This is material related to Control Therapy as part of a grant submitted to DOD "A Study of Risk Perception and Communication on Psychosocial Outcomes in Heredity Breast Cancer"

Material Included:

- Purpose, Hypotheses
- Role of Control Therapy
- Sense of control, anxiety, depression, and health behavior
The purpose of this project is to (1) evaluate factors influencing the use of and response to genetic testing for hereditary breast cancer, (2) develop tools and strategies for effective communication of the complex genetic information needed for informed decision-making, (3) describe the psychosocial impact of the testing process on individuals and their families, and (4) assess the extent of behavior/preventive health changes that may occur over time. Information gained through this research should provide insights that will improve the quality of genetic counseling for other adult-onset diseases and genetic predispositions as tests for these genes are developed.

Among factors to be evaluated are at-risk individual's initial knowledge and attitudes about genetic testing for cancer risk, including their understanding of the nature of the test and the meaning of various possible test results, their own self-assessment of anticipated emotional and behavioral responses to receiving an increased or decreased risk, and factors that would influence their decision about being tested. The project will evaluate the efficacy of different methods of presenting information about: (1) the genetics of cancer and the nature of the test; (2) possible outcomes of testing; (3) issues to consider in deciding whether to be tested, and (4) options for management of cancer risk. Specific questions and working hypotheses are outlined below:

**Question one: What is the psychological state and health behavior practices of individuals upon entering this study?**

**Hypothesis 1:** Individuals in this study will perceive themselves as more vulnerable than a normative population, and have higher scores on psychological measures of depression (CES-D) and anxiety (Hopkins SCL).
Hypothesis 2: Do prior beliefs, personality variables, coping strategies, family functioning, and psychological distress influence the effectiveness of risk communications, comprehension, response, and adaptation to genetic risk information?

Hypothesis 1: Perceptions of personal risk and the adoption of self-protective health behaviors will be more associated with subjective factors and coping styles than with the objective genetic risk information. For example, individuals displaying the most distress about genetic testing and having the greatest perceptions of cancer risk will be those who have lower sense of control, who are emotionally "closer" to the proband or other family members with a diagnosis of cancer, and who believe less in the efficacy of early detection or in the effectiveness of cancer treatments.

Hypothesis 2: Considering prior beliefs about cancer risk and genetic susceptibility will improve our ability to predict the effects of screening on psychological well-being and risk perceptions. For some individuals, discordance between prior expectations and test results will be predictive of long-term misperceptions of personal risk and psychological distress independent of the test result, itself.

Hypothesis 3: Higher levels of anxiety and depression will impair the processing and understanding of probabilistic risk information, and the understanding of the limitations of predictive testing (e.g., that results do not imply disease status nor do they predict the timing or progression of disease). Also, independent of levels of anxiety, individuals with more extreme prior beliefs about cancer risk will process and remember less complex features of the risk information.

Hypothesis 4: Study subjects who (a) are low in optimism (Life Orientation Test) and commitment (Crumbough Purpose of Life); (b) have a poor sense of control (SCI); (c) use denial and escape-avoidance as coping strategies (Ways of Coping–repressors); (d) are members of families low in cohesion and high in conflict (Family Environment Scale); or (e) have limited support networks (Social Support Assessment) will either (a) reject additional genetic information, (b) perceive the risk as larger than the information warrants, or (e) adapt more poorly to information which they perceive as increasing their risk vulnerability.

Hypothesis 5: Individuals with similar screening test results but with dissimilar prior beliefs about cancer risk are likely to display: different interpretations of and emphasis on the uncertainties of the scientific information, differences in the amount of change in psychological distress from time, and dissimilar perceptions of personal risk for breast cancer. The size of these differences are expected to decrease over time.

Hypothesis 6: An individual's risk perceptions, behavioral responses, and level of psychological distress following genetic screening will be affected by relationships with other family members and the level of cohesion and conflict within a family; Risk perceptions and distress will be associated with the screening results of other family members who are emotionally or socially more "significant" to the individual.

Question three: What are the psychological and health-behavior effects of genetic information, and counseling; and, for those at high risk, psychological therapy?

Hypothesis 1: Genetic counseling and psychological intervention (when needed) will increase individual adaptability, sense of control, and the practice of adaptive and preventive health behaviors, and decrease depression and anxiety.

Hypothesis 2: When genetic tests are inconclusive, this situation will result in the highest amounts of psychological distress and worry about health status. This will be manifested in the short-term, as well as over time.
1-F. Psychological Assessment and Psychological Counseling

Medical and technological advances in genetic mapping, however, are outstripping psycho-social research about whether the individual in fact wishes such knowledge; and, if so, the psychological effects of receiving such information. Fundamental questions need to be addressed about when, how, and under what conditions information is conveyed to individuals at risk in a way which minimizes maladaptive adaptation and enhances positive coping and life-style modification.

In the proposed study we will assess the psychological state of individuals before, during and after the genetic screening process, pinpoint which individuals receiving what type of information have psychologically adaptive and maladaptive responses, and provide psychological counseling including stress management, coping, and cognitive/behavioral interventions for those at risk. A control-based model of psychotherapy is the type of clinical intervention selected because it not only shows signs of effectiveness, but because it is also especially relevant to individuals in high stress, ambiguous, and physically threatening situations (Shapiro, 1994; Rodin, 1986; Rodin et al., 1990; Shapiro et al., 1991). Control-related coping has been shown to be an important strategy for individuals with breast cancer (Taylor, 1983; for families with individuals who have cancer and other genetic disorders Shapiro, J., 1989; 1990). In our recent work (Shapiro, Anton-Culver, et al., 1993 Monograph Report for Fetzer Institute) a sense of control has been shown to be an important stress and depression buffer, and multiple modes of control and self-control strategies have been shown to be effective cognitive and behavioral coping strategies for individuals dealing with breast cancer.

Because of the lack of knowledge currently available for this target population regarding the most effective genetic and psychological counseling, a multi-year study is needed. Evaluation of psycho-social information gathered each year, via a system's feedback model (Shapiro, 1983), can help refine and enhance the genetic and psychological counseling for the subsequent years. Initially, the interventions will be generic, but subsequent refinement based on personality variables, family configurations, and social support structures, can help begin the construction of both nomothetic and idiographic genetic and psychological counseling interventions. In this way, the importance for all subjects of the specific issue faced is addressed, while still honoring individual styles and differences.

