The following protocol information is provided solely to describe how the authors conducted the research underlying the published report associated with the following article:

Randomized Non-Inferiority Trial of Telephone versus In-Person Genetic Counseling for Hereditary Breast-Ovarian Cancer

Schwartz, et al

DOI: 10.1200/JCO.2013.51.3226

GEORGETOWN UNIVERSITY

Print Close

Date: 5/1/2013 9:44:19 AM
View: 1.0 - Application Information

1.0 - Application Information

1. * Please enter the title of your study:
Telephone-Based Genetic Counseling: An Equivalence Trial

2. * Please specify the Principal Investigator:
Marc Schwartz

3. If the Responsible Participant is somebody other than the Principal Investigator, please specify that individual here:

Investigator(s): Any person who is responsible for the design, conduct or reporting of research.

Engaged Study Team Members: An individual is "engaged" in human subjects research when the individual, (i) intervenes or interacts with living individuals for research purposes; or (ii) obtains individually identifiable private information for research purposes [45 CFR 46.102(d),(f)].

Please note: All members of the study team that are "engaged in research" (i.e. investigators, co-investigators, consultants, etc.) or who appear on the grant will be required to submit a Study Specific Disclosure Form at the time of initial and continuing review for this study.

4. Please specify the Co-Investigators:

Name	Department	E-Mail
Jeanne Mandelblatt	Lombardi Comprehensive Cancer Center	mandelbj@georgetown.edu
Claudine Isaacs	Lombardi Comprehensive Cancer Center	isaacsc@georgetown.edu
Beth Peshkin	Cancer Control Program	peshkinb@georgetown.edu

5. Please specify the Regulatory Coordinator(s)

Name	Department	E-Mail

There are no items to display

6. Please specify the Study Coordinator(s):

Name	Department	E-Mail
Morgan Butrick	Cancer Control Program	mnb42@georgetown.edu

7. Please specify the Research Nurse(s):

Last Name	First Name	Department	Email
There are no items to display			

8. Please specify the Biostastician(s):

Name	Department	E-Mail
There are no items to display		

9. Please list additional study team members engaged in research, if any, including consultants, and anybody not listed above who appears on the grant or 1572 (if applicable):

Last Name	First Name	Department	Email
There are no items to display			

10. Please list any study team members who do not have a Georgetown University NetID (i.e. sponsored university associates, outside consultants, etc.):

Last Name	First Name	Affiliation	Email Address	Engaged In Research	SSDF
There are no items to display					

11. * If you are applying to the GU SFS-Qatar IRB, please select "State of Qatar". Otherwise, please select "United States of America"
United States of America

View: 1.1 - Training Summary

1.1 - Training Certification Summary:

Note: The dates in this section are intentionally blank as we move toward digitizing the IRB training records. In the future the fields will be populated with real data.

1. If the Responsible Participant is somebody other than the Principal Investigator, please specify that individual here:

2. Training Certifications for all Study Team Members engaged in research

Last Name	First Name	Dept.	Title	Certification Date	IRB Renewal Deadline
Butrick	Morgan	Cancer Control Program			
Isaacs	Claudine	Lombardi Comprehensive Cancer Center	Asssoc Prof and Director, Clinical Breast Cancer		

Mandelblatt	Jeanne	Lombardi Comprehensive Cancer Center	Assoc Director for Population Sciences
Peshkin	Beth	Cancer Control Program	Senior Genetic Counselor
Schwartz	Marc	Cancer Control Program	Professor of Oncology

3. Training Certifications for additional team members listed on grant:

Last Name	First Name	Dept.	Title	Certification Date	IRB Renewal Deadline

There are no items to display

View: 1.3 - Is Institutional Review Board (IRB) review required?

1.3 - Is institutional Review Board (IRB) review required?

1. * Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge? In other words, do you intend to publish or otherwise share the results outside the institution?

(•) **Yes** ( ) No

2. * Does the research involve obtaining information about living individuals?

(•) **Yes** ( ) No

3. * Does the research involve intervention or interaction with the individuals?

(•) **Yes** ( ) No

4. Is this activity an **individual use** of a Humanitarian Use Device (HUD)?

( ) Yes ( ) No

Help Information on HUD

View: 1.5 - Type of Review

1.5 - Type of Review

Please select the review type that you are seeking.
If you believe that your research is eligible for either Expedited or Exempt Review, you may select it below. Otherwise you should apply for Full Board Review.

Expedited Review

Research activities that (1) present no more than minimal risk to human subjects and (2)

involve only procedures listed in one or more of the categories (link) may be reviewed by the IRB through the expedited review procedure. Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Exempt Review
Some research involving human subjects may be exempt from IRB review. The categories (link) describe these exemptions. Please note that an exemption can be invoked only if all components of the research fit the category as described. You might find the following decision charts helpful: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

Full Board Review
All research that does not meet the criteria listed above should apply for Full Board Review.

1. * Please select the review type you are seeking:

- ○ Exempt Review
- ○ Expedited Review
- ◉ **Full Board Review**
- ○ Facilitated (NCI CIRB, IRB of record)

View: 2.0 - Type of Research

2.0 - Type of Research

1. * Please select the research type that best describes the current study

- ○ Biomedical
- ◉ **Oncology**
- ○ Social/Behavioral

View: 2.0.1 - Status of Research

2.0.1 - Status of Research

1. * What is the status of your research?
Long Term Follow-up of Subjects

"Other" should be selected if:

- No participants have been enrolled to date
- Recruitment and/or enrollment of new participants or review of records/specimens continue; OR
- The study is no longer actively enrolling, but subjects are still involved in research-related activities. (e.g., still receiving

treatment, obtaining blood draws)

"Long Term Followup" should be selected when the study is no longer enrolling and participants have completed research-related activities. The study remains active **only** for long-term follow-up.

"Data Analysis" is intended for studies where study enrollment is permanently closed, all participants have completed all research-related activities, and long-term followup as been completed. All data collection is complete and the remaining research activities are related to data analysis only.

View: 2.0.2 - Pediatric Oncology

2.0.2 - Pediatric Oncology

1. * Is this a Pediatric Oncology study?
- ○ Yes
- ◉ **No**

View: 2.1 - GHUCCTS

2.1 - GHUCCTS

1. * Is this study a GHUCCTS study?
- ○ Yes ◉ **No**

GHUCCTS is the Georgetown-Howard Universities Center for Clinical and Translational Science.

