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The present study aims to increase a woman's knowledge of: 1) the factors that determine genetic predisposition to breast/ovarian cancer, 2) personal family history and other risk factors, 3) the benefits and drawbacks of genetic testing for breast/ovarian cancer, 4) the range of surveillance and preventive behaviors available and, 5) the process of genetic testing. Participants will be 200 women who have contacted the Cancer Information Service (CIS) requesting information on inherited breast/ovarian cancer. Women will be randomly assigned to a standard or enhanced intervention testing the effectiveness of the CIS in increasing a woman's knowledge of inherited disease, risk assessment and genetic testing. As planned, this first year was dedicated to a formative evaluation of the informational/emotional needs of women pursuing risk assessment services. The structured interviews and focus groups conducted with women from the lay population, women at high risk and genetic counselors informed the development of the enhanced intervention. The interviews/groups supported previous research demonstrating that women are unprepared for and have limited knowledge about the process and outcomes of risk assessment for genetic predisposition to breast/ovarian cancer. A comprehensive training program and formalized standard protocol will ensure competence and consistency when accrual begins in the Fall.

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Suzanne M. Miller 6/30/99

PI - Signature Date

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(5) Introduction

Previous research has shown that women often lack knowledge regarding the kinds of information that are required to determine inherited risk as well as on the process and content of risk assessment/genetic testing. This lack of information leads them to feel unprepared for risk assessment/genetic testing, if they choose to seek it. This study will develop an enhanced intervention, from material gathered during focus groups and structured interviews, to increase a woman's knowledge of: 1) the factors that determine a genetic predisposition to breast/ovarian cancer, 2) personal family history and other risk factors, 3) the benefits and drawbacks of genetic testing for breast/ovarian cancer, 4) the range of surveillance and preventive behaviors available, and 5) the actual process of risk assessment/genetic testing. The intervention will be guided by the leading "information processing" theory, the Cognitive-Social Health Information Processing Model (C-SHIP). Participants are 200 women who contact the Cancer Information Service (CIS) requesting information on inherited breast/ovarian cancer. Women are randomly assigned to either the standard intervention or the enhanced intervention. A randomized study in which the standard intervention is being compared to the enhanced intervention will test the effectiveness of the CIS in increasing a woman's knowledge of inherited breast/ovarian cancer and the process of risk assessment/genetic testing.

(6) Body

The identification of specific genes that predispose individuals and families to certain cancers is a milestone in medical research. Understanding the genetic basis of inherited cancers may lead to new approaches to treating and even preventing disease. For those in the general population who perceive themselves to be at risk, however, the identification of these cancer causing genes is as unsettling and unnerving as it is exciting and fraught with possibilities. The recent developments in cancer genetics, particularly the identification of the BRCA 1 and BRCA 2 genes, were highly publicized and created a demand for genetic information and counseling. A review of articles dating from 1994 shows a growing interest in providing risk assessment, information, education and counseling about genetic risk and testing, options for 'at risk' individuals and surveillance recommendations for non-affected persons. (Hoskins, Stopfer et al. 1995; Lerman and Croyle 1995; Cole, Gallinger et al. 1996; Weitzel 1996; Koenig, Greely et al. 1998). Although public awareness has increased, women may not have the information they need and are likely to overestimate their risk for inherited disease. (Iglehart, Miron et al. 1998) This project is designed to identify and address the needs of women who have concerns about their genetic risks for breast/ovarian cancers. In addition, for those women who intend to pursue high risk counseling and/or genetic testing, the pilot aims to educate and prepare them for what will more than likely be a lengthy process.

Because of the relative scarcity of formalized, in-depth information about the informational and emotional needs of women concerned about their risks for inherited breast/ovarian cancer,

the first year of this pilot study necessitated a period of formative evaluation. In collaboration with counselors from the Family Risk Assessment Program at Fox Chase Cancer Center, we identified sample populations, both lay and professional, whom we could target to gather information about what women knew, what they thought they knew and what they needed to know about cancer risks and before pursuing high risk counseling for inherited breast/ovarian cancer. Through a series of focus groups and structured interviews with women from the lay population, women at actual and perceived high risk and health professionals with a special interest in cancer and genetics, we yielded a treasure trove of always valuable, sometimes conflicting, information about the needs of women pursuing high risk counseling and genetic testing. This information, described in a subsequent section of this report, informed both the development of the enhanced intervention as well as the staff training outline. In addition to the information derived from the structured interviews and focus groups, we relied on the Cognitive-Social Health Information Processing Model (C-SHIP) to guide the design and contents of the protocol.

A. Formative Evaluation

1. Structured Interviews - Lay

We conducted twenty (20) structured interviews with women who were participating in the Family Risk Assessment Program (FRAP). The majority of the interviews were conducted just prior to the education session; however several interviews were completed after education, but before counseling. Interview questions addressed the following issues: motivation, risk factors, perceptions about risk assessment/genetic testing, understanding of the process of risk counseling and testing, preparedness, how women come by their information about risk factors and risk counseling programs, what other women need to know about inherited breast/ovarian cancer and whether or not they ever heard of the Cancer Information Service (CIS), 1-800-4-CANCER. (See Appendix A for a complete list of questions) All interviews were audio taped and transcribed for content analysis. Transcribed interviews were entered into the SPSS Textsmart program. The reports generated from this analysis were used to guide the content analysis conducted with the transcriptions. Specifically, keywords were identified from the transcripts and frequencies were manually calculated. After the research group reviewed keyword frequencies, categories were established. Frequencies were then calculated for the categories.

2. Focus Group - Lay

In addition to the structured interviews with women at perceived or actual high risk for breast/ovarian cancer, we also conducted a focus group in November 1998, with a group of 9 African American women at the Heureka Health Center in Burlington City, NJ. These women, none of whom reported themselves to be at increased risk for either breast or ovarian cancer, ranged in age from early twenties to mid-sixties. Each woman was paid $25.00 in compensation for her time and effort. We asked the same questions as those asked in the structured interviews. However, we phrased them slightly differently to make them more readily accessible to this group of women who were unlikely to be knowledgeable about assessment of and genetic testing

for hereditary cancer risk. (See Appendix B)

3. Professional Focus Group - Structured Interviews

While the informational needs garnered from women at perceived and/or actual high risk for breast/ovarian cancers cannot be understated, the information obtained from professionals with expertise in counseling such women proved equally critical in informing the development of our enhanced intervention and assessment. From September 29, 1998 through November 20, 1998, we interviewed a total of 17 health professionals in New Jersey and Pennsylvania who specialized or had a special interest in genetic counseling for cancer risk. Mostly nurses and some genetic counselors, their experience in providing counseling for high risk women ranged from less than one year to more than twenty years. We conducted a focus group with 11 representatives from Fox Chase Cancer Center (FCCC) network hospitals, all of whom had undergone training with FCCC's Family Risk Assessment Program (FRAP) and were coordinating or implementing risk assessment programs at their own institutions. Asking the same questions, (see Appendix C) we used structured interviews with the remaining six genetic counselors and nurses to gather information about the informational and educational needs of women pursuing high risk counseling as well as educational strategies of and limitations to services currently offered.

4. Content Analysis - Lay Structured Interviews

Family history of breast/ovarian cancer was found to be the main motivating factor for enrolling in the FRAP program. Other motivating factors included provider's influence, personal history of breast/ovarian cancer, and concerns regarding health in general. The majority of the participants interviewed had found out about the program through either a family member or a health care provider. Risk factors that were given for breast and ovarian cancer included lifestyle, family history (breast/ovarian cancer or other forms of cancer), genetics, age, personal health history, medications, environmental factors, and ethnicity. Participants found out about these risk factors through a variety of means. However, most stated that either family or a health care provider informed them of risk factors for breast/ovarian cancer. Women stated that when they thought about participating in a risk assessment program they were interested in obtaining information on breast/ovarian cancer and that they planned to share this information with other family members. All women coming into the FRAP program are given a lengthy overview of what to expect and what to bring to the initial education session by the program coordinator prior to their first appointment. As a result, many of their responses were inconsistent in that while they often said they felt prepared and/or knew what to expect, they also said that they had no idea that the risk assessment process would be so involved and time-consuming. Several said that, before having spoken to the program coordinator, they assumed that they would have their blood drawn and get their results back that day. When discussing the process of risk assessment most women believed they were going to participate in an education/information session. Of those who responded directly to the question about preparedness, three women stated that they felt prepared, while two other women stated that they felt somewhat prepared or unprepared. The majority of the participants had not heard of the Cancer Information Service (60%), 15% had

heard of the CIS and had contacted them in the past; 10% had heard of the CIS but never utilized their service, another 10% stated that they were unsure whether or not they had heard of the CIS, and 5% did not respond. (Appendix D lists the complete categories that comprised the major concerns and issues reported by the present sample.)

5. Content Analysis - Lay Focus Group

The women who participated in the focus group offered insightful comments about the way women who do not consider themselves at increased risk for breast/ovarian cancer perceive such concepts as heritability, predictive gene testing, high risk and risk assessment with regard to cancer. Like the women in the structured interviews, they had a good grasp on what is meant by inherited disease, often however, linking the concept to more personally relevant disorders like hypertension and sickle cell anemia than to cancer. They had an understanding that things like multiple affected family members and lifestyle could put a person at increased risk for inherited breast/ovarian cancer, although the concept of 'age of onset' was less tenable. Similar to other women interviewed, their information about genetics and breast cancer came from the media (i.e., magazines, newspapers and radio), physicians and other family members. In fact, most of their answers were comparable to those of the women who were actually pursuing risk assessment/genetic testing. Their understanding of what risk assessment/genetic testing would entail and what a person would learn from such a process, for example, included such things as: an analysis of lifestyle and family history, information about how to take care of oneself as well as a greater or heightened awareness of what can happen to one's body and how a person can take steps to prevent disease, or, at least, find it early. Where they mainly differed was in the discussion of the disadvantages of genetic testing. The women in this group spoke frequently and fervently about the role of faith and a positive attitude in coping with risk and disease. For instance, one person said that there was no disadvantage to knowing one's genetic risk "as long as you think positive." Another felt that because the mind was very powerful, having knowledge of one's genetic risk could "persuade the body to think up something." Several women talked about the important role of faith in coping with a positive genetic test. None of the nine women knew that bilateral mastectomy was an option for those at high risk and all were appalled by such a radical act in the absence of disease. They suggested that we dramatically simplify our language in talking to other women who, like them, were not familiar with inherited breast/ovarian cancer syndromes or genes. We should say 'cancer of the ovaries' instead of 'ovarian cancer', for example. Five of the nine participants had heard of the Cancer Information Service before attending the focus group.

6. Content Analysis - Professional

Our interviews with health professionals who counsel women about their genetic risks for cancer has generated relevant and comprehensive information. The counselors identified important informational and emotional needs, strategies they found helpful in promoting an understanding of inherited breast/ovarian cancer and genetic testing, limitations to services currently offered and concerns about the CIS providing an intervention. (See Appendix E for a more detailed analysis) Important informational needs included such things as: the benefits and

limitations of genetic testing, details about what to expect from risk counseling, good explanations of the hallmarks of inherited breast/ovarian cancer, an understanding that risk counseling and/or genetic testing takes a lot of time and, sometimes, a lot of money as well as the importance of following through with the information that counseling provides. Counselors also addressed the emotional needs of women pursuing high risk counseling/genetic testing. They felt it was important to do a thorough assessment to determine, not only the woman's extent of knowledge, but her levels of stress and distress as well. Emotional needs like the impact on the family, issues of confidentiality and survivor's guilt are as important to consider as the informational needs; sometimes more important. The health professionals provided a list of strategies they used to promote a greater understanding of the indicators of inherited breast cancer and genetic testing that included visual aids, computer models, role plays and videotapes. Many stressed the importance of reinforcing all the information using a multidisciplinary team approach. In discussing the major limitations to counseling/testing services that are currently offered, the counselors cited the problems of discrepancies and variations among regional high risk programs, financial barriers, a dearth of counselors trained in both oncology and genetics and simply keeping pace with the literature.

The counselors' responses were occasionally inconsistent when asked what women should know before coming into a high risk program and then what concerns they might have about the CIS providing an intervention. While many believed that women should be informed about the risks and benefits of testing, the specifics about the process of risk assessment and counseling and the hallmarks of inherited breast/ovarian cancer, they also had issues with the CIS providing an intervention that addressed such information. Their concerns stemmed from a fear that the information would be delivered in the absence of a thorough assessment and might steer people in the wrong direction. There was a general consensus that the CIS would be useful in providing women an overview of the costs of risk assessment services, the general risk factors for breast/ovarian cancer and basic genetics. Those counselors who were familiar with or had previous experience working with the CIS were much less fearful and more supportive of the planned intervention, indicating an appreciation for the quality of information the CIS routinely delivers as well as an acknowledgment of the time and attention given each caller to the service. All counselors agreed that any woman, regardless of risk, should have access to risk assessment services. They felt that even those clearly not at increased risk could benefit from the education.