The use of genetic technology and screening as part of an overall prevention and early detection strategy is reasonable only if a diverse lay population is prepared and able to understand relevant scientific information, can accurately assess personal risk, and responds to this information in ways that result in early identification and treatment of malignancies, or the adoption of a lifestyle that decreases the chances of ever developing this disease. An integral part of this four-year longitudinal study examines factors that influence how genetic risk information is perceived and responded to over time, and what impact the provision of this information may have on the well-being of those who may be carriers of a genetic predisposing factor, or who may be at-risk for hereditary breast cancer. We hope to identify significant factors that differentiate and are predictive of maladaptive and adaptive responses to this information, and based on these results, can assist in the development of effective risk communication, genetic counseling approaches, and clinical psychological interventions most likely to lead to desirable health outcomes.
Life Events

A self-report written instrument will be used to assess changes in life circumstances over the course of the study. This measure is a modified version of a checklist included previously on the Orange County Health Survey (described in the previous section on Assessment of Health Behavior) and used by several of the investigators named on this project. The expanded version to be used in this investigation includes items where participants rate the subjective negative or positive impact of each life event experienced in the designated time period. This modification is derived from the Life Experiences Survey (LES) developed by Sarason et al. (1978), and the inclusion of this measure in the longitudinal design conceptualizes life events as an extraneous variable (or covariate) potentially affecting risk perceptions, behaviors, sense of control, and psychological distress during the course of the study.

4-D. Patient Support Procedures

4-D1. Prevention Information

The recommendations set forth by the NCI concerning use of clinical breast examination, mammography, pelvic examination and the potential reduction in morbidity and mortality resulting from early detection are applicable to women in the general population. In this study however, all participants will be drawn from families at high risk for breast/ovarian cancer. Medical screening recommendations concerning clinical breast examination, mammography, pelvic examination, and ultrasound examination will take into account that participants are in relatively high risk families, i.e., it may be recommended that examinations be initiated at earlier ages and/or at more frequent intervals. These recommendations will be developed by Drs. Love, Gerard, Ku, and DiSaia of the Clinical Team. We will also discuss the adoption of a healthy lifestyle, availability of chemoprevention trials such as the Tamoxifen Study, the option of prophylactic surgery, and developments in gene therapy.

4-D2 Control Psychotherapy

Based on profiles derived from measures of psychological distress (i.e., depression, anxiety, and control scales), participants identified as high-risk will be offered control psychotherapy. Control psychotherapy is a short-term intervention to help individuals develop adaptive cognitive and behavioral strategies, to gain, re-gain, and maintain a sense of control. Two positive modes of control are taught: an assertive, active change strategy in which individuals learn to identify, monitor, and gain active control over those aspects of their life under personal control; and a yielding, accepting mode of control in which individuals learn to positively accept with serenity (and without helplessness and feelings of resignation) those aspects of their life which are not under personal control. Specifically, the question asked is what combination of control-enhancing strategies are most effective for a particular individual with a specific control profile and with a particular control-related problem.

Our longitudinal findings in women diagnosed with breast cancer (Shapiro and Anton-Culver, 1994A and 1994B) showed 17% of women were at high risk, a finding congruent with other breast cancer studies. Control psychotherapy has been shown to be an effective intervention for individuals experiencing severe psychological distress due to serious illness. This will be the first time it has been used specifically to help ameliorate stress stemming from risk of disease. Continuing assessment of these individuals will provide some indication of the usefulness of this form of therapy in this situation. In future studies it may be possible to begin to address other questions such as does a control-based counseling intervention "work" more effectively than other interventions such as stress management/relaxation alone or supportive therapy alone. For ethical reasons, it is inappropriate to have a no-contact control group for those at high psychological risk. Control psychotherapy will be provided by Dr. Shapiro, in collaboration with Drs. McQuade, Nezami, and Josephs.
1. Importance of Psychosocial Issues
   1.1 Early Detection
   1.2 Decisions Regarding Treatment;
   1.3 Illness Stages: Coping, Adaptation, Sense of Control
   1.4 Family/ Interpersonal Context
   1.5 Who gets better and why: psychosocial factors as predictors, and/or mediators of impact on ways to improve perceived loss of control; lifestyle issues.
   1.6 Genetic Testing: Psychosocial issues and costs

2. Psychosocial Factors in Early Detection
   2.1 Internal Health Locus of Control (Rotter)
   2.2 External Health Locus of Control (Rotter/Wallston)

3. Illness Stages (After Heim, 1992)
   3.1 Detection of change, of problem, medical evaluation, preliminary diagnosis
   3.2 Hospitalization; confirmation of cancer diagnosis; surgery
   3.3 Postdischarge and convalescence; resume daily activities; no additional therapy
   3.4 Postdischarge and adjunctive (aggressive) chemotherapy and/or radio-therapy
   3.5 Rehabilitation and adaptation; latency; no new signs or symptoms
   3.6 Metastatic disease; recurrence and advanced illness
   3.7 Terminal Illness
   3.8 Dying

4. Psychosocial Distress, Coping, Sense of Control
   4.1 High at time of diagnosis: 95% 5 on 5 pt scale: helplessness, loss of control: physical health and function; fear of disease recurrence; feelings of isolation; anxiety about death; body image; relationship; fear regarding future; overall uncertainty; pain of treatment.
   4.2 20-30% of patients continue to have clinically significant distress and poorer psychological health
   4.3 Some studies: 50% of variance in psychosocial adjustment to breast cancer is accounted for by non-medical intro-individual variables.
   4.4 Why do some do better: Psychological factors?
   4.5 In a study of psychological adaptation among survivors of cancer, through multiple regression shown that the only psychosocial factor related to adaptation at six months was sense of control (Ell, Nishimoto, Morvay, 1989)
3. Nature of Sense of Control: Positive Assertive, Fighting Spirit
5.1 Early Literature: Fighting Spirit vs. helplessness, fatalism (quadrants four and one).
5.2 Lack of control and depression, anxiety
5.3 Feelings of personal control related to positive quality of life (even in late stage cancer patients). (Lewis, 1982; Cunningham, 1990).
5.4 Watson and Greer (1991) denial and fighting spirit: 75% recurrence free at five years; 55% at ten years; vs. 35% and 22% for helpless/hopeless.
5.5 Spiegel: overcontrol of emotions: positive assertive. Decrease in morbidity/mortality in psychotherapy group.

6. Overcontrol.
6.1 Too strong pendulum shift. Shapiro and Shapiro: NEJM 1979; Helpless patient, omnipotent doctor: to too much individual responsibility.