View: 2.4 - Initiating Site

2.4 - Initiating Site

1. * Please select the MedStar Health Research Institute/Georgetown University initiating site:
Please Note: the initiating site is the site responsible for coordinating and submitting all regulatory documents for oncology network studies.
Lombardi Comprehensive Cancer Center

2. * Intiating site accrual target:
450

3. Alternatively, if the accrual target is a range instead of a specific number, please enter the range here and the upper bound for question #2:

View: 2.5 - MedStar Network Study

2.5 - MedStar Network Study

1. * Is this a MedStar Health Research Institute-Georgetown University Oncology Network study?:
○ Yes ◉ **No**

View: 2.7 - NCI Central IRB

2.7 - NCI Central IRB

1. * Are you using the NCI Central IRB (NCI-CIRB) for this study?
○ Yes ◉ **No**

NCI is the National Cancer Institute at the National Institutes of Health (NIH)

View: 2.9 - Collaboration With Another Institution

2.9 - Collaboration With Another Institution

1. * Are you collaborating with another institution for this study?
○ Yes ◉ **No**

View: 3.0 - Funding [Basic Information]

3.0 - Funding

1. * Is the project being sponsored or funded by GHUCCTS?
○ Yes ◉ **No**

2. *

Does the project utilize GHUCCTS services or facilities?
(for example study is conducted on the Clinical Research Unit (CRU) http://cru.gumc.georgetown.edu/)

○ Yes ◉ **No**

3. * Please select the source(s) of funding for your project:

- ☐ No Funding
- ☐ PI's internal department funds and/or unrestricted University (discretionary) funds
- ☐ Industry/Commercial Sponsor
- ☐ Cooperative Group
- ☐ Federal, non-NIH
- ☑ **Federal, NIH**
- ☐ Local/State Government
- ☐ Foundation/Non-Profit
- ☐ Other external support (for example, PI initiated or other)

View: 3.5 - Funding - Federal NIH

3.5 - Funding - Federal NIH

You selected:
Federal NIH funding.

1. * Please select the sponsor NIH agency:
National Cancer Institute (NCI)

2. * Has the grant been awarded, or is the award pending?
Awarded

3. * Is Georgetown University (GU) the primary awardee institution?
GU is the primary awardee institution

3.1. If you selected "Other" above, please explain:

View: 3.9 - Funding - NCI

3.9 - Funding - NCI

You selected:
National Cancer Institute (NCI) funding.

1. * Please select the NCI Funding Mechanism:
R-Series Award

View: 3.8 - Funding - Mechanism Detail

3.8 - Funding - Mechanism Detail

You selected:

R-Series, K-Series, P-Series, U-Series, or Other funding.

1. Please specify the funding mechanism:
R01

View: 3.11 - Funding [Grant and PI Information]

3.11 - Funding - Grant and PI Information

You selected:
GU is the primary awardee institution

1. * Is the PI on the grant the same as the PI of the study?
(●) **Yes** ( ) No

2. * Is the title of the grant the same as the title of this human subject research application?
(●) **Yes** ( ) No

3. * Please provide the identifying grant number:
5R01CA108933-05

4. * Please attach a copy of the entire grant proposal (excluding appendices) **AND** the Grants & Contracts Transmittal Form submitted to the Office of Sponsored Research, if available.
Please remove salary information, SSNs, and DOBs.

Name	Version
TCS grant | History	0.01

Note: The IRB is required by the Federal Office of Human Research Protection (OHRP) to review the grant proposal and human research application for consistency. You may be asked to explain discrepancies, if any, identified by the IRB during the review process.

See http://www.hhs.gov/ohrp/humansubjects/guidance/aplrev.htm for more information about IRB responsibilities regarding grant review.

View: 4.0 - Conflict of Interest

4.0 - Conflict of Interest

Each "investigator" must submit a Georgetown University Study Specific Disclosure Form as part of this protocol application. "Investigator" includes the principal investigator and any other person who is responsible for the design, conduct, or reporting of research.

The Georgetown University Study Specific Disclosure Form can be submitted from the study workspace.

Questions about the Georgetown University Study Specific Disclosure Form can be directed to the Office of Regulatory Affairs, Conflicts Regulation Office at (202) 784-5313 or conflictsregulation@georgetown.edu

1. * Do any of the investigators (as defined above) have a financial interest related to the research?

If the answer is "Yes" the financial interest must be disclosed in the consent form; you will receive guidance on what needs to be disclosed and how you should proceed from the Office of Regulatory Affairs via the IRB office.

○ Yes ◉ **No**

Guidance for Conflicts Disclosure in Publications and Presentations
Financial and/or Intellectual property interests (e.g. patents or patent applications) must be disclosed in all related press releases, publications, and presentations.

View: 5.0 - Regulatory Information - Study Phase

5.0 - Regulatory Information

1. * Please specify the study phase. *Select all that apply:*
III

View: 5.2 - Scientific Review

5.2 - Scientific Review

1. * Has this study undergone previous scientific review?
Yes

Please note that independent scientific review and approval are required for all DOD sponsored studies.

View: 5.3 - Scientific Review (Continued)

5.3 - Scientific Review (Continued)

1. * Please specify state where reviewed:
NIH

2. Please attach scientific review correspondence if you were privy to it:

Document	Description
There are no items to display	

View: 5.4 - Drug/Device/Biologic

5.4 - Drug/Device/Biologics

1. Please populate this table with a row for each drug, device or biologic used in this study

Type Name Manufacturer Drug/Device/Biologic

There are no items to display

View: 6.0 - Biohazardous Materials, Recombinant DNA, Gene Transfer

6.0 - Biohazardous Materials, Recombinant DNA, Gene Transfer

1. * Does this project involve the use of biohazardous materials, recombinant DNA and/or gene transfer?:

○ Yes ◉ **No**

View: 6.4 - Radioisotopes or Radiation Producing Devices

6.4 - Radioisotopes or Radiation Producing Devices

1. * Does this project include the use of radioisotopes and/or radiation producing devices, regardless of whether the use is incidental to the project?:

○ Yes ◉ **No**

View: 6.8 - Fetal Tissue

6.8 - Fetal Tissue

1. * Does this project involve the use of fetal tissue?

○ Yes ◉ **No**

View: 6.10 - Placebo Control Group

6.10 - Placebo Control Group

1. * Does this study include a placebo control group?

○ Yes ◉ **No**

View: 6.12 - Collection and Storage of Biological Specimens

6.12 - Collection and Storage of Biological Specimens

1. * Does this study involve the collection and storage of biological specimens for research use?