B. Intervention

1. Training Plan

Once the formative evaluation was completed, training development began in March 1999. A training plan and curriculum for the project is attached. (Appendices F & G) As a means of identifying current competency levels among Telephone Information Specialists, we conducted a training needs assessment in April 1999. We employed two approaches in conducting the assessment - a qualitative focus group and a quantitative survey. We led two focus groups with staff to determine the attitudes and comfort level of the Information Specialists toward providing information about inherited risk and predictive gene testing. The quantitative

survey was designed to test the knowledge and skill level of the Information Specialists in providing information on inherited breast and ovarian cancer. In analyzing the results of the focus groups and the survey, we realized that a comprehensive approach was needed to adequately educate and prepare the Information Specialists for this project. Copies of the focus group questions, survey questions and report are attached. (Appendices H, I & J) Upon completion of the training needs assessment, we developed a set of behavioral objectives and a training curriculum.

An important issue throughout the training development process has been the identification of new resources and the review of existing ones. In addition to the many resources available in print, we reviewed two CD-ROM programs. While both were extremely comprehensive and will be incorporated in training, neither truly met our needs in terms of how the information was being presented. We located several outstanding resources including the ASCO Cancer Genetics Curriculum: Cancer Genetics & Cancer Predisposition Testing. A list of key resources is attached. (Appendix K)

In reviewing the original project timeline regarding training implementation, we realized that, given the complexity of the subject matter and issues related to Information Specialists' comprehension and retention of the material, training needed to be conducted in several sessions rather than the two sessions that were originally planned.

We plan to begin training in June 1999. The first session will cover the basics of genetics and will be facilitated by Dr. Cynthia Keleher, a consultant for the Family Risk Assessment Program.

2. Enhanced Protocol

a. Draft Intervention

The development of the *enhanced intervention* (Enhanced Interventions; see Appendix L) was based on the findings from the focus group methodology, and was guided by the Cognitive-Social Health-Information Processing (C-SHIP) model (Miller et al., 1996; Miller & Schnoll, in press). The actual content of the Enhanced Intervention (i.e., the information provided back to the study participants) was formulated using National Cancer Institute and American Cancer Society publications, and from information furnished by the Family Risk Assessment Program (FRAP) at Fox Chase Cancer Center, which is a formal clinical program designed to provide family risk assessment and counseling to women concerned about their inherited risk for breast and ovarian cancers.

b. Formative Evaluation of Lay and Professional Structured Interviews/Focus Groups:

The results of the structured interviews/focus groups indicated several content areas for assessment and the provision of information by the Enhanced Interventions. The

content areas are summarized in Table 1, and comprise the specific questions that make up the Enhanced Interventions. In sum, the content areas identified through the focus groups related to knowledge concerning: 1) genetic factors in disease; 2) familial and general risk for cancer; 3) genetic alterations associated with cancer risk; 4) interpreting family pedigrees; 5) the role of age of onset among familial cancers; 6) procedures involved in risk assessment/genetic testing; 7) advantages and disadvantages of testing; 8) typical psychological reactions to testing; 9) methods for reducing risk if BRCA1/2 positive; and 10) referral for local risk assessment programs. In particular, these were areas that women interested in risk assessment/genetic testing reported being concerned or uncomfortable about; many women expressed the desire to know more about, or have known more about, these issues prior to seeking risk assessment/genetic testing. Each of these content areas was converted into a specific question on the Enhanced Interventions (e.g., "How much do you know about what genes are and how they influence risk of disease?"). For each anticipated response, scripts are provided to Information Specialists who will provide tailored answers to respondents. The material for each response is the latest available information for each respective area, and was provided by the National Cancer Institute's Cancer Information Service.

Table 1: Content Areas for the Enhanced Intervention.

General Content Area	Specific Content
1. Genetic Knowledge	Role of genes in affecting disease risk; chromosomes, gene alterations
2. Assessing Familial Risk	Family pedigree; patterns of family history
3. Familial and other Risk Factors	Review of family and general risk factors (e.g., age, hormones)
4. Genetic Alterations and Cancer Risk	Review of BRCA1/2 as risk factors
5. Family History other than Breast/Ovarian	Risk associated with family history of cancers other than breast/ovarian cancer
6. Age of Onset of Cancers in the Family	The importance of the age of onset of cancers among family members
7. Procedures for Determining Risk	The specific process of risk assessment and genetic testing
8. Proportion of Cancers Linked to BRCA1/2	Rates of breast/ovarian cancer among BRCA1/2 positive/negative individuals
9. Advantages to Risk Assessment/Genetic Testing	Clarify uncertainty, enhanced screening
10. Disadvantages to Risk Assessment/Genetic Testing	No proven therapy, discrimination
11. Psychological Distress of Risk Assessment/Genetic Testing	Typical psychological responses; clinical referral services
12. Methods for Reducing Risk if BRCA1/2 Positive	Surveillance; surgery; chemoprevention; lifestyle
13. Referral to Risk Assessment Programs	Provision of referral list

3. Theoretical Model

While formulating the content area questions for the Enhanced Interventions, we relied on the C-SHIP theoretical model for guidance to ensure that as many key psychosocial factors associated with adherence to cancer-relevant health-protective behaviors were accounted for. Briefly, the C-SHIP model was devised as a theoretical framework to help describe, explain, and predict human behavior in response to health-relevant threats that could have either health-enhancing or health-jeopardizing consequences (see Miller et al., 1996; Miller & Diefenbach, 1998). The model builds on the relevant cumulative findings of cognitive and social science as well as health psychology (e.g., Bandura, 1977; Carver & Sheier, 1981; Curry & Emmons, 1994; Leventhal, 1989). The C-SHIP model seeks to analyze systematically how individuals cognitively and affectively process information about their health, medical risks, and options. The model was launched with the intention of providing a theory-guided strategy and unifying approach for analyzing the psychosocial processes that underlie - and potentially undermine - health protective behavior, particularly in the oncologic context (see Lerman, Schwartz et al., 1996; Schwartz, Lerman et al., 1995), by building upon already existing social cognitive models (e.g., Lazarus & Folkman, 1984; Leventhal, 1989).

One priority during the development of the model was for it to serve a unifying function, capturing the range of cognitive-emotional processes that have been found to be operative in the face of health-relevant threatening life events (Miller & Diefenbach, 1998). These include: the individual's encodings and construals, their expectancies about outcomes, their self-efficacy and control beliefs, the affects that become triggered, the individual's health-relevant values and goals, and their self-regulatory competencies and skills, including the individual's knowledge base and strategies for dealing with barriers - skills that must be both available and readily activated for successful adaptation. By identifying the cognitive-emotional processes that reduce psychosocial well-being and undermine physical heath during encounters with health threats, the model converges with, and complements, recently developed biobehavioral models of disease (e.g., Anderson et al., 1994). In more detail, the C-SHIP mediating units are:

> Health-Relevant Encodings/Self-Construals. Strategies and constructs for appraising one's own health and wellness, personal health risks and vulnerabilities, and illness and disease.
>
> Health-Related Beliefs and Expectancies. Specific beliefs and expectations activated in health information processing. Includes expectancies about the disease (e.g., the individual's optimistic/pessimistic beliefs about prevention and control options) and self-efficacy and control beliefs (e.g., the individual's confidence about his/her ability to adhere to recommended screening, diagnostic, and treatment regimens).
>
> Health-Relevant Affects/Emotions. Affective/emotional states activated in health-related information processing and behavioral responses (e.g., anxiety, depression, anger, intrusive and avoidant thinking).

Health-Relevant Goals/Values: Desired and valued health outcomes and their subjective importance (e.g., whether or not the individual believes that it is critical to be healthy) and goals for achieving health-relevant life projects (e.g., the individual's intention to diet and exercise regularly).

Health-Relevant Self-Regulatory Coping Behaviors. Knowledge and strategies for dealing with barriers to disease prevention and control behaviors and for the constructions and maintenance of effective behavioral scripts over time. Includes coping skills for executing, maintaining, and adhering to long-term, health-protective behavioral and medical regimens (e.g., planning, self-reward, anxiety management).

The C-SHIP model, like the cognitive-affective meta-theory from which it is derived (Mischel & Shoda, 1995), also conceptualizes individuals as differing in two basic ways with respect to these mediating psychosocial processes. That is, individuals predictably differ in the ease with which they typically or chronically access relevant cognitions and affects, and in the pattern of interactions among the relevant cognitions and affects. Not only does the model, therefore, account for the effects of individual differences in singular cognitive-affective processes, but it also delineates the role played by the processing structure and dynamics within the system of cognitive-affective mediating variables (see Miller, Shoda et al., 1996). In our research (Miller, 1995; Miller, 1996), we have been exploring these signature patterns of interrelationships among the cognitive-affective mediating processes, and we have characterized them as *monitoring* versus *blunting*. Monitors, in the context of serious health threats, respond with a predictive cognitive-affective pattern that includes heightened affective distress, low perceptions of control and self-efficacy, and maladaptive coping responses, whereas blunters react with less affective distress, higher levels of perceived control and self-efficacy, and adaptive coping responses.

In utilizing the C-SHIP model, the content areas - and thus the enhanced intervention - will address the individual's encoding perceptions, beliefs and expectancies (e.g., about the pros and cons of testing, control), affect, and knowledge-based self-regulatory processes. Specific questions were designed with these factors in mind; for instance, the questions concerning familial risk endeavor to assist women to formulate accurate risk perceptions.

4. Standard Protocol

The response mode of CIS Information Specialists is a reactive one. Information is tailored to the specific needs of the caller. While there are no formal protocols used, Information Specialists are trained in a specific process. The specialist assesses the information needs of the caller, clarifies the subject of inquiry, identifies the appropriate resource for the information requested, tailors the response to the caller's needs, delivers the requested and any related information, checks the caller's understanding of the information, verifies that this is the information sought, and offers to mail written information on the topic.

We are using a variety of methods to define a standard intervention for callers seeking

information about inherited risk and/or genetic testing. To date, we have interviewed Information Specialists about what they consider to be the usual care, we developed a test call form to document what information is sought and delivered on such calls, and we have completed 3 test calls to test our supposition. (See Appendix M) The result of this process is a draft of a standard intervention. We will continue to test usual care with test calls, focusing on changes to usual care as training begins. It is our intention to have two distinct interventions, which can be separately applied, as needed. The Standard Intervention draft is attached. (Appendix N)

5. Referral Resources

The CIS maintains a current database of regional and national genetic counselors and high risk programs as part of its usual service. Counselors and programs provide the National Cancer Institute with information about the type(s) of service(s) they offer, the names of counselors and program directors and whether or not they offer research, in addition to clinical, services. Most, but not all, of the programs/counselors are affiliated with major teaching institutions. In keeping with the recommendations of the genetic counseling professionals we interviewed that women who perceive themselves at high risk should receive counseling from a multidisciplinary team with an oncology focus, we have identified institutions and programs that match that profile. We compiled a short questionnaire (see Appendix O) that we will use to confirm the information we already have about the high risk programs in our region and in surrounding areas. In addition, though, the questionnaire is designed to gather new information such as cost, length of session(s), patient criteria and breadth of services offered. This pilot project aims to facilitate the process of risk counseling/genetic testing for women calling the CIS. To that end, it is imperative that the CIS refer callers only to organizations/counselors whose programs are of the highest caliber. Because predictive gene testing for cancer is still in its infancy, it is also important that we refer women to programs that are affiliated with research institutions to help ensure that they receive the most current, advanced and credible information available. Also, the differences and variations among high risk programs dictate that we find out as much as possible so as to inform women about the types and availability of high risk programs in their areas. We plan to use the questionnaire to survey high risk programs this summer so that the most up-to-date information can be compiled and ready when we begin to accrue women to the study in the Fall.

6. Outreach/Promotion

To ensure that we reach our accrual goals, we will implement a number of promotional strategies which will increase the number of CIS calls related to breast and ovarian cancer risk. We have long-standing and well-established relationships with key breast cancer organizations in the tri-state area which will be important in the promotion of this project. In the next few months, we will develop a promotional brochure using information from the formative evaluation that will be distributed to these partner organizations. We will also disseminate these materials through other community programs and events. We have been working closely with the research and outreach teams for the STAR Trial (Study of Tamoxifen and Raloxifene) and

will collaborate on the promotion of the CIS for this study. In addition, we have already met with the Public Affairs Director at Fox Chase Cancer Center and will explore opportunities to generate media coverage and promotion. A promotional plan is being developed and will be implemented this Fall.