7. Positive Accepting Mode of Control
7.1 Cultural bias re: Control: Shapiro, Evans, Science, 1987
7.2 Little help from my friends: Taylor at UCLA: Control by a powerful benevolent other: Doctor.
7.3 Cameron et al (1987) religiosity: vicarious control: interpretive control;

8. Integrating Sense of Control Modes at Different Illness Stages: Our Research
8.1 Control profile at Time One
8.2 Psychological morbidity, quality of life and health-related behaviors and lifestyle
8.3 Association between control profile and other assessment measures
8.4 Sense of control not correlated with severity.
8.5 q1 and q2 and overall sense of control
8.6 Q2: significant (negative) correlation with anxiety and depression and positively with quality of life.
8.7 Time Two: 25% same # SCI scales: non healthy direction; 32.2% an increase; 42.3% a decrease. Not related to severity of disease.
8.8 40% Bi-directional shifts in coping (q1, q2) over time.
8.9 Examples: What gives you the most positive sense of control in your life
T1: That I made all the choices for treatment
T2: The support from my children
T1: I believe that sense of control is based on one's perceptions in life. Therefore I am the only one that gives me a positive sense of control.
T2 That I can reason and believe in my own ability
T3 I wish it did not happen

Figure 1
A Four Quadrant Model of the Modes of Control

<table>
<thead>
<tr>
<th>Quadrant 1</th>
<th>Quadrant 2</th>
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<tbody>
<tr>
<td>Positive Assertive</td>
<td>Positive Yielding</td>
</tr>
<tr>
<td>Anxious, Change</td>
<td>Accepting, Yielding</td>
</tr>
<tr>
<td>Mode of Control</td>
<td>Mode of Control</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quadrant 3</th>
<th>Quadrant 4</th>
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</thead>
<tbody>
<tr>
<td>Negative Assertive</td>
<td>Negative Yielding</td>
</tr>
<tr>
<td>Overcontrol</td>
<td>Too Little Control</td>
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</tbody>
</table>
Name: One way to conceptualize the linkage grants between the three groups is to frame them as a bio-psycho-social model. Group one looks at individual issues: the individual as unit; group two looks at biological and physiological subsystems; and group three looks at macro systems: social, family, culture. If this makes sense, then group one could be called the PSYCHO GROUP.

RATIONALE:
Over the past three decades there has been nearly two hundred studies related to psychosocial aspects of breast cancer. These studies have attempted to determine which psychosocial variables may contribute to the incidence and progression of the disease course; as well as the effect of breast cancer on psychological morbidity. Unfortunately, many of these studies are retrospective, poorly designed, compare different psychosocial variables, and/or may be comparing similar variables with different names. Therefore, the field remains in a state of confusion, with a lack of consensus on what is the extent of psychosocial effect, and what are the major constructs. Major overarching categories include personality, social support, coping, health practices (exercise, nutrition, relaxation, treatment compliance <preventive measures>) and stressful circumstances. All eight factors have not been put together in any previous truly prospective study.

What is needed is a well-designed prospective study which identifies the major psycho-social variables from previous studies. Such a study can help answer the first order question of the percent of variance of disease incidence and progression effected by the above eight psychosocial variables. In addition, it would be possible to determine their interaction; and whether there is a cumulative effect from their usage (seven positive factors; one negative factor—stress). A further second order question of clarifying and prioritizing active from inert variables which may be contributing to disease incidence and progression could also be refined. On a biological level, the study could determine the mediating physiological mechanisms where by the effects of psychosocial factors on the cancer process takes place. Finally, on an intervention level, the identification of conditions under which reliable psychological factors affect cancer progression and under what conditions they do not sets the foundation for potentially effective and efficient treatment interventions to be researched at several points: screening, prevention efforts, treatment compliance, psycho-social education of those at high genetic risk, intervention for those at high risk psychological risk at various progression stages.

SIGNIFICANCE:
Because of the current confusion in the field, there is not a sufficient research base of existing data upon which to develop and tailor thoughtful clinical interventions. Ultimately the goal of this research would be to serve as a carefully planned,
sizable study which could provide such a base, both in a preventive way (to reduce incidence); and in a rehabilitative way (to extent quantity and quality of life post disease). The study can thus serve as a bridge between the research and clinical literature; go beyond previous uni-dimensional construct studies to look at multiple psychosocial variables, including coping flexibility; and help refine active from inert psychosocial variables in disease incidence and progression.

AIMS: This study has six aims, which are refined in several specific hypotheses.

1) Empirically determine psychosocial factors which effect disease incidence, including personality, social support, coping, health practices (exercise, nutrition, relaxation, preventive measures) and stressful circumstances.
2) Empirically determine psychosocial factors which effect disease progression; personality, social support, coping, health practices (exercise, nutrition, relaxation, treatment compliance) and stressful circumstances.
3) Having identified active psychosocial variables, to investigate the physiological markers which may be mediating mechanisms by which psychosocial factors effect cancer incidence and progression.
4) To determine the interaction and relative importance of different psychosocial factors on cancer incidence and progression.
5) To determine whether there is a summative (synergistic) effect of the identified psychosocial variables.
6) To build a psychosocial research foundation which can contribute to the development of a person-based, flexible, broad-spectrum but individually tailored clinical intervention.

INCIDENCE STUDY:
Independent Variables
Stress: results showing that major stressor increased risk; regular stress exposure reduced the risk (Cooper and Fairghe, 1993; Geyer, 1993). Need clarification of family of origin stress; stress at what ages, etc.
Emotional Expressiveness and anger. Contradictory findings re: high aggression and incidence (Wirsching et al, 1985); vs. three studies showing emotional control associated with incidence.

HYPOTHESES: INCIDENCE
1. Repressive coping as measured by lack of expression of negative emotionality (e.g., anger), and Taylor Manifest Anxiety (low) and Social Desirability scale (high) and high level of major stressor and lower levels of minor stressors associated with increased incidence.
2. The percentage of variance due to psychosocial factors will decrease from population samples one to three, as genetic influences increase. (counter view or subpoint: there will be greatest beneficial effect of these psychosocial factors
as inherited vulnerability for cancer mounts).

3. Those who have positive sense of control, high hardiness (commitment, control, challenge), low repression, a coherent (basic trust) view of the universe, social support, positive cognitive and behavioral modes of control, transformational coping, low major stressor, high everyday stress; low repression, engage in positive preventive health practices will have decreased disease incidence.

Secondary questions regarding incidence and preventive behaviors:

a) what are the psychosocial factors (e.g., denial, fear, resistance, anxiety, avoidance behaviors) that might effect decrease in breast self-examination and mammography screening. What is difference between those that do and those that don't do breast self-examination, mammography? (e.g., fear plus control; fear plus helplessness; invincible?

b) general questions: how do informed women at high risk receive or get information; does information that is received from a physician increase or decrease anxiety; are women at high risk more anxious than women with no family history of BCA; can genetic screening alleviate or exacerbate anxiety for women at high risk?

WHERE HELP WANTED:

Group Two: physiological markers.

Group Three: social support (we want to see sources; quality of support; characteristics of support (empathy, assistance, encouragement); risk perception.

VARIABLE HELD CONSTANT (or to be investigated by group three): ethnic, cultural, and racial factors; family factors; treatment interventions (both medical and psycho-social)

PROGRESSION

Physiological Progression:

Dependent variables of a) recurrence frequency and type; b) length of survival; c) disease free interval: time to relapse; d) severity of progression: spread, tumor size, node status; e) physiological markers of progression.


Questions: At what point, if any, do the physical factors overwhelm the psychological ones.

