms

The Claudia Nance Rollins Building and Grace Crum Rollins Building have conference rooms that allow for the easy hookup of laptops and other computers to be displayed on a large LCD or a projected screen. Each conference room has access to the CATV systems as well. Audio conferencing is built into the room where no external sound units are required to hold a conference call. Each conference room has connectivity abilities for high-end video conferencing systems that are wheeled in on a cart. The cart provides a Picture Tel system that can share up to four sessions and all of the content and sound connected in the room. The audio and video integrated in the room are also available for any PC hooked up to the systems so audio can be captured in the room and then used for PC-based video conferencing systems such as Skype.

Data protection and backup

We do full back ups of the HPC and servers once a week with incremental back ups on other nights. These back ups are kept for 90 days and are encrypted at an off-site location. Network shares have snapshots taken nightly, which are kept for 30 days.

Email/Vmail

We use a central IT services resource using Microsoft Office365 for our email. Our email is considered sensitive, so we have policies in place that control automated routing of email and we use a central spam engine to control propagation of virus and spam attacks. Our phone voice mail system is integrated with our email, so voice mails automatically produce email audio files upon receipt.

Office

Secretarial and computer support (including fax, e-mail, Internet, color printing, scanning and photocopying) are available to all Public Health faculty.

Other

Six campus libraries are available for use, including the Woodruff Library for Advanced Studies, and the Health Sciences Center Library. The university library system has access to thousands of journals and periodicals as well as, reference services which include computerized database searching. Computer laboratory and audiovisual facilities are also available within the university system. The CDC library is also available for use.

Emory University

Emory University is an international leader in research. Investigators at Emory University received $572.4 million from external funding agencies in fiscal year 2015, marking the sixth consecutive year of greater than half a billion dollars in research funding. Federal agencies awarded more than $375 million, or 66% of the total, led by the National Institutes of Health (NIH), with nearly $300 million in awards. NIH funding represented 80% of total federal dollars awarded to Emory.

Emory Woodruff Health Sciences Center

Emory's Robert W. Woodruff Health Sciences Center (WHSC) is an academic health science and service center focused on missions of teaching, research, health care, and public service. Its components include the Rollins School of Public Health; School of Medicine; School of Nursing; Yerkes National Primate Research Center; Winship Cancer Institute; and Emory Healthcare. The WHSC has a $3.5 billion budget, 23,400 employees, including 2,940 full-time and 1,300 affiliated faculty, 5,246 students and trainees, and a $6.8 billion economic impact on metro Atlanta. Researchers in WHSC received $537 million in external funding, or approximately 94% of the University total.

Emory's Genetic Counseling Training Program

The Emory University School of Medicine Genetic Counseling Training Program was established in
2011, and is the only program of its kind in the state of GA. The program has full accreditation through the Accreditation Council for Genetic Counseling. Graduates receive a Master of Medical Science
(MMSc) degree in Human Genetics and Genetic Counseling and are qualified to sit for the American
Board of Genetic Counseling (ABGC) certification examination.

The Genetic Counseling Training Program's vision is to transform students through a variety of scholarly activities into practitioners, leaders, and advocates for the advanced role of genetic counseling within an integrated care team model. The Program's mission is to provide an innovative and rigorous program of training that prepares genetic counselors to serve the needs of the healthcare community today while paving the way for incorporating the genomic medicine advances of tomorrow.

The program is housed within the Department of Human Genetics on the Emory Campus in Atlanta,
GA. The Emory Department of Human Genetics ranks in the top 15 departments in the country, with a full-fledged basic research faculty and a comprehensive medical genetics division that includes Emory Genetics Clinics and Emory Genetics Laboratory. The department also provides training in human and medical genetics for graduate students, laboratory fellows, PAs, medical students, and residents. The program offers a unique combination of cutting-edge coursework, extensive and varied clinical experiences, and a research-based Focus Internship. The 5-semester internship allows the student in depth exploration of a specialty area within the

settings of public health genomics, clinical genetics practice and research, and laboratory genetic services. These internships will be the platform used to engage genetic counseling trainees in providing genetic services to ovarian cancer survivors and their relatives who complete the B-RST™ screening tool.

Emory's Visual Medical Education Team

The VME has a team of four medical illustrators trained in science and digital arts. Mr. Michael Komonos serves as team leader.

VME endeavors to create innovative designs and models that can revolutionize research, education, and patient care. VME is currently working on strategic projects in Surgery, Transplant, Neurosciences, Cancer, and Lean process improvement. These projects are intended to solve important educational problems that affect a significant number of learners and change outcomes.

VME applies design thinking to solve problems and guide innovation. VME has a number of service capabilities including: animation of 3D and 2D movies; illustrations of static images created for various media, design of information and graphics and interface design, virtual reality visual illustrations and 3D printing. These skills are applied in the world of medical discovery, care, and teaching.

Georgia Cancer Registry, Emory University

All of the necessary facilities and resources needed for this project are present at Emory University and are listed and described below. The project requires office space for the PI and research staff; supported desktop and server computing; and networking for all personnel. This combination of needed facilities and resources was successfully used for our other very similar studies. The specific facilities and resources of the Georgia Cancer Registry are described below.

We propose a population-wide recruitment approach and will use Georgia Cancer Registry (GCR) to retrospectively identify, screen, and enroll all living ovarian cancer patients in GA, diagnosed between January 2005 and December 2017. GCR contains information on demographic characteristics, condition at time of diagnosis (e.g., stage, histologic types, and other clinical and demographic variables), and treatment history of all cancer patients in GA.118 Since 2001, the database excludes borderline (low malignant potential) neoplasms. We will consider women in GCR for study participation if they meet four criteria: 1) diagnosed with ovarian, fallopian tube, or peritoneal cancers; 2) lived in GA at the time of diagnosis; 3) are not deceased per the registry's records; and 4) have a mailing address. Our review of registry files as of May 2019 revealed: of the 8,760 women with a diagnosis of ovarian, fallopian tube, or peritoneal cancer, excluding those who were deceased or lost to follow as of 2017, we will have addresses for approximately 2,918 survivors during the 16-month recruitment period. GA is the 8th largest state with almost 10.5 million residents; 1.8 million (~17%)119 residents live in rural areas.120 The state enjoys substantial racial-ethnic diversity: 32% of the state is Black or African American alone (4th largest African American population in the U.S.), 9.6% is Hispanic or Latino and 4.2% is Asian alone, 15% of the population lives in poverty, and 15% lack health insurance.119

Availability of Facilities

The Georgia Cancer Registry (GCR) is located on the seventh floor of the Grace Crum Rollins School of Public Health (RSPH) at Emory University (2 floors above the Behavioral Sciences and Health Education Department – offices of Drs. McBride, Guan, Escoffery and Haardoerfer). The cancer registry occupies approximately 1/3 of this floor and employs 28 staff who conduct the operations of the registry from this location. Dr. Ward has his own private office located directly outside the registry and GCR research staff share offices next to Dr. Ward.

The CDC's Cancer Program, including the National Program for Cancer Registries (NPCR), is located within a few miles. Within the Rollins School of Public Health are the Departments of Epidemiology, Biostatistics, Environmental and Occupational Health, Health Education and Behavioral Science, Health Policy and Administration, and International Health. The Emory Medical School is located within two blocks and the State Health Department is within 15 miles. The location of the GCR within Emory University and its proximity to state collaborators provide a unique environment with excellent facilities and the opportunity for enhanced interaction with other epidemiologic and cancer-related investigators.

