UNIVERSITY OF CALIFORNIA, IRVINE

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OFFICE OF THE VICE CHANCELLOR FOR RESEARCH
DEAN OF GRADUATE STUDIES

IRVINE, CALIFORNIA 92717

September 15, 1992

Scott K Fairhurst, Psychiatry & Human Behavior

RE: HSM# 92*265
Predictors of Self-Efficacy and the Relationship to Control: A Study of Smoking, Drinking and Over-Eating.

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 Bradsky, M.D.
Chair, Human Subjects Review Committee

Approval Period: 9/14/92 to 9/30

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

_____Expedited Review ✓ Full Board Review

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

Rev. 10/91

University of California, Irvine
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

PREDICTORS OF SELF-EFFICACY AND THE RELATIONSHIP TO CONTROL:
A STUDY OF SMOKING, DRINKING, AND OVER-EATING

Scott K. Fairhurst, MA
Dept. of Psychology/ U. Houston
(818) 585-1440

Deane H. Shapiro, Jr., Ph.D.
Dept. of Psychiatry/CCM/UCI
(714) 497-5090

NAME OF SUBJECT _____

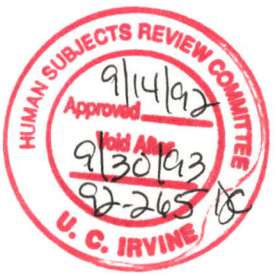
PURPOSE OF THIS STUDY. I have been asked to participate in a research project designed to examine confidence to change one's smoking, drinking, or over-eating habit. Confidence to change is one of the most important variables in maintaining successful change. This study will examine variables that can influence this confidence as well as my sense of control.

PROCEDURE. If I agree to participate, the following will occur: I will fill out a packet of questionnaires. These questionnaires will be specific to one of the three habits. For example, if I am thinking about quitting or have recently quit smoking, I will fill out the packet of questionnaires for smoking. The questionnaires will ask about my prior attempts to quit, my stress level, friends and family who have tried to quit, persuasion from my doctor, overall sense of control, and confidence to maintain a quit attempt. There are no right or wrong answers and the packets should take about 40 minutes to complete. I also understand that I may be contacted to participate in follow-up research.

RISKS. I understand that some of the questions will be of a personal nature about my behaviors, 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 completing the questionnaires I may learn more about myself and the psychological aspects of quitting smoking, drinking, or over-eating. The results may also benefit future patients as well as general medical and psychological knowledge.

COSTS/COMPENSATIONS. I understand that, if I choose to complete these questionnaires, there are no additional costs to me and 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 affect my treatment at the Student Health Center. 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 the psychological tests and research, I may contact Mr. Fairhurst, or Dr. Shapiro 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 Mr. Fairhurst, Dr. Shapiro, 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

This project has been reviewed by the University of Houston Committee for the Protection of Human Subjects 713-743-9222 and the University of California, Irvine Committee for the Protection of Human Subjects 714-856-7114.

CONSENT FORM - PART II

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 _____

UNIVERSITY OF CALIFORNIA IRVINE

HUMAN SUBJECTS REVIEW COMMITTEE-MEDICAL

INVESTIGATOR'S ASSURANCE

NAME OF PRINCIPAL INVESTIGATOR* Scott K. Fairhurst, MA

NAME OF FACULTY SPONSOR* Deane H. Shapiro, Jr., Ph.D.

NAME OF RESPONSIBLE PHYSICIAN**

TITLE OF PROJECT Predictors of Self-efficacy and the Relationship to Control: A Study of Smoking, Drinking, and Over-eating

I AGREE TO COMPLY WITH ALL APPLICABLE REGULATIONS, LAWS AND POLICIES REGARDING THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH.

I understand and agree that:

I AM TO USE ONLY THE APPROVED, STAMPED CONSENT FORM WITH HUMAN SUBJECTS.

I AM TO MAKE NO CHANGES TO THE APPROVED PROTOCOL OR CONSENT FORM WITHOUT FIRST HAVING SUBMITTED THOSE CHANGES FOR REVIEW AND APPROVAL TO THE UCI HUMAN SUBJECTS REVIEW COMMITTEE.

I AM PERSONALLY AND FULLY RESPONSIBLE FOR THE PERFORMANCE OF THIS STUDY, INCLUDING THE OBTAINING OF LEGALLY EFFECTIVE INFORMED CONSENT FROM ALL SUBJECTS OR THEIR LEGALLY RESPONSIBLE REPRESENTATIVE.

I WILL SUBMIT A STATUS REPORT FORM FOR CONTINUING REVIEW PRIOR TO THE DATE APPROVAL FOR THIS STUDY IS SCHEDULED TO EXPIRE. I UNDERSTAND IF I DO NOT SUBMIT THIS FORM, APPROVAL FOR THE STUDY WILL EXPIRE AND I WILL CEASE ITS PERFORMANCE.

