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DEPARTMENT OF PSYCHIATRY AND HUMAN BEHAVIOR
Deane H. Shapiro Jr., PhD

Please Reply to:
1009 Canyon View Drive
Laguna Beach, Ca., 92651
(714) 497-5090

D'scc89.

December 4, 1991

Professor David Spiegel, M.D.
Department of Psychiatry and Behavioral Sciences
Stanford University
Stanford, California, 94305

Dear David:

Thanks for taking the time to meet with me Thursday regarding possible inclusion of the control inventory in your study. Per your request, I am resending the background material from my August 8 letter to you, as well as some updated data.

I am quite sensitive to your concern regarding not overtaxing the patients, and ensuring that any new instrument be of potentially sufficient contribution that it outweighs that patient cost.

Therefore, I have carefully reviewed Watson and Greer's work and would like to try to make a case here why the SCI measuring sense of control not only would give you different data than Watson and Greer, but also additional data relevant to your study. In the following, I will first outline subscales of the SCI and compare them with Watson and Greer (W and G); and then summarize by stating additional hypotheses regarding cancer and sense of control which could be uniquely addressed using the SCI.

The SCI provides four areas related to a GENERAL DOMAIN CONTROL PROFILE, as follows:

1) Overall Positive Sense of Control (derived from positive items related to self-efficacy; as well as reversed items related to losing or lacking control)

Watson and Greer, by their own admission, acknowledge that their fatalism and helplessness subscales are significantly associated; and closer inspection of their fatalism subscale suggests that it combines both external locus of control (helplessness) and external locus of control benevolent other (the Doctor can help me). Thus, they do not have on their scale a Positive Sense of Control Score; and their "negative sense" items actually confound helplessness with a potential positive sense of control from the Doctor. Using the SCI can help assess wheth-

er positive sense of control (regardless of agency) is a potential stress buffer related to morbidity.

2) Agency for Sense of Control. The SCI assesses the Agent for the positive source of control (self, family, friends, higher power).

As we discussed, our research shows that it may not be so important what the agent is (e.g., God, self, family), as it is important that there be some way in which the person feels a positive sense of control. Watson and Greer do not specifically measure different sources of agency as they contribute to positive sense of control.

3) Mode of Control. This is the four quadrant model we discussed: positive assertive, negative assertive (overcontrol); positive yielding; negative yielding (too little control).

At first glance, there does appear to be overlap here: quadrant one (positive assertive) may be highly correlated with Watson and Greer's fighting spirit; and quadrant four (too little control) may be highly correlated with W and G's helplessness/fatalism scales. However, the quadrant three (overcontrol) is a general domain category and does not refer just to emotional overcontrol, and so I would expect a low correlation. Finally, and most importantly, W and G do not have the equivalent of POSITIVE YIELDING, Quadrant two. This is the accepting mode by which one gains a sense of control. In Neihbur's prayer, it is "to accept that which I cannot change." I would hypothesize that you will see a large change in this mode in your group over the course of therapy.

Note, however, that both positive yielding (acceptance) and positive assertive (change) can increase. The enclosed study on Type A individuals receiving cognitive/behavioral counseling shows that both quadrant one and quadrant two shifted over the course of counseling. As you said regarding your patients, they may learn to accept what they cannot control, but learn to develop active control (e.g., hypnosis for pain management) in other areas. This is not at all assessed by W and G.

4) Desire/Efforts for Control. This scale assesses how important it is for the person to feel in control (and reverse items include fear of losing control).

When we did our initial alpha reliability studies on this scale, two items were removed because they had such low overall correlations with the scale "I have too much self-control" and "I hold my anger in, even when I want to express it." Interestingly, the latter is one of the more significant items W and G are trying to measure on their emotional control scale. Our results surprised me (I thought anger in would be part of a desire for control scale). However, this scale would not appear to overlap with W and G's emotional control scale.

DOMAIN SPECIFIC ITEMS

SENSE OF CONTROL: SPECIFIC DOMAINS. Research has shown that there is often better predictive validity when there are domain specific items. Therefore, six domains (twenty-five items)are assessed on a likert scale from very in control to very out of control:

body (including exercise, appearance, weight);
mind (thoughts, attention, sadness, stress);
relationships (friends, significant other; family of origin;
self;
work:employment situation; finances; work habits;
environment and other:

W and G cover the emotional control area more thoroughly, but do not look at control issues in the other domains.