Property

The GCR is equipped with two high capacity, networked laser printers, one Hewlett Packard (HP) Laser Jet 600 M602, and one HP Color Laser Jet 4600 dtn. Other office equipment includes a Konica Minolta C224e copy machine. There is a Brother Intellifax 4100e Business Class Laser Fax for the exclusive use of GCR, as well as a Fellowes Powershred C-480 shredder. Additional equipment is available from the Rollins School of Public Health and the University.
Our basic computing needs at the GCR are served by the exclusive use of a Dell PowerEdge 2970 Quad Core with 4 Gigs of memory. Storage is provided through our SAN (storage area network) over a fiber channel network, with 54 terabytes of RAID-protected HIPAA-compliant storage local on the cluster. It currently has a 20 terabytes of disk space assigned with the ability to quickly expand. Personal desktop computers with are assigned to each in-house staff member, and laptop computers are assigned to those that telecommute or perform functions in the field. Currently, all computers are at least an I7 CPU configuration with 8GB of RAM memory, and have CD/DVD-RW and 20" or higher flat panel monitors standard with 500 gigs local diskspace and 64 bit Windows. All computers used by the GCR are encrypted with PGP Whole Disk Encryption and require an Aladdin eToken for pre-boot authentication. They are also managed via LanDesk to ensure the latest patches and Symantec anti-virus software. Trend Micro Anti-Virus Server software provides additional protection on the server.

Support

The GCR receives administrative support, office supplies and all equipment (e.g. computers, printers, fax machines, phones, etc) necessary to conduct their operations from the Rollins School of Public Health. All Information Technology support, including day-to-day maintenance of our server and IT security infrastructure development and support are provided as well. Computers are refreshed by the RSPH on a 3-year cycle. Some of the key features of the computing environment are presented below.

The Information Technology (IT) Department of the Rollins School of Public Health is a state-of-the-art desktop and server infrastructure that supports over 2500 users. From the ground up, it was designed to be modular and expandable so as to give the School the greatest computing capability, flexibility and growth potential.

Server Environment:
The School server environment is based on a combination of UNIX and Windows 2008 and can be divided into a number of service areas:

Compute Services: The core of our compute services is provided by high performance computing cluster composed of 8 compute nodes and 5 job submission nodes with an aggregate of 124 core processing cores and 768GB of RAM. Storage is provided through our SAN (storage area network) over a fiber channel network, with 54 terabytes of RAID-protected HIPAA-compliant storage local on the cluster. The server hosts analysis and programming tools including: SAS, SPlus, Fortran 77/90, C, C++, Java, R, MATLAB and IMSL. The application environments are 64 bit and parallel computing enabled when the product supports the capability. Services are provided to the desktop using the X Windows and Sun Grid Engine interfaces. The files systems are GFS2 based for efficiency and stability.
Virtual Server Environments: We provide almost all of our servers through a VMWare virtual server farm. Our database, specific applications, web services, and experimental application servers are provided through this environment. A faculty member can rent a virtual server specifically setup to their specifications for a services fee per month if one of the other general server environments does not meet their needs.
Internet/Web Services: Our mail services are provided by a central campus resource through Exchange and we have access through a browser or direct interface such as Outlook. We provide dual web servers split between our secure and our open access areas. The secure web areas are controlled at the HIPAA level. There are a number of services that support various CMS, JAVA environments, and other web services. We also take advantage of a central IT CMS service for our main school web pages being CASCADE. All RSPH web content is served up through our local web servers, and they also support center, program, and personal specific web areas. We have a number of application environments to support research endeavors such as a Cold Fusion development server, RedHat and Feedback server survey tools.
Database Services: We run a number of database services that range from SQLServer 2005-2008 and also an instance of mySQL that are provided across both the VM windows environments and the LInux systems. These databases are used to services a number of application systems across our administrative and research needs. Database accounts are available for any faculty as requested.
File and Print Services: Based on Windows NT, seven servers work together to provide file and print service to the School's desktop network. These state-of-the-art systems provide the latest in general use programs, including statistical and mathematical modeling software, database management, graphics and office support tools.
Network Environment: The RSPH network consists of Fast Ethernet hardware running TCP/IP. Gigabit Ethernet provides high-speed transmission to each of 10 floors and across the RSPH

campus buildings and al the other buildings across campus. Ethernet provides high speed (100 Mbps) access to most desktop computers and peripheral devices. The network terminates at over 2500 locations. The RSPH network is connected to the Emory Campus backbone via a 1Gigabit Ethernet connection, making campus services and wide area network services readily available. We also have an extensive wireless network providing "N" class connections and speeds that cover all of our buildings and the nearby external areas. This network has guest services as well as secure services for our faculty and staff. Our voice communications are connected into a Unified Communications system that provides phones through VOIP and are integrated with our Email systems for VMail access. All of the secured services inside our firewalls including network storage and other services can be access through our VPN firewall authenticated specifically to Emory faculty, staff, and students.

Emory's Winship Cancer Institute

Designated with comprehensive status in 2017, Winship Cancer Institute participates in the robust research environment of the Woodruff Health Sciences Center of Emory University, a national leader in life sciences. Emory's primary focus on translational research fuels the rapid development of discoveries in the laboratory into advances in patient care. Winship Cancer Institute is supported by a collaborative infrastructure, modern facilities, and programs of wide breadth and depth. Winship Cancer Institute of Emory University is Georgia's first and only cancer center designated by the National Cancer Institute (NCI).

Winship, within the broader community of Emory University, participates with four full scientific programs and a number of developing scientific programs. Each program is comprised of a critical mass of Emory investigators whose cancer research interests in a particular area are complementary and synergistic. Numerous opportunities for collaborative studies and large team science research endeavors result from a variety of intra and inter-programmatic activities. There are four cores: Cancer Cell Biology, Cancer Control and Population Sciences, Cancer Genetics and Epigenetics, and Discovery and Developmental Therapeutics. The Cancer Control and Population Sciences (CCPS) Program organizes all of the cancer prevention-related research activities of the Winship Cancer Institute. These activities span the cancer prevention continuum from primary to secondary to tertiary prevention at the individual, select population, and societal levels.

The Winship Cancer Institute Clinical Trials Office (Winship CTO) is a Shared Resource of the Cancer Institute. It supports clinical research by providing scientific review, prioritization, and monitoring of clinical trials involving cancer patients. The long-term goal of the Winship CTO is to advance progress in cancer care through the support of high-quality, high-impact clinical research by Cancer Institute members. The focus of the Winship CTO is to help develop and support Institutional clinical research studies, particularly phase 1 and institutional studies.

The Clinical and Translational Research Committee (CTRC) maintains the scientific integrity of clinical research conducted through the WCI CTO by ensuring that the scientific question being addressed is significant, that the study will yield new information relevant to the cancer

problem, and that the conduct of the study, including accrual rates, is sufficient to answer the scientific question that it is addressing.