I WILL FILE A FINAL REPORT WITH THE HSRC AT THE CONCLUSION OF THIS PROJECT.

I WILL REPORT SIGNIFICANT, UNTOWARD ADVERSE EFFECTS TO THE HSRC VERBALLY WITHIN 48 HOURS AND IN WRITING WITHIN 5 WORKING DAYS OF OCCURRENCE.

SIGNATURE: PRINCIPAL INVESTIGATOR — DATE 8/13/92

SIGNATURE: FACULTY SPONSOR* — DATE 8/17/92

SIGNATURE: RESPONSIBLE PHYSICIAN** — DATE

* A member of the UCI faculty must be principal investigator, co-investigator or faculty sponsor for projects utilizing human subjects in research at the University of California Irvine. The faculty member is considered the responsible party for legal and ethical performance of the project.

** A UCIMC staff physician is required to accept responsibility for medical care of human subjects on projects where there is even a remote possibility of physical injury to human subjects.

Rev. 4-91

HSM # _____
(Leave Blank)

UNIVERSITY OF CALIFORNIA IRVINE
APPLICATION TO HUMAN SUBJECTS REVIEW COMMITTEE- MEDICAL

Check one: __x__ EXPEDITED REVIEW (CATEGORY # __9__) OR ____ FULL COMMITTEE REVIEW

This form must be typed and filled in completely. Insert N/A if not applicable. **Note: A member of the UCI faculty must either be principal or co-investigator or faculty sponsor, and a UCIMC staff physician may be required to be associated with the study (see page 1).*

1. **PRINCIPAL INVESTIGATOR** Scott K. Fairhurst, MA Check one: ____ Faculty __x__ Student ____ Staff
Department Psychiatry and Human Behavior Telephone 456-7760
Mailing Address UCIMC until 8/31/92
(If UCIMC, include Building & Route #)

2. **PERSON TO CALL FOR QUESTIONS** (Name & Telephone #) Scott K. Fairhurst, MA 818-585-1440

3. ***FACULTY SPONSOR (IF APPLICABLE) OR CO-INVESTIGATOR** Deane H. Shapiro, Jr., Ph.D. Check one: __x__ Faculty ____ Student ____ Staff
Department Psychiatry and Human Behavior Telephone 714-497-5090
Mailing Address Route 88, Bldg. 2, 101 City Drive South Orange, CA 92668
(If UCIMC, include building & route #)

4. **CO-INVESTIGATOR** _____ Check one: ____ Faculty ____ Student ____ Staff
Department _____ Telephone _____
Mailing Address _____
(If UCIMC, include building & route #)

(If there are additional co-investigators, use attachment sheet.)

5. **TITLE OF STUDY** Predictors of Self-efficacy and the Relationship to Control: A Study of Smoking, Drinking, and Over-eating

6. **GOG/ECOG/SWOG/ETC. #** (if applicable) _____ 7. **PROJECT PERIOD:** 9/92 - 5/93 (month/year - month/year)

8. **PERFORMANCE SITES:** UCI Student Health Center

9. **SUBJECT POPULATIONS** (Enter all that apply):

#__x__ PATIENTS

#__x__ ADULTS COMPETENT TO CONSENT
#____ ADULTS NOT COMPETENT TO CONSENT
#__x__ UCI STAFF/STUDENTS
#____ DEVELOPMENTALLY DISABLED
#____ NON-ENGLISH SPEAKING

#__210__ TOTAL NUMBER OF SUBJECTS

#__x__ NORMALS

#____ MINORS
#____ PREGNANT WOMEN
#____ NURSING MOTHERS
____ CHART REVIEW ONLY
____ DISCARDED TISSUE ONLY

10. **Will subjects be compensated for participating?** ____ Yes __x__ No. If yes, discuss compensation and terms within protocol under "Costs/ Compensation."

THIS IS A TWO PAGE FORM - CONTINUE ON NEXT PAGE

11. Does the study involve investigational drugs? _____ Yes __x__ No. If yes, list below:

Name of Drug | Phase | IND # | Date of IND Filing*

(Continue on attachment sheet if necessary)

* Provide date IND was filed for the drug's use in this study.

12. Does the study involve investigational devices? _____ Yes __x__ No. If yes, list below:

Name of Device | IDE # (if applicable | IDE Filing Date

(Continue on attachment sheet if necessary)

13. Will radiation (including radioisotopes) be used? _____ Yes __x__ No. If yes, identify within protocol, include dosages, and radiation exposure information. (Note: Requirements of the UCI/UCIMC Radiation Safety Committee must be met independent of HSRC review and approval.)

14. Is this study being funded? _____ Yes __x__ No. If yes, name of sponsor or source of funds (e.g. NIH, departmental, etc.): _____

If no, how will research costs be met? Privately by the P.I. (this is a dissertation)

If some or all costs of the research will be billed to the subject or a third party carrier, justification must be provided within the protocol, under "Costs."