○ Yes ◉ **No**

View: 7.0 - Categories of Scientific Review

7.0 - Categories of Scientific Review

1. * Please select the scientific review category:
   External Peer Reviewed

2. * Please select the scientific review subcategory:
   Multi-institutional

3. * Please select the program type:
   Cancer Prevention & Control

4. * Please select the trial type:
   N/A

5. If applicable, please select the cooperative group:

View: 8.0 - Required Summary

8.0 - Required Summary

1. The following applies ONLY to Biomedical and Oncology clinical research studies: Please create a brief summary, in Layman's Terms (8th grade language) of 200 words or less for this protocol, outlining the salient features that may be useful to the public and/or health care professionals.
   This is a non-therapeutic, non-inferiority randomized trial of standard in-person genetic counseling vs. telephone genetic counseling (GC) for hereditary breast and ovarian cancer syndrome for high-risk women. The primary aims were to determine the impact of telephone vs in-person GC on utilization of genetic testing uptake and to determine the relative efficacy of telephone GC vs. in-person GC on satisfaction with GC, informed decision making, psychosocial distress and quality of life. Recruitment has now ceased and the protocol is active for long-term follow up.

View: 9.0 - Information for Protocol Review [Study Description]

9.0 - Information for Protocol Review - Study Description

Please summarize the protocol according to the following:

1. * Purpose of project (one or two sentences):
   The purpose of this project is to compare telephone-based genetic counseling to traditional face-to-face genetic counseling among women at risk for carrying BRCA1/BRCA2 mutations

2. * Study design (for example, hypothesis, research questions, standard and experimental procedures/drugs/devices or equipment, etc.):

   Participants will be randomized to in-person or telephone genetic counseling and receive both pre-test and post-test counseling (when applicable) in the randomized delivery fashion.

Primary Aims

1. To determine the relative efficacy of TGC vs. SGC on satisfaction with counseling, informed decision making, psychosocial distress and quality of life impact of telephone genetic counseling (TGC) vs. standard genetic counseling (SGC) on utilization of BRCA1/2 testing:

Hypothesis 1: We predict that TGC will be non-inferior to SGC on measures of knowledge, satisfaction, decisional conflict, psychosocial distress and quality of life.

2. To determine the impact of TGC vs. SGC on utilization of BRCA1/2 testing:

Hypothesis 2: SGC and TGC will result in equivalent rates of BRCA1/2 testing.

Secondary Aims

3. To explore the mechanisms by which the interventions impact distress and quality of life:

Hypothesis 3: Consistent with the Ottawa Framework for Informed Decision Making, improvements on the intermediate outcomes of decisional conflict and knowledge, will predict improved distress and quality of life outcomes.

4. To identify participant characteristics that predict differential response to TGC:

Hypothesis 4: We predict that treatment assignment will interact with baseline anxiety such that participants with higher levels of baseline anxiety will fare better in the SGC arm.

3. * Rationale and justification for study (i.e. historical background, investigator's personal experience, pertinent medical literature, etc.):

Genetic susceptibility testing has become increasingly available over the past 10 years, and it is widely expected that the demand for testing will increase exponentially as additional susceptibility genes are identified (Collins, 1999; Collins et al., 2003; Guttmacher et al., 2001). Given the complexity of genetic susceptibility testing, it is critical that participants be adequately informed of the potential benefits, risks, and limitations, as well as alternatives to testing (Green, McInerney et al., 2001; Green Biesecker et al., 2001). Such information, along with a detailed risk assessment is typically delivered during face-to-face genetic counseling (McKinnon et al., 1997). This traditional model of genetic service delivery has been the dominant approach to cancer susceptibility counseling and testing. Although evidence demonstrates the efficacy of traditional cancer genetic counseling (Sagi et al., 1998; Schwartz et al., 2002; Stadler & Mulvihill, 1998), there are several reasons to consider alternatives to this delivery model. First, the reach and availability of clinic-based genetic counseling is limited. There are large areas of the country in which there is little or no access to genetic counseling services. This lack of access will worsen as the number of available genetic susceptibility tests continue to increase (Guttmacher et al., 2001). As the variety of available tests increases, even individuals with access to a genetic counselor may not have access to a counselor with necessary expertise about the specific test desired by the patient. Although some physicians may choose to provide genetic information, evidence suggests that most physicians lack the time and knowledge to provide adequate genetic counseling (Greendale & Pyeritz, 2001). Given the limited reach and access of traditional genetic susceptibility counseling and the anticipated increase in demand, it is imperative that we develop and evaluate alternatives to traditional genetic susceptibility counseling. Alternatives must provide comparable efficacy while improving availability and deliverability. Telephone-based genetic counseling might be one such alternative. Indeed, genetic counseling via the telephone is already commercially available and marketed (Aetna US Healthcare, 2003; Gollust et al., 2003). Despite its commercial availability, telephone-based genetic counseling remains highly controversial as there is little evidence to support its efficacy (Ormond et al., 2000; Wang, 2000).

We have provided BRCA1/2 genetic counseling and testing to over 2000 high-risk women in a variety of clinical research studies. Abundant data indicate high satisfaction and few adverse effects of BRCA1/2 counseling and testing (Butow et al., 2003; Coyne et al., 2002; Lerman et al., 1996, Lerman et al., 1998; Lodder et al., 2001; Schwartz et al., 2002; Kaufman et al., 2003). These positive outcomes, along with the wide availability of BRCA1/2 testing, make BRCA1/2 counseling/testing an ideal setting in which

to test alternatives to standard counseling. Given the effectiveness of standard genetic susceptibility counseling, the goal of telephone-based genetic counseling must be to obtain comparable outcomes on informed decision making and psychosocial adjustment. By obtaining comparable outcomes, but expanding the reach and availability of genetic counseling, telephone-based counseling could have important public health and cancer control benefits.

4. * Primary objective:
To determine the impact of telephone genetic counseling (TGC) vs. standard genetic counseling (SGC) on satisfaction with the counseling process, informed decision making, psychosocial distress, quality of life and testing uptake.

5. * Secondary objectives:
To identify participant characteristics that predict differential response to TGC.

6. * Inclusion criteria:
Persons eligible for this study are women, age 21 to 85 years old who have at least a 10% prior probability of carrying a BRCA1/2 mutation (Parmagiani et al., 1998; Frank et al., 1998; Couch et al., 1997) or by the presence of a known mutation in the family. This denominator includes first-degree relatives of affected family members who have a 50% risk of inheriting a BRCA1/2 mutation, a small number of second degree relatives who have a 25% risk (parent deceased), and persons who are obligate gene carriers or who have been affected themselves. We are including affected women in this study because the standard 'cascade approach' to genetic testing always begins with a previously affected individual.

7. * Exclusion criteria:
Male members of hereditary breast cancer families will not be enrolled in this study. The counseling issues, decision making and psychosocial concerns of these groups vary considerably from those of the target population. However, we will make provisions for genetic counseling of these individuals through other clinical research protocols. Individuals with metastatic breast or ovarian cancer will be ineligible for the study since their illness is likely to interfere with their participation. These individuals will be offered standard clinical genetic counseling if they are interested. Individuals who live more than 100 miles away from the LCCC will be ineligible for the study since they would likely be unwilling to attend an in-person disclosure session. These individuals will be offered participation in other studies or in clinical genetic counseling. Persons are also ineligible for this study if they have a psychiatric or cognitive disorder which precludes informed consent. This determination will be made based upon the participants' self-reported medical history and the clinical determination of the genetic counselor. Additionally, if at the time of the pre-test

genetic counseling session, it is determined that a participant requires genetic counseling for an alternative hereditary cancer susceptibility syndrome (i.e. a syndrome other than hereditary breast and ovarian cancer), the participant will be ineligible for the study.