The Intervention Development, Dissemination, and Implementation (IDDI) Shared Resource of the Winship Cancer Center

The IDDI Core supports the development, testing, and implementation of cancer-focused interventions through dedicated research infrastructure. Emory investigators can draw on IDDI expertise for support in developing and testing interventions and translating effective interventions into real-world practice that makes a difference for patients and communities. The IDDI shared resource supports behavioral, educational and systems interventions that prevent cancer, detect cancer early, or improve survivorship. **Michelle Kegler DrPH, MPH**, serves as director of the IDDI Core. She is a Professor in the BSHE Department and the Director of the Emory Prevention Research Center since 2009. Dr. Kegler is a recognized expert in implementation science, participatory research, community partnerships, program evaluation, and community-based intervention research in tobacco control and obesity prevention. **Cam Escoffery, PhD, MPH**, co-directs the CORE. Dr. Escoffery provides expert consultation is an evaluator and implementation science researcher. She has employed dissemination and implementation science theories and models such as CFIR to evaluate the uptake of evidence-based cancer prevention strategies by CDC's Colorectal Cancer Control Program grantees and care coordination among high utilizers in the Atlanta Veterans Administration Medical Center. **Colleen McBride** also Co-directs and provides expert consultation research focuses on innovative public health interventions to promote risk-reducing behaviors, specifically using genetic information to motivate healthy behaviors.

The IDDI shared resource provides access to a cadre of senior faculty researchers with over 70 collective years of experience in behavioral science, intervention research, and implementation science. They are supported by an experienced team of three MPH-level staff (1.3 FTE) and two Graduate Research Assistants (0.6 FTE). The IDDI shared resource offers many services including scientific support on study design and intervention approaches, developing surveys and qualitative data collection instruments, assisting with community engagement, data collection, and qualitative data analysis. IDDI occupies offices in the Rollins School of Public Health and has access to a wide range of infrastructure and resources, including a telephone call center with seven stations for survey research and NVivo software for qualitative data analysis.

Peachtree Solutions

See http://www.peachtreesolutions.com for detailed description of the company.

Leadership

Scott Munn
CEO and Founder
System Architect / Software Developer
PCI Security Consultant

Scott Munn earned his degree at Georgia Tech in Aerospace Engineering. Scott serves as the technical lead on all Peachtree Solutions projects. He is hands-on in every phase of project design, development and deployment. There are few people with Scott's mix of technical knowledge and business savvy, and clients benefit from his ability to implement even the most complex projects. A zealous student of current technology. Scott is an active participant in several technology forums.

Lei Lydle
Director of User Experience and Quality Assurance
Web Developer
SEO & Marketing Consultant

Lei graduated from the University of Georgia in 1994 with a Bachelor's Degree in Risk Management.
Lei began as a freelance web design for small businesses in 1996. Lei's skills include Project Requirements Consulting, Information Architecture, Usability Testing, User Experience Design, Graphic
Design, Web Development, Quality Assurance Testing, Management and Online Marketing Consulting.
Before joining Peachtree Solutions, Lei worked for several large Atlanta based agencies as Web Developer where she worked on projects for BellSouth, Delta Air Lines, Chase Manhattan Bank, and
WebMD.

Other Staff
Peachtree subcontracts with freelancers from a pool of trusted contractors that are engaged on a project-by project basis. These include graphic designers, project managers, programmers, and writers.

Facilities
Peachtree Facilities includes a main office (1500 sq ft) located in Peachtree City, GA (a suburb of Atlanta). The main office houses a meeting room with presentation hardware and equipment, 3 internal offices/workstations with computers and monitors, color and black and white printers and is secured by an alarm system. An internal file server and backup file server also is located in this office.

Our web servers and database servers are housed in the Tier 1 data center at SunGuard, a server hosting facility located in midtown Atlanta. SunGuard has over 35,000 square foot building equipped with raised flooring and a separate network/data cabling and power cabling to minimize interference. Additionally, regular ISO-controlled preventive maintenance on all mission-critical systems are conducted. The SunGuard data centers is where Peachtree Solutions host both the development servers and the production servers – (i.e., web servers and database servers).

Equipment
No equipment is required for this application/project.

Georgia CORE: Center for Oncology Research & Education georgiacore.org

Ms. Nancy Paris is President of the Georgia CORE, a public-private partnership that connects cancer care providers, leaders, organizations, and advocates. Led by a Board of Directors of experts from cancer centers, hospitals and academic institutions, collaboration orchestrated by Georgia CORE improves access to personalized cancer care and support for patients, survivors, and caregivers.

In fact, connection and collaboration are at the core of everything we do. Georgia CORE builds and nurtures collaboration among people, organizations and institutions dedicated to improving cancer care in Georgia. Our statewide network is dedicated to generating creative, personalized resources. Because we are the only statewide organization working with such a vast array of groups, we are able to leverage public and private funding to provide greater impact and generate improved results.

One advantage of our collaborative efforts is being able to gather nearly all of Georgia's resources and information related to cancer care in one place. In 2012, Georgia CORE created GeorgiaCancerInfo.org to catalog details on oncologists, clinical trials and treatment centers throughout the state, including resources and support services for survivors and caregivers, and best practices in survivorship care for oncology professionals.

As a result of the width, breadth and depth of our collaboration, *Georgia CORE increases access to innovative cancer resources and research* to improve quality of care for patients and quality of life for survivors. Our work ensures equitable distribution of programs and research to Georgia's minority, rural and underserved populations across the state.

We also raise awareness about survivorship issues, and educate and engage survivors to help them achieve their best possible quality of life. At the heart of these efforts is the Cancer Survivorship Connection, within GeorgiaCancerInfo.org, where an online library of resources and interactive tools provide support to survivors and anyone involved with their care.

Through partnerships with oncologists, researchers, nurses, educators, navigators and survivors, *Georgia CORE leads impactful programs and clinical trials* Funding from the National Cancer Institute, Patient Centered Outcomes Research Institute, Georgia Department of Public Health, Georgia Department of Community Health, Georgia Society of Clinical Oncology and others provides services, support, education and care in every corner of the state. Since the creation of our research network and statewide promotion of clinical trials, Georgia CORE has contributed to a seven-fold increase in the number of clinical trials in Georgia.

<u>Hereditary Breast and Ovarian Cancer (HBOC) Genetic Testing Fund</u>

The **Genetic Testing Fund** was established by Georgia CORE in January 2014 to provide access to genetic testing for hereditary breast and ovarian cancer (HBOC) by underinsured Georgians. Genetics professionals around the state identified eligible individuals based on specific income and medical criteria including those at high risk for HBOC or a recent HBOC - related cancer diagnosis. Funded through the Breast Cancer License Tag Program, the Fund has provided support for **70 tests** for **underinsured Georgians, including 26 individuals with a recent cancer diagnosis,** who would not have otherwise been able to afford testing with subsequent surveillance and management guidance**.** For more information or to access the online application, visit: www.georgiacore.org/genetic-counseling.aspx.

Cancer Patient Navigators of Georgia

Georgia is one of the first states in the country to form a statewide multi-disciplinary organization for Cancer Patient Navigators. This organization was formed in 2009 to connect people who guide individuals and their families throughout the cancer care continuum. Cancer Patient Navigators of Georgia (CPNG) is comprised of individuals who serve people with all types of cancer, at all stages, in all types of settings, with a diversity of education and training, but one shared mission. The mission of CPNG is to connect, educate and share best practices among patient navigators in Georgia, as well as to successfully reduce barriers and increase access to services specifically related to cancer.

www.GACancerPatientNavigators.org has a "members only" section where cancer patient navigators across the state can share information and resources and join special interest groups within CPNG. Co-sponsored by Georgia CORE and the Georgia Society of Clinical Oncology (GASCO), CPNG has more than 275 members, including nurses, social workers and lay navigators.