Assessments: Severe Stressor, social support, emotional expression, anger, stoicisim, fatigue, depression, adjustment to cancer, quality of life, psychiatric diagnosis, hardiness, sense of control, modes of control, coping flexibility (Carver and
Schier; Lazarus and Folkman); transformational coping, regressive coping; philosophical, spiritual beliefs about the nature of the universe.

Psychological Progression:
Dependent Variable of Quality of Life. To differentiate the psychosocial factors (independent variables) from quality of life, the latter could emphasize more ideographic information, including qualitative and quantitative measures: Domain specific sense of control; areas of concern; mode for addressing areas of concern; existential issues raised by the cancer (e.g., have children, pursue a career, physical pain and how to handle it, sexual attractiveness; decisions regarding these issues; emotional impact of existential issues and decision making process.

HYPOTHESES: PROGRESSION
1. Those who have positive sense of control, high hardiness (commitment, control, challenge), low repression, a coherent (basic trust) view of the universe, social support, positive cognitive and behavioral modes of control, transformational coping, low major stressor, high everyday stress; low repression, engage in positive preventive health practices will have decreased disease physiological progression and better psychological wellbeing/quality of life.

2. Those who engage in positive flexible coping over time and stage will have decreased disease physiological progression and better psychological wellbeing/quality of life.

Some questions regarding beliefs about nature of the universe.

1. Does the context of spiritual or philosophical orientation increase the sense of wellbeing, quality of life, disease progression in cancer experience.
   a) Those who believe in a benevolent universe that they can trust at the deepest level will evidence an enhanced quality of life vs. those that don't.
      a2) But maybe less positive assertive
   b) Those who believe in an existential view that the universe is neutral and provides no a priori meaning, and who create a philosophy of self-effort will evidence an enhanced quality of life vs those that don't.
      b1) More Positive assertive
      b2) But maybe less positive yielding
      b3) Can have too high belief in control (-)

2. Which view allows for more flexible coping: basic trust in universe, or neutral universe?

3. Can disease experience lead to a shift in view of universe: more basic trust, less basic trust. When is that helpful, when not?
SUMMARY BREAST CANCER PATIENTS:

Marital Status: Some evidence that marital status associated with long-term survival even after controlling for delay in seeking treatment and other variables. Some studies support reduced psychological distress related to marital status; others find no such relationship. Marital status is associated with earlier diagnosis in whites, but not other ethnic groups.

Age: Younger age tends to be associated with greater and more prolonged psychosocial distress.

Psychosocial Adjustment: Some controversy about extent to which breast cancer patients are clinically depressed. Prevalence may be lower than previously suggested and may be similar or just slightly higher than that in general population. Best predictors of depression seem to be functional status and prior history. In recurrence, however, clinical depression may affect almost 50% of patients.

Factors associated with poor psychological adjustment are poor prognosis, more extensive surgery (but not lumpectomy vs. mastectomy), type of treatment, control over treatment (including choice of procedure). In another study, performance dysfunction, presence/absence of adjuvant therapy appear to have no independent effects on psychological adjustment.

Women at risk for psychological distress have more physical, psychosocial, sexual, marital, and medical interaction problems than no-risk women.

Some studies show psychological morbidity greater in breast cancer pts. when compared to benign and control groups, but some similarly designed studies show greatest psychosocial morbidity in patients with benign breast disease.

Physical problems tend to subside over first year, but psychologic distress, communication problems, sexual dysfunction often persist. Other studies cite significant decreases in anxiety and depression in the year following surgery, and overall improvement in emotional coping, with one study suggesting measures of psychological adjustment approach normality within 3 months of surgery.

Pessimism is associated with poorer psychological adjustment.

Acceptance, positive reframing, use of religion most common coping reactions; denial and behavioral disengagement the least common. Cognitive avoidance an important predictor of high distress and low vigor.

Perceived loss of control cited as the most important factor in predicting overall psychological adjustment.
Emotional control, fatalism, helplessness, and anger suppression also all linked to psychological morbidity.

Positive adaptation may emphasize such features as gratitude for life and confidence in one's ability to manage life crises.

Coping: Downward comparison is a widely used strategy. There is some evidence some breast cancer pts. use denial as a defense mechanism. Women with breast cancer may engage in fewer coping strategies than women with benign breast disease, and fewer positive coping strategies. There is some association between positive psychological adaptation and positive/confronting coping and high internal locus of control, as well as with information-seeking and perceived invulnerability. One study suggests no relationship between coping strategies and course of disease, but significant relationships between biological parameters and course of disease. One study found denial and psychiatric illness to be associated with LESS likelihood of recurrence of malignancy, and another study also suggested that palliative measures (i.e., avoidance of speaking about threat or refusal to accept implications of disease) were associated with better adjustment.

Life Stress and Incidence: Severe stressors are related to development of breast cancer in some studies, although milder daily hassles stressors do not appear to be related. Regular exposure appears to reduce risk of malignancy, while a single major life event is associated with malignancy, especially in women who are unable to externalize emotions and seek support. One study finds no relationship between life events, coping, Type A and breast cancer. Another study find no evidence that psychosocial stress contributes to relapse of breast cancer patients.

Psychological Profile: (Many methodological problems). Associated characteristics that have been identified in the literature include regarding illness as personal weakness, need to control others, tendency to avoid confronting problems, irritability, psychoticism, less social support (the finding regarding social support is contradicted in a later, better designed study); narcissism, hysterical disposition, unresolved grief; inaccessible, altruistic, suppressing feelings, rationalizing and harmonizing; dependent, anxious, aggressive, health-conscious, family-bound and antiseosexual (!).

Social Support: Social support operates differentially depending on type and stage of cancer. One study shows association of survival with number of supportive friends and size of social network. Three other studies found perceived emotional support positively correlated with psychological adjustment. Women with chronic diseases report receiving most support from spouse. Social support in chronic diseases associated with less depression, higher marital and family functioning. One study found no association between social support and likelihood of developing breast cancer. Another study found attitudes toward cancer and mastectomy predicted greater proportion of variance in self-esteem of breast cancer women than did social support.
The issue of psychosocial variables in cancer progression is a continued struggle of the definition of independent, mediating and dependent variables.

The independent variables would obviously affect either cancer progression, cancer markers or the set of psychological outcome variables often titled as quality of life.

Personality and Symptoms

- Expression
- Repression
- Hardiness
- Optimism
- Depression
- Control
- Stress -- frequency, intensity
- IE

The mediating variables would affect the path and effect of the independent on the dependent. This gets weir when depression could affect social support, which could affect the effect of depression as an IV and depression as a QOL measure.