8. * Treatment Plan:

Pre-Test Education. Immediately following randomization, TGC participants will be scheduled for a telephone counseling session and SGC participants will be scheduled for a clinic-based counseling session. All SGC participants will receive an in-person genetic counseling session with a genetic counselor. These sessions typically last from 1.5-2 hours. Written consent is obtained from all subjects prior to the session. The protocol for pre-test education has been extensively pre-tested as part of our ongoing research. The TGC protocol is also based upon our standard genetic counseling. TGC will parallel SGC as closely as possible. However, SGC will be modified for telephone delivery in the following ways: 1) Detailed visual aids for all major sections of the counseling sessions will be developed specifically for use over the telephone; and 2) Counseling probes will be inserted into the TGC protocol to assess participants' understanding of and emotional reactions to critical portions of the genetic counseling session. Whereas in SGC, probes may be utilized spontaneously in response to visual cues, in TGC these probes are built into the protocol to compensate for the absence of visual cues. Below, we summarize the specific components of TGC and SGC interventions.

☐ Collection of family history information and development of family pedigree. Basic family history information needed to complete the pedigree will be collected as part of the baseline assessment. A more detailed family history form will then be mailed to participants before their initial counseling session along with educational materials. These materials will provide information to be reviewed prior to the scheduled session. In addition, TGC participants will be sent a coordinated set of visual aids designed specifically for telephone-based genetic counseling. These visual aids will be used during the telephone counseling session.
☐ Review of consent form and study procedures. The session will begin with a review of the informed consent document to ensure that participants have a full understanding of the study.
☐ Review of the potential risks, limitations and benefits of genetic testing. This will include a detailed discussion of the potential risks, benefits and limitations of genetic testing. Measures to protect patient privacy will be reviewed.
☐ Review of family and medical history. A detailed family and medical history will be taken. A comprehensive pedigree will be compiled.
☐ Risk assessment. A qualitative, pedigree-based, risk assessment will be provided and discussed. The focus will be on the features

suggestive of hereditary breast cancer. Other factors related to the likelihood of a BRCA1/2 mutation will be addressed. Quantitative risk assessment based on models contained in the CancerGene software package (e.g., BRCAPRO; Myriad and Penn models) will also be provided to participants (CancerGene, 2003). This information will be discussed in detail and the genetic counselor will help the participant to interpret all risk estimates.

☐ Management. The strong emphasis of this section will be on breast and ovarian cancer risk management based upon the possible outcomes of genetic testing (or no testing). Patients will be provided with information about each of their options.

☐ Summary of testing options and test result interpretation. Options for genetic testing and test result interpretation will be discussed.

☐ Wrap-up. The counselor will assess patient understanding of the information and preferences for testing. Patient resources and support will be assessed and discussed. Questions will be answered. Arrangements for obtaining blood (in-person, in clinic, blood kit) will be made (blood kit will be sent to TGC participants who wish to proceed with testing).

Determination of Carrier Status. All SGC participants who choose to proceed with BRCA1/2 testing, will have the option of having their blood drawn by a trained phlebotomist immediately following their pre-test genetic counseling session. All TGC participants who wish to proceed with testing will be mailed a pre-labeled blood kit that will be bar-coded with the participants study ID for tracking by LCCC and MSSM. Participants who choose to be tested can take the kit to any laboratory for a free blood draw. The blood will then be returned to LCCC via Federal Express for tracking and paperwork purposes. The genetic counselor will then forward the sample directly to Myriad Genetics for analysis as described above. We will also provide TGC participants with a list of local laboratories to facilitate these blood draws. All genetic test results (regardless of group assignment) will be sent by Myriad Genetics directly to the participant's genetic counselor. The genetic counselor will then contact the participant to schedule the disclosure session. The use of blood kits for TGC participants is an important difference between the TGC and SGC conditions. Evidence suggests that most individuals who attend an in-person genetic counseling session will choose to provide blood for testing (Schwartz et al., 2000). In contrast, it is conceivable that participants who do not have the option of an immediate blood draw, may have lower rates of testing. This is an important 'real-world' difference between clinic-based testing and telephone-based genetic counseling. Thus, we have chosen to maintain the option of immediate blood draw for SGC participants. All gene sequencing for both groups will be performed in accordance with Myriad Genetic Laboratories' Technical Specifications, current as of February 2003 (see http://www.myriadtests.com/provider/doc/tech_specs_brac.pdf). Participants of Ashkenazi Jewish descent can opt for an inexpensive

and highly sensitive test designed to detect specific founder mutations (187delAG, 5385insC, and 6174delT) common among Ashkenazim. This highly specific and sensitive approach is the standard for testing individuals of Ashkenazi Jewish descent.

Disclosure Session. For SGC participants, test results will be revealed in a private individual meeting. TGC participants will have their test results revealed in a telephone disclosure session. The SGC and TGC disclosure protocols have been extensively piloted as part of our ongoing research. These sessions typically last 30-minutes to 1 hour and include the following components:
☐ Detailed discussion of the test result and its interpretation including risks for breast cancer (second breast cancer for previously affected women), ovarian cancer and other cancers
☐ Discussion of management options as they relate to test result.
☐ Discussion of the implications of the test result for family members.
☐ Discussion of psychological responses to test results
☐ Review of relevant issues from the pre-test session.
☐ Provision of referrals for medical and/or psychological follow-up
☐ Following the disclosure session, participants are sent a letter reviewing and summarizing key points.
☐ All participants will receive a follow-up telephone call within two weeks of receiving their test results

Similar to pre-test education, the TGC protocol will include visual aids and counseling probes developed specifically for telephone-based counseling.

