**Department of Health & Human Services**

**Public Health Service**

**National Institutes of Health**
**National Cancer Institute**
**Bethesda, Maryland 20892**

iRIS Reference Number ***335657***

Type of Action: Initial Review Submission Form
Project Number: P141583

***TO:*** Rebecca Ferrer
NCI - Division of Cancer Control and Population Sciences

***FROM:*** Chairperson, Special Studies Institutional Review Board, NCI

***SUBJECT:*** Action on Clinical Research Protocol

The Initial Review of your protocol and consent document, "Self-affirmation and defensiveness to health messages for the self vs. a close other," was reviewed by the National Cancer Institute Special Studies Institutional Review Board (NCI-SSIRB) by full board review on 07/28/2014.

The IRB has taken the following action:

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| | Approved as written. Forwarded to the CC OPS for administrative processing. |
| X | Approved with stipulations pending re-review by the full SSIRB. See review. |
| | Approved with stipulations pending re-review by a subcommittee of the Board. See review. |
| | Deferred pending response to stipulations and re-review by the full SSIRB. See review. |
| | Disapproved. See review. |

**RESPONSE DUE BY: 9/5/2014**

Stipulations/Conditions:

1) Provide data regarding the risk of epilepsy induction due to the use of the eye tracking device*.

2) If written consent is obtained, describe in the protocol how the signed document will be completed and safeguarded.

3) In the protocol and consent, provide an explanation for whether/how subjects can withdraw their data from the study.

4) Provide the Craigslist advertisement as an attachment to the protocol.

5) In the consent document, acknowledge that information previously provided by participants to Knowledge Networks (or GFK), regarding alcohol consumption and cancer, will be used for this protocol.

6) Explain the basis for including the first paragraph of Appendix C.

7) Correct the discrepancies and typographical errors in the protocol and consent documents as detailed in the pre-review.

8) In the consent document, change the wording referring to this as a "cancer risk study".

*Heather Bridge from OHSRP may also be able to provide some information regarding this risk.

(c) Recommendations:

None.

This study was determined to be no more than minimal risk with no direct benefit to participants. Continuing review will occur annually.

NCI Special Studies Institutional Review Board
Meeting Minutes - 07/28/2014

PI Name: Rebecca Ferrer
Protocol Title: Self-affirmation and defensiveness to health messages for the self vs. a close other

**Précis:**

Self-affirmation, a process by which individuals reflect on cherished personal values – is a potent means of augmenting the effectiveness of threatening health communications. Individuals tend to be defensive against information suggesting their behavior puts them at risk for disease or negative health. Previous evidence suggests that self-affirmation may reduce defensiveness to threatening health information, increasing openness to the message and resulting in increased disease risk perceptions, disease-related worry, intentions to engage in preventive behavior, and actual behavioral change. One mechanism by which self-affirmation may be effective is by reducing self-focus and expanding self-concept. If this is the case, self-affirmation may not be effective in reducing defensiveness against information that is threatening to one's close other. We are proposing two studies to examine whether self-affirmation is equally effective at reducing defensiveness against threatening information for the self and for a close other. These studies will not only highlight conditions under which self-affirmation is effective, but also shed light on mechanisms underlying the effect.

(a) Discussion

The Secondary Reviewer presented an overview of the protocol and concerns as noted in the checklist below. The check list also includes the study team response to the questions raised by the pre-review.

## Pre-Review of Initial Protocols

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|---|---|
| Protocol Name: | Self-affirmation and defensiveness to health messages for the self vs. a close other |
| PI Name: | Rebecca Ferrer |
| Date of SSIRB meeting: | July 28, 2014 |

**General Comments/Questions:**
SSIRB reviewer questions:
Secondary Reviewer:
If the subjects are extremely anxious, are you going to provide counseling?

You are planning to use eye tracking system and head tracking system capable of capturing video. Will the captured data have any personally identifying characteristics? How are you going to store and protect it?

**PI response to questions**:
We appreciate concerns about participant well-being and anxiety. However, we maintain that the information presented is comparable or identical to risk information that participants would encounter in everyday life, and thus does not pose an additional threat to anxiety or well-being. The information provided to subjects regarding risk for cancer is based on empirical evidence and is readily available on the National Cancer Institute website (http://www.cancer.gov/cancertopics/pdq/prevention/prostate/Patient for prostate cancer; http://www.cancer.gov/cancertopics/pdq/prevention/breast/Patient for breast cancer; each section contains multiple pages, on which all information in these preventive messages was presented). Importantly, this information was taken

from sections of the website intended for the general public, rather than sections intended for health professionals. Moreover, such information is similar to information that may be presented on the news and in other media outlets, particularly given that it reflects the presentation of information on risk and prevention from the National Cancer Institute, a reputable source form which the media may draw information. As such, it is not anticipated that subjects will become anxious about the information presented above and beyond anxiety they would experience in daily life. We do not have a clinical psychologist among study personnel, and as such do not have the capacity to provide counseling. However, if subjects become anxious, we can direct them to appropriate resources (e.g., provider and counseling recommendations).