C. Outcome Measures/Provisional Assessment Tool

Key outcome measures specified in the original grant submission are: 1) intention to undergo risk assessment/genetic testing; 2) sense of preparation to undergo risk assessment/genetic testing; 3) satisfaction with the information provided by the Enhanced Interventions; and 4) degree of knowledge regarding: familial risk, environmental risk factors, procedures for conducting risk assessment/ genetic testing, advantages and disadvantages associated with risk assessment/genetic testing, methods for reducing risk, and available risk assessment programs. In addition, drawing from the C-SHIP model, several additional measures will be included in the Assessment Tool as indicators of process or mediating variables (i.e., variables that may explain how the intervention influences outcome measures). These include measures of: 1) risk perceptions, 2) beliefs and expectancies, 3) affect, 4) self-regulatory behaviors, and 5) monitoring-blunting. Examples of the outcome and process measures can be seen in Table 2.

Table 2

Outcome and Process Measures Comprising the Provisional Assessment Tool.

Measure	Example
Process Measure	
Encoding (Risk Perception)	How would you rate your risk of developing cancer? (1 = very low, 5 = higher than average)
Beliefs/Expectancies	Beliefs: I believe that I am capable of undergoing risk assessment/genetic testing. (1 = strongly disagree, 5 = strongly agree) Expectancies: *Pro:* Genetic testing can help me understand my risk so that I may increase my screening; *Con:* Genetic testing may result in the loss of my insurance coverage (1 = strongly disagree, 5 = strongly agree)
Affect	Thinking about my possible risk for breast or ovarian cancer makes me feel extremely anxious. (1 = strongly disagree, 5 = strongly agree)
Self-regulatory Skills	I am trying to get as much information about my possible risk for breast or ovarian cancer. (1 = strongly disagree, 5 = strongly agree)
Monitoring/Blunting	The Monitoring-Blunting Styles Scale (Miller, 1996).
Outcome Measures	
Intention to undergo risk assessment/ genetic testing	To what degree do you expect to pursue risk assessment or genetic testing (1 = definitely not, 5 = definitely yes)
Sense of preparation to undergo risk assessment/genetic testing	If you were given the opportunity to pursue risk assessment/genetic testing, how prepared would you be to undergo these procedures? (1 = not at all prepared, 5 = very prepared)
Satisfaction with the information by the Enhanced Interventions	How satisfied do you feel with the present information you received? (1 = not at all satisfied, 5 = very satisfied)
Knowledge	Breast Cancer and Hereditary Knowledge Scale (Ondrusek et al., 1999) plus additional items covering: familial risk, environmental risk factors, procedures for conducting risk assessment/genetic testing, advantages and disadvantages associated with risk assessment/genetic testing, methods for reducing risk, and available risk assessment programs

Lastly, Table 3 lists the time points when the specific psychosocial assessments (process and outcomes) will be conducted. As listed in the Revisions section of this report, an additional assessment time-point was included at 2-weeks following the intervention in order to assess short-term changes.

Table 3: Time-points for Assessments

Measure	Baseline	2-Week	2-Month	6-Month
Process Measure				
1. Encoding (Risk Perception)	x	x	x	x
2. Beliefs/Expectancies	x	x	x	x
3. Affect	x	x	x	x
4. Self-regulatory Skills	x	x	x	x
5. Monitoring/Blunting		x	x	x
Outcome Measures				
1. Intention to undergo Risk Assessment/Genetic Testing	x	x	x	x
2. Sense of preparation to undergo Risk Assessment/ Genetic Testing	x	x	x	x
3. Satisfaction with the information provided by the Enhanced Interventions	x	x	x	x
4. Knowledge	x	x	x	x

D. External Advisory Board

The development of this project has been a collaborative effort with a number of programs within Fox Chase Cancer Center, including the regional CIS, Behavioral Oncology and the Family Risk Assessment Program. The formative evaluation efforts have also provided an opportunity to informally gather feedback regarding the project from other professionals in the Philadelphia area that have expertise in risk assessment and counseling. As the formative evaluation has been completed and the interventions are being developed, we would like to establish a more formal mechanism to garner input from a variety of professionals both regionally and nationally. We have identified a number of these professionals and have initiated the invitational process. This summer we will hold the first External Advisory Committee meeting to review the draft interventions and promotional plan.

E. Revisions

As indicated above, the training plan was extensively revised to include a multi-tiered process that will reinforce the Information Specialists' basic training, expand their current knowledge base and introduce them to new concepts relevant to predictive gene testing. We revised the eligibility criteria to include only women calling the CIS about their risk(s) for inherited breast/ovarian cancer and/or genetic counseling. In reviewing the proposed criteria, we determined that including others who are calling for family members or for breast/ovarian cancer information unrelated to risk would be to enrol people who do not match the population we are trying to reach. Because we have revised our eligibility, we have held off on developing promotional materials. We intend to create targeted materials with input from our regional breast and ovarian cancer partners. In this way, we hope to generate calls from women who may benefit from risk assessment and may even be appropriate candidates for genetic testing. We postponed our start date for accrual until Fall 1999. This delay should not jeopardize the study in any way and will give us time to pilot the intervention with test calls from partner organizations. More importantly, the revised start date will coincide with National Breast Cancer Awareness Month - a national promotion that generates a lot of press as well as a period in which we traditionally see a great increase in calls about familial risk.

The External Advisory Board will meet within the next two months to review and offer recommendations about the draft protocol. They will advise, as well, on effective promotion of the study and promotional materials to target 'at risk' women. Having them meet before we conducted the interviews and focus groups and before we even had a draft of the enhanced intervention seemed an inappropriate use of their time and expertise. We hope that by meeting later than originally planned, we will benefit more from their expert advice. Finally, where the original schema called for two follow-up calls, one at 2 months and the other at 6 months, we believe that an additional follow-up at 2 weeks will improve the study. This early follow-up is important for two reasons: 1) it would reduce the respondent burden at the time of the intervention and, 2) it would allow for the measurement of a key indicator of process or mediating variables - including the Monitoring-Blunting Style Scale (MBSS). We anticipate that the intervention will take approximately 18-20 minutes. Adding the MBSS at that time could mean an additional 10-15 minutes per call. Instead, we plan to administer the MBSS and other measures of process and outcome at 2 weeks to obtain preliminary information about the effectiveness of the intervention. These will be repeated at the 2 and 6 month follow-ups.

(7) Key Research Accomplishments

- From September 1998 through February 1999, we conducted structured interviews and focus groups with women from the lay population, women at perceived or actual increased risk for inherited breast/ovarian cancer, genetic counselors and nurses who counsel women about their risk for inherited disease.

- The information obtained from the structured interviews and focus groups was analyzed and incorporated into the design of the intervention as well as the overall training plan.

- Structured interviews and focus group with lay women and women at increased risk support

previous research which demonstrated that women are unprepared for and have limited knowledge about the process and outcomes of risk assessment for genetic predisposition to breast/ovarian cancer.

- Genetic counselors and other health professionals who counsel women about their risk(s) for inherited disease want women to know more about the process of risk assessment but have concerns about how much information a women should have before contacting and/or participating in a high risk program.

- Guided by the C-SHIP model, a theoretical model for information processing, we drafted an enhanced intervention that was influenced by information gathered from the structured interviews and focus groups.

- We designed an extensive and comprehensive training program for the CIS staff.

- We developed a formal standard protocol after extensive research, assessment, pilots and pre-tests.

(8) Reportable Outcomes

Miller, S.M., Buzaglo, J.S., Simms, S., Green, V.A., Bales, C., Mangan, C.E., & Sedlacek, T.V. (1999). Monitoring styles in women at risk for cervical cancer: Implications for the framing of health-relevant messages. In Special Issue "Innovative Approaches to Health Behavior Change," Annals of Behavioral Medicine, **21,** 91-99.

Miller, S.M., Fang, C.Y., Diefenbach, M.A., & Bales, C. (in press). Tailoring psychosocial interventions to the individual's health information processing style: The influence of monitoring versus blunting in cancer risk and disease. In A. Baum & B. Anderson (Eds.), Psychosocial interventions and cancer. Washington D.C.: American Psychological Association.

Savard, J., Miller, S.M., Mills, M., O'Leary, A., Douglas, S., Mangan, C.E. Belch, R., & Winokur, A. (in press). The influence of sleep quality and depression on immunocompetence in low-income women at risk for cervical cancer. Psychosomatic Medicine.

(9) Conclusions

The design of this extensive pilot testing and preliminary data analysis required systematic planning and development. This past year has demonstrated the importance of having sufficient time to formulate and refine both the intervention and the training plan. Determining that genetics and cancer were far too complex to be taught and, more importantly, comprehended, in just a few days led to a modification of the original training outline. The new training module will likely prove to be a model for the entire CIS network and other outreach organizations. The scope of resources and

publications to be used has expanded to include such tools as CD-ROMS, websites and videotapes. The intervention has also benefitted from these baseline evaluations. Structured interviews and focus groups with women from the lay population, women at increased risk for breast/ovarian cancer, professional nurses and genetic counselors enabled us to gain a better and deeper understanding of women's concerns about risk, cancer and genetic predisposition. They also gave us invaluable information about the needs of women pursuing risk assessment/genetic counseling.

During the preparation and background activity, it became clear that some of what we proposed to do in the first year was either premature, in need of revision, or more feasiblely implemented at a later date. It seemed more appropriate, for example, to have the External Advisory Board meet after we had conducted interviews and focus groups, designed a draft intervention and developed a comprehensive training plan. In this way, the Advisory would be better served by having material to review and we would, in turn, benefit from their advice on that material. Eligibility needed to be honed down to include only women calling the CIS for information about breast/ovarian cancer familial risk and genetic testing to ensure consistency in accrual. We have postponed the development of promotional materials until we have an adequate working draft of the intervention. Any materials we design will then be targeted to the population of women we are trying to reach.

This past year has given us important insight into the world of high risk counseling and genetic testing. The genetic counseling professionals to whom we spoke, for instance, adamantly believed that any woman who feels she is at increased risk for inherited breast/ovarian cancer is an appropriate candidate for risk counseling services. As more and more cancer genes are discovered and more and more publicity is given them, however, health care deliverers must consider the difficulties ahead in refocusing highly specialized services on women who are truly at high risk. Of key concern is whether it is an effective use of the counselor's time and the woman's money, for example, to go through a risk assessment program when she is clearly not at increased risk. Given the growing interest in genetic predisposition to cancer and the shortage of oncology trained counselors, there is a need for better assessment tools to ensure that women have access to correct information and that those women who are 'at risk' may benefit from credible risk assessment programs.

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(11) Appendices

A. Structured Interview Questions - Lay

We want to thank you for your help and your time today. The fact that you have made an appointment with the Family Risk Assessment Program demonstrates that you are concerned about your personal risk for breast and/or ovarian cancer. The Cancer Information Service has a grant to find out more about how women perceive their risk(s) for these types of cancers as well as to help prepare those women who, like you, are interested in risk assessment and genetic testing information. The answers you give us today will help us understand the specific areas of concern that women have so that our methods of preparation can be tailored to meet those needs. In the end, with your assistance, we will be able to examine directly the potential benefits of a method that is based on the needs and concerns of women interested in risk assessment and genetic testing information - women like you.

1. Name (Optional)
2. What motivated you to come to this program?
3. How did you hear about the program?
4. You are here because you have concerns about your risk for breast/ovarian cancer. What factors are you considering that you believe contribute to this risk?
   FOLLOW-UP: Number of family members affected
   Age of onset of cancers
   Media reports about the role of genetics in cancer
   Information provided by your physician
   Your own perceptions of your physical health
5. How did you find out about these risks? Where did you get this information?
   PROBE: Doctor
   Family
   Media
6. When you think about risk assessment/genetic counseling for cancer risk, what comes to mind? What do you hope you're going to learn?
   FOLLOW-UP: Do you understand exactly what will occur during this risk assessment process?
   How will such information help or benefit you?
   Are you worried about what this information means?
   Are there any disadvantages to knowing your genetic risk?
   What will you do when you know more about your risk?
   How will this information change the way you think and act? (Preventive behaviors?)
   How will this information affect you and your family?
7. What is your understanding of what will be happening today? What is your understanding of what the next steps will be? How prepared do you feel about seeking genetic testing information for breast/ovarian cancer?
   FOLLOW-UP: Do you feel that you need more information about testing?
   Do you feel you have good sense about what will occur during testing?
   What would help you feel more prepared to seek genetic testing?
8. Thinking about friends or relatives, what information do you think they need to know about

inherited breast/ovarian cancer?