9. * Primary Study Endpoint:
1. Knowledge, satisfaction decisional conflict, psychosocial distress and quality of life.
2. Uptake of BRCA1/BRCA2 mutation testing

10. * Setting in which the study will be conducted/locations where study procedures will take place (i.e. GUMC, GCRC, physician's ofice, main campus, etc.):
Lombardi Comprehensive Cancer Center (Washington, DC)
Mount Sinai School of Medicine (New York, NY)
Dana Farber Cancer Institute (Boston, MA)
Virginia Piper Cancer Center (Minneapolis, MN)

11. * Is this a multicenter study?
◉ **Yes** ○ No

12. If this is a multicenter study, please select the type below:
National

Local accrual targets provided elsewhere in the protocol

Site	Accrual Target
Lombardi Comprehensive Cancer Center	450

13. * Please provide the estimated local number of subjects (including controls):
450

14. * Please provide the estimated total number of subjects (including controls):
699

15. * Please specify how long the study will be open for accrual:
Now closed for accrual; study was open for accrual for 84 months

16. * Please provide the total study duration, including subject follow-up and data analysis:
96 months

17. * Are there any open MedStar/GU trials that compete for this subject population?
○ Yes ◉ **No**

18. * Please provide a description of the statistical considerations (justifications for sample size or n, power or degree of change):
Preliminary Group Comparisons. The TGC and SGC groups will be compared on sociodemographics, medical/family history variables, psychological, and quality of life variables at baseline. Categorical variables will be tested with Chi-Square test. Continuous variables will be tested by the Student t-test or by the Mann-Whitney U test for non-normal data. Equality of variances across groups will be tested, and the Welch unequal variances modification of the t-test will be used if necessary. Using a conservative approach, any variable that exhibits a $p < .10$ difference between the groups, will be controlled in subsequent analyses. Using an identical approach, we will also identify background variables that are associated with any of our key outcomes, putative mediators or putative moderators. Those variables that exhibit $p<.10$ associations with outcomes, mediators or moderators will be controlled in analyses involving those variables.

Evaluation of Hypotheses and Sample Size Calculations.

Hypothesis 1.1: The TGC intervention will be non-inferior to SGC on measures of knowledge, satisfaction (with counseling and with decision making), decisional conflict, psychosocial distress and quality of life.

Our primary hypotheses center on non-inferiority. Thus, we will

determine the group difference (d) on each outcome at each follow-up along with the 95% confidence intervals for the group differences. If neither d nor the appropriate tail of the CI crosses the non-inferiority limit, we concluded that TGC is non-inferior to SGC. If there is evidence for superiority, analyses will proceed as a traditional superiority trial. In follow-up analyses we will repeat the above analyses stratified by BRCA1/2 test result (positive, uninformative, true negative, decline). This will allow us to evaluate non-inferiority of TGC and SGC within each test result group. As above, if non-inferiority is not demonstrated, we will conduct standard, multivariate analyses.

Power Calculation: For this hypothesis we are actually testing noninferiority of TGC. In other words, we are interested in knowing whether the TGC intervention produces equivalent or superior outcomes. Thus, we will use symmetric ranges, but instead apply a one-sided test of equivalence. For each of our outcomes, we test power for the combined sample assuming that: 1) there will be no interactions between treatment and test result; 2) the distribution of test result will be roughly the same across study arms (if not, means will be statistically adjusted for test result); 3) we will have 15% attrition at 3-months. We present illustrative power for outcomes with the lowest power so that all non-presented outcomes have equal or superior power to those presented. Estimated means for each of these outcomes come from our previous research (Schwartz et al., 2002; Schwartz et al., 2001; and our ongoing CD-ROM decision aid trial). Table 2 displays our power estimates and equivalency limits for cancer-specific distress (IES), satisfaction with decision making, and knowledge. As shown in Table 2, with our projected sample size of 594 at three months, we have ample power for the proposed tests of noninferiority. For scores on the IES, we have selected a non-inferiority range of d=4 points. This is a difference that is clinically nonsignificant and that represents a small effect size (i.e., less than 0.3 SDs). We followed a similar process for determining d for all other variables.

Table 2. Effects Sizes and Power for Continuous Outcomes

Variable	Non-Inferiority Limit	Sample Size	Power
IES (SD=14)	4	594	>90%
Knowledge (SD= 3.0)	1	594	>95%
Decision Satisfaction (SD = 2.5)	1	594	>95%

Power is based upon 3-month follow-up for IES and decision satisfaction and the post-counseling follow-up for knowledge.

Hypothesis 2.1: Overall rates of BRCA1/2 testing will be equivalent across the two study arms.

We will first conduct standard bivariate analyses in which we will utilize Fisher Exact Test, to compare the proportion of participants in each group who opt for genetic testing. In multivariate modeling, we will utilize logistic regression models to control for any variables

which differ across groups at baseline. We will also control for potential confounders identified in initial bivariate analyses. We will utilize logistic models with hierarchical variable entry. However, since our primary aim is to test for equivalence between the groups on this outcome, our main analyses will focus on addressing this question. Thus, we will follow standard procedures for data analysis in an equivalence trial (Lesaffre et al., 2001; Friedman et al, 1998; Fleiss et al., 1992). The first step in an equivalency trial is to determine the range of equivalence. The range of equivalence is the difference between the groups (d) that is considered equivalent. In our previous research, we have found that approximately 80% of those who seek genetic counseling, ultimately choose to be tested (Schwartz et al., 2000; Schwartz, Lerman et al., in press). We have set our range of equivalence as a probability difference of d=0.075. In this analysis, our range of equivalence is symmetric (-0.075 to 0.075) because we are interested in determining whether TGC results in comparable rates of uptake. Thus, if TGC resulted in higher or lower rates of uptake, equivalence would be rejected. Importantly, for the interventions to be considered equivalent, the 95% confidence interval of the difference between the two groups must fall completely within the range of equivalence. Thus, the next step in the analysis is to generate 95% confidence intervals around the difference between the two groups on BRCA1/2 test utilization. If both ends of the confidence interval are within the pre-determined equivalence range (72.5% to 87.5%), the interventions are considered equivalent (regardless of statistical significance). If either end of the confidence interval falls outside of the equivalence range, the interventions are considered non-equivalent. (regardless of statistical significance). However, if the confidence interval falls outside of the equivalence range and the groups differ significantly, this is evidence of superiority. In this case all subsequent analyses would proceed as in a traditional superiority trial.

Power Calculation: To calculate power for an equivalency trial, the first step is to determine the range of equivalence (see above). For utilization of BRCA1/2 testing, we have defined a probability difference of d= 0.075 as equivalent. As described above, we use a symmetric equivalency range for this analysis (-0.075 to 0.075). In our previous research in this clinical population, we have obtained rates of BRCA1/2 test utilization of about 0.90 (Schwartz et al., 2000; Schwartz, Kaufman et al., in press). With a sample size of 699 for this analysis (we will have no attrition in this analysis because we will receive all test results from Myriad and will not be dependent upon follow-up interviews), we will have power of 90%. If the rate of test uptake is lower than expected (e.g., 80%) our power will be below 80%.

Hypothesis 3.1: Consistent with the Ottawa Framework for Informed Decision Making, improvements on the intermediate

outcomes of decisional conflict and knowledge, will predict improved distress and quality of life outcomes.