In 2011, Tom and Karen Chapman contributed a $250,000 gift to expand patient navigation efforts in Georgia. To date, the gift has funded Georgia's 1st Statewide Integrative Oncology Conference, a Lay Navigation Train-the-Trainer pilot program, a Lay Navigation Training Module, and a research grant for navigation.

25.0 Resources Available

The resources available to conduct the research are described in detail in section 24.0.

26.0 Multi-Site Research* ☐

- N/A.

27.0 References

1 Howlader, N. *et al.* SEER Cancer Statistics Review, 1975-2014, National Cancer Institute. Bethesda, MD. *SEER Cancer Stat Facts: Kidney and Renal Pelvis Cancer* **2017** (2017).

2 Norquist, B. M. *et al.* Inherited Mutations in Women With Ovarian Carcinoma. *JAMA Oncology* **2**, 482, doi:10.1001/jamaoncol.2015.5495 (2016).

3 Roberts, M. C. *et al.* Delivery Of Cascade Screening For Hereditary Conditions: A Scoping Review Of The Literature. *Health Affairs* **37**, 801-808, doi:10.1377/hlthaff.2017.1630 (2018).

4 Katapodi, M. C. *et al.* Cancer Predisposition Cascade Screening for Hereditary Breast/Ovarian Cancer and Lynch Syndromes in Switzerland: Study Protocol. *JMIR Research Protocols* **6**, e184, doi:10.2196/resprot.8138 (2017).

5 Dheensa, S., Lucassen, A. & Fenwick, A. Limitations and Pitfalls of Using Family Letters to Communicate Genetic Risk: a Qualitative Study with Patients and Healthcare Professionals. *Journal of Genetic Counseling* **27**, 689-701, doi:10.1007/s10897-017-0164-x (2017).

6 Pozzar, R. A. & Berry, D. L. Patient-centered research priorities in ovarian cancer: A systematic review of potential determinants of guideline care. *Gynecologic Oncology* **147**, 714-722, doi:10.1016/j.ygyno.2017.10.004 (2017).

7 Williams, C. D. *et al.* Racial/Ethnic Disparities in BRCA Counseling and Testing: a Narrative Review. *J Racial Ethn Health Disparities* **6**, 570-583, doi:10.1007/s40615-018-00556-7 (2019).

8 Freedman, J. L. & Fraser, S. C. Compliance without pressure: The foot-in-the-door technique. *Journal of Personality and Social Psychology* **4**, 195-202, doi:10.1037/h0023552 (1966).

9 Bastani, R., Maxwell, A. E., Bradford, C., Das, I. P. & Yan, K. X. Tailored Risk Notification for Women with a Family History of Breast Cancer. *Preventive Medicine* **29**, 355-364, doi:10.1006/pmed.1999.0556 (1999).

10 Bowen, D. J. *et al.* Effects of a web-based intervention on women's breast health behaviors. *Translational Behavioral Medicine* **7**, 309-319, doi:10.1007/s13142-016-0439-z (2017).

11 Brouwer, W. *et al.* Which Intervention Characteristics are Related to More Exposure to Internet-Delivered Healthy Lifestyle Promotion Interventions? A Systematic Review. *Journal of Medical Internet Research* **13**, e2, doi:10.2196/jmir.1639 (2011).

12 Uy, C. *et al.* Text Messaging Interventions on Cancer Screening Rates: A Systematic Review. *J Med Internet Res* **19**, e296, doi:10.2196/jmir.7893 (2017).

13 Chavez, L. R., Hubbell, F. A., Mishra, S. I. & Valdez, R. B. The Influence of Fatalism on Self-Reported Use of Papanicolaou Smears. *American Journal of Preventive Medicine* **13**, 418-424, doi:10.1016/s0749-3797(18)30134-x (1997).

14 Michielutte, R., Dignan, M. B., Sharp, P. C., Boxley, J. & Wells, H. B. Skin Cancer Prevention and Early Detection Practices in a Sample of Rural Women. *Preventive Medicine* **25**, 673-683, doi:10.1006/pmed.1996.0106 (1996).

15 Miles, A., Voorwinden, S., Chapman, S. & Wardle, J. Psychologic Predictors of Cancer Information Avoidance among Older Adults: The Role of Cancer Fear and Fatalism. *Cancer Epidemiology Biomarkers & Prevention* **17**, 1872-1879, doi:10.1158/1055-9965.epi-08-0074 (2008).

16 Tu, S.-P. *et al.* Adaptation of an evidence-based intervention to promote colorectal cancer screening: a quasi-experimental study. *Implementation Science* **9**, doi:10.1186/1748-5908-9-85 (2014).

17 Leadbeater, B. J. *et al.* Ethical Challenges in Promoting the Implementation of Preventive Interventions: Report of the SPR Task Force. *Prevention Science* **19**, 853-865, doi:10.1007/s11121-018-0912-7 (2018).

18 Cohen, D. J. *et al.* Fidelity Versus Flexibility. *American Journal of Preventive Medicine* **35**, S381-S389, doi:10.1016/j.amepre.2008.08.005 (2008).

19 Geller, M. A. *et al.* Learning about ovarian cancer at the time of diagnosis: Video versus usual care. *Gynecologic Oncology* **119**, 370-375, doi:10.1016/j.ygyno.2010.06.032 (2010).

20 Petzel, S. V. *et al.* Effects of web-based instruction and patient preferences on patient-reported outcomes and learning for women with advanced ovarian cancer: A randomized controlled trial. *Journal of Psychosocial Oncology* **36**, 503-519, doi:10.1080/07347332.2018.1457125 (2018).

21 Kuchenbaecker, K. B. *et al.* Risks of Breast, Ovarian, and Contralateral Breast Cancer for BRCA1 and BRCA2 Mutation Carriers. *JAMA* **317**, 2402-2416, doi:10.1001/jama.2017.7112 (2017).

22 Petrucelli N, D. M., Pal T. *BRCA1- and BRCA2-Associated Hereditary Breast and Ovarian Cancer. 1998 Sep 4 [Updated 2016 Dec 15]. In: Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2018. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1247/.*

23 Barrow, E., Hill, J. & Evans, D. G. Cancer risk in Lynch Syndrome. *Familial Cancer* **12**, 229-240, doi:10.1007/s10689-013-9615-1 (2013).

24 Daly, M. B. *et al.* NCCN Guidelines Insights: Genetic/Familial High-Risk Assessment: Breast and Ovarian, Version 2.2017. *Journal of the National Comprehensive Cancer Network* **15**, 9-20, doi:10.6004/jnccn.2017.0003 (2016).

25 Febbraro, T. *et al.* Adherence patterns to National Comprehensive Cancer Network (NCCN) guidelines for referral to cancer genetic professionals. *Gynecologic Oncology* **138**, 109-114, doi:10.1016/j.ygyno.2015.04.029 (2015).

26 Manrriquez, E., Chapman, J. S., Mak, J., Blanco, A. M. & Chen, L.-m. Disparities in genetics assessment for women with ovarian cancer: Can we do better? *Gynecologic Oncology* **149**, 84-88, doi:10.1016/j.ygyno.2017.10.034 (2018).