CONCERN AND MODE OF CONTROL FOR ADDRESSING CONCERN. Finally, the SCI provides information on whether the domain item (no matter how in or out of control) is a concern to the person; and, if it is a concern, how they want to address it: e.g., change (quadrant one) or accept (quadrant two).

This model of coping (utilizing change and/or accept) is similar in some ways to the model of R. Lazarus, or Rudy Moos' that you mentioned on problem and emotional-focused coping. The SCI gives an item by item breakdown so it is possible to see if there is change over time in terms of a) concern/lack of concern; and b) the nature of the coping strategy to address the concern.

Overall, in your study, I believe the following questions could be addressed by adding the SCI, that are not addressed by using only W and G's emotional control (and helpless/fatalism/ fighting spirit scales):

MAIN HYPOTHESES

Between Group:

Main Hypothesis 1) Increase in general domain Positive sense of control (and decrease in subscale of negative loss of control) will be significantly greater in the therapy group than in the information control group.

Main Hypothesis 2) Increase in general domain positive yielding will be significantly greater in the therapy group than in the information control group.

Main Hypothesis 3) Increases in general domain positive assertive will be significantly greater in the therapy group than in the information control group.

Main Hypothesis 4) Changes in Sense of Control and Mode of Control (Hypothesis 1-3) will be associated with increased psychological health (quality of life) and decreased morbidity (including progression and severity of metastasis; relapse; length of remission).

Within Group:
A) Those with a higher positive sense of control score (regardless of agency) will evidence greater psychological and physical wellbeing than those with lower scores.

B) Those with a higher positive yielding mode of control score will evidence greater psychological and physical wellbeing than those with lower scores.

C) Those with higher positive ~~yielding~~ assertive mode of control score will evidence greater psychological and physical wellbeing than those with lower scores.

SECONDARY HYPOTHESIS
i) Agency for source of sense of control for friends will increase significantly more in the therapy group than in the control group.

ii) If a patient has a high positive sense of control, the agency for the source of that sense of control will not be significant (e.g., God versus self; friend vs. self; family vs. God, etc). (Addresses the question of what agency is most functional for obtaining a positive sense of control).

iii) Change in <u>both</u> general domain positive assertive mode of control and positive yielding mode of control will have a significantly more positive effect than changes in either one alone. (Addresses the question of what mode<s> are most functional for obtaining a positive sense of control).

iv) In the therapy group, there would be a significant decrease in domain specific concerns compared to the control group.

v) Where domain specific concerns existed, there would be significantly more flexibility (measured by differential endorsement of both assertive mode <u>and</u> yielding mode of control) to address the concerns in the therapy group than in the information group.

In summary, I believe the above questions are germane to your study, and are addressed by the SCI, but not by W and G's scales. The SCI generally takes less than twenty minutes to complete (and requires an eighth grade education). Although that is certainly a "cost" in terms of patient time, I hope you will feel that the advantages gained in terms of important information relevant to your study warrant that cost, and that you will determine it worthwhile to consider using the SCI with at least some of the subjects you are still in the process of recruiting. Certainly, the scope and design of your study would help me go far beyond the limited resources I have received from Fetzer for my cancer and control grant. I also truly believe the addition of the SCI can make a small, though important contribution to your study.

Finally, Dave, regarding your question re: placing the algorithm in your computers, I have talked with Behaviordyne, and

they said there would be no problem with that.

Thanks again for your consideration. I would again be happy to fly up and talk with your group about this. Looking forward to hearing from you.

With warm regards,

Deane H. Shapiro, Jr, Ph.D.
Associate Professor in Residence

PS. Monte Buchsbaum, Joe Wu and I have just completed a study looking at dreams and control with Positron Emission Topography (PET). We used a control content analysis scale to determine whether patient's dreams were in or out of control. Although the results are not directly applicable to your study, the findings are fascinating in terms of the high degree of correlation between different brain regions and dreams in which a person has a high sense of control or a high degree of loss of control. Our next study is going to involve using the SCI to determine the relationship between a person's waking "sense of control" and their dreams (Freudians and Jungians should love that study!).

PPS. Shauna's volleyball team won the CIF--Southern Section finals, the smallest school ever to win the championship! Proud papa.