9. Have you ever heard of the Cancer Information Service (CIS)? 1-800-4-CANCER?

B. Focus Group Questions - Lay

We want to thank you for your help and your time today. The Cancer Information Service has a government grant to find out more about what women know about their risk(s) for breast cancer, particularly their risk for inherited disease. The grant will also help prepare women who are interested in personalized risk assessment and genetic testing information. The answers you give us today will help us understand the specific areas of concern that women have so we can develop methods that can be tailored to meet those needs. In the end, with your help, we will be able to determine the potential benefits of a method that is based on the needs and concerns of women interested in breast cancer, breast cancer risk(s) and genetic testing. Thank you again.

1. Name (Optional)

2. We are here today to talk about breast cancer and what puts a woman at risk for getting this disease. What do you understand to be risk factors for breast cancer?

3. What does the term "inherited breast cancer" mean to you?
   FOLLOW-UP: Number of family members affected
   Age of onset of cancers
   Media reports about the role of genetics in cancer
   Information provided by your physician
   Your own perceptions of your physical health
4. How did you find out about these risks? Where did you get this information?
   PROBE: Doctor
   Family
   Media
5. When you think about risk assessment/genetic counseling for cancer risk, what comes to mind? What do you think women learn from high risk counseling?
   FOLLOW-UP: Do you understand what occurs during a risk assessment ?
   How does such information help or benefit a woman?
   Are there any disadvantages to knowing your genetic risk?
   What would you do if you knew more about your risk?
   How would that information change the way you think and act? (Preventive behaviors?)
   How would that information affect you and your family?
6. What is your understanding of what happens during a risk assessment/counseling session? What is your understanding of what happens after that? How prepared would you feel if you were going to seek counseling because of your family history?
   FOLLOW-UP: Do you feel that you would need more information about testing?
   Do you feel you have good sense about what would occur with testing ?
   What would help you feel more prepared to seek genetic testing?
7. Thinking about friends or relatives, what information do you think they need to know about inherited breast/ovarian cancer?
8. Have you ever heard of the Cancer Information Service (CIS)? 1-800-4-CANCER?

C. Focus Groups/Structured Interview Questions - Professional

1. Tell us your name, and describe your professional experience preparing women for breast cancer risk assessment and/or genetic testing.

2. What to you are the most important informational needs of women who are interested in pursuing breast cancer risk assessment or genetic testing.

3. What to you are the most important emotional needs of women interested in risk assessment and genetic testing for breast cancer?

4. What strategies help you to promote a better understanding about *indicators of inheritable breast cancer* and *genetic testing issues* among women seeking risk assessment?

5. What do you seen as the major limitations to the kinds of service that are currently offered women to prepare them for risk assessment and genetic testing procedures?

6. If women were to be informed prior to risk assessment and genetic testing procedures as a preparation for these services, what would you want them to be told?

Follow-up Questions:

7. What concerns would you or your colleagues have about the CIS providing an intervention that helps to prepare women for breast cancer risk assessment and genetic testing?

8. How should we handle women whose family history clearly does not indicate genetic risk, but who maintains an inaccurate, elevated risk perception?

9. How would you say the risk assessment and genetic testing services vary from site to site?

10. Could you briefly tell us about your site and specifically how it may differ from other sites?

D. Content Analysis-Lay

Results of Content Analysis.

What motivated you to come to this program?	
Family history	15
Concern for other family members	4
General health	4
Provider	3
Conditions other than cancer	2
Family wants to know	2
Personal history	2
Other	2
How did you hear about the program?	
Family	8
Provider	7
Friends	1
Medical journal	1
Other written materials	1
Other	1
What factors are you considering that you believe contribute to your risk?	
Lifestyle	22
Family history (breast/ovarian cancer)	17
Genetics	8
Other	6
Age	5
Family history (other)	5
Personal health history	5
Medications	3
Environment	3
Ethnicity	1
How did you find out about these risks?	
Provider	8
Family	8
Media	4
Brochures	2
Computer	2
Referral (word of mouth)	2
Other	9
When you think about risk assessment/genetic testing for cancer risk, what comes to mind? What are you hoping to learn?	
Share information with my family	8
Information	7
Other	7
Increase self-control	5
Ambivalence	3
Know how to protect myself	3

Insurance/employment issues	2
Am I a carrier	1
Seek genetic counseling	1

What is your understanding of what will be happening today? What is your understanding of what the next steps will be? How prepared do you feel about seeking genetic testing information for breast/ovarian cancer?

Education/information	9
Individual/group counseling	3
Prepared	3
Screening	2
Testing blood	2
Other	2
Computer (CDI)	1
Somewhat prepared	1
Unprepared	1

Thinking about friends or relatives, what information do you think they need to know about inherited breast/ovarian cancer?

Basic information	6
Screening	4
Other	3
Social support	2
Lifestyle	1

Have you ever heard of the Cancer Information Service? 1-800-4-CANCER?

No	12
Yes (used)	3
Yes (not used)	2
Maybe	2

E. Content Analysis - Professional

Professional Focus Group/Structured Interviews

1. **Professional experience**
   Oncology Social Worker
   Research Coordinator
   Oncology Clinical Nurse Specialist
   Clinical Research Nurse
   Cancer Risk Coordinator
   Oncology Community Educator
   Radiation Oncology Nurse/Cancer Risk Counselor
   Oncology Program Administrator
   Genetics Coordinator
   Nurse Practitioner
   Genetic Counselor

2. **Important Informational Needs** (What women considering high risk counseling/genetic testing need to know beforehand)

RISK	GENETIC TESTING	HIGH RISK COUNSELING	MISCELLANEOUS
What is risk? Who is at risk?	It's a blood test.	How long it takes (e.g., constructing a pedigree, time with counselors).	Why is it important to you?
Benefits and limitations of a genetic test.	There is a long turnaround time (1-2 yrs.)	It is not a one-time visit and then you're done.	The importance of following through with the information provided.
What to do with the information.	+ test doesn't necessarily mean you'll get cancer.	The importance of medical records in confirming cancer incidence in a family.	The connection between inherited breast and ovarian cancers.
Women overestimate or have no clear conception of their risks.	- test doesn't mean you won't get cancer.	It is a process.	The difference between sporadic, familial and inherited disease.
No recognition of other risk factors like age.	The person who needs to be tested is the person who has cancer.	Awareness of the implications for the rest of the family.	MDs lack knowledge and relay insufficient information.
Mutated gene can be passed down through father's side	There is a high probability of an indeterminate test.	It won't be life threatening if a person has to wait a few weeks or a month for an appointment.	Media is confusing and provides lots of misinformation.
	Cost is expensive if not done as part of research		Showing risk does not alleviate the fear

3. **Important Emotional Needs**

The impact on the family – concerns for children and other family members.
Confidentiality
Survivor's guilt
Control issues.
Important to assess why woman is there at a particular time. (Is there a recent death in the family? Has someone close been diagnosed?)
Important to allay anxiety about how long it might take to get an appointment.
Concerns about + test results and subsequent cancer (related to whether a person has seen a family member die from cancer).
Testing doesn't change the level of distress (sometimes it might relieve it).
Some may benefit from peer counseling
Should have some support mechanism.
Finances: Will insurance pay? How will I pay?
Overriding concern for daughters – have they passed on something that will cause pain?
Concerns about how they view themselves – many already believe they're sick and will get cancer.

4. **Strategies used to help promote an understanding of indicators of inherited breast cancer and genetic testing issues:**
   - One on one education
   - Testing doesn't change the level of distress (sometimes it might relieve it).
   - Visual aids (flip charts, laminated cards, pie charts, timelines)
   - Analogies, tailored to the individual
   - Computer models
   - Newsletters
   - Reinforcement of everything by a multidisciplinary team
   - Hallmarks of genetic risk, how genes work
   - Adult learning principles
   - Two part educational strategy
   - Videotape
   - Pictures, photos
   - Written materials
   - Role plays
   - Gail, Claus Models (the models themselves are not necessarily important to women, but, the fact that these models have been used to assess individual risk is important to women in the program)
   - Accurate, clear, simple information

5. **Major limitations to services currently offered**
   - Small operations – per diem counselors and surgeons calling themselves a high risk program
   - Programs should be multidisciplinary
   - Genetic counselors should be oncology focused

- Insurance not covering the services and/or the testing
- Other financial barriers
- Anyone can hang a shingle
- Level of service drastically different from one program to the next
- People can't keep up with the literature, especially if genetic counseling is not their primary responsibility
- Patients can't be reasonably assured of the level of service – unless it's at an academic institution, how does the patient evaluate it? Will it be valuable? Of high caliber?
- Very few providers with training in genetics and oncology

6. **If women were to be informed, what should they be told**
   - It's a process
   - It's not free
   - Refocus from "How do I get the test?" to "How do I get my risk assessed?'
   - Although it's not for everyone, some may be eligible for chemoprevention
   - There's a difference between participating in research and getting a diagnostic test
   - A little knowledge is a dangerous thing
   - At one institution the scheduling coordinator takes the prospective patient through all that – tells them what will be involved in the process
   - Information re: limits, benefits of testing
   - The program will take a lot of time
   - The program will be holistic, multidisciplinary
   - If they're going to be tested, there are limitations on reimbursement
   - Insurance interactions should be delicate
   - Understand the difference between having relatives with cancer and having an inherited cancer syndrome
   - They'll need permission from other family members
   - They'll need to know a lot about the family history – information should be at hand
   - Should start the process of getting medical records
7. **Concerns about the CIS providing an intervention**
   - Should be OK as long as the CIS is not doing risk assessment over the phone
   - Information should be general – costs, basic risk factors, genetics
   - Concerns re: information/education without detailed assessment
   - Don't want people to feed into the information
   - Delivery of information in the absence of assessment
   - Steering people in the wrong direction
   - Information should be generic
   - Be careful about how much information is given
8. **Miscellaneous**
   - All professionals interviewed believed that any woman, regardless of risk, should have access to risk assessment services. Even those clearly not at risk can benefit from the education.
   - Address psychosocial as well as moral/legal issues.

F. Training Plan

Facilitating Breast Cancer Genetic Counseling
Training Plan

PURPOSE

The purpose of this project is to develop a three-to-four month training plan in preparation for the DOD Research Grant. This plan defines and directs a training method for Telephone Information Specialists to increase their skill, knowledge, and attitudes to perform at a level needed when responding to women seeking information about inherited breast and ovarian cancer.

SCOPE

All Telephone Information Specialists will attend the training. This includes anyone with supervisory responsibilities whose job it will be to ensure that the performance standards established for this project are met. A future performance planning session will identify the individual standards for this project.

PRODUCT DEVELOPMENT

The products to be developed for this multi-unit training program include:

1. Trainers guide.
2. Participant workbook/training manual in a uniform format.
3. Participant handout materials in a uniform format.
4. Corresponding activities, role-plays, and skill practice exercises.

The training content areas for this project will be more thoroughly defined upon completion of a Training Needs Analysis conducted with the Telephone Information Specialists. The methods that will be used in establishing training need include focus group and survey.

An outline of the proposed training elements is attached.

A full review of available resources for this project in an on-going process, however, a preliminary examination reveals some insufficiencies in a few of the proposed content areas. In addition, decisions regarding the utilization of a CBT model for this project is still undecided.

See attachment for a representative sample of those resources reviewed to date.

EVALUATION

Level 1

The Telephone Information Specialist will be asked to identify how the training met their needs through an end of course evaluation for each unit of content developed.

Level 2

Through a pre-test (which will resemble more of a survey, rather than a test), prior knowledge will be gathered in the assessment process. Post-test evaluation will take place during the course of training as knowledge will be demonstrated in discussions and skill performance demonstrated through training exercises.

Level 3

The administrators of this project will establish performance standards. Issues addressing incentives, feedback, and standards will be discussed with the Telephone Service Manager, Training Coordinator and Supervisors. Periodic performance review sessions will be on-going.

Performance indicators will be collected throughout the duration of the study via methods like call monitoring and observation.

Level 4

The effectiveness of the training will be evaluated based on the outcome variables established for the Grant. Specifically, was the Cancer Information Service effective in providing women in-depth information about inherited breast and ovarian cancer, did that information increase their understanding of inherited risk, and finally, did the intervention raise their level of preparedness for high risk counseling?