27 Kurian, A. W. *et al.* Genetic Testing and Counseling Among Patients With Newly Diagnosed Breast Cancer. *JAMA* **317**, 531-534, doi:10.1001/jama.2016.16918 (2017).

28 Kurian, A. W. *et al.* Genetic Testing and Results in a Population-Based Cohort of Breast Cancer Patients and Ovarian Cancer Patients. *J Clin Oncol* **37**, 1305-1315, doi:10.1200/JCO.18.01854 (2019).

29 Samimi, G. *et al.* Traceback: A Proposed Framework to Increase Identification and Genetic Counseling of BRCA1 and BRCA2 Mutation Carriers Through Family-Based Outreach. *J Clin Oncol* **35**, 2329-2337, doi:10.1200/JCO.2016.70.3439 (2017).

30 Chen, W. Y. *et al.* BRCA1/2Genetic Testing in the Community Setting. *Journal of Clinical Oncology* **20**, 4485-4492, doi:10.1200/jco.2002.08.147 (2002).

31 Greenberg, S. *et al.* Evaluating and improving the implementation of a community-based hereditary cancer screening program. *Journal of Community Genetics* **10**, 51-60, doi:10.1007/s12687-018-0357-5 (2018).

32 Katz, S. J. *et al.* Gaps in Receipt of Clinically Indicated Genetic Counseling After Diagnosis of Breast Cancer. *J Clin Oncol* **36**, 1218-1224, doi:10.1200/JCO.2017.76.2369 (2018).

33 Bellcross, C. A., Lemke, A. A., Pape, L. S., Tess, A. L. & Meisner, L. T. Evaluation of a breast/ovarian cancer genetics referral screening tool in a mammography population. *Genetics in Medicine* **11**, 783-789, doi:10.1097/gim.0b013e3181b9b04a (2009).

34 Kinney, A. Y. *et al.* Expanding Access to BRCA1/2 Genetic Counseling with Telephone Delivery: A Cluster Randomized Trial. *JNCI Journal of the National Cancer Institute* **106**, dju328-dju328, doi:10.1093/jnci/dju328 (2014).

35 Kinney, A. Y. *et al.* Randomized Noninferiority Trial of Telephone Delivery ofBRCA1/2Genetic Counseling Compared With In-Person Counseling: 1-Year Follow-Up. *Journal of Clinical Oncology* **34**, 2914-2924, doi:10.1200/jco.2015.65.9557 (2016).

36 Schwartz, M. D. *et al.* Randomized Noninferiority Trial of Telephone Versus In-Person Genetic Counseling for Hereditary Breast and Ovarian Cancer. *Journal of Clinical Oncology* **32**, 618-626, doi:10.1200/jco.2013.51.3226 (2014).

37 Pasick, R. J. *et al.* Effective Referral of Low-Income Women at Risk for Hereditary Breast and Ovarian Cancer to Genetic Counseling: A Randomized Delayed Intervention Control Trial. *American Journal of Public Health* **106**, 1842-1848, doi:10.2105/ajph.2016.303312 (2016).

38 Butrick, M. *et al.* Disparities in uptake of BRCA1/2 genetic testing in a randomized trial of telephone counseling. *Genetics in Medicine* **17**, 467-475, doi:10.1038/gim.2014.125 (2014).

39 Lipscomb J, E. C., Gillespie TW. *Randomized study of high- vs. low-intensity intervention to promote screening among breast cancer survivors and first-degree relatives at elevated risk of breast cancer* [under review].

40 Owen, J. E. *et al.* Representativeness of two sampling procedures for an internet intervention targeting cancer-related distress: a comparison of convenience and registry samples. *Journal of Behavioral Medicine* **37**, 630-641, doi:10.1007/s10865-013-9509-6 (2013).

41 Mendes, Á., Paneque, M., Sousa, L., Clarke, A. & Sequeiros, J. How communication of genetic information within the family is addressed in genetic counselling: a systematic review of research evidence. *European Journal of Human Genetics* **24**, 315-325, doi:10.1038/ejhg.2015.174 (2015).

42 Niendorf, K. B. *et al.* A model for patient-direct screening and referral for familial cancer risk. *Familial Cancer* **15**, 707-716, doi:10.1007/s10689-016-9912-6 (2016).

43 Moyer, V. A. Risk Assessment, Genetic Counseling, and Genetic Testing for BRCA-Related Cancer in Women: U.S. Preventive Services Task Force Recommendation Statement. *Annals of Internal Medicine* **160**, 271-281, doi:10.7326/m13-2747 (2014).

44 *American Cancer Society. Cancer Statistics Center.*, <https://cancerstatisticscenter.cancer.org> (2018).

45 Zheng, G. *et al.* Familial Ovarian Cancer Clusters with Other Cancers. *Scientific Reports* **8**, doi:10.1038/s41598-018-29888-4 (2018).

46 Kobayashi, L. C. & Smith, S. G. Cancer Fatalism, Literacy, and Cancer Information Seeking in the American Public. *Health Education & Behavior* **43**, 461-470, doi:10.1177/1090198115604616 (2015).

47 Moser, R. P. *et al.* Perceptions of cancer as a death sentence: Prevalence and consequences. *Journal of Health Psychology* **19**, 1518-1524, doi:10.1177/1359105313494924 (2013).

48 Emanuel, A. S. *et al.* Avoiding cancer risk information. *Social Science & Medicine* **147**, 113-120, doi:10.1016/j.socscimed.2015.10.058 (2015).

49 Brownson, R. C., Fielding, J. E. & Maylahn, C. M. Evidence-Based Public Health: A Fundamental Concept for Public Health Practice. *Annual Review of Public Health* **30**, 175-201, doi:10.1146/annurev.publhealth.031308.100134 (2009).

50 Masters, R., Anwar, E., Collins, B., Cookson, R. & Capewell, S. Return on investment of public health interventions: a systematic review. *Journal of Epidemiology and Community Health* **71**, 827-834, doi:10.1136/jech-2016-208141 (2017).

51 Marsh, K., Phillips, C. J., Fordham, R., Bertranou, E. & Hale, J. Estimating cost-effectiveness in public health: a summary of modelling and valuation methods. *Health Economics Review* **2**, 17, doi:10.1186/2191-1991-2-17 (2012).

52 *Internet World Statistics*, <https://internetworldstats.com/> (2019).

53 Smith, A. Record shares of Americans now own smartphones, have home broadband. *Pew Research Center* **12** (2017).

54 *National Society of Genetic Counselors. About Genetic Counselors* <https://www.nsgc.org/page/genetic-counselor-workforce-initiatives-532> (2019).

55 Hilgart, J. S., Hayward, J. A., Coles, B. & Iredale, R. Telegenetics: a systematic review of telemedicine in genetics services. *Genetics in Medicine* **14**, 765-776, doi:10.1038/gim.2012.40 (2012).

56 Cohen, S. A., Huziak, R. C., Gustafson, S. & Grubs, R. E. Analysis of Advantages, Limitations, and Barriers of Genetic Counseling Service Delivery Models. *Journal of Genetic Counseling* **25**, 1010-1018, doi:10.1007/s10897-016-9932-2 (2016).

57 Christensen, K. D. *et al.* Associations between self-referral and health behavior responses to genetic risk information. *Genome Medicine* **7**, 10, doi:10.1186/s13073-014-0124-0 (2015).