ENC:

a) August 8 letter

b) Copy of SCI

c) Overview Background and Introduction to the SCI

d) Brief technical note published in Science on Human Control (Shapiro, Evans, Shapiro).

e) Article in International Journal of Psychosomatics on Changes in Mode of Control and Self-Control in Post Myocardial Infarction Patients Evidencing Type A Behavior (Shapiro, Friedman, Piaget).

f) Some updated data on our study using the SCI with Normals, Depressed, Panic, Borderline, Generalized Anxiety, and Panic Attack patients. Data presented here compares SCI scales on sense of control with Rotter Internal Locus of Control Scale and Wallston Health Locus of Control Scales (Internal, external benevolent, external chance), using discriminate functional analysis and jackknifed classification. This work is being done with Drs. Steven Potkin, Yi Jin, and Bo Brown.

THE DEVELOPMENT AND REFINEMENT OF THE SHAPIRO CONTROL INVENTORY (SCI): ASSESSING SENSE OF CONTROL

Deane H. Shapiro, Jr., Ph.D. and Hoda Anton-Culver, Ph.D

Purpose of the Research.

Research has shown that a "sense of control" is important for both an individual's physical and mental health. Unfortunately, however, there has been little systematic effort by researchers to develop a standard measure by which to assess "sense of control." The current effort involves a continuation of previous work designed to develop and refine a psychological inventory to assess the different aspects of human control, and to apply it to both clinical and normal populations. Previous work has utilized the inventory with eating disorder patients (including adolescents); depressed patients; borderline patients; adult children of alcoholics; patients with generalized anxiety disorder; patients suffering from panic attacks; individuals with Type A behavior who have suffered one myocardial infarction; UCI students; and healthy normals.

The current study has two goals: 1) increasing the base of "normal patients" by giving the SCI to a randomized sample of Orange County Residents; 2) extend the work on the psychological construct of sense of control to cancer patients.

This study asks, for two types of cancer patients (breast and ovarian), 1) is there a relationship between sense of control and physical wellbeing: morbidity and mortality; 2) is there a relationship between sense of control and emotional wellbeing; 3) what mode(s) of control are most functional for obtaining this sense of control; and 4) are there differences in questions one, two, and three above depending upon the severity and prognosis of the cancer (the between group comparison).

For more detailed information, please see Appendix A, describing the Shapiro Control Inventory (SCI), research bearing on the importance of the construct of control, and the rationale for developing another control inventory. Appendix B provides a copy of the SCI.

RESEARCH PLAN

The SCI inventory will be given to individuals recently diagnosed with either breast or ovarian cancer; and at repeated six month follow-ups; as well as given to the general Orange County population. There will be an effort to hold several within group factors constant (or appropriately balanced) between the groups: sex (female); age; and severity of cancer at onset; nature of oncological care. The variables addressed will be severity of prognosis between groups; and sense of control (both within and between groups).

SUBJECTS Subjects will be female individuals drawn from the

Cancer Surveillance Project of Orange County, directed by Dr. Hoda Anton-Culver; and Orange County Hospitals. Non-cancer subjects will be drawn from the Orange County Health Survey Subjects. Only women subjects will be utilized. Over the two year period, approximately 80 patients with breast cancer, 80 with ovarian cancer, and 80 normals will be assessed.

Risks/Discomforts/Inconvenience. This instrument involves minimal risk. It is a paper and pencil test asking only for the person's belief about personal control. The only possible risk that might result from this is reflecting upon a topic which is of some concern to the person. However, Parts One and Three of the instrument ask only general domain questions. Part Two asks more domain-specific questions, such as interpersonal relations, sexuality, drug abuse, etc. However, the questions do not ask specific information about habits, and patterns, but only whether the person feels in control or not in control of that particular area. Therefore, the questions are not invasive in terms of content about a person's behavior and actions, and only ask about the persons's self-perception. As such, there should only be minimal risk, even from the psychological standpoint. And there is no health or medical risk involved. In the several hundred administrations of the inventory to a variety of clinical and normal populations (detailed in purpose of the research) there has never been a concern or complaint or problem. The inventory takes about twenty minutes to complete, and requires an eighth grade education. Although the time required for completion is small, that time factor may be considered a patient inconvenience.

BENEFITS. In this early stage of pilot testing, there will in all likelihood be minimal direct advantage to the patient. Perhaps some of the questions may help the patient recognize that even though in some areas their life is lacking control, there are other areas where control is possible. However, the results of the test should help determine the relationship of sense of control for both quality of life and mortality; the most effective modes for that sense of control and that information should provide substantial gains to future patients. Better assessment of control can have direct implications for the development and matching of clinical self-control strategies and management strategies for patient care.