The eye tracking system will capture video of eye movements - essentially, the video is of the stimulus material (i.e., the health message) and depicts a dot moving across the stimulus that reflects the eye movements of the participant. This video will therefore not contain any personally identifying characteristics. We have updated the protocol to reflect this clarification.

SSIRB reviewer comments to which PI may or may not respond:

**PI response to comments (optional):**

**Regulatory review requirement**

**1. The proposed research design is adequately described and scientifically sound.**

Yes

**2. Selection of subjects is equitable.**

Yes

**3. Risks to subjects are minimized:**

Yes

**4. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.**

SSIRB reviewer comments to which PI may or may not respond:
Primary Reviewer:
This is a minimal risk study. There are no direct benefits to subjects, other than knowing that they are contributing to the body of knowledge in social and health psychology.

**PI response to comments (optional):**

**5. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.**

N/A

**6. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.**

SSIRB reviewer questions:
Primary Reviewer:
Study 2 subjects will be recruited by a government contractor. Names and contact information will be collected during the screening process, but will not be connected to data nor retained once subjects have participated. Will the contractor retain names and contact information?

Secondary Reviewer:
Does the 'Knowledge Networks' follow Human Subjects Protection rules and guidelines?

**PI response to questions**:
The contractor will retain names and contact information for a period of six months following the study. Storage procedures for this information are standardized, and the contractor has an Institutional Review Board that will review all storage procedures. These storage procedures are consistent with studies for which this contractor has recruited subjects under previously approved SSIRB protocols (e.g., 13-C-N021).

Knowledge Networks follows Human Subjects Protection rules and guidelines (see http://www.knowledgenetworks.com/ganp/irbsupport/).

SSIRB reviewer comments to which PI may or may not respond:
Primary Reviewer:
Study 1 subjects will be recruited through Knowledge Networks, an internet survey panel provider. The PI should provide information about how Knowledge Networks maintains privacy and confidentiality.

**PI response to comments (optional):**
This information is located at http://www.knowledgenetworks.com/ganp/irbsupport/. We have now included this information in the Appendices.

7. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

Yes

8. Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.

Yes

Pre-review of Consent Form

1. Statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

SSIRB comments to which PI may or may not respond:
Primary Reviewer:
I suggest inserting the word research into the first sentence of the consent form: Today, you will be asked to participate in two research studies...

In Study 2, subjects will use an eye-tracking system. This is not mentioned in the consent form.

PI response (optional):
We have made the suggested changes to the consent forms .

2. A description of any reasonably foreseeable risks or discomforts to the subject.

SSIRB comments to which PI may or may not respond:
Secondary Reviewer:
Eye-tracking system and head tracking camera capable of capturing video will be used in the study to track subject's gaze. However, the PIs do not disclose it to subjects in the consent form. They do not describe how they will store or protect the data.

PI response (optional):
We have made changes to the consent form to explain eye tracking procedures. We have also clarified in the revised application that the videos captured are of eye-tracking movements (reflected as dots) on the stimulus material, not personally identifying videos.

3. A description of any benefits to the subject or to others which may reasonably be expected from the research.

SSIRB comments to which PI may or may not respond:
Secondary Reviewer:
The consent form does not state that the study offers no direct benefit to participants. The PI might consider adding this information.

PI response (optional):
We have now amended the consent form.

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

N/A

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

SSIRB reviewer questions:
Primary Reviewer:
The consent form for Study 2 states that data will be accessible only to those working on the project. Where will the data be stored? How will it be secured?

PI response:
We have now updated the consent form to reflect storage considerations.

SSIRB comments to which PI may or may not respond:
Primary Reviewer:
More information regarding confidentiality of the data should be provided in the consent form. The PI might consider including the information contained in the Collection and Storage of Human Specimens or Data section of the Human Subjects Protection section in the consent form (e.g., will data be anonymized? Stored on a secure government server?)

PI response (optional):
We have now added this material to the consent form.