Coping
- Social Support
- Compliance
- Health Behaviors

Quality of life is also difficult. One can look at common domains and at upsetting symptoms. Many QOL scales (e.g., as the FACIT) try both.
Recreation

How has cancer affected these

SYMPTOMS -- some may be existential

Depression

Anxiety

Strain-- other

Anger -- resentment -- unfair -- maybe mediating

Sleep change -- nightmares

Tired weary

Pain -- physical side -- Nausea

Existential

Sexual problems -- reproduction if applicable

Appearance problems -- body -- attractiveness

Physical functioning

Religious, faith problems

Meaning of life

Identity

Change in role

Death

Not meeting life goals
PSYCHOSOCIAL ASSESSMENT
SENSE OF CONTROL, ANXIETY, DEPRESSION, AND HEALTH BEHAVIOR

SPECIFIC AIMS

The overall aim of this component of the project is to develop an integrated psychosocial assessment which can investigate the following:

1) To assess psychosocial variables prior to risk communication, to determine whether individual personality variables might predict response outcomes (Psychosocial variables as independent variable, Time One, Year One).

2) To assess the effect of risk communication on psychosocial variables (psychosocial variable as dependent variable, Time Two, Three, Four, Year One), and health behavior.

3) To gather information about adaptive cognitive and behavioral strategies with which individuals seek to gain and maintain a sense of control (Time 1,2,3,4).

4) To utilize the information gathered in 1-3 above, to determine how most effectively to begin the construction of both nomothetic and idiographic genetic counseling interventions, thereby recognizing the importance for all subjects of the specific issue faced, while still honoring individual styles and differences. This information can be obtained from examining what modes and styles of sense of control seem to provide a stress and depression buffer for individuals receiving difficult information (items one and two above); and what coping responses/ flexibility seem to be effective in helping individuals maintain a sense of control in addressing the threat information (item 3 above).

5) To incorporate the information from year one into the genetic counseling intervention for year two, and evaluate its effectiveness, as well as continue the follow-up on year one group.

6) To continue to refine and develop the genetic counseling component through this systems feedback model--of intervention and evaluation--for years three, four, and five.
ASSESSMENT INSTRUMENTS

A) Shapiro Control Inventory (SCI), provides a nine scale "Control Profile" covering four content areas:

*Sense of Control includes three sense of control scales in the general domain; and one domain specific sense of control scale which incorporates twenty-five specific parameters of control and self-control.

*Modes of Control involves four scales reflecting four characteristic cognitive and/or behavioral styles of responding to control-related issues: positive assertive, positive yielding, negative assertive, and negative yielding.

*Motivation for Control contains a desire for control scale, information on mode and parameter satisfaction, overcontrol issues, and preferences for dealing with domain-specific parameters of concern regarding control.

*Agency of Control provides information on the source of a person's sense of control.

B) Depression will be measured by the CDC-D, the Center for Disease Control standard depression inventory.

C) Anxiety will be measured by the CDC-A, the Center for Disease Control standardized anxiety inventory.

D) Health (Risk) Behaviors will be measured by Farquahr's five component health risk questionnaire, as well as two additional aspects:

*diet and nutrition
*exercise
*stress management
*smoking
*body weight
*alcohol consumption
*social support

Questions, thoughts:

Blame attribution
Survival guilt
Meaning/ existential issues.
September 1, 1994

To: Hoda and Psychosocial Br. Cancer Genetic Testing Grant Group

From: Deane

DOD queries:

HYPOTHESIS ONE NOT CLEARLY STATED:

Hypothesis 1 Individuals in this study will perceive themselves as more vulnerable than a normative population, and have higher scores on psychological measures of depression (CES-D) and anxiety (Hopkins SCL).

Note to colleagues I assume the ambiguity involves the words more vulnerable (e.g., physically, psychologically, etc.). The literature suggests that those who voluntarily consider genetic counseling are more anxious and distressed than a normal population. It is hypothesized that, overall, high risk families (genetically) would feel more psychological vulnerability.

REVISION: p. 14. Hypothesis 1 Individuals in this study, will have higher scores on psychological measures of depression (CES-D) and anxiety (Hopkins SCL) than a normative population. Clearer?

PSYCHOLOGICAL INTERVENTION

1. Not clearly stated regarding two modes; who will give it; how many sessions; how evaluated.

This material is described on p. 22, paragraph 4 beginning Psychological Intervention. Perhaps it should be highlighted, or placed in bold, to help the reviewers

PSYCHOLOGICAL COUNSELING INTERVENTION: CONTROL PSYCHOTHERAPY.

For Whom: Who will be at high risk? As can be seen from the experimental design, families in year one receive psychological and health behavior assessment four times in year one (upon beginning the project, and at three, six and twelve months), and yearly thereafter (times five, six seven). Psychological intervention occurs only for those who are at risk, either self-perceived or as evaluated by assessment instruments. This intervention is designed to occur at two different assessment points in the study. The first point is at three months, following the decision to receive or not receive test results. The second point is at six months, based on the follow-up psychological assessment.

We can only extrapolate regarding the percentage of individuals who will be at high psychological risk. One source is women diagnosed with breast cancer; a second source is pilot studies of genetic testing from Huntington's Disease. Regarding the former, our longitudinal findings with women diagnosed with breast cancer (Shapiro, Anton-Culver, et al, 1994a,b), showed 17% of women were at high risk, a finding congruent with other breast cancer stud-
ies. Regarding the second, the figure ranges from 10-28%. We are assuming 15% of the individuals will need psychological counseling over the course of the year.

At this time, we can make educated guesses about who (and what percentage of individuals) will be at high psychological risk, but part of the reason for the study is to further refine that determination. We will be assessing the interaction between

1) nature of information that is conveyed at time two (categorized by level of completeness and certainty).
2) subject's perception of that information (and the level of personal controllability that they feel regarding it).
3) subject's psychological control profile, family functioning, social support, and normal coping styles.

**Number of Sessions, Who Will Provide it, How to be Evaluated.** Psychological Intervention--control psychotherapy--will be provided only for those at high risk (as described above) and will be provided by and or supervised by Dr. Shapiro, in collaboration with Dr. McQuade, Dr. Nezami, and John Astin.

The clinical intervention will involve 8-10 sessions, and evaluation of successful outcome will be determined by the psychosocial assessment instruments: Depression, Anxiety, Sense of Control.

**Description.** Generically, control psychotherapy is a short-term 8-10 session intervention to help individuals develop adaptive cognitive and behavioral strategies, to gain, re-gain, and maintain a sense of control. The main principles of control therapy involve: clarifying assumptions about personal control brought into the therapy session; addressing the assault to the patient's sense of control; examining the control profile of the individual; and evolving individually tailored strategies for helping them re-gain a sense of control.

Two positive modes of control are taught: an assertive, active change strategy in which individuals learn to identify, monitor, and gain active control over those aspects of their life under personal control; and a yielding, accepting mode of control in which individuals learn to positively accept with serenity (and without helplessness and feelings of resignation) those aspects of their life which are not under personal control. Specifically, the question asked is what combination of control-enhancing strategies are most effective for a particular individual with a specific control profile and with a particular control-related problem.