58 Valerio, M. A. *et al.* Comparing two sampling methods to engage hard-to-reach communities in research priority setting. *BMC Medical Research Methodology* **16**, doi:10.1186/s12874-016-0242-z (2016).

59 Coomes, C. M. *et al.* Beyond reminders: a conceptual framework for using short message service to promote prevention and improve healthcare quality and clinical outcomes for people living with HIV. *AIDS Care* **24**, 348-357, doi:10.1080/09540121.2011.608421 (2011).

60 Gurol-Urganci, I., de Jongh, T., Vodopivec-Jamsek, V., Atun, R. & Car, J. Mobile phone messaging reminders for attendance at healthcare appointments. *Cochrane Database of Systematic Reviews*, doi:10.1002/14651858.cd007458.pub3 (2013).

61 Kannisto, K. A., Koivunen, M. H. & Välimäki, M. A. Use of Mobile Phone Text Message Reminders in Health Care Services: A Narrative Literature Review. *Journal of Medical Internet Research* **16**, e222, doi:10.2196/jmir.3442 (2014).

62 Vodopivec-Jamsek, V., de Jongh, T., Gurol-Urganci, I., Atun, R. & Car, J. in *Cochrane Database of Systematic Reviews* (John Wiley & Sons, Ltd, 2008).

63 Armanasco, A. A., Miller, Y. D., Fjeldsoe, B. S. & Marshall, A. L. Preventive Health Behavior Change Text Message Interventions: A Meta-analysis. *American Journal of Preventive Medicine* **52**, 391-402, doi:10.1016/j.amepre.2016.10.042 (2017).

64 Baranoski, A. S. *et al.* Patient and provider perspectives on cellular phone-based technology to improve HIV treatment adherence. *AIDS Care* **26**, 26-32, doi:10.1080/09540121.2013.802282 (2013).

65 Broom, M. A., Ladley, A. S., Rhyne, E. A. & Halloran, D. R. Feasibility and Perception of Using Text Messages as an Adjunct Therapy for Low-Income, Minority Mothers With Postpartum Depression. *JMIR Mental Health* **2**, e4, doi:10.2196/mental.4074 (2015).

66 Arya, M. *et al.* Mitigating HIV Health Disparities: The Promise of Mobile Health for a Patient-Initiated Solution. *American Journal of Public Health* **104**, 2251-2255, doi:10.2105/ajph.2014.302120 (2014).

67 Özdemir, V. Precision Medicine Goes Global: How to Get It Right? Four Ways to Mobilize Scientific Knowledge. *OMICS: A Journal of Integrative Biology* **22**, 539-543, doi:10.1089/omi.2018.0104 (2018).

68 Asiedu, G. B., Ridgeway, J. L., Carroll, K., Jatoi, A. & Radecki Breitkopf, C. "Ultimately, mom has the call": Viewing clinical trial decision making among patients with ovarian cancer through the lens of relational autonomy. *Health Expectations* **21**, 981-989, doi:10.1111/hex.12691 (2018).

69 Jennings, B. Reconceptualizing Autonomy:A Relational Turn in Bioethics. *Hastings Center Report* **46**, 11-16, doi:10.1002/hast.544 (2016).

70 Zimmerman, F. J. Public Health Autonomy: A Critical Reappraisal. *Hastings Center Report* **47**, 38-45, doi:10.1002/hast.784 (2017).

71 Den Broeder, L., Devilee, J., Van Oers, H., Schuit, A. J. & Wagemakers, A. Citizen Science for public health. *Health Promot Int* **33**, 505-514, doi:10.1093/heapro/daw086 (2018).

72 McBride, C. M. *et al.* Characteristics of users of online personalized genomic risk assessments: Implications for physician-patient interactions. *Genetics in Medicine* **11**, 582-587, doi:10.1097/gim.0b013e3181b22c3a (2009).

73 Kaphingst, K. A. *et al.* Patients' understanding of and responses to multiplex genetic susceptibility test results. *Genet Med* **14**, 681-687, doi:10.1038/gim.2012.22 (2012).

74 Hensley Alford, S. *et al.* Participation in genetic testing research varies by social group. *Public Health Genomics* **14**, 85-93, doi:10.1159/000294277 (2011).

75 Guan, Y., Maloney, K. A., Roter, D. L. & Pollin, T. I. Evaluation of the Informational Content, Readability and Comprehensibility of Online Health Information on Monogenic Diabetes. *Journal of Genetic Counseling* **27**, 608-615, doi:10.1007/s10897-017-0155-y (2017).

76 Guan, Y. *et al.* Disclosing genetic risk of Alzheimer's disease to cognitively impaired patients and visit companions: Findings from the REVEAL Study. *Patient Education and Counseling* **100**, 927-935, doi:10.1016/j.pec.2016.12.005 (2017).

77 Guan, Y. *et al.* The impact of genetic counselors' use of facilitative strategies on cognitive and emotional processing of genetic risk disclosure for Alzheimer's disease. *Patient Education and Counseling* **101**, 817-823, doi:10.1016/j.pec.2017.11.019 (2018).

78 Melnyk, D. & Shepperd, J. A. Avoiding Risk Information About Breast Cancer. *Annals of Behavioral Medicine* **44**, 216-224, doi:10.1007/s12160-012-9382-5 (2012).

79 Howell, J. L. & Shepperd, J. A. Reducing Information Avoidance Through Affirmation. *Psychological Science* **23**, 141-145, doi:10.1177/0956797611424164 (2012).

80 Howell, J. L. & Shepperd, J. A. Reducing Health-Information Avoidance Through Contemplation. *Psychological Science* **24**, 1696-1703, doi:10.1177/0956797613478616 (2013).

81 Pentz, R. D. *et al.* Hereditary Nonpolyposis Colorectal Cancer Family Members' Perceptions about the Duty to Inform and Health Professionals' Role in Disseminating Genetic Information. *Genetic Testing* **9**, 261-268, doi:10.1089/gte.2005.9.261 (2005).

82 Beskow, L. M. *et al.* Ethical issues in identifying and recruiting participants for familial genetic research. *American Journal of Medical Genetics* **130A**, 424-431, doi:10.1002/ajmg.a.30234 (2004).

83 Escoffery, C. *et al.* Assessment of training and technical assistance needs of Colorectal Cancer Control Program Grantees in the U.S. *BMC Public Health* **15**, doi:10.1186/s12889-015-1386-1 (2015).

84 Escoffery, C. *et al.* A grey literature review of special events for promoting cancer screenings. *BMC Cancer* **14**, doi:10.1186/1471-2407-14-454 (2014).

85 Paris, N. M., Burke, J. J. & Schnell, F. M. Shared Vision, Collective Impact, and Persistent Challenges: The First Decade of Georgia's Oncology Research Network. *Journal of Oncology Practice* **9**, 283-286, doi:10.1200/jop.2013.000969 (2013).

86 Bellcross, C., Hermstad, A., Tallo, C. & Stanislaw, C. Validation of Version 3.0 of the Breast Cancer Genetics Referral Screening Tool (B-RST™). *Genetics in Medicine* **21**, 181-184, doi:10.1038/s41436-018-0020-x (2018).

87 Bellcross, C. A. The changing landscape of genetic testing for hereditary breast and ovarian cancer. *Current Problems in Cancer* **38**, 209-215, doi:10.1016/j.currproblcancer.2014.10.001 (2014).

