**Attachment 2Ci: Questionnaire (Word Format)**

OMB No.: 0925-0645
Expiration Date: 12/31/2014

Collection of this information is authorized by The Public Health Service Act, Section 411 (42 USC 285a). Rights of study participants are protected by The Privacy Act of 1974. Participation is voluntary, and there are no penalties for not participating or withdrawing from the study at any time. Refusal to participate will not affect your benefits in any way. The information collected in this study will be kept private under the Privacy Act. Names and other identifiers will not appear in any report of the study. Information provided will be combined for all study participants and reported as summaries. You are being contacted by telephone and mail to complete this instrument so that we can learn more about informed consent and perspective taking.

Public reporting burden for this collection of information is estimated to average 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0645). Do not return the completed form to this address.

**Note: Blue text indicates the answers to the questions and will not be shown to the participants.**

**The PANAS**

This scale consists of a number of words that describe different feelings and emotions. Read each item and then mark the appropriate answer in the space next to that word. Indicate to what extent you felt this way while watching the film clip. Use the following scale to record your answers.

1 = very slightly or not at all
2 = a little
3 = moderately
4 = quite a bit
5 = extremely

| | | |
|---|---|---|
| _____ Interested | _____ Angry | _____ Sad |
| _____ Distressed | _____ Enthusiastic | _____ Determined |
| _____ Excited | _____ Nervous | _____ Attentive |
| _____ Upset | _____ Irritable | _____ Jittery |
| _____ Strong | _____ Alert | _____ Active |
| _____ Hostile | _____ Ashamed | _____ Afraid |
| _____ Scared | _____ Inspired | _____