G. Training Outline

Training Curriculum

Introduction
- Background on the DOD Grant
- Training
  - Purpose
  - Schedule

Module 1: Basic Concepts in Genetics
- DNA Basics
  - Genes & Chromosomes
- Mutations
  - Patterns of inheritance

- Overview of Carcinogenesis
  - Cell Cycle
  - Cell Death

Module 2: The Role of Genes in Cancer
- Identify genes responsible for breast and ovarian cancer
  - BRCA1
  - BRCA2

Module 3: Patterns of Cancer & Assessing Risk
- Sporadic, familial and hereditary patterns of cancer
- Pedigrees
  - the importance of the family history information

Module 4: Inherited Risk
- Definition
- Factors that influence risk perception
- Current risk models
  - Estimating risk
- Presenting risk information
  - Background of theoretical model
  - Impact of cancer risk information

Module 5: Genetic Counseling & Services
- The role of the genetic counselor
- The range of programs and services

Module 6: Genetic Testing

- Considerations
  - Who should be tested
  - Reason for testing
    - Patient perspective
    - Physician perspective
  - How will test result influence medical management
- Informed consent
- Techniques used
- Interpreting results
  - What does it all mean for the patient
- Benefits
- Risks
- Limitations
- Ethical, Legal and social issues
- Psychological issues
  - Ethnic and cultural issues
- Management strategies and follow-up

Module 7: Resources

Module 8: Putting it all together
- Case studies
- Group discussions

Module 9: Intervention
- Theories of Information processing
  - C-SHIP model

Module 10: Study Procedures
- Informed consent
- Randomization
- Computer forms
- Mailouts
- Issues

H. CIS Focus Group Interview Questions

1. A 34 y.o. woman is calling the CIS. The callers 52 y.o. mother has been treated for breast cancer and the caller is concerned because she recently read an article which indicated that some cancers, including breast cancer can be passed down from one generation to another. The caller is asking you how this is determined.
   - Walk me through this call.
   - What questions are important to ask this caller?
   - What points need to be addressed with this caller?

2. How do you decide on which genetic counseling program to refer a caller?

3. Walk me through what you think happens to those callers when they go to the program.

4. What questions do you typically ask a caller if they are seeking referrals for genetic testing?

5. How well do you think the initial training you received has helped you when responding to questions about genetic risk?

6. How comfortable are you in (How do you feel about) providing genetic risk information to callers?

7. Do you think that our service should provide genetic risk information to our callers? Why or why not.

I. Survey Questions for Information Specialists

Please circle the correct answers.

1. A woman who does not have an altered BRCA1 or BRCA2 gene can still get breast or ovarian cancer. T F

2. Breast cancer that occurs at a younger age (before 50) is less likely due to an altered BRCA1 gene than breast cancer that occurs after age 50. T F

3. A sister of a woman with an altered BRCA1 or BRCA2 gene has a 50% chance of having the altered gene. T F

4. If no alteration on BRCA1 or BRCA2 is found in a family with a lot of breast cancer, there could still be another breast cancer gene alteration at work. T F

5. A father can pass down an altered BRCA1 or BRCA2 gene to his children. T F

6. All women who have an altered BRCA1 or BRCA2 gene will get breast cancer. T F

7. DNA is located:
   A. In the chromosomes.
   B. In the nucleus of the cell.
   C. In the enzymes that repair genetic errors.
   D. None of the above.

8. DNA makes proteins, and proteins make:
   A. Enzymes.
   B. Amino acids.
   C. Cells.
   D. Genes.

9. What is the goal of genetic testing? Circle all that apply.
   A. To identify those women who will eventually develop breast cancer.
   B. To assure that individuals who test positive for a gene alteration get appropriate medical follow-up.
   C. To look for possible predisposition to disease as well as to confirm a suspected mutation in either an individual or family.
   D. To provide individuals or families with important health information.
   E. All of the above.

10. All of the following are risk factors for breast cancer *except*:
   A. Age.
   B. Family history.
   C. Personal history of breast cancer.
   D. Use of oral contraceptives.

11. A pedigree is:
   A. A device used to determine a person's susceptibility to a specific disease.
   B. A tool used by geneticists to look at a pattern of disease in a family.
   C. A term used to describe the line of descendants of a pure-breed animal.
   D. An instrument that measures an individual's risk of developing a cancer.

12. All of the following are benefits to genetic testing *except*:
   A. To make better informed decisions concerning the future.
   B. To help other family members.
   C. To gain a sense of control or peace of mind.
   D. To lead the way for all individuals to receive genetic testing.

13. Which of the following are characteristics of the BRCA1 gene? Circle all that apply.
   A. Is located on Chromosome 17.
   B. Contains over 200 alterations.
   C. Lifetime risk for breast cancer is 60 - 80%.
   D. Is a tumor suppressor gene.

14. What is the difference between familial and hereditary patterns of breast cancer?
    A. There are less familial cancer cases than hereditary cancer cases.
    B. The family history is stronger in hereditary cancers than in familial cancers and may indicate a greater likelihood of having an altered BRCA1 or BRCA2 gene.
    C. Familial cases tend to occur in younger women whereas hereditary cases occur more frequently in older women.
    D. The more relatives there are in the family with breast cancer, the more likely it is that a familial pattern exists.

15. If one identical twin develops breast cancer, will the other twin develop breast cancer as well?
    A. Yes, the other twin will almost certainly develop breast cancer.
    B. No, both women will not have received the altered gene.
    C. The answer depends on the rest of the family history.
    D. The other twin has a higher risk for both breast and ovarian cancer.

16. How often do you find yourself referring women with a family history of breast cancer to a genetic counselor?
    frequently fairly often occasionally seldom never

17. How confident are you that the callers you refer for genetic counseling and testing are truly candidates for these services?
    very confident somewhat confident not very confident

18. Which of the following best describes how you feel about explaining the relationship between genes and cancer to a caller?
    very capable somewhat capable not at all capable

19. What is your current level of skill in providing information about the issues related to genetic testing?

1	2	3	4	5
I can perform this task	I need assistance to perform this task	I can do this task without assistance	I excel at this task	I've never done this task

20. How well can you explain the rationale for genetic testing to a caller?

1	2	3	4	5
I can perform this task	I need assistance to perform this task	I can do this task without assistance	I excel at this task	I've never done this task

21. What is your current level of skill in explaining the meaning of lifetime risk of developing a cancer to a caller?

1	2	3	4	5
I can perform this task	I need assistance to perform this task	I can do this task without assistance	I excel at this task	I've never done this task

22. How important do you think it is to obtain family history information from an individual considering genetic testing?

very important somewhat important not at all important

THANK YOU FOR YOUR RESPONSES!

J. Needs Analysis

Date: April 6 & 7, 1999

Brief Description of Group: Two focus groups were held. The first group was comprised of five senior, more experienced Telephone Information Specialists who have been with the CIS for two or more years. The second group consisted of six newer, less experienced Information Specialists who have been with the CIS for less than 1 year, with the average length of employment in this group of 5 ½ months.

Number of Participants: 11

INFORMATION COLLECTION
Problems with Existing/Initial Training:

During both focus group sessions, staff felt that while the initial training they received provided a good overview of the basic concepts of genetics and was presented by an experienced genetic counselor, they nonetheless felt that additional trainings would facilitate a better overall understanding. The majority of senior staff felt that at the time of their initial training, many of the issues surrounding genetics and cancer were not fully known. As information about genetics unfolded and as the service received more inquiries and information to respond to those inquiries, they have subsequently become more educated. The newer staff felt that the initial training did not provide enough information about both the risk counseling and genetic testing process to allow them to feel comfortable when responding to caller inquiries.

1. What do "senior/experienced" staff do that "newer, less experienced" staff do not do?

   Senior staff seemed more able and more willing than newer staff to explore issues about heredity and risk with a caller along with the issues surrounding the genetic testing process. Newer staff admitted that their lack of unfamiliarity with the genetic counseling and testing process limited their ability to assist callers seeking information on this topic. Throughout the session, newer staff seemed unable to communicate and utilize the appropriate language when discussing genetic issues. For example, when attempting to discuss the many genetic alterations found on a gene, one Information Specialist called the alterations "sections." When responding to the scenario that was presented, senior staff was able to formulate more focused assessment questions and addressed key points related to genetics with more accuracy than newer staff. Furthermore, senior staff tended to refer callers to genetic programs based upon the scope and level of service which the program offered whereas geographical location was the main factor in the referral process among the newer staff. In both sessions, several staff members was unaware that some risk programs do not provide the participant with the genetic testing results if the testing is being provided as part of a research study.

2. What are the most common/frequent problems staff face when providing genetic information?

   All staff felt that they did not know enough about the genetic counseling process to speak confidently to callers or to answer questions regarding the intake process when referring callers to a genetic counseling or risk assessment program. Staff also felt that they did not know enough about the individual programs and what services they do and do not provide. Senior staff related that a portion of the difficulty stemmed from the fact that our service does not receive a substantial number of calls about genetics and it is therefore not something that is easily recalled. Senior staff felt that the resources the CIS has available and which they currently use when discussing genetic issues with callers are helpful whereas newer staff felt that our service did not have enough resources to help them on these calls. Upon querying the newer staff as to what resources they have used, the interviewer found that a significant number of staff were unaware of what was available. Further, of the resources that they did know, many weren't sure what was contained in them.

3. What are the issues related to staff attitude about providing genetic risk information?

   While staff felt that it is within our role to be providing genetic risk information, all felt that there should be limits set on what was appropriate to provide. While they felt that our service should be providing basic genetic information to callers, they also emphasized that the scope of our service is such that answering more specific questions concerning individual risk is best left to a genetic counselor. One senior staff member used an appropriate analogy as far as the role of the Telephone Information Specialist in explaining prognosis to callers and that, while staff does not discuss or calculate one individual's survival, they can and do discuss the issues surrounding prognosis.

   Identified Needs:

   - Basic terminology.
   - Basic genetics review.
   - Review of issues related to the genetic testing process.
   - Review of risk assessment programs and their individual services.
   - Review of CIS resources.

   General Plan for Training Development:

   A multi-tiered approach will be utilized for the training. This will be accomplished through several sessions designed to foster both understanding and proficiency.

K. Representative Resources and Publications

Training Resource List

Representative Publications	Lindor N, Greene MH, the Mayo Familial Cancer Program.: The Concise Handbook of Family Cancer Syndromes. Journal of the National Cancer Institute 90 (14): 1039-1071, 1998.	Isaacs CJD, Peshkin BN.: Genetic Testing for Breast Cancer--Who Should Be Tested and What to Do with the Results. Medscape Oncology 1 (4), 1998.	Breast Cancer Linkage Consortium, et al.: Pathology of familial breast cancer: differences between breast cancers in carriers of BRCA1 or BRCA2 mutations and sporadic cases. The Lancet 349 (9064): 1505 - 1510, 1997.
	Kamm BL.: The genetics of sporadic and inherited breast cancer; includes glossary of genetic terms and continuing education post test. Radiologic Technology 4 (69): 299, 1998.	Lynch HT, Watson P, Tinley S, Snyder C, Durham C, Lynch J, Kirnarsky Y, Serova O, Lenoir G, Lerman C, Narod SA.: An update on DNA-based BRCA1/BRCA2 genetic counseling in hereditary breast cancer. Cancer Genet Cytogenet 109 (2): 91-98, 1999.	Moore MM.: The Role of Specialized Genetic Counseling for the Patient at Risk for Breast Cancer. Cancer Control: Journal of the Moffitt Cancer Center 5 (3s): 19-20, 1998.
	Stephenson J.: As Discoveries Unfold, a New Urgency to Bring Genetic Literacy to Physicians. JAMA: Journal of the American Medical Association 278 (15): 1225-1226, 1997.	Geller G.: Genetic Testing for Susceptibility to Adult-Onset Cancer: The Process and Content of Informed Consent. JAMA: Journal of the American Medical Association 277 (18): 1467-1474, 1997.	Lawson EJ.: A Narrative Analysis: a Black Woman's Perceptions of Breast Cancer Risks and Early Breast Cancer Detection. Cancer Nursing 21 (6): 421-429, 1998.
	Drossaert CC, Boer H, Seydel ER.: Perceived Risk, Anxiety, Mammogram Uptake, and Breast Self-Examination of Women with a Family history of Breast Cancer: The role of knowing to be at increased risk. Cancer Detection & Prevention 20 (1): 76-85, 1996.	Hughes C, Lerman C, Lustbader E.: Ethnic Differences in Risk Perception among Women at Increased Risk for Breast Cancer. Breast Cancer Research & Treatment 40 (1): 25-35, 1996.	Jacobsen PB, Valsimarsdottier HB, Brown KL, Offit K.: Decision-making about Genetic Testing among Women at Familial Risk for Breast Cancer. Psychosomatic Medicine 59 (5) 459-466, 1997.
	ASCO, et al.: Resource Document for Curriculum Development in Cancer Genetics Education, 1997.		