Measures Taken to Protect the Rights and Welfare of Subjects. As noted above, the risks are minimal. However, subjects will be told in the informed consent, that they may stop the questionnaire at any time, if they so wish, and that they may contact the principal investigator if there is a problem arising from the taking of the instrument.

Every effort will be made to ensure privacy and confidentiality. The inventory is a scantron form, and only subjects ID number will be coded in the final data analysis. Further, the design calls for group comparisons, and no individual subject data will be reported. Finally, even though subject identifiers will be used so that repeated measures can be ob-

tained, all subject tests will be kept in locked files and only the PI and Co-PI will have access to them.

Costs. There is neither cost to the subject, nor payment to subjects. All costs for test administration will be paid for out of a grant for this project from the Fetzer Institute.

Alternative Treatment: Not applicable.

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OFFICE OF THE VICE CHANCELLOR FOR RESEARCH
DEAN OF GRADUATE STUDIES

IRVINE, CALIFORNIA 92717

December 27, 1991

Deane H Shapiro, Psychiatry & Human Behavior

RE: HSM# 92*003
THE DEVELOPMENT AND REFINMENT OF THE SCI: ASSESSING SENSE OF CONTROL.

The research project referenced above has been approved by the Human Subjects Review Committee (HSRC). Any stipulations of approval imposed by the Committee are recorded below.

Approval of the Human Subjects Review Committee does not, in and of itself, constitute approval for implementation of this project. Other levels of review and approval may be required (e.g. EH&S, Radiation Safety, School Dean) and *the project should not begin until all required approvals have been obtained.*

No changes are to be made to either the approved protocol nor the approved, stamped consent form without the prior review and approval of the HSRC. The enclosed consent form with the UCI approval stamp must be used for all human subjects entered into this study.

In accordance with U.S. Food and Drug Administration regulations and UCI policy, all unanticipated or untoward adverse effects must be reported to the HSRC (via Human Research Administration) within two working days of occurrence.

Unless this research is "exempt," approximately 60 days prior to expiration of this approval, you should receive an "Application Form for Continuing Review" which must be submitted for HSRC review and approval *prior* to the expiration date noted below. It is the investigator's responsibility to assure current approval of his/her projects; therefore, Human Research Administration (856-6068) should be notified if the Application Form for Continuing Review is not received.

Michael Brodsky, M.D.
Chair, Human Subjects Review Committee

Approval Period: 12/26/91 to 12/31/92

UCI has an approved Multiple Project
Assurance: # M-1305

THIS APPROVAL EXTENDS TO RESEARCH PERFORMED AT UCI/UCIMC ONLY.

UNIVERSITY OF CALIFORNIA, IRVINE
Consent to Act as a Human Research Subject

THE DEVELOPMENT AND REFINEMENT OF THE SHAPIRO CONTROL INVENTORY (SCI): ASSESSING SENSE OF CONTROL

Deane H. Shapiro, Jr., Ph.D.
Department of Psychiatry
714-497-5090

Hoda Anton-Culver, Ph.D.
Department of Medicine
714-856-7416

NAME OF SUBJECT_____

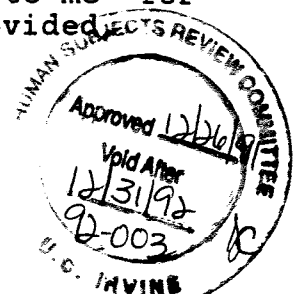
PURPOSE OF THIS STUDY. I have been asked to participate in a research project designed to develop a standard psychological test, the Shapiro Control Inventory (SCI), to measure a person's "sense of control." Research suggests that a person's perception of how much he/she can control events in his/her life relates to his/her physical and mental health. The development of this test will help us better understand that relationship.

PROCEDURE. If I agree to participate, the following will occur: I will take the SCI. This Inventory is a paper and pencil test that asks me to answer questions about my views of how much control I feel I have in different aspects of my life. I understand that there are no right or wrong answers to this inventory, and all that is being asked is that I put down my beliefs. This inventory takes less than thirty minutes to complete. I understand that the length of this study is for two years. I further understand as follow-up I will be asked to re-take this inventory at approximately six month intervals during that two year period.

RISKS. I understand that some of the questions will be of a personal nature about my feelings and ideas and that I may become uncomfortable responding to certain questions. I understand that I may refuse to answer any of the questions that make me too uneasy or too stressed.