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

N/A

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| 7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. |
| SSIRB comments to which PI may or may not respond:<br>Secondary Reviewer:<br>Contact information for IRB chair should be removed.<br><br>PI response (optional):<br>We have now removed this information. |
| 8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. |
| Yes |
| Additional elements: |
| 9. A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable. |
| N/A |
| 10. A statement that if the participant is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. |
| N/A |
| 11. Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent. |
| N/A |
| 12. Any additional costs to the participant that may result from participation in the research. |
| N/A |
| 13. The consequences of a participant's decision to withdraw from the research. |
| Yes |
| 14. Procedures for orderly termination of participation by the participant. |
| Yes |
| 15. A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant. |
| N/A |
| 16. The approximate number of subjects involved in the study. |
| SSIRB comments to which PI may or may not respond:<br>Primary Reviewer:<br>The approximate number of subjects involved in the study is not provided in the consent form. |

Secondary Reviewer:
Yes, 700: 500+200

PI response (optional):
We have now included this information in the consent form.

17. The amount and schedule of all payments to the participant.

SSIRB comments to which PI may or may not respond:
Primary Reviewer:
The consent form for Study 2 incorrectly states that subjects will receive $1 as remuneration for their participation.
Secondary Reviewer:
The investigators mention $1 on one page and on another $4-6 for participation in study 1. Similarly for Study 2, on one page $25 and on a different page $50. Correct it.

PI response (optional):
We have now made these corrections. Participants receive $4-6 dollars per month to be members of the standing Knowledge Networks panel; however, they will receive not additional remuneration for participating in Study 1. For study 2, participants will receive $30.

18. The information that is given to the subject or the representative is in language understandable to the subject or the representative.

SSIRB comments to which PI may or may not respond:
Secondary Reviewer:
Language in the consent form is understandable and it is at 5th grade level, but the consent form has errors. The PIs mention Values Study at one place and refer it as Self Study in another place.
This is a cancer risk perception assessment study, and not a cancer risk study. PIs need to correct that. Also, PIs should remove IRB chair name and contact information.
This is not an Alcohol and Breast Cancer Study. Correct it. If you are using alcohol and other behaviors information collected by Knowledge Networks, please include description of collection, and IRB approvals received for collecting that data in the protocol.

PI response (optional):
We have now made these changes.

19. Other comments or Concerns:

Primary Reviewer:
1. Page 3, paragraph 4 of the protocol states that a convenience sample of 200 will be recruited for the study. Page 3, paragraph 6 states We are requesting approval to enroll 500 subjects.

2. On page 6, under Analysis of the Study, it states that for Study 2 the PI is requesting approval to enroll 200 subjects. Using GPower...we determined that 440 subjects would provide high power... Is this correct?

3. On page 7 of the protocol it states that participants in Study 2 will receive $25 for participating in the study. On page 10 of the protocol, under Study 2 Screener, it states that subjects will receive $50 for their participation.

4. Will subjects who do not complete Study 2 be offered full compensation or any compensation?

5. Will the contractor (Study 2) destroy names/contact information for potential subjects once this information is supplied to the PI?

6. The following statement appears on the consent form: Answer questions about the information you read and your beliefs cancer risk. The sentence is missing the word about.

Secondary Reviewer:
There are several typos in the Protocol, Appendix A: Study Materials, and the Consent form. Please correct them. A pdf with highlighted errors will be sent to you.
Is the Craigslist the best social media option for advertising the subject recruitment?
The subjects have to be affluent to have computer literacy and access. That is, basically, you are excluding non-affluent populations, even though, their perception about cancer risk is more important than educated and well informed individuals'' perception about cancer risk.
Statements like one out of five men will be diagnosed with prostate cancer and one out of eight women will be diagnosed with breast cancer may be disturbing to the general public who are not clinically/medically/scientifically savvy. These risk estimates may be true, but the statement may create unnecessarily suspicion and cause stress in the individuals. That may be the post-study effect, or a study-induced outcome which you may not be studying.

Is the following question in the Study Materials necessary and scientific?
.....it seems like everything causes cancer?
You are just going to scare the general public with statements/questions like that?
PI response:
1. We have now clarified these power calculations. For study 1, which will take place online, we were more conservative in power calculations, given that effect sizes may be smaller in online studies compared to laboratory studies (due to less experimental control). Using a small effect size estimate (.15), a sample of 500 will yield high (.90) power to detect differences. For the laboratory study, based on previous laboratory research on self-affirmation, we estimated power based on medium effect sizes. Using a medium effect size estimate (.25), a sample of 200 will yield high (.90) power to detect differences.
2. We have changed the language in the protocol to reflect the power calculations described in detail above.
3. Participants will receive $30 for participating in the study. We initially estimated $25 ($50 was a typo), but since this protocol was submitted we have done additional research and determined that remuneration for laboratory studies below $30 in this area yields estremely high rates of no-show and substantially increases the cost to the federal government for recruitment.
4. Yes, subjects who do not complete the study will receive full remuneration.
5. Yes, the contractor will destroy the names and contract information of participants after 6 months. This information will never be connected to the data collected in the study.
6. We have made this correction on the consent form.