••

[signature], MA — 8/13/92

SIGNATURE: PRINCIPAL INVESTIGATOR — *DATE*

[signature] — 8/13/92

SIGNATURE: CO-INVESTIGATOR — *DATE*

SIGNATURE: FACULTY SPONSOR (if applicable) — *DATE*

SIGNATURE: UCIMC PHYSICIAN (if applicable)

DEPARTMENTAL CERTIFICATION AND APPROVAL:

I have read the protocol and find that the research is appropriate in design and the investigator (and/or faculty sponsor) is competent to perform (or supervise) this study. My signature below denotes departmental approval of this study as submitted.

SIGNATURE: DEPARTMENT CHAIR/DIRECTOR — **DATE**

INSTRUCTIONS REGARDING NUMBER OF COPIES AND REQUIRED MATERIALS APPEAR ON PAGE 7 UNDER "REQUIREMENTS FOR SUBMISSION."

Rev. 4/91

University of California, Irvine
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

PREDICTORS OF SELF-EFFICACY AND THE RELATIONSHIP TO CONTROL:
A STUDY OF SMOKING, DRINKING, AND OVER-EATING

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RISKS. I understand that some of the questions will be of a personal nature about my behaviors, 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.

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COSTS/COMPENSATIONS. I understand that, if I choose to complete these questionnaires, there are no additional costs to me and no compensation provided.

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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

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SIGNATURE OF INVESTIGATOR Date

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CONSENT FORM - PART II

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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. Confidentiality will be protected to the extent provided 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 Research Committees' 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 the Research Committees' Office at (714) 856-7114.

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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. 4/91)

PREDICTORS OF SELF-EFFICACY AND THE RELATIONSHIP TO CONTROL: A STUDY OF SMOKING, DRINKING, AND OVER-EATING

Scott K. Fairhurst, MA, and Deane H. Shapiro, Jr., Ph.D.

Purpose of the Research.

Research has shown that confidence in your ability (self-efficacy) to refrain from smoking, drinking, or over-eating is a major predictor of success in a quit attempt. Now that this confidence has been established as critical, research is beginning to study its own predictors. This study will examine predictors of confidence to quit for people thinking about quitting and people who have recently quit smoking, drinking, or over-eating. In addition, subjects will complete a questionnaire addressing their sense of control. This questionnaire has been used with several clinical and normal populations; this will be its first use with these behaviors.

This study has four goals: 1) to examine predictors of self-efficacy, 2) to examine the relationship of these variables to a sense of control, 3) to compare these results for people contemplating change and those who have taken action, and 4) to compare these findings across the three behaviors.

Three different groups of subjects will be used in this study: 1) people who are thinking about quitting or who have recently quit smoking, 2) people who are thinking about quitting or who have recently quit drinking alcohol, and 3) people who are thinking about or who have recently stopped over-eating.

Research Plan.

Packets of questionnaires will be given to people presenting at the UCI Student Health Center. They will be shown packets relevant to smoking, drinking, or over-eating and will be asked to select the appropriate packet. They will complete the packets in the lobby of the Student Health Center before or after their appointment. Subjects will be asked to return their completed packets to a locked box near the front desk. Demographic data including age, gender, education, and ethnic identification will be collected but will not be involved in the selection of subjects.

Subjects.

Subjects will be students or employees at U.C. Irvine who are being treated at the Student Health Center. Smoking, drinking, or over-eating may not necessarily be the presenting problem. Subjects will be asked, upon signing in for their regular appointment, to fill out one of the packets if it is applicable. Approximately 100 subjects will be needed for each of the three habits.

Risks/ Discomforts/ Inconvenience.

These questionnaires involve minimal risk. They are paper and pencil tests that ask questions related to behaviors and thoughts relevant to the specific habit as well as overall stress and sense of control. The only possible risk that might result from this is reflecting upon a topic which is of some concern to the person, whether that is related to their habit, their stress, or their sense of control. The questions are neither invasive nor overly detailed. They should not require much thought before answering. The packets take about 40 minutes to complete. Although the time required is minimal, it may be considered an inconvenience.

Benefits.

There is not likely to be any direct benefit to the subject. Some research suggests that assessment can be a motivator and can encourage people to move toward quitting a habit. Additionally, the patients may see that psychological variables, such as stress and a sense of control, are part of the picture when preparing to quit or trying to maintain that quit.

Measures Taken to Protect the Rights and Welfare of Subjects.

As noted above, the risks are minimal. Subjects will be told in the informed consent that they may stop the questionnaires 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 these questionnaires.

Every effort will be made to ensure privacy and confidentiality. For the purposes of data analysis, only subject ID numbers will be used and no individual subject data will be reported. Finally, even though subject identifiers will be used so that follow-up data can be obtained, all subject data will be kept in locked files and only the P.I. and Co-P.I. will have access to them.

Costs.

There is neither cost to subjects, nor payment to subjects. All costs for test administration will be paid by the principal investigator.

Alternative Treatment.

Not applicable.