CD-ROMS	Centers for Disease Control and Prevention: Steinberg K.: The Genetic Basis For Cancer.	National Cancer Institute: The Breast Cancer Risk Assessment Tool	The Margaret Dyson Family Risk Assessment Program @FCCC.
Websites	www.cancergenetics.org	www.pbs.org/gene/welcome	www.myriad.com
	www.asco.org	www.hhmi.org/GeneticTrail	www.hhmi.org/ GeneticTrail
	www.cancernet.nci.nig. gov/p_genetics.html	www.tricaresw.af.mil/breastcd/hosp tial/read_the_book/ toc.htm	
Videotapes	Zeneca Pharmaceuticals: Assessing Your Risk for Breast Cancer: There is Something You Can Do, 1998.		
Publications	National Cancer Institute Cancer Fact Sheet: Genetic Testing for Breast Cancer Risk: It's Your Choice, 1997.	National Cancer Institute: Understanding Gene Testing, 1995.	
Other Resources	ASCO Curriculum: Cancer Genetics & Cancer Predisposition Testing: Slides & Speakers Notes., 1998.		

L. Draft Intervention

PROVISIONAL ENHANCED INTERVENTION PROTOCOL AND ASSESSMENT TOOL

CIS-DOD TELEPHONE RECRUITMENT PROTOCOL

Office _____ Case _____ Staff I.D. _____ Date _____

Start time of call: _____

1. CIS Introduction: "Hello, you have reached the Cancer Information Service. How may I help you?"

2. Is caller: ____ current patient calling about genetic testing/risk assessment
____ woman interested in risk assessment/genetic testing for breast/ovarian cancer

____ (1) Eligible —> Informed Consent
____ (2) Ineligible —> usual service & complete CIS Electronic Call Record Form

3. Informed Consent: Thank you for calling us today about information on inherited breast/ovarian cancer risk. The Cancer Information Service, as part of a project supported by the Federal Government, can provide you with information and free materials about breast/ovarian cancer risks and genetic testing. I can share information over the phone as well as send you materials that you might find helpful. You may also be interested in a study we are conducting to learn more about the information needs of women concerned about breast/ovarian cancer and to examine different approaches to provide this information. Specifically, we are working to improve our services to woman calling for information about risk assessment/genetic testing for breast/ovarian cancer. To do so, we are evaluating two different approaches for providing women with information about genetic testing and risk assessment for breast/ovarian cancer. Your participation is voluntary and all your answers will be confidential. Your participation would require three things on your part: First, you will need to agree to be randomly chosen for one of two educational programs which would take just a few moments of your time and provide you with free information and materials about genetic testing and risk assessment for breast/ovarian cancer. Second, you would need to agree to participate in a brief, 10 minute, interview which will assess your specific thoughts, feelings, and behaviors concerning your genetic risk for breast/ovarian cancer. Finally, you would need to agree to participate in three (3) 15-20 minute telephone interviews, to take place following today's call and provision of information, that would help us evaluate the short-term and long-term effectiveness of these two types of approaches to assisting women like yourself.

There is very little risk associated with participating in this study. It is possible that talking about your breast cancer risk might make you anxious. In such an event, I can provide you with referrals to support services to discuss your feelings. These support services can help you cope with your specific worries. Also, in the event that you feel anxious, worried or uncomfortable with any of the questions,

you can choose to not answer those questions. The benefits, however, include helping us formally test a newly developed approach to helping women like yourself understand their risk for breast/ovarian cancer, understand the process, advantages, and disadvantages involved in participating in a formal risk assessment/genetic testing program, and feel better prepared to make decisions about seeking out risk assessment/genetic testing programs.

Would you be willing to participate in this study to help us formally test our new approach to providing women like yourself with information concerning their potential genetic risk for breast/ovarian cancer?

____ (1) yes, agree –> continue with next question
____ (2) no, do not agree –> Complete CIS Electronic Call Record Form, then go to standard counseling

Can I have your telephone number so that we can contact you in two weeks, two months, and six months from now?

Phone Number ( ) _____ - _____

When is the best time to reach you? ____ Morning ____ Afternoon ____ Early Evening

Is there another number where we can reach you?

Phone Number (_____) _____- _____

Is this a/your: ____ Relative ____ Work ____ Other

Before we get started with the information you are requesting, I need to ask you your address so that materials you request can be sent to you by mail. Please be assured that all information provided by you will be kept strictly confidential.

First Name _____ Last Name _____

Address_____ City _____ State ___ Zip Code _____

___Yes ___No: **Use last number of phone number to randomize**

____ Standard Counseling (Odd Numbers: 1,3,5,7,9)
____ Enhanced Counseling (Even Numbers: 0,2,4,6,8)

If randomized to the enhanced counseling session: Thank you very much! Now let's get back to your reason for calling. We want to begin by asking you a few questions to help us better understand you perceptions, beliefs, feelings, and behaviors regarding your potential genetic risk for

breast/ovarian cancer.

If randomized to the standard counseling session: Thank you very much! Now let's get back to your reason for calling.

5. <u>Initial (Baseline) Assessment Tool</u>: (Note. This section is provisional and is still being developed. The following, however, provides detailed sample items that are drawn from existing, relevant, funded research protocols currently underway at Fox Chase Cancer Center under the direction of the present research staff).

1) How would you rate your risk of developing cancer?
___ very much lower than average ___ somewhat lower than average
___ average ___ somewhat higher than average
___ much higher than average

2) Do believe that you are capable of undergoing risk assessment/genetic testing?
___ strongly disagree ___ mildly disagree ___ mildly agree ___ strongly agree

3) Genetic testing can help understand your risk so that you may increase your screening.
___ strongly disagree ___ mildly disagree ___ mildly agree ___ strongly agree

4) Genetic testing may result in the loss of your insurance coverage.
___ strongly disagree ___ mildly disagree ___ mildly agree ___ strongly agree

5) In thinking about your possible risk for breast or ovarian cancer, you have been feeling very anxious.
___ strongly disagree ___ mildly disagree ___ mildly agree ___ strongly agree

6) Concerning your possible genetic risk for breast/ovarian cancer, you are trying to get as much information about your possible risk.
___ strongly disagree ___ mildly disagree ___ mildly agree ___ strongly agree

7) To what degree do you expect to pursue risk assessment or genetic testing?
___ definitely not ___ probably not ___ probably yes ___ definitely yes

8) If you were given the opportunity to pursue risk assessment/genetic testing, how prepared would you be to undergo these procedures?
___ not at all prepared ___ somewhat prepared ___ quite prepared ___ very prepared

9) How satisfied do you feel with the present information you received?
___ not at all satisfied ___ somewhat satisfied ___ quite a bit satisfied ___ very satisfied

10) Breast Cancer Heredity Knowledge Scale: Please answer true or false to the following questions.

Many women who do not have any of the known risk factors still get breast cancer	True	False
Over a lifetime, 1 out of 9 women will develop breast cancer	True	False
Women who are over 50 years of age are more likely to get breast cancer than are younger women	True	False
The best time to perform breast self-examination is just before a woman's menstrual period, when lumps are most easily detected	True	False
If a woman gets a regular mammogram, she does not have to do breast self-examination or have physical examinations	True	False
Early detection means a greater chance of surviving breast cancer	True	False
A complete breast examination includes examination of the underarm and neck regions	True	False
Women over age 50 should have mammograms at least every two years	True	False
Mammography can detect lumps that can't be felt	True	False
A woman whose mother was diagnosed with breast cancer at age 69 is considered to be at high risk for breast cancer	True	False
A woman can inherit breast cancer gene mutations from her mother or her father	True	False
Most women who develop breast cancer do not have a family history of the disease	True	False
Ovarian cancer and breast cancer in the same family can be a sign of hereditary breast cancer	True	False
Testing for breast cancer gene mutations can tell a woman if she has breast cancer	True	False
Men can not inherit breast cancer gene mutations	True	False

11) To what degree do you feel ready to pursue genetic risk assessment for breast/ovarian cancer?

Definitely not	probably not	maybe	probably	definitely
1	2	3	4	5

12) Do you intend to contact a risk assessment/genetic testing program in the next 30 days?

___Yes ___ No

13) Do you intend to contact a risk assessment/genetic testing program in the next 6 months?

___ Yes ___ No

6. **<u>The Enhanced Protocol</u> (Note. We are still in the process of writing the specific messages for each the following protocol/intervention questions).**

1. How much do you know about what genes are and how they influence risk of disease?

(1) <u>No knowledge</u>: Genes, which are past on to you by your parents, are found on the chromosomes of each cell. Each cell contains 23 pairs of chromosomes, half are passed down from your mother and the other half are passed down from your father. Therefore, genes also come in pairs. One half of each chromosome pair will have the same genes as the other half of the pair. Cells are constantly reproducing in order to create new cells. This process is called cell division. During cell division, chromosomes make copies of themselves, then the cell splits into two thereby creating a new cell with its own 23 pairs of chromosomes. This is how genetic material is passed from one cell to the next. Whenever cells reproduce, there is the possibility that an alteration or mistake may occur. Most alterations are repaired by repair enzymes, however sometimes an alteration escapes repair and reproduces. This reproduction causes a number of altered cells, which can accumulate in a particular organ, such as the breast or ovary. As long as one copy of the gene remains healthy, it can probably do its job. However, when both copies of a gene become altered, disease can occur. It is important to remember that both copies of a particular cancer gene would need to be altered in order to develop cancer.

(2) <u>Some knowledge</u>: As you probably already know, genes, which are past on to you by your parents, are found on the chromosomes of each cell. Each cell contains 23 pairs of chromosomes; half are passed down from your mother and the other half are passed down from your father. Therefore, genes also come in pairs. One half of each chromosome pair will have the same genes as the other half of the pair. Cells are constantly reproducing in order to create new cells. This process is called cell division. During cell division, chromosomes make copies of themselves, then the cell splits into two thereby creating a new cell with its own 23 pairs of chromosomes. This is how genetic material is passed from one cell to the next. Whenever cells reproduce, there is the possibility that an alteration or mistake may occur. Most alterations are repaired by repair enzymes, however sometimes an alteration escapes repair and reproduces. This reproduction causes a number of altered cells, which can accumulate in a particular organ, such as the breast or ovary. As long as one copy of the gene remains healthy, it can probably do its job. However, when both copies of a gene become altered, disease can occur. It is important to note that both copies of a particular cancer gene would need to be altered in order to develop cancer.

(3) <u>Very knowledgeable</u>: Just to review then, genes, which are past on to you by your parents, are found on the chromosomes of each cell. Each cell contains 23 pairs of chromosomes; half are passed down from your mother and the other half are passed down from your father. Therefore, genes also come in pairs. One half of each chromosome pair will have the same genes as the other half of the pair. Cells are constantly reproducing in order to create new cells. This process is called cell division. During cell division, chromosomes make copies of themselves, then the cell splits into two thereby creating a new cell with its own 23 pairs of chromosomes. This is how genetic material is passed from one cell to the next. Whenever cells reproduce, there is the possibility that an alteration or mistake may occur. Most alterations are repaired by repair enzymes, however sometimes an alteration

escapes repair and reproduces. This reproduction causes a number of altered cells, which can accumulate in a particular organ, such as the breast or ovary. As long as one copy of the gene remains healthy, it can probably do its job. However, when both copies of a gene become altered, disease can occur. It is important to note that both copies of a particular cancer gene would need to be altered in order to develop cancer.

2. In thinking about the risk for breast/ovarian cancer in your family, would you say that family members are at average or high risk?

(1) Average risk: Families without a large number of relatives diagnosed with breast/ovarian cancer would be considered at average risk for developing breast or ovarian cancer. When thinking about family risk for breast/ovarian cancer, it is important to also look at your father's family history as well as your mother's since it is possible to inherit an altered gene from your father. When we evaluate family risk for cancer, we begin by identifying family risk as one of three distinct patterns of family history. These patterns are sporadic, heredity, and familial patterns. Most patterns of cancer within a family are sporadic resulting from changes in the makeup of a particular gene. These changes can be caused by environmental exposures or normal changes that occur with age. A smaller number of family histories of cancers are characterized as hereditary. That is the individual inherited an altered copy of a cancer gene at birth. In familial cancers, the third type of pattern of family history, chance, environmental and family history all play a part and it is difficult to determine which factor has the strongest influence.

(2) High risk: Families with high risk would be characterized by extremely high rates of breast/ovarian cancer. An example of a significant family history would be two or more close family members diagnosed with breast or ovarian cancer before age 50. When thinking about family risk for breast/ovarian cancer, it is important to also look at your father's family history as well as your mother's since it is possible to inherit an altered gene from your father. When we evaluate family risk for cancer, we begin by identifying family risk as one of three distinct patterns of family history. These patterns are sporadic, heredity, and familial patterns. Most patterns of cancer within a family are sporadic resulting from changes in the makeup of a particular gene. These changes can be caused by environmental exposures or normal changes that occur with age. A smaller number of family histories of cancers are characterized as hereditary. That is the individual inherited an altered copy of a cancer gene at birth. In familial cancers, the third type of pattern of family history, chance, environmental and family history all play a part and it is difficult to determine which factor has the strongest influence.