**Research Background.** Research over the past three decades has shown that control is a more complex, multi-faceted construct than initially thought, whether in psychoanalytic terms (Menninger, Maynam, Pruyser, 1963) or in social learning terms (Rotter, 1966). Simple unidimensional views of control, with resultant one-dimensional therapeutic interventions are insufficient. There are culture bound features to Western psychology's under-
standing of control as active and instrumental (Shapiro, Evans, Shapiro, 1987; Weisz, Rothbaum et al, 1984) and that having active, instrumental control is not always positive (Thompson, 1988; Burger, 1989; Evans, Shapiro, Lewis, 1993). To reflect this increased understanding, measurement of the psychological construct of control requires similar sophistication of its multi-faceted nature (cf. Levenson, 1974; Wallston et al, 1976, 1978; Shapiro, 1985, 1994). Similarly, clinical intervention is requiring more precision in developing and tailoring control-related interventions (Bandura, 1989; Syme, 1989; Peterson and Stunkard, 1989; Shapiro, 1995a).

Based on cross-cultural findings, previous research over the past fourteen years has developed a four quadrant model of modes of control (Shapiro, 1978, 1982, 1985, 1994). Positive psychological health is considered to occur when individuals have high scores in both a positive yielding and positive assertive mode of control, and low scores on a negative assertive (overcontrol) and negative yielding modes of control.

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<tr>
<th>QUADRANT ONE</th>
<th>QUADRANT TWO</th>
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<td>POSITIVE ASSERTIVE</td>
<td>POSITIVE YIELDING</td>
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<td>Altering, Change Mode of Control</td>
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<th>QUADRANT THREE</th>
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<td>Overcontrol</td>
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Figure 1. A Four-quadrant Model of the Modes of Control

The assertive mode of control refers to behaviors, cognitive strategies, choices, and/or personal beliefs designed to alter the environment or the self in accordance with personal needs or goals. This active altering mode of control can be distinguished from a yielding, accepting mode of control wherein the individual accepts and accommodates to his/her surroundings and/or self by altering affect and cognitions so that the individual feels comfortable with him or herself and/or the environmental situation as it is.

Negative Yielding (Quadrant Four to Positive Assertive, Quadrant One). The diagnosis of breast cancer can cause feelings of loss of control (Gottesman & Lewis, 1982; Taylor, Lichtman, & Wood, 1984; Andersen et al, 1994)). This loss of control can be multi-faceted, including loss of physical function and health, fear of pain of treatment and/or disease recurrence, (Gray and Doan, 1991), feelings of isolation, anxiety about death (Spiegel, 1992:), body image, relationship (Wortman & Dunkel-Schetter, 1979), fear regarding the future and overall uncertainty (Hilton,
1989).

Coping strategies reflecting a helplessness/fighting spirit (our positive yielding quadrant four—positive assertive quadrant one continuum) have been promisingly investigated as predictors, and/or mediators of impact, and on ways to improve adjustment and coping to perceived loss of control. Loss of control and a concomitant sense of helplessness may have negative effects on behavior, mood, and physiology (Lefcourt, 1973; Lazarus, 1981; Folkman, 1984; Bandura, 1977, 1989; Seligman, 1975). It has also been shown that lack of control is related to the anxiety and depression experienced by many cancer patients (Meyerowitz, 1980; Freidenbergs, Gordeon, Hibbard, et al, 1982; Greer & Silberfarb, 1982, Derogatis et al, 1983).

Similarly, an attitude in which a person feels in control and self-efficacous is related to positive outcome in cancer patients, including quality of life, self-esteem, purpose in life, and negatively correlated with anxiety (Lewis et al, 1982; Taylor et al, 1984; Cunningham et al (1990)); better adjustment (Ell, Nishimoto, Morvay, et al, 1989.)); problem solving, social support and seeking strategies (Hilton (1989); and hope (Cassileth, Zupkin, Sutton-Smith, & March, (1980).

Limits to Active Personal Control: Problems of Overcontrol. There has recently been a series of articles and studies raising both theoretical and empirical issues regarding whether the desire for active, assertive personal control is always good (Burger, 1988; Thompson, 1988; Evans, Shapiro, Lewis, 1993). Might our culture be placing too much weight on the psychology of personal responsibility in terms of individuals being perceived as the cause and cure of their disease, with the danger of an unhealthy self-blame (Shapiro & Shapiro, 1979; Cassileth, cited in Dreher, 1988; Speigel 1991; Gray & Doan 1990. Active internal personal control are not always facilitative. Active attempts at mastery are most effective when events are actually controllable; when events are beyond an individual's personal control, persistent efforts at control may actually exacerbate the problems.

Positive Acceptance. Rotter's (1966) and Wallstones' (1978) control inventories tests have an implicit cultural bias in understanding control, and assume that if one does not have active control, one is either resigned or helpless, engaging in passive resignation/acceptance, and/or escape/withdrawal. Most of the Western psychological research on control has focused on the active, altering mode of control (Shapiro, 1982, 1983; Thompson, 1981; Weisz, Rothbaum & Blackburn, 1984; Shapiro, 1982). This mode of control, involving active, instrumental efforts to influence or change a situation (or oneself), has been referred to by various researchers as a mastery model (Wolpe, 1959), problem-focused instrumental coping (Lazarus, 1981); and primary control (Weisz, Rothbaum, & Blackburn, 1984).

This bias can also be seen in many coping questionnaires. For example, Feifel et al's (1987) medical coping modes question-
naire has only three categories: confrontation, avoidance, and acceptance/resignation. Personal resignation and avoidance are seen as passive modes and unhealthy responses, and are contrasted with confrontation as the healthy, active mode of control and coping.

However, as noted in *Science* several years ago regarding the issue of human control in general (Shapiro, Evans, Shapiro, 1987, p. 260) equating control with active efforts to alter or change, or to use restraint to refrain from altering or interfering may reflect a limiting, culture-bound definition. Other cultures conceptualize control in terms of yielding, accepting, and letting go of active control. More of a sense of control may be gained from letting go of control (acceptance) than continuing efforts to try to change that over which we do not have active control.

The spiritual element—what can be called control by a powerful, benevolent Other (Shapiro, 1989, 1993)—has been ignored in all but a few studies. In one of the few to examine religion and sense of control, Cameron et al (1987) administered Norwicki-Strickland Child Locus of Control and Faulkner-Dejong Religiosity scales to 28 adolescent cancer patients. Religion was conceptualized in this study as a secondary source of control. Specifically, the authors asked about the positive effect of vicarious control: Do you count on a supreme being to aid you or take care of things which are otherwise beyond your control? and interpretive control: Does your faith in a supreme being allow you to understand, as part of a divine plan, those things in life which you would otherwise not be able to understand or accept? The majority practiced their religion and indicated this provided support by offering security in the face of death and by helping them understand and accept their experience.