Response to secondary reviewer comments:
We have now thoroughly reviewed the protocol, appendices, and consent for typos.

Craigslist is the social media option most used by the federal contractor who will conduct the study. Craigslist is a resource that is readily available to participants of varying affluence, and can be accessed by anyone with computer and internet accessibility through a home computer or apublic resource (e.g., library). Although the digital divide is still a concern, iit is narrowing, and individuals of all socioeconomic status are represented as internet users. Craigslist was used as a recruitment tool for a study previously conducted in the Rockville area by the NCI, yielding a fairly representative sample with respect to socioeconomic status and race (13-C-NO21). Although individuals do need to be computer literate to use craigslist, computer use and literacy are required for the study (because subjects will be asked to read text on a computer). Although it does increase the cost to the federal government, should the IRB believe craigslist is not a viable option for representative recruitment, we can have the contractor recruit via real bulletin boards in addition to craigslist

These statements were taken directly from the National Cancer Institute website (http://www.cancer.gov/cancertopics/pdq/prevention/prostate/Patient for prostate cancer; http://www.cancer.gov/cancertopics/pdq/prevention/breast/Patient for breast cancer; each section contains multiple pages, on which all information in these preventive messages was presented), and such statements are routinely used to convey risk in health intervention research (e.g., Fagerlin, Zikmund-Fisher, & Ubel, 2011). Importantly, these statements were taken verbatim from portions of the NCI website intended for the general public, rather than from sections intended for health professionals. As such the study is not anticipated to increase stress levels above the context of naturalistic or intervention studies. Thus, we hope the IRB will consider allowing us to include this information, and would welcome a

discussion about this issue. We certainly also agree that stress or anxiety about the message is certainly an important outcome, and as such we have now included questions to capture this information (we moved the affect items to the beginning of the questionnaire, and included an item about stress).
Fagerlin, A., Zikmund-Fisher, B. J., & Ubel, P. A. (2011). Helping patients decide: ten steps to better risk communication. Journal of the National Cancer Institute, 103(19), 1436-1443.

The question It seems like everything causes cancer is a question that has been validated as an assessment of perceived cancer prevention ambiguity for the general public, and has appeared in every administration of the National Cancer Institutes Health Information National Trends Survey (HINTS, 2003; 2005; 2007; HINTS 4 Cycles 1-4). We have included this item so that we can make comparisons with nationally representative estimates ofcancer prevention ambiguity.

Discussion continued:

(Dr. Ferrer discussed both protocols when she attended the meeting beginning at 3:35 PM)

There was discussion regarding the potential impact of the eye tracking device on individuals who are either undiagnosed epileptics or possibly susceptible to seizures.

The screening question about epilepsy comes directly from the eye tracking device manufacturer. Dr. Ferrer explained that, although the device does not use any flashing lights, the protocol excludes people who suffer from seizures or have been diagnosed with epilepsy. She was not certain the reason for this exclusion. She indicated that she will investigate this further with the eye tracking device manufacturer. Although the device doesn't use flashing lights, there is a calibration process that requires participants to follow a red dot across a screen. That dot also disappears and reappears.

As for the previous protocol, the questions regarding how the payment system will work and how participants may withdraw their data from the database were raised and discussed.

Dr. Ferrer explained that only Knowledge Networks (now GFK) can remove a participant's data.

Participants are included in a panel selected by GFK. They participate in a series of studies and are paid by GFK to be part of that panel rather than being paid for a specific study.

Dr. Ferrer explained that the participants recruited through Craigslist advertisements come to NCI in-person to participate and are paid in cash so no PII is needed for issuing payment. Dr. Ferrer indicated that Westat developed the ad and can provide it for review.

There was a question regarding the survey question suggesting that "everything causes cancer". Dr. Ferrer explained that the question was directly taken from a validated national survey and has been included for the purpose of comparison to previous responses.

It was asked whether the investigator was planning to seek a waiver of documentation of informed consent for this study. Dr. Ferrer indicated that they intend to obtain a signed consent.