88 Bellcross, C. A. *et al.* Characteristics associated with genetic counseling referral and BRCA1/2 testing among women in a large integrated health system. *Genetics in Medicine* **17**, 43-50, doi:10.1038/gim.2014.68 (2014).

89 McDonald, B., Haardoerfer, R., Windle, M., Goodman, M. & Berg, C. Implications of Attrition in a Longitudinal Web-Based Survey: An Examination of College Students Participating in a Tobacco Use Study. *JMIR Public Health and Surveillance* **3**, e73, doi:10.2196/publichealth.7424 (2017).

90 Scherr, C. L., Bomboka, L., Nelson, A., Pal, T. & Vadaparampil, S. T. Tracking the dissemination of a culturally targeted brochure to promote awareness of hereditary breast and ovarian cancer among Black women. *Patient Education and Counseling* **100**, 805-811, doi:10.1016/j.pec.2016.10.026 (2017).

91 McBride, C. M. *et al.* A cluster randomized intervention trial to promote shoe use by children at high risk for podoconiosis. *Int J Health Sci Res* **5**, 518-528 (2015).

92 Colleen M. McBride, S. H. G. Maximizing the Motivational Impact of Feedback of Lung Cancer Susceptibility on Smokers' Desire to Quit. *Journal of Health Communication* **5**, 229-241, doi:10.1080/10810730050131406 (2000).

93 Allen, C. G., McBride, C. M., Engdawork, K., Ayode, D. & Tadele, G. Applying mental model methods to characterize understanding of gene-environment influences: the case of

podoconiosis in Ethiopia. *Critical Public Health* **29**, 84-99, doi:10.1080/09581596.2017.1409885 (2017).

94 Willis, G. B. *Cognitive interviewing: A tool for improving questionnaire design*. (Sage Publications, 2004).

95 Helitzer, D., Hollis, C., Cotner, J. & Oestreicher, N. Health Literacy Demands of Written Health Information Materials: An Assessment of Cervical Cancer Prevention Materials. *Cancer Control* **16**, 70-78, doi:10.1177/107327480901600111 (2009).

96 Burger, J. M. The Foot-in-the-Door Compliance Procedure: A Multiple-Process Analysis and Review. *Personality and Social Psychology Review* **3**, 303-325, doi:10.1207/s15327957pspr0304_2 (1999).

97 Girandola, F. Sequential Requests and Organ Donation. *The Journal of Social Psychology* **142**, 171-178, doi:10.1080/00224540209603893 (2002).

98 Dolin, D. J. & Booth-Butterfield, S. Foot-in-the-Door and Cancer Prevention. *Health Communication* **7**, 55-66, doi:10.1207/s15327027hc0701_4 (1995).

99 Taylor, T. & Booth-Butterfield, S. Getting a foot in the door with drinking and driving: A field study of healthy influence. *Communication Research Reports* **10**, 95-101, doi:10.1080/08824099309359921 (1993).

100 Bloom, P. N., McBride, C. M., Pollak, K. I., Schwartz-Bloom, R. D. & Lipkus, I. M. Recruiting Teen Smokers in Shopping Malls to a Smoking-Cessation Program Using the Foot-in-the-Door Technique. *Journal of Applied Social Psychology* **36**, 1129-1144, doi:10.1111/j.0021-9029.2006.00034.x (2006).

101 Lipkus, I. M. *et al.* A Randomized Trial Comparing the Effects of Self-Help Materials and Proactive Telephone Counseling on Teen Smoking Cessation. *Health Psychology* **23**, 397-406, doi:10.1037/0278-6133.23.4.397 (2004).

102 Leahy, W. & Sweller, J. Cognitive load theory, modality of presentation and the transient information effect. *Applied Cognitive Psychology* **25**, 943-951, doi:10.1002/acp.1787 (2011).

103 Paas, F. & Ayres, P. Cognitive Load Theory: A Broader View on the Role of Memory in Learning and Education. *Educational Psychology Review* **26**, 191-195, doi:10.1007/s10648-014-9263-5 (2014).

104 Office of Disease Prevention and Health Promotion. Health Literacy Online. (2016).

105 Orbe, M. P. Laying the foundation for co-cultural communication theory: An inductive approach to studying “non-dominant” communication strategies and the factors that influence them. *Communication Studies* **47**, 157-176, doi:10.1080/10510979609368473 (1996).

106 Neuhauser, L. & Kreps, G. L. Online cancer communication: Meeting the literacy, cultural and linguistic needs of diverse audiences. *Patient Education and Counseling* **71**, 365-377, doi:10.1016/j.pec.2008.02.015 (2008).

107 Petty, R. E. & Cacioppo, J. T. in *Advances in Experimental Social Psychology* 123-205 (Elsevier, 1986).

108 Chaiken, S. Heuristic versus systematic information processing and the use of source versus message cues in persuasion. *Journal of Personality and Social Psychology* **39**, 752-766, doi:10.1037//0022-3514.39.5.752 (1980).

109 Sweeney, A. M. & Moyer, A. Self-affirmation and responses to health messages: A meta-analysis on intentions and behavior. *Health Psychology* **34**, 149-159, doi:10.1037/hea0000110 (2015).
110 Cohen, G. L. & Sherman, D. K. in *Encyclopedia of Social Psychology* (SAGE Publications, Inc.).
111 Kahlor, L. PRISM: A Planned Risk Information Seeking Model. *Health Communication* **25**, 345-356, doi:10.1080/10410231003775172 (2010).
112 Wiggins, N. Popular education for health promotion and community empowerment: a review of the literature. *Health Promotion International* **27**, 356-371, doi:10.1093/heapro/dar046 (2011).
113 Wang, C. & Burris, M. A. Empowerment through Photo Novella: Portraits of Participation. *Health Education Quarterly* **21**, 171-186, doi:10.1177/109019819402100204 (1994).
114 Wang, C. & Burris, M. A. Photovoice: Concept, Methodology, and Use for Participatory Needs Assessment. *Health Education & Behavior* **24**, 369-387, doi:10.1177/109019819702400309 (1997).
115 Lee, S., Yoon, H., Chen, L. & Juon, H. S. Culturally appropriate photonovel development and process evaluation for hepatitis B prevention in Chinese, Korean, and Vietnamese American communities. *Health Educ Behav* **40**, 694-703, doi:10.1177/1090198112474003 (2013).
116 McGinnis, K. *et al.* Photonovels: an innovative approach to address health disparities and sustainability. *J Cancer Educ* **29**, 441-448, doi:10.1007/s13187-014-0607-0 (2014).
117 Mohr, D. C. *et al.* The Selection and Design of Control Conditions for Randomized Controlled Trials of Psychological Interventions. *Psychotherapy and Psychosomatics* **78**, 275-284, doi:10.1159/000228248 (2009).
118 Georgia Department of Public Health. Georgia Comprehensive Cancer Registry. . (2018).
119 U.S. Census Bureau. Quick facts Georgia, United States. . (2018).
120 *RHIhub. Georgia rural healthcare facilitites* <https://www.ruralhealthinfo.org/states/georgia> (2019).
121 Bertram, L. A. C., Chung, G., Yu, H., Salovey, P. & Irwin, M. Feasibility of Institutional Registry-Based Recruitment for Enrolling Newly Diagnosed Breast Cancer Patients in an Exercise Trial. *Journal of Physical Activity and Health* **8**, 955-963, doi:10.1123/jpah.8.7.955 (2011).
122 Rogerino, A., Grant, L. L., Wilcox, H., 3rd & Schmitz, K. H. Geographic recruitment of breast cancer survivors into community-based exercise interventions. *Med Sci Sports Exerc* **41**, 1413-1420, doi:10.1249/MSS.0b013e31819af871 (2009).
123 Irwin, M. L. *et al.* Recruiting and retaining breast cancer survivors into a randomized controlled exercise trial. *Cancer* **112**, 2593-2606, doi:10.1002/cncr.23446 (2008).
124 Snyder, D. C. *et al.* Differences in Baseline Characteristics and Outcomes at 1- and 2-Year Follow-up of Cancer Survivors Accrued via Self-Referral versus Cancer Registry in the FRESH START Diet and Exercise Trial. *Cancer Epidemiology Biomarkers & Prevention* **17**, 1288-1294, doi:10.1158/1055-9965.epi-07-0705 (2008).
125 Vallance, J. K. H., Courneya, K. S., Plotnikoff, R. C., Yasui, Y. & Mackey, J. R. Randomized Controlled Trial of the Effects of Print Materials and Step Pedometers on Physical Activity