BENEFITS. I understand that no benefits to me can be guaranteed. However, in taking the inventory I may learn more about myself and the importance of a sense of control to me. The results may also benefit future patients and general medical knowledge.

COSTS/COMPENSATIONS. I understand that if I am a patient, and I choose to take this test, there are no additional costs to me for taking the test, and that there is no compensation provided. I understand that I or my insurance company will be responsible for the usual costs of my therapy (treatment). If I am a volunteer control subject, I understand that there are no costs to me for taking this test, and that there is no compensation provided.



I understand that I may refuse to participate and may refuse to answer any and all questions and may withdraw at any time for any reason. If I choose to withdraw, it will not in any way effect my treatment program. If at any time I have comments or complaints relating to the conduct of this research or my rights as a research subject, I should contact the Human Research Administration, 115 Administration Building, UC Irvine, Irvine, Ca., 92717; 714-856-7114. I also understand that if I have comments or concerns about this psychological test and research, I may contact Dr. Shapiro or Dr. Anton-Culver at the number at the top of the previous page.

I understand that any information derived from this research project which personally identifies me will not be voluntarily released or disclosed without my separate consent, except as specifically required by law. I understand that only Dr. Shapiro, Dr. Anton-Culver and/or their research and clinical associates will have access to these test results, and that my name will not appear in any publication resulting from this study.

I have read the above, the Experimental Subjects Bill of Rights (next page), and I have had the opportunity to ask questions pertaining to this study. I have been given a copy of the Experimental Subjects Bill of Rights and this consent form to keep.

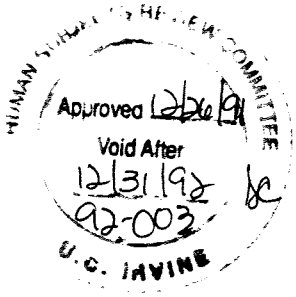
I consent to participate.

PART ONE OF TWO--SEE NEXT PAGE

SIGNATURE OF SUBJECT Date

SIGNATURE OF WITNESS Date

SIGNATURE OF INVESTIGATOR Date



1. Participation in research is entirely voluntary. You may refuse to participate or withdraw from participation at any time without jeopardy to future medical care, employment, student status or other entitlements. The investigator may withdraw you at his/her professional discretion.

2. If, during the course of the study, significant new information which has been developed becomes available, which may relate to your willingness to continue to participate, this information will be provided to you by the investigator.

3. Information derived from the research which personally identifies you will not be voluntarily released or disclosed without your separate consent, except as specifically required by law.

4. In studies involving investigational drugs and devices, the U.S. Food and Drug Administration may inspect your medical records which relate to your participation in this study. This may include copying of medical records.

5. If at any time you have questions regarding the research or your participation, you should contact the investigator who must answer all questions. A telephone number is provided at the top of Part I of the consent form.

6. If at any time you have comments or complaints relating to the conduct of this research, questions about your rights as a research subject, or if you feel you have suffered a research-related illness or injury, you should contact the UC Irvine Human Research Administration Office. The University will provide medical treatment reasonably necessary for any injury or illness which a human subject suffers as a direct result of participation in a University approved research study or reimburse a subject for such costs except when the injury or illness is a consequence of a medical research procedure which is designed to benefit the subject directly. The University does not provide any other form of compensation, however.

For additional information regarding the items above, you should telephone Human Research Administration at (714) 856-7114.

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EXPERIMENTAL SUBJECTS' BILL OF RIGHTS

Any person who is asked to consent to participate as a human subject in a medical investigation or who is asked to consent on behalf of another, has the following rights:

1. To be told what the study is trying to find out.

2. To be told what will happen in the study and whether any of the procedures, drugs or devices is different from what would be used in standard medical practice.

3. To be told about the risks, side effects or discomforts which may be expected.

4. To be told if the subject can expect any benefit from participating and if so, what the benefit might be.

5. To be told of other choices available and how they may be better or worse than being in the study.

6. To be allowed to ask any questions concerning the study, both before agreeing to be involved and anytime during the course of the study.

7. To be told of any medical treatment available if complications arise.

8. To refuse to participate at all, either before or after the study has started. This decision will not affect any right to receive standard medical treatment.

9. To receive a signed and dated copy of Parts I and II of the consent form and this Bill of Rights.

10. To be allowed time to decide to consent or not to consent to participate without any pressure being brought by the investigators or others.

Subject's/Parent's/Guardian's Initials ____________ Date __________

Rev. 10/91.A