Cross sectional and Longitudinal Studies. Over the past two decades research has been devoted to developing more precise ways to measure human control, and to construct psychotherapeutic interventions to address control issues, thereby attempting to bridge theory, research, and clinical practice.

Item development of the SCI scales was multi-method involving a combination of three approaches to personality inventory construction—external (empirical); inductive; and deductive (Burisch, 1984). Rater reliability and factor analytic studies were employed in item development (cf. Shapiro, 1982; 1983, 1985). Reliability studies show alpha reliability of internal scale item consistency between \( r = .70 \) to \( r = .89 \). There have been twelve different studies directed toward assessing the validity of the SCI (See Shapiro, 1994 for detailed summary). Research has shown that the psychological construct "sense of control" and the two "modes of control" involved in the SCI show neurobiological brain correlates evidenced by glucose uptake utilizing Positron Emission Tomography (Shapiro, Wu, et al, 1994); are related to biochemical and psychophysiological parameters involved in cardiovascular risk (Shapiro, Lindberg, et al, 1994). The SCI has been
shown to have higher predictive validity (both sensitivity and specificity) than Rotter's Internal/External Locus of Control and Wallstons' Health Locus of Control in both clinical and normative populations (Shapiro, Potkin, et al, 1993).

Content analysis research on speech samples of psychotherapy populations showed that individuals entering therapy (regardless of diagnosis) evidenced significantly more statements of feelings of fear of loss of control, losing control, and lack of control that statements of having control and/or belief they could gain control (Shapiro, Bates et al, 1990, 1991).

Cross sectional studies have also been conducted to develop a control profile of patients with restricted eating disorders (Shapiro, Blinder, et al, 1993); at risk individuals--Adult Children of Alcoholics-- (Shapiro, Weatherford, Kaufmann, 1994); clinical disorders including depression, panic attack, generalized anxiety disorder, borderline personality disorder (Shapiro, Potkin et al, 1993); and women diagnosed with breast cancer (Shapiro, Anton-Culver, et al, 1994a).

Longitudinal studies have shown that control-related clinical intervention effected changes in increasing the two positive modes of control in case studies (Shapiro, 1990): with Type A individuals suffering one myocardial infarction (Shapiro, Friedman, Piaget, 1991). Longitudinal research with women diagnosed with breast cancer has also shown that flexible coping strategies involving both the positive assertive and positive yielding modes of control are associated with overall sense of control, less depression and anxiety (Shapiro, Anton-Culver, et al, 1994b).
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INVESTIGATORS QUALIFICATIONS

Deane H. Shapiro, Jr. Ph.D., is a Professor in Residence, Department of Psychiatry and Human Behavior, California College of Medicine, University of California, Irvine, and a Diplomate of the American Board of Professional Psychology, Clinical Specialty. He has served as Director of Outpatient Psychiatry, Adult Services at the University of California Medical Center; Director of the Executive Stress Center and Co-Director of the Executive Wellness Center, University of California Medical Faculty Group.

Professor Shapiro has over twenty years of research and clinical work involved in issues of human control and self-control. He is the author/co-editor of four books on self-control, meditation, stress management, and psychological health, and over seventy scientific and professional publications. His co-edited book on meditation was selected as one of the outstanding academic books of the year (1984-1985) by Choices: The Association of College and Research Libraries. He also has two forthcoming books, The Human Quest for Control (Tarcher/Putnam) and Control in Psychotherapy and Health Care (John Wiley) which explore the themes of decreasing individual psychopathology through the process of therapeutic change; the role of control as a health-care intervention. His work has been requested and studied by thousands of scientists and health care professionals in over twenty-five countries.

Dr. Shapiro has been the recipient of a three year Kellogg National Fellowship to study stress and control in U.S. and Japanese business communities; and a two year Fetzer Foundation grant to study the effects of control in women with breast cancer.
PSYCHOLOGICAL ASSESSMENT AND PSYCHOLOGICAL COUNSELING

1. BACKGROUND

Advances in genetic mapping are increasingly able to pinpoint markers which determine risk for inherited diseases. These medical and technological advances, however, are outstripping psycho-social research about whether the individual in fact wishes such knowledge; and, if so, the psychological effects of receiving such information. Fundamental questions need to be addressed about when, how, and under what conditions information is conveyed to individuals at risk in a way which minimizes maladaptive adaptation and enhances positive coping and lifestyle modification.

This study selects forty families which have a high statistical probability of a hereditary breast cancer. These families will have been screened from an initial population of 20,000 (Anton-Culver, et al), and will have had their blood sampled to determine the presence or absence of an alteration of genes which are known to cause breast cancer (BRCA1, and any others that have been discovered by the time of the study).

The overall purpose of this section of the study is to assess the psychological state of individuals before, during and after this genetic screening process; to pinpoint which individuals receiving what type of information have psychologically adaptive and maladaptive responses, to provide psychological counseling including stress management, coping, and cognitive/behavioral interventions for those at risk. A control-based model of psychotherapy is the type of clinical intervention selected because it not only shows signs of effectiveness, but because it is also especially relevant to individuals in high stress, ambiguous, and physically threatening situations (Shapiro, 1990, 1993). Control-related coping has been shown to be an important strategy for individuals with breast cancer (cite sources Taylor, 1983; for families with individuals who have cancer and other genetic disorders (Shapiro, J., 198-; 198--). In our recent work (Shapiro, Anton-Culver, et al., 1993a,b,c) a sense of control has been shown to be an important stress and depression buffer, and multiple modes of control and self-control strategies have been shown to be effective cognitive and behavioral coping strategy for individuals dealing with breast cancer.

Because of the lack of knowledge currently available for this target population regarding the most effective genetic and psychological counseling, a multi-year study is needed. Evaluation of psycho-social information gathered each year, via a system's feedback model (Shapiro, 1983), can help refine and enhance the genetic and psychological counseling for the subsequent years. Initially, the interventions will be generic, but subsequent refinement based on personality variables, family configurations, and social support structures, can help begin the construction of both nomothetic and idiographic genetic and psychological counseling interventions. In this way, the importance for all subjects of the specific issue faced is addressed,
while still honoring individual styles and differences.

2. HYPOTHESIS/PURPOSE

   The specific aims of this section of the study are to provide an integrated psychosocial assessment and a psychological intervention--control psychotherapy--for those at high risk which can help us investigate the following:

   QUESTION ONE. What is the psychological state and health behavior practices of individuals upon entering this study?

   Hypothesis 1 Individuals in this study will perceive themselves as more vulnerable than a normative population, and have higher scores on psychological measures of depression (CES-D) and anxiety (Hopkins SCL).

   Hypothesis 2. There is a subset of this population who have already used the vulnerable situation to develop positive and adaptive coping strategies (Ways of Coping, SCI Modes). These strategies help promote a high positive sense of control, increase the likelihood of precautionary health-behavior efforts to decrease the risk of development of breast cancer, and serve as a stress/depression buffer.