and Quality of Life in Breast Cancer Survivors. *Journal of Clinical Oncology* **25**, 2352-2359, doi:10.1200/jco.2006.07.9988 (2007).

126 Lijovic, M. *et al.* Use of a cancer registry is preferable to a direct-to-community approach for recruitment to a cohort study of wellbeing in women newly diagnosed with invasive breast cancer. *BMC Cancer* **8**, doi:10.1186/1471-2407-8-126 (2008).

127 Newcomb, P. A., Love, R. R., Phillips, J. L. & Buckmaster, B. J. Using a population-based cancer registry for recruitment in a pilot cancer control study. *Preventive Medicine* **19**, 61-65, doi:10.1016/0091-7435(90)90008-8 (1990).

128 Andersen, M. R., Schroeder, T., Gaul, M., Moinpour, C. & Urban, N. Using a Population-Based Cancer Registry for Recruitment of Newly Diagnosed Patients With Ovarian Cancer. *American Journal of Clinical Oncology* **28**, 17-20, doi:10.1097/01.coc.0000138967.62532.2e (2005).

129 Ashing-Giwa, K. & Rosales, M. Recruitment and Retention Strategies of African American and Latina American Breast Cancer Survivors in a Longitudinal Psycho-Oncology Study. *Oncology Nursing Forum* **39**, E434-E442, doi:10.1188/12.onf.e434-e442 (2012).

130 Lin, Y., Zhu, M. & Su, Z. The pursuit of balance: An overview of covariate-adaptive randomization techniques in clinical trials. *Contemporary Clinical Trials* **45**, 21-25, doi:10.1016/j.cct.2015.07.011 (2015).

131 Suresh, K. P. An overview of randomization techniques: An unbiased assessment of outcome in clinical research. *Journal of Human Reproductive Sciences* **4**, 8, doi:10.4103/0974-1208.82352 (2011).

132 Zagoraiou, M. Choosing a covariate-adaptive randomization procedure in practice. *Journal of Biopharmaceutical Statistics* **27**, 845-857, doi:10.1080/10543406.2017.1289944 (2017).

133 Colavincenzo, J. Doctoring Your Clinical Trial with Adaptive Randomization: SAS® Macros to Perform Adaptive Randomization.

134 Rogerino, A. M. Y., Grant, L. L., Wilcox, H. & Schmitz, K. H. Geographic Recruitment of Breast Cancer Survivors into Community-Based Exercise Interventions. *Medicine & Science in Sports & Exercise* **41**, 1413-1420, doi:10.1249/mss.0b013e31819af871 (2009).

135 Ramirez, A. G. *et al.* Testing Three Different Cancer Genetics Registry Recruitment Methods with Hispanic Cancer Patients and Their Family Members Previously Registered in Local Cancer Registries in Texas. *Community Genetics* **11**, 215-223, doi:10.1159/000116882 (2008).

136 Singal, A. G. *et al.* Mailed Outreach Invitations Significantly Improve HCC Surveillance Rates in Patients With Cirrhosis: A Randomized Clinical Trial. *Hepatology*, doi:10.1002/hep.30129 (2018).

137 Friebel, T. M. *et al.* Active recruitment increased enrollment in a hereditary cancer registry. *Journal of Clinical Epidemiology* **57**, 1172-1176, doi:10.1016/j.jclinepi.2004.04.007 (2004).

138 Sutherland, H. J. *et al.* The Cooperative Familial Registry for Breast Cancer Studies. *Journal of Clinical Epidemiology* **54**, 93-98, doi:10.1016/s0895-4356(00)00263-8 (2001).

139 Halbert, C. H. Minority Recruitment in Hereditary Breast Cancer Research. *Breast Diseases: A Year Book Quarterly* **16**, 114-116, doi:10.1016/s1043-321x(05)80085-2 (2005).

140 Vogt, T. M., Glass, A., Glasgow, R. E., La Chance, P. A. & Lichtenstein, E. The Safety Net: A Cost-Effective Approach to Improving Breast and Cervical Cancer Screening. *Journal of Women's Health* **12**, 789-798, doi:10.1089/154099903322447756 (2003).

141 Georgia Center for Oncology Research and Education. Hereditary breast and ovarian cancer (HBOC) genetic testing fund. . (2018).

142 Guan, Y., Condit, C. M., Escoffery, C., Bellcross, C. A. & McBride, C. M. *Do women who receive a negative BRCA1/2 risk result understand the implications for breast cancer risk? [under review]*.

143 Haas, J. S. *et al.* Perceived Risk of Breast Cancer among Women at Average and Increased Risk. *Journal of Women's Health* **14**, 845-851, doi:10.1089/jwh.2005.14.845 (2005).

144 Taber, J. M. *et al.* Prevalence and Correlates of Receiving and Sharing High-Penetrance Cancer Genetic Test Results: Findings from the Health Information National Trends Survey. *Public Health Genomics* **18**, 67-77, doi:10.1159/000368745 (2014).

145 Vrinten, C. *et al.* What do people fear about cancer? A systematic review and meta-synthesis of cancer fears in the general population. *Psycho-Oncology* **26**, 1070-1079, doi:10.1002/pon.4287 (2016).

146 Glasgow, R. E., Vogt, T. M. & Boles, S. M. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health* **89**, 1322-1327, doi:10.2105/ajph.89.9.1322 (1999).

147 Dickert, N. W. *et al.* Reframing Consent for Clinical Research: A Function-Based Approach. *The American Journal of Bioethics* **17**, 3-11, doi:10.1080/15265161.2017.1388448 (2017).

148 NW, D. Patient-centered approaches to research enrollment decisions in acute cardiovascular disease. (2014-2019).

149 Everitt, B. S., Landau, S., Leese, M. & Stahl, D. Miscellaneous clustering methods. *Cluster Analysis, 5th Edition, John Wiley & Sons, Ltd, Chichester, UK* (2011).

150 Hall, J. A., Roter, D. L. & Rand, C. S. Communication of affect between patient and physician. *J Health Soc Behav* **22**, 18-30 (1981).