Assuming that the TGC and SGC groups do not differ significantly on our primary outcomes, we will evaluate whether improvements (from pre- to post counseling) on the intermediate outcomes of knowledge and decisional conflict can account for pre- to post-counseling improvements on our more distal outcomes of distress and quality of life as predicted by the Ottawa Framework (O'Connor et al., 2001). First, we will identify potential confounders that are related to our intermediate and distal outcomes (e.g., sociodemographics, family history, etc). Next we will conduct multiple regression analyses to determine whether changes on intermediate outcomes predict changes on our more distal outcomes. Each of the psychosocial/quality of life outcomes will serve as the dependent variable in separate regressions. On step 1, we will enter the baseline value on the outcome of interest. On step 2, we will enter intervention group (as a control). On step 3, we will enter any sociodemographic, medical or family history confounders that we have previously identified. On the final step, we will enter the change on decisional conflict and knowledge (from baseline to post-counseling). A significant change in the R2 value on the final step will indicate that the intermediate outcomes do account for significant variance in the more distal outcomes. We will evaluate the independent effects of knowledge and decisional conflict via evaluation of the standardized beta weights.

Power Calculations: Given the stringent power requirement for equivalency trials, we have extremely high power to test our more traditional (i.e., nonequivalency) hypotheses. We have ample power to detect associations between our intermediate and distal outcomes. For example, with our projected sample size (at 3-months) of 699, we will have 99% power to detect Pearson correlations as low as r=0.2 between any of these variables.

Hypothesis 4.1: We predict that treatment assignment will interact with baseline anxiety such that participants with higher levels of baseline anxiety will fare better in the SGC arm.

To identify subgroups of TGC participants most and least likely to benefit from the intervention, we will evaluate the interaction between intervention assignment (TGC vs. SGC) and state anxiety. For each of the models described in Aim 2, we will test the group by anxiety interaction effect. The interaction term will be included in the models after the inclusion of the confounding variables, group assignment main effect, and anxiety main effect. Change in R2 (for linear regression models) will be used to test the significance of the interaction. Significant interaction effects will be followed up with analysis of simple main effects.

Power Calculations: To test the power of the group by state anxiety

interaction effect, we evaluate power to detect predicted subgroup differences. The power to conduct this subset analysis is high. Assuming our projected N at 6-months and a median split on anxiety, we would have 350 individuals classified as high in anxiety and 350 classified as low. We would have ample power to conduct group comparisons within either of these subgroups.

19. * Please state the relative importance/value of the trial, considering standard therapy and competing trials:
This is among the first randomized trial to directly compare telephone to in-person genetic counseling for BRCA1/2. As demand for genetic counseling and testing increases, it will become progressively more important to evaluate alternate modes of genetic services delivery.

View: 9.2 - Information for Protocol Review [Risks]

9.2 - Information for Protocol Review - Risks

1. Please provide a comprehensive scientific description of the risks related to each drug/combination of drugs/device/procedure involved in the study and list them by likelihood and severity:

* Example:
Drug 1
- Likely
- Less likely
- Rare but serious

Drug 2...

Potential Risks. Risks associated with participating in this study fall into three categories. First is the risk associated with completing the study surveys. There is a low risk of adverse psychological reactions to the study surveys. Asking women from hereditary breast cancer families to reflect on their risks for breast and ovarian cancer, their management options, and their reactions to genetic testing could generate anxiety for some individuals. However, since these individuals are seeking genetic counseling, these are likely topics that they are willing to discuss. Thus, we consider this to be a minimal risk to patients.

Second, there may be modest risks associated with participation in genetic counseling. Patients may experience psychological distress regarding their risk for carrying a BRCA1/2 mutation and the increase in risk for additional cancers. Participants may also experience distress regarding the cancer risk of their family members.

For patients who are assigned to the TGC arm of the study, there might be a slightly increased risk of adverse reactions to counseling due to the

lack of face-to-face contact with a genetic counselor.

Our plan for addressing adverse psychological reactions is comprehensive and is modeled on our current approach within our ongoing genetic counseling and testing program. All genetic counseling (whether in-person or via telephone) is delivered by trained and experienced genetic counselors who assess subjects' well-being during the session and at the end of the session. Counselors routinely call subjects 2-weeks after result disclosure to answer any additional questions, address any ongoing concerns and assess emotional reaction to test result. Subjects who report high levels of distress or difficulty coping with their test results will be referred for follow-up psychological assessment to a mental health provider in their local area. Since attention to psychological issues has been a longstanding component of comprehensive genetic counseling and is part of telephone follow-up, it is anticipated that psychological injury will be infrequent. In fact, quite to the contrary, considerable research documents beneficial psychosocial effects of counseling. Even for patients who receive positive test results, there is little evidence to suggest adverse psychological effects. To ensure that distress is identified (particularly in patients in the TGC arm), we have developed distress screening algorithms using our standardized psychosocial assessments that will alert us to any participants who report distress levels indicative of a need for clinical intervention or assessment. These algorithms are automated as part of our CATI system. In instances where these screeners are activated, measures are reviewed by a licensed clinical psychologist and a decision about whether to contact the participant is made. If the participant is contacted based upon these measures, contact will be conducted by a member of the study team to ensure the maintenance of confidentiality. Participants will be referred for additional assessment and counseling if necessary.

In addition to psychosocial risks that may be associated with genetic counseling, there may also be risks related to confidentiality and loss of privacy should a third-party learn that the participant received genetic counseling.

Our plan for maintaining confidentiality is as follows: protection of privacy of participants in studies involving genetic data is of the utmost importance. We will attempt to do this in several ways. First, we will minimize communications across study sites that involve names or other identifying information. Where this is unavoidable (e.g., sites transmitting names to LCC for purposes of the telephone interviews), all communications will be made via priority overnight mail (as opposed to fax or e-mail). Such materials will <u>not</u> include any information which identifies individuals as participants in a genetic counseling program. Second, any communications made by e-mail will use ID#s only and

never include names or other personal information. Third, test results and other clinical information will never be communicated together with names in any written materials. This information will be attached only to ID#s and will be communicated to sites via priority overnight mail. Fourth, at the individual sites, all clinical information will be kept in locked files in the genetic counselors' offices. Information about participants' pedigrees or results will not be included in their medical records unless participants provide specific permission to do so. Of course, participants themselves may choose to disclose this information to their primary care providers. Fifth, we will obtain a federal Certificate of Confidentiality to protect confidentiality of study participants. Sixth, in all data sets, including those with test results, we will use ID#s only. A separate data set linking names with ID#s will be accessible only to the senior programmer and the Principal Investigator.

For patients who choose to proceed with BRCA1/2 testing, there may be additional risks. It is important to note here, however, that participants will neither be encouraged nor discouraged to undergo testing as part of this study. However, the fact remains that participants in this study will choose to receive genetic test results. Thus, the risks associated with genetic testing must be considered. There are social risks related to the gathering of family information and participation in genetic testing. These risks include risks regarding to the loss of confidentiality, insurance and employment discrimination, incorrect or inaccurate test results, and adverse psychological reactions to the receipt of test results.

Our plan for protecting patients from the societal risks of gathering family history, genetic test results, and medical information is as follows: Information obtained during or as a result of this study will not be released without the expressed written consent of the participating individual. Of course, patients can always choose to disclose this information on their own to healthcare providers. Since women may use information from this study to make medical decisions, the involvement of local health care providers (such as oncologists and surgeons) or insurance providers, may be desirable; however, this involvement carries risks. Participants will be fully informed of these risks during our verbal and written informed consent process. Health and insurance providers will only be informed of a patient's test result after the patient has provided written consent. We will keep separate research files for test results; this information will not be included in patients' medical records.

2. For each drug/device/biologic specified in section 5.4, please use the [Update] button to specify how long women should avoid pregnancy and breast feeding as well as how long men should avoid fathering children:

If you did not specify any drugs/devices/biologics, you may disregard this question.

Name of drug/device/bilogic	Drug Category	Avoidance of Pregnancy for Women	Avoidance of Conception for Men	Drug/Device/Biologic
There are no items to display				

View: 12.9 - Type of Consent

12.9 - Type of Consent

1. * Please indicate type(s) of consent:

Written Consent

Waiver of documentation of consent (i.e. verbal consent)

2. * Please attach consent/assent documents and consent/assent scripts:

	Document	Description
View | History	Stamped TCS consent 2012(0.01)	

3. Please attach questionnaires, survey tools, etc:

	Document	Description
View | History	TCS 12 month survey(0.01)	
View | History	TCS 2 week survey(0.01)	
View | History	TCS 3 month survey(0.01)	
View | History	TCS 6 month survey(0.01)	
View | History	TCS baseline survey(0.01)	

View: 12.11 - Waiver of Consent Documentation

12.11 - Waiver of Documentation of Consent

1. * Please justify the need or a waiver of documentation of consent by sellecting one of the following and addressing if below
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.

* All eligible women who refer to the BRCA1/2 genetic counseling programs will be mailed two copies of the informed consent document and scheduled for a baseline telephone interview. Participants will be asked to review the consent documents prior to the interview. At the start of the interview, the research assistant will review the informed consent document with the participant, answer any questions and obtain verbal consent to proceed with the interview. Thus, there is a small subset of participants who

completed this baseline interview but did not mail back their written consent and did not attend the scheduled genetic counseling sessions. Written documentation of consent has been waived in these cases.

View: 12.12 - Informed Consent Process

12.12 - Informed Consent Process

1. *

Please describe the process that will be used to obtain consent for this study. Include an explanation of:
(1) who will be obtaining consent,
(2) where these discussions will take place,
(3) the plan for ensuring that prospective participants are provided sufficient opportunity to review the consent form and consider participating before signing the informed consent document,
(4) the plan to minimize the possibility of coercion or undue influence, **and**
(5) the information to be communicated to prospective participants.

If the research may include **participants less than 18 years of age**, please describe whether or not all, some, or none of these individuals are capable of giving assent and describe the assent process as described above, including how permission will be obtained from the parent(s) and/or legally authorized representative.

Similarly, if the research may include **adult participants who lack decision-making capacity**, please explain the plan for obtaining consent from the legally authorized representative.

All eligible women who refer to the BRCA1/2 genetic counseling programs will be mailed two copies of the informed consent document and scheduled for a baseline telephone interview. Participants will be asked to review the consent documents prior to the interview. At the start of the interview, the research assistant will review the informed consent document with the participant, answer any questions and obtain verbal consent to proceed with the interview. Following the interview, the research assistant will randomize the participant (via computer). Within 48-hours, all participants will be directly contacted by their genetic counselor to schedule the counseling session. Participants will then be asked to return one completed copy of the informed consent document prior to the scheduled session (for TGC participants) or to bring the completed copy with them to the initial session (SGC group). A toll-free number will be provided for participant questions regarding the consent form. In addition, the informed consent document and procedures will be reviewed again by the genetic counselor at the

initial genetic counseling session.

View: 12.13 - Collection of Private Information On Individuals Other Than Study Subject

12.13 - Collection of Private Information On Individuals Other Than Study Subject

1. * Will this research involve collection of private information pertaining to individuals other than the study subject who is giving consent (i.e. third parties)?

○ Yes ◉ **No**

View: 12.18 - Subject Compensation

12.18 - Subject Compensation

1. * Will subjects receive any compensation for participation either in cash or in kind?

◉ **Yes** ○ No

View: 12.19 - Subject Compensation Description

12.19 - Subject Compensation Description

1. * Please describe the type, frequency, and amount of compensation.
Participants will receive a small incentive (valued at $10.00) following the completion of each of the follow-up interviews. These incentives will include the participants' choice of: 1) Amazon.com gift card or 2) Borders gift card. In addition, all genetic counseling provided to study participants will be provided free of charge.

View: 13.0 - Privacy and Confidentiality of Data and Records

13.0 - Privacy and Confidentiality of Data Records

1. * **Describe methods for protecting the confidentiality of data provided by study participants**. Please address the following in the description: What information about study participants is being collected, why it is necessary to the conduct of this study, what is the plan for protecting these data from improper use and disclosure, and when and how the plan will be initiated. Protection of privacy of participants in studies involving genetic data is of the utmost importance. We will attempt to do this in several ways. First, we will minimize communications across study sites that involve names or other identifying information. Where this is unavoidable (e.g., sites transmitting names to LCCC for purposes of the telephone interviews), all communications will be made via priority overnight mail (as opposed to fax or e-mail). Such materials will not include any information which identifies individuals as participants in a genetic counseling program. Second, any communications made by e-mail will use ID#s only and never include names or other personal information. Third, test results and

other clinical information will never be communicated together with names in any written materials. This information will be attached only to ID#s and will be communicated to sites via priority overnight mail. Fourth, at the individual sites, all clinical information will be kept in locked files in the genetic counselors' offices. Information about participants' pedigrees or results will not be included in their medical records unless participants provide specific permission to do so. Of course, participants themselves may choose to disclose this information to their primary care providers. Fifth, we have obtained a federal Certificate of Confidentiality to protect confidentiality of study participants. Sixth, in all data sets, including those with test results, we will use ID#s only. A separate data set linking names with ID#s will be accessible only to the senior programmer and PI. Information obtained during or as a result of this study will not be released without the expressed written consent of the participating individual. Of course, patients can always choose to disclose this information on their own to healthcare providers. Since women may use information from this study to make medical decisions, the involvement of local health care providers (such as oncologists and surgeons) or insurance providers, may be desirable; however, this involvement carries risks of which participants will be fully informed. Health and insurance providers will only be informed of a patient's test result after the patient has provided written consent. We will keep separate research files for test results; this information will not be included in patients' medical records.