(3) Don't Know: Families with high risk would be characterized by extremely high rates of breast/ovarian cancer. An example of a significant family history would be two or more close family members diagnosed with breast or ovarian cancer before age 50. When thinking about family risk for breast/ovarian cancer, it is important to also look at your father's family history as well as your mother's since it is possible to inherit an altered gene from your father. When we evaluate family risk for cancer, we begin by identifying family risk as one of three distinct patterns of family history. These patterns are sporadic, heredity, and familial patterns. Most patterns of cancer within a family are sporadic resulting from changes in the makeup of a particular gene. These changes can be caused

by environmental exposures or normal changes that occur with age. A smaller number of family histories of cancers are characterized as hereditary. That is the individual inherited an altered copy of a cancer gene at birth. In familial cancers, the third type of pattern of family history, chance, environmental and family history all play a part and it is difficult to determine which factor has the strongest influence.

3. How might you assess your own risk for developing breast/ovarian cancer?

Unlikely to develop it: Keep in mind that one in eight women will develop breast cancer at some point during their lifetimes. Also, there is a one in seventy chance of developing ovarian cancer over the course of your lifetime. There are also a number of other risk factors, which will now discuss. Some factors, such as family history and age, play a strong role in the development of breast or ovarian cancer. Other factors, such as age at first period and menopause, are not as strongly linked but important in understanding breast cancer risk. Family history may be an important risk factor if a pedigree indicates the possibility indicates the possibility of a hereditary or family pattern. Age plays a big role in the development of breast or ovarian cancer. Two thirds of women diagnosed with breast cancer are over age 50. Risk for ovarian cancer increases with each decade of life and peaks at age 80. Women who began menstruating at an early age or undergo menopause later in life have a slightly increased risk of developing breast cancer. Monthly hormone fluctuations cause the cells within the breast to grow. Since women who begin menstruating early or undergo menopause later have an increased number of menstrual cycles their cells experience extended growth changes leading to more opportunities for alterations to take place.

Might develop it: Keep in mind that one in eight women will develop breast cancer at some point during their lifetimes. Also, there is a one in seventy chance of developing ovarian cancer over the course of your lifetime. There are also a number of other risk factors, which will now discuss. Some factors, such as family history and age, play a strong role in the development of breast or ovarian cancer. Other factors, such as age at first period and menopause, are not as strongly linked but important in understanding breast cancer risk. Family history may be an important risk factor if a pedigree indicates the possibility indicates the possibility of a hereditary or family pattern. Age plays a big role in the development of breast or ovarian cancer. Two thirds of women diagnosed with breast cancer are over age 50. Risk for ovarian cancer increases with each decade of life and peaks at age 80. Women who began menstruating at an early age or undergo menopause later in life have a slightly increased risk of developing breast cancer. Monthly hormone fluctuations cause the cells within the breast to grow. Since women who begin menstruating early or undergo menopause later have an increased number of menstrual cycles their cells experience extended growth changes leading to more opportunities for alterations to take place.

Likely to develop it: Keep in mind that one in eight women will develop breast cancer at some point during their lifetimes. Also, there is a one in seventy chance of developing ovarian cancer over the course of your lifetime. There are also a number of other risk factors, which will now discuss. Some factors, such as family history and age, play a strong role in the development of breast or ovarian cancer. Other factors, such as age at first period and menopause, are not as strongly linked but important in understanding breast cancer risk. Family history may be an important risk factor if a

pedigree indicates the possibility indicates the possibility of a hereditary or family pattern. Age plays a big role in the development of breast or ovarian cancer. Two thirds of women diagnosed with breast cancer are over age 50. Risk for ovarian cancer increases with each decade of life and peaks at age 80. Women who began menstruating at an early age or undergo menopause later in life have a slightly increased risk of developing breast cancer. Monthly hormone fluctuations cause the cells within the breast to grow. Since women who begin menstruating early or undergo menopause later have an increased number of menstrual cycles their cells experience extended growth changes leading to more opportunities for alterations to take place.

4. If many of your family members have been diagnosed with breast/ovarian cancer, to what degree does this mean that you are at genetic risk yourself?

(1) I am at a little risk: Family history is one of the strongest indicators of genetic risk. Several family members with a diagnosis of breast/ovarian cancer may indicate that you have a higher than average risk of developing breast or ovarian cancer. If an individual pedigree indicates the possibility of a hereditary pattern within a family history that individual is probably a good candidate for genetic testing for BRCA 1 and BRCA 2. Up to 85% of the women who test positive for BRCA 1 or BRCA 2 mutation will develop breast cancer in their lifetimes. An alteration of the BRCA 1 gene has also been linked to an up 60% chance of developing ovarian cancer in a lifetime. Alterations of the BRCA 2 gene have also been linked to an increase in ovarian cancer however scientists are not yet sure how much. There are also a number of other factors that contribute to your risk for breast/ovarian cancer. These factors include age, previous diagnosis of breast cancer or atypical hyperplasia, early menstruation, late menopause, first pregnancy after age 30 or no pregnancies, hormone use (hormone replacement therapy or oral contraceptives), high fat diet and smoking.

(2) I am at average risk: Actually your risk may be greater, family history is a strong predictor of genetic susceptibility. Several family members with a diagnosis of breast/ovarian cancer may indicate that you have a higher than average risk of developing breast or ovarian cancer. If an individual pedigree indicates the possibility of a hereditary pattern within a family history that individual is probably a good candidate for genetic testing for BRCA 2. Up to 85% of the women who test positive for BRCA 1 or BRCA 2 mutation will develop breast cancer in their lifetimes. An alteration of the BRCA 1 gene has also been linked to an up 60% chance of developing ovarian cancer in a lifetime. Alterations of the BRCA 2 gene have also been linked to an increase in ovarian cancer however scientists are not yet sure how much. There are also a number of other factors that contribute to your risk for breast/ovarian cancer. These factors include age, previous diagnosis of breast cancer or atypical hyperplasia, early menstruation, late menopause, first pregnancy after age 30 or no pregnancies, hormone use (hormone replacement therapy or oral contraceptives), high fat diet and smoking.

(3) I am at high risk and likely to be at genetic risk: Yes family history is a strong predictor of genetic risk and suggests the need for genetic testing. Several family members with a diagnosis of breast/ovarian cancer may indicate that you have a higher than average risk of developing breast or ovarian cancer. If an individual pedigree indicates the possibility of a hereditary pattern within a family history that individual is probably a good candidate for genetic testing for BRCA 1 and BRCA

2. Up to 85% of the women who test positive for BRCA 1 or BRCA 2 mutation will develop breast cancer in their lifetimes. An alteration of the BRCA 1 gene has also been linked to an up 60% chance of developing ovarian cancer in a lifetime. Alterations of the BRCA 2 gene have also been linked to an increase in ovarian cancer however scientists are not yet sure how much. There are also a number of other factors that contribute to your risk for breast/ovarian cancer. These factors include age, previous diagnosis of breast cancer or atypical hyperplasia, early menstruation, late menopause, first pregnancy after age 30 or no pregnancies, hormone use (hormone replacement therapy or oral contraceptives), high fat diet and smoking.

5. If there have been several cases of cancer in your family history, other than breast/ovarian cancer, to what degree does this mean that you are at genetic risk yourself?

(1) I am at a little risk: Family history is one of the strongest indicators of genetic risk. Several family members with a diagnosis of cancer may indicate that you have a higher than average risk of developing cancer. There are also a number of other factors that contribute to your risk for cancer. These factors include previous diagnosis of breast cancer, early menstruation, late menopause, first pregnancy after age 30 or no pregnancies, hormone use, high fat diet and smoking…

(2) I am at average risk: Actually your risk may be greater, family history is a strong predictor of genetic susceptibility. Several family members with a diagnosis of cancer may indicate that you have a higher than average risk of developing cancer. There are also a number of other factors that contribute to your risk for cancer. These factors include previous diagnosis of breast cancer, early menstruation, late menopause, first pregnancy after age 30 or no pregnancies, hormone use, high fat diet and smoking…

(3) I am at high risk and likely to be at genetic risk: Yes family history is a strong predictor of genetic risk. Several family members with a diagnosis of cancer may indicate that you have a higher than average risk of developing cancer. There are also a number of other factors that contribute to your risk for cancer. These factors include previous diagnosis of breast cancer, early menstruation, late menopause, first pregnancy after age 30 or no pregnancies, hormone use, high fat diet and smoking…

6. If many of these cancers have been diagnosed at an early age, how does this impact your risk for inherited breast/ovarian cancer?

(1) It doesn't impact: Actually, age of onset is one of the strongest predictors of genetic risk. Most breast cancers occur in women age 50 or older. When there is a hereditary pattern, the cancer sometimes occurs at younger ages, in the 30's or 40's. The same is true for ovarian cancer. The average age for a diagnosis of ovarian cancer is 59. When there is a hereditary family pattern, it sometimes occurs at younger ages, in the 30's or 40's.

(2) It may impact a bit: Along with other factors, age of onset is a very important factor to consider. Most breast cancers occur in women age 50 or older. When there is a hereditary pattern, the cancer sometimes occurs at younger ages, in the 30's or 40's. The same is true for ovarian cancer. The average age for a diagnosis of ovarian cancer is 59. When there is a hereditary family pattern, it

sometimes occurs at younger ages, in the 30's or 40's.

(3) It impacts greatly: Yes, you are right, along with other factors, age of onset is a very important factor to consider. Most breast cancers occur in women age 50 or older. When there is a hereditary pattern, the cancer sometimes occurs at younger ages, in the 30's or 40's. The same is true for ovarian cancer. The average age for a diagnosis of ovarian cancer is 59. When there is a hereditary family pattern, it sometimes occurs at younger ages, in the 30's or 40's.

7. How much do you know about the procedures involved with determining your genetic risk for breast/ovarian cancer?

(1) Not at all: Well, you should know that the process can include extensive paperwork, several hospital visits, lab work, and there may be a financial cost to you. During the process of genetic counseling a family pedigree will be established. A pedigree is kind of like a family tree that documents which types of diseases family members have been diagnosed with. It is important to confirm cancer diagnosis with medical records since it is possible that an individual may have had an illness that turns out to have been cancer. Women who are eligible for genetic testing are individuals whose pedigrees strongly suggest a hereditary pattern of cancer. Since there is more than 100 known places on the gene where an alteration can occur, it is best to begin screening for a genetic alteration in a person who has already developed breast or ovarian cancer. That way if an alteration is found, other family members can be tested for that specific alteration.

(2) Moderately: Well, you should know that the process can include extensive paperwork, several hospital visits, lab work, and there may be a financial cost to you. During the process of genetic counseling a family pedigree will be established. A pedigree is kind of like a family tree that documents which types of diseases family members have been diagnosed with. It is important to confirm cancer diagnosis with medical records since it is possible that an individual may have had an illness that turns out to have been cancer. Women who are eligible for genetic testing are individuals whose pedigrees strongly suggest a hereditary pattern of cancer. Since there is more than 100 known places on the gene where an alteration can occur, it is best to begin screening for a genetic alteration in a person who has already developed breast or ovarian cancer. That way if an alteration is found, other family members can be tested for that specific alteration.

(3) Very much: Just to review then, you should know that the process can include extensive paperwork, several hospital visits, lab work, and there may be a financial cost to you. During the process of genetic counseling a family pedigree will be established. A pedigree is kind of like a family tree that documents which types of diseases family members have been diagnosed with. It is important to confirm cancer diagnosis with medical records since it is possible that an individual may have had an illness that turns out to have been cancer. Women who are eligible for genetic testing are individuals whose pedigrees strongly suggest a hereditary pattern of cancer. Since there is more than 100 known places on the gene where an alteration can occur, it is best to begin screening for a genetic alteration in a person who has already developed breast or ovarian cancer. That way if an alteration is found, other family members can be tested for that specific alteration.

8. Are you aware of the financial cost associated with genetic testing for BRCA 1 and BRCA 2 gene mutations?

(1) No: Some insurance companies (i.e., HMOs) do cover the costs of the assessment and testing. In addition, many research centers and hospitals, like Fox Chase Cancer Center, provide such assessment at no cost, if you volunteer to participate in a specific research study that includes such services. Otherwise, the costs of such services can vary greatly from site to site.

(2) Yes: Then just to review, some insurance companies (i.e., HMOs) do cover the costs of the assessment and testing. In addition, many research centers and hospitals, like Fox Chase Cancer Center, provide such assessment at no cost, if you volunteer to participate in a specific research study that includes such services. Otherwise, the costs of such services can vary greatly from site to site.