   QUESTION TWO. Do individual personality variables and coping styles predict response outcomes? Based on these factors, can we make predictions about who might be most or least likely to request being given genetic information? Through assessment of these variables, can we gain information that would help us make suggestions and offer guidance about who might psychologically benefit the most and the least from this information? Can we incorporate this data in ways that improve the presentation of genetic counseling and psychological counseling?

   Hypothesis Three. Individuals low in optimism (Life Orientation Test) and commitment (Crumbough Purpose of Life), and who have a poor sense of control (SCI); who use denial and escape-avoidance as coping strategies (Ways of Coping--repressors); whose families are low in cohesion and high in conflict (Family Environment Scale); and who have limited support networks (Social Support Assessment) will either reject additional genetic information, will perceive the risk as larger than the information warrants, and will adapt more poorly to information which they perceive as increasing their risk vulnerability.

   QUESTION THREE. What are the psychological and health-behavior effects of genetic information, and genetic counseling; and, for those at high risk, psychological counseling?

   Hypothesis Four: Genetic counseling and psychological intervention (when needed) will increase individual adaptability, sense of control, and the practice of adaptive health behaviors, and decrease depression and anxiety.

3. METHODS (EXPERIMENTAL DESIGN)

   As can be seen from the overall design, multiple measures of psychological health, including sense of control, anxiety, depression, and health behavior will be employed before blood sampling, after blood sample results and genetic counseling, are
given, after psychological therapy (for those in need), and at follow-up. Variables mediating the relationship between information and psychological outcome, including personality variables, coping strategies, family functioning, and social support will also be assessed at these points in time. Data analysis will be primarily by analysis of variance and covariance, as well as, where appropriate, canonical analysis.

There are two critical components of this section of the study. One is the psychological and physical life-style assessment battery selected for use at times one to seven; the second is the psychological counseling intervention to be used for those at high risk.

As can be seen from the experimental design, families in year one receive psychological and health behavior assessment four times in year one (upon beginning the project, and at three, six, and twelve months), and yearly thereafter (times five, six seven). Psychological intervention occurs only for those who are at risk, either self-perceived or as evaluated by assessment instruments. This intervention is designed to occur at two different assessment points in the study. The first point is at three months, following the decision to receive or not receive test results. The second point is at six months, based on the follow-up psychological assessment.

ASSESSMENT INSTRUMENTS

Psychological Health:

- **Depression** will be measured by the CES-D, a standard 20 item, six point inventory used by the Center for Epidemiological Studies.
- **Anxiety** will be measured by the anxiety questions of the SCL-90 (Symptoms Check List), a ten question, four point scale format.
- **Coping** will be measured by the Ways of Coping Scale (Folkman and Lazarus) which yields subscales of confrontation, distancing, escape-avoidance, planful problem solving, positive reappraisal, accepting responsibility, and seeking social support (Alt: Carver, Schierer, COPE, 1989).
- **Personality Variables of Optimism and Commitment** will be assessed through the Life Orientation Test ( ) and the Crumbaugh Purpose in Life Scale (Crumbaugh, ).
- **Control** will be measured by Shapiro Control Inventory (SCI), a 187 item, inventory which provides a nine scale "Control Profile" covering four content areas: Sense of Control includes three sense of control scales in the general domain; and one domain specific sense of control scale which incorporates twenty-five specific parameters of control and self-control. Modes of Control involves four scales reflecting four characteristic cognitive and/or behavioral styles of responding to control-related issues: positive assertive, positive yielding, negative assertive, and negative yielding. Motivation for Control contains a desire for control scale, information on mode and parameter satisfaction, overcontrol issues, and preferences for dealing with domain-specific parameters of concern regarding
control. **Agency of Control** provides information on the source of a person's sense of control.

**Family Functioning** will be assessed by three subscales of the **Family Environment Scale**: cohesion, conflict, and control (Moos, 198-).

**Social Support** will be measured with...............

**Health (Risk) Behaviors** will be measured by Farquhar's five component health risk questionnaire, covering diet and nutrition; exercise; stress management; smoking; body weight as well as two additional aspects: alcohol consumption; and social support. (Add mammogram, breast self-examination etc) here or elsewhere?

**Psychological Counseling Intervention.** Psychological Intervention will be used only for those at high risk. Generically, control psychotherapy is a short-term intervention to help individuals develop adaptive cognitive and behavioral strategies, to gain, re-gain, and maintain a sense of control. The main principles of control therapy involve: clarifying assumptions about personal control brought into the therapy session; addressing the assault to the patient's sense of control; examining the control profile of the individual; and evolving individually tailored strategies for helping them re-gain a sense of control.

Two positive modes of control are taught: an assertive, active change strategy in which individuals learn to identify, monitor, and gain active control over those aspects of their life under personal control; and a yielding, accepting mode of control in which individuals learn to positively accept with serenity (and without helplessness and feelings of resignation) those aspects of their life which are not under personal control. Specifically, the question asked is what combination of control-enhancing strategies are most effective for a particular individual with a specific control profile and with a particular control-related problem.

**Who will be at high risk?** At this time, we can make educated guesses about who (and what percentage of individuals) will be at high psychological risk, but part of the reason for the study is to further refine that determination. We will be assessing the interaction between

1) nature of information that is conveyed at time two (categorized by level of completeness and certainty).

2) subject's perception of that information (and the level of personal controllability that they feel regarding it).

3) subject's psychological control profile, family functioning, social support, and normal coping styles.

Psychological assessment, combined with psychological intervention (where warranted) will provide information as to which modes and styles of gaining a sense of control seem to provide a stress and depression buffer for individuals receiving (or not) certain types of information and which coping responses are effective in helping individuals make a healthy behavioral and psychological adaptation to conditions of both no new information, new genetic information, and the varying levels of uncer-
tainty and health risk involved. Issues to be investigated include a) congruence of information received in terms of risk perception; b) blame attribution; c) potential survival guilt (for those receiving disconfirming information); d) effects on family cohesion and dynamics; and e) meaning attributed to the information.

YEARS 2-3-4 will involve modification of the psychological intervention based on the information gained in year one. Psychological lessons learned in year one will also be incorporated into and help to refine and augment the genetic education and counseling component of subsequent years. Thus, in a preventive way, there will be an effort to minimize the psychological risks of subjects in later years, based on what we have learned. This enhancement of the genetic education and counseling should also help determine the most cost effective way of presenting this information to individuals.

The first order question is, of course, does genetic counseling and psychological counseling "work" as defined by the measures we are using. Subsequent years (2-3-4) can begin to address second order questions such as does a control-based counseling intervention "work" more effectively than other interventions such as stress management/relaxation alone; supportive therapy alone. For ethical reasons, it is inappropriate to have a no-contact control group for those at high psychological risk.