2. * Will Protected Health Information be accessed or used in this study?

(•) **Yes** ( ) No

View: 13.2 - Privacy and Confidentiality of Data and Records [PHI Sources]

13.2 - Privacy and Confidentiality of Data Records - PHI Sources

1. * Please select the source(s) of protected health information:

Hospital/physician medical records

Lab, pathology and/or radiology results

Information derived from biological samples (including blood)

Interviews/questionnaires

View: 13.6 - Privacy and Confidentiality of Data and Records [Recording of Information]

13.6 - Privacy and Confidentiality of Data Records - Recording of Health Information

1. * Please indicate how the research team will **receive** health information:

With identifiers (includes codes derived from patient identifiers; e.g. initials, reversed social security number)

2. * Please indicate how the research team will **record** health information:
With a code (cannot be derived from patient identifiers)

View: 13.8 - Direct Identifiers

13.8 - Direct and Indirect Identifiers

1. * Please select any of the following identifiers that will be recorded with or linked by code to the data:

Names
Geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code, if according to the current publicly available data from the Bureau of the Census: (1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and (2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000
Elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
Phone numbers
Electronic mail addresses

View: 13.10 - Privacy and Confidentiality of Data and Records [Protection/HIPAA Waiver]

13.10 - Privacy and Confidentiality of Data Records - Protection / HIPAA Waiver

1. * How long will you be retaining this information?
This information will be stored until 7 years following the completion of the study.

2. * With whom will this information be shared?
This information will be shared among the PI and co-investigators. Results from this study will be published in aggregate; specific participant identifiers will not be used.

3. * Please describe the plan to protect the privacy of participants:
Protection of privacy of participants in studies involving genetic data is of the utmost importance. We will attempt to do this in several ways. First, we will minimize communications across study sites that involve names or other identifying information. Where this is unavoidable (e.g., sites transmitting names to LCCC for purposes of the telephone interviews), all communications will be

made via priority overnight mail (as opposed to fax or e-mail). Such materials will not include any information which identifies individuals as participants in a genetic counseling program. Second, any communications made by e-mail will use ID#s only and never include names or other personal information. Third, test results and other clinical information will never be communicated together with names in any written materials. This information will be attached only to ID#s and will be communicated to sites via priority overnight mail. Fourth, at the individual sites, all clinical information will be kept in locked files in the genetic counselors' offices. Information about participants' pedigrees or results will not be included in their medical records unless participants provide specific permission to do so. Of course, participants themselves may choose to disclose this information to their primary care providers. Fifth, we have obtained a federal Certificate of Confidentiality to protect confidentiality of study participants. Sixth, in all data sets, including those with test results, we will use ID#s only. A separate data set linking names with ID#s will be accessible only to the senior programmer and PI. Information obtained during or as a result of this study will not be released without the expressed written consent of the participating individual. Of course, patients can always choose to disclose this information on their own to healthcare providers. Since women may use information from this study to make medical decisions, the involvement of local health care providers (such as oncologists and surgeons) or insurance providers, may be desirable; however, this involvement carries risks of which participants will be fully informed. Health and insurance providers will only be informed of a patient's test result after the patient has provided written consent. We will keep separate research files for test results; this information will not be included in patients' medical records.

4. Please attach MedStar or other applicable HIPAA authorization form (if DC mental health study, attach DC mental health authorization): *Link to MedStar HIPAA Forms*

Document	Description
There are no items to display	

5. Please attach MedStar or other applicable HIPAA waiver (if DC mental health study, attach DC mental health authorization): *Link to MedStar HIPAA Forms*

Document	Description
There are no items to display	

6. * Please specify how confidentiality will be maintained for research data and/or tissue/blood:
We have obtained a federal Certificate of Confidentiality to protect confidentiality of study participants

7. * Please provide details on the measures taken to ensure the confidentiality of electronically transmitted data:
There will be no personally identifying information stored on the web-servers or used in the delivery of the intervention. Participants will be identified by ID number only. The website will be housed on a secure web-server that is not the server housing the study data. Access to this server will be user id and password protected. Participant access will not be initiated until the completion of the disclosure session. User IDs and passwords will be provided to participants via overnight mail.

8. * Do you plan to use the names of your subjects in your publication? (Please note: subject consent is required)
○ Yes ◉ **No**

9. * Do you plan to make public any digital, video, audio, or photographic recordings of the subject?
○ Yes ◉ **No**

View: 13.13 - Privacy and Confidentiality of Data and Records [Data Security]

13.13 - Privacy and Confidentiality of Data Records - Data Security

1. * **Electronic Data Storage :** All information must be stored using at least two of the following safeguards and must be kept in accordance with the GU Information Security Policy. Please select the safeguards currently in use: (mark all that apply)

Secure network

Password access

Coded, with master list kept as a hardcopy or on a secure network

2. * **Hardcopy Data Storage :** All information must be stored using at least two of the following safeguards and must be kept in accordance with the GU Information Security Policy. Please select the safeguards currently in use: (mark all that apply)

Locked suite

Locked office

Locked file cabinet

3. * Please clarify for how long you will retain the information (both electronic and hardcopy):
All information will be retained for 7 years following the conclusion of the study.

4. * Please clarify how data will be destroyed (both electronic and hardcopy):
Hard copy data will be shredded and electronic data will be deleted.

5. Please attach sponsor HIPAA authorization if one was provided by the sponsor:
Note: Please be aware that if you intend to deviate from template

confidentiality or authorization language, please be advised that this will require legal review and that it will delay the approval of your research.

6. * Please indicate personnel, other than members of the research team, who will have access to the study data. (mark all that apply)
Note: If you cannot meet the safeguard minimum for PHI or PII, contact your business unit privacy liaison or contact the University Privacy Office at 202-687-8571 to find out who your liaison is.

No one / not applicable

7. * Please indicate how the data will be shared:

The data will not be shared

8. * Please specify the purpose of data sharing:
This data will not be shared outside of the individuals involved in the study.

View: 14.0 - Attachments

14.0 - Attachments

1. *

Please attach the following items:
- Any recruitment materials, notices, or advertisements
- Any research questionnaires, survey instruments, psychological tests, interview forms, or scripts to be used
- Investigator's Brochure from the sponsor, if applicable
- Research protocol and sample consent document from the sponsor or Cooperative Group, if applicable
- Grant application

Name	Description
TCS 12 month survey | History	
TCS 2 week survey | History	
TCS 3 month survey | History	
TCS 6 month survey | History	
TCS baseline survey | History	
TCS consent 2012 | History	
TCS grant | History	