9. Do you believe you must have an altered gene to develop breast cancer?

(1) Yes: Actually, at most, 1 in 10 breast cancer cases involve an inherited altered gene. Most patterns of cancer within a family are sporadic resulting from changes in the makeup of a particular gene. These changes can be caused by environmental exposures or normal changes that occur with age. A smaller number of family histories of cancers are characterized as hereditary. That is the individual inherited an altered copy of a cancer gene at birth. In familial cancers, the third type of pattern of family history, chance, environmental and family history all play a part and it is difficult to determine which factor has the strongest influence. Also, there are a number of factors that influence risk for breast/ovarian cancer. These include previous diagnosis of breast cancer, early menstruation, late menopause, first pregnancy after age 30 or no pregnancies, hormone use, high fat diet and smoking. Most patterns of cancer within a family are sporadic resulting from changes in the makeup of a particular gene. These changes can be caused by environmental exposures or normal changes that occur with age. A smaller number of family histories of cancers are characterized as hereditary. That is the individual inherited an altered copy of a cancer gene at birth. In familial cancers, the third type of pattern of family history, chance, environmental and family history all play a part and it is difficult to determine which factor has the strongest influence.

(2) No: Right, at most, 1 in 10 breast cancer cases involve an inherited altered gene. Most patterns of cancer within a family are sporadic resulting from changes in the makeup of a particular gene. These changes can be caused by environmental exposures or normal changes that occur with age. A smaller number of family histories of cancers are characterized as hereditary. That is the individual inherited an altered copy of a cancer gene at birth. In familial cancers, the third type of pattern of family history, chance, environmental and family history all play a part and it is difficult to determine which factor has the strongest influence. Also, there are a number of factors that influence risk for breast/ovarian cancer. These include previous diagnosis of breast cancer, early menstruation, late menopause, first pregnancy after age 30 or no pregnancies, hormone use, high fat diet and smoking. Most patterns of cancer within a family are sporadic resulting from changes in the makeup of a particular gene. These changes can be caused by environmental exposures or normal changes that occur with age. A smaller number of family histories of cancers are characterized as hereditary. That is the individual inherited an altered copy of a cancer gene at birth. In familial cancers, the third type

of pattern of family history, chance, environmental and family history all play a part and it is difficult to determine which factor has the strongest influence.

10. Are you convinced that there are many advantages to testing?

Yes: You are right. There are a number of advantages to pursuing genetic testing, including: clarify uncertainty, making plans to engage in more intensive screening practices, making changes to your current lifestyle, deciding whether or not to have prophylactic surgery, relaying this information to family members, and contributing to research.

No: Although there are disadvantages-which we will talk about-there are many advantages, including: clarify uncertainty, making plans to engage in more intensive screening practices, making changes to your current lifestyle, deciding whether or not to have prophylactic surgery, relaying this information to family members, and contributing to research.

11. Are you convinced that there are no disadvantages to testing?

(1) Yes: Actually, there are some disadvantages to testing. These include: no proven way to reduce risk, discrimination from life and health insurance companies, knowing your results may make it more difficult to deal with you cancer risk, and test results may be inconclusive.

(2) No: You are right there are some disadvantages. To review, these include: no proven way to reduce risk, discrimination from life and health insurance companies, knowing your results may make it more difficult to deal with you cancer risk, and test results may be inconclusive.

12. Does considering pursuing genetic testing for breast/ovarian cancer create in you any sense of psychological distress, such as fear, anxiety, or depression?

(1) No: Some individuals facing genetic testing experience some degree of anxiety and worry about their testing. Thus, such reactions are normal and expected, and many programs like the one at FCCC offer support programs and services as a standard part of their risk assessment programs. Deciding to under genetic testing for breast/ovarian cancer is a very intense, personal experience. Genetic counseling can help provide women with information and support during the decision making process.

(2) Yes: Such reactions are normal and expected, and many programs like the one at FCCC offer support programs and services as a standard part of their risk assessment programs. Deciding to under genetic testing for breast/ovarian cancer is a very intense, personal experience. Genetic counseling can help provide women with information and support during the decision making process.

13. If you are found to be BRCA 1 or BRCA 2 positive, do you believe there are choices you can make to reduce your risk or help find it earlier?

(1) Yes: That's right, and these include increased surveillance, prophylactic surgery, participating in chemoprevention studies (e.g. tamoxifen) and lifestyle changes. Increased surveillance may include more frequent mammograms and clinical breast exams than you currently receive. Prophylactic surgery is the removal of healthy breast or ovarian tissue in order to reduce the likelihood of developing breast/ovarian cancer. While surgery has been known to reduce the risk significantly, since it is difficult to remove 100% of the tissue, we can not say that it is 100% effective. Chemoprevention is the use of medications to slow, prevent or reverse the process of cancer progression in healthy at risk individuals. To lower overall cancer risk you can change your lifestyle by eating 5-9 servings of fruit and vegetables daily and cutting your fat intake to 20-30% of your daily calories.

(2) No: Actually, there are, including increased surveillance, prophylactic surgery, participating in chemoprevention studies (e.g. tamoxifen) and lifestyle changes. Increased surveillance may include more frequent mammograms and clinical breast exams than you currently receive. Prophylactic surgery is the removal of healthy breast or ovarian tissue in order to reduce the likelihood of developing breast/ovarian cancer. While surgery has been known to reduce the risk significantly, since it is difficult to remove 100% of the tissue, we can not say that it is 100% effective. Chemoprevention is the use of medications to slow, prevent or reverse the process of cancer progression in healthy at risk individuals. To lower overall cancer risk you can change your lifestyle by eating 5-9 servings of fruit and vegetables daily and cutting your fat intake to 20-30% of your daily calories.

14. Even if you are not found to be BRCA 1 or BRCA 2 positive, do you believe there are choices you have to reduce your risk of breast/ovarian cancer?

(1) Yes: True and these include: increased surveillance and lifestyle changes. Increased surveillance may include more frequent mammograms and clinical breast exams than you currently receive. Prophylactic surgery is the removal of healthy breast or ovarian tissue in order to reduce the likelihood of developing breast/ovarian cancer. While surgery has been known to reduce the risk significantly, since it is difficult to remove 100% of the tissue, we can not say that it is 100% effective. Chemoprevention is the use of medications to slow, prevent or reverse the process of cancer progression in healthy at risk individuals. To lower overall cancer risk you can change your lifestyle by eating 5-9 servings of fruit and vegetables daily and cutting your fat intake to 20-30% of your daily calories.

(2) No: Actually, there are things that you can do. These include increased surveillance and lifestyle changes. Increased surveillance may include more frequent mammograms and clinical breast exams than you currently receive. Prophylactic surgery is the removal of healthy breast or ovarian tissue in order to reduce the likelihood of developing breast/ovarian cancer. While surgery has been known to reduce the risk significantly, since it is difficult to remove 100% of the tissue, we can not say that it is 100% effective. Chemoprevention is the use of medications to slow, prevent or reverse the process of cancer progression in healthy at risk individuals. To lower overall cancer risk you can change your lifestyle by eating 5-9 servings of fruit and vegetables daily and cutting your fat intake to 20-30% of your daily calories.

15. Would you be interested in knowing more about places in your area that provide risk assessment programs?

(1) Yes: Provide list.

(2) No: Okay. If you in the future you change your mind just give the Cancer Information Service a call back and someone will get that information for you.

That concludes the part of our service where we provide information about the key issues and concerns with regard to breast/ovarian cancer genetic testing/risk assessment. Before we conclude this call we have just a few more questions we would like to ask you.

1. How satisfied do you feel with the present information you received?

not at all	a little bit	moderately	quite a bit	very much
1	2	3	4	5

2. To what extent would you recommend that others contact the Cancer Information Service for this information?

definitely not	probably not	maybe	probably	definitely
1	2	3	4	5

3. May I ask in which of the following age groups you fall?

____ 18 – 28 ____ 29 – 34 ____ 40 – 44 ____ 45 – 49
____ 50 – 54 ____ 55 – 61 ____ 61 and over

4. Our goal is to serve callers of all ethnic and educational backgrounds. (Check only one ethnic background). May I ask, are you:

____ American Indian/Alaskan Native ____ Asian or Pacific Islander
____ African American/Black ____ White
____ Other ____ Refused

5. May we ask what is the highest level of education you have achieved?

____ Grade School ____ Some High School ____ High School Graduate
____ Some College ____ College Graduate ____ Post-Graduate
____ Refused

The next couple of questions are going to be regarding your current preventive practices. Once again please be assured that all information provided is kept confidential.

6. Have you ever been diagnosed with breast/ovarian cancer?

____ yes ____ no

7. Have you ever been diagnosed with benign breast disease?

____ yes ____ no

8. How often do you perform Breast Self Exam (BSE)?

____ more than once a week
____ at least once a week
____ a couple of times a month
____ at least once a month
____ a few times each year
____ at least once a year
____ almost never
____ never

9. How often do you go for mammograms?

____ once every few months
____ a couple of times each year
____ once a year
____ once every few years
____ almost never
____ never

10. Have you ever had a breast biopsy? YES NO

If YES: How many biopsies have you had? _____
When was your last biopsy? _____
What were the results of your biopsy? _____

11. At what age did you first start menstruating? _____

12. At what age did you stop menstruating? _____

13. Do you have any children? YES NO

If YES: How many children do you have? _____
How old were you when your first child was born? _____

14. In the past six months:
How many transvaginal ultrasounds have you had? _____
How many pelvic exams have you had? _____
How many CA 125 blood tests have you had? _____

End time of call _____

M. Test Call Form

Call Identifiers

Participant Monitor_____ Date_____

Subject of Call_____

_____

Initial Assessment: (Please check)

Caller's Age	❒ YES	❒ NO
Caller's Personal Cancer History	❒ YES	❒ NO
Caller's Family History (Who in family has/had cancer & type)	❒ YES	❒ NO
Age of onset of family cancers	❒ YES	❒ NO
Clarified caller's question	❒ YES	❒ NO

Other, (Please specify)_____

_____

Response/Topics Covered

Risk Factors (Please check)

Age	❒ YES	❒ NO
Personal History	❒ YES	❒ NO
History of LCIS	❒ YES	❒ NO
Age at Menarche & Menopause	❒ YES	❒ NO
Childbearing History	❒ YES	❒ NO
History of Benign Breast Disease	❒ YES	❒ NO
Hormones/Oral Contraceptives	❒ YES	❒ NO
Family History	❒ YES	❒ NO
Affected relatives	❒ YES	❒ NO
Number of affected relatives and/or degree (1^{st} , 2^{nd})	❒ YES	❒ NO
Occurrence in *every* generation	❒ YES	❒ NO
Occurrence of *other* cancers in family	❒ YES	❒ NO

Age when *their* (family member) cancer occurred ❒ YES ❒ NO

Bilateral breast cancer ❒ YES ❒ NO

Sporadic vs. Hereditary Cancer Patterns ❒ YES ❒ NO

Review of Screening Recommendations ❒ YES ❒ NO

Other Topics Covered (Please check)

❒ genetic testing ❒ genetic counseling

❒ pros/cons of genetic testing

❒ Other, (Please specify)_____

_____

Did TIS Provide Referral ❒ YES ❒ NO

If yes, what was referral (please check all that apply)

❒ Referral back to physician ❒ Referral to Family Risk Program

❒ Referral to genetic counselor ❒ Referral for genetic testing

❒ Other referral(s)(please specify)_____

_____

Resource used ❒ YES ❒ NO

Did TIS offer to send pubs ❒ YES ❒ NO

N. Standard Protocol

Standard Intervention For Genetic Risk/Testing Inquiries

Initial Assessment

- Caller's Age
- Caller's Personal Cancer History
- Caller's Family's Cancer History (who?, what type?)
- Age of Onset of Family Cancer
- Clarify Caller's Question

Intervention

- Review Basic Risk Factors
  - Age
  - Personal History
  - Age of Menarche and Menopause
  - Family History
  - Number/Degree of Affected Relatives
- Define Sporadic vs. Hereditary vs. Familial
- Review Screening Needs

Resources Used

- CancerFacts, "It's Your Choice"

Referral

- Personal Physician
- Risk Assessment Program
- Genetic Counselor

Situational Response

- Pros and Cons of Genetic Testing (if appropriate to caller's question)

O. Questions for Risk Assessment Programs

1. Do you have a high-risk program? What services does it include?
   Education?
   Nutrition?
   Surveillance?
   On-site genetic testing?

2. Do you provide genetic testing?

3. Do you conduct research or are all your services strictly clinical or both?

4. Is there a charge for your service? If so, how much?

5. Can you tell me a little about your program:
   How long is each session?

   Is everything done in one day or do patients have to return for additional services?

   Is education done in groups or individually?

   Do patients fill out questionnaires before their appointments?

   Do you accept patients who, in preliminary assessment, clearly do not have significant risk?

   What do patients need to bring with them to their first appointment?

6. Do all patients requesting genetic testing receive counseling? From whom?

7. For which cancers do you offer counseling services?

8. What kind of follow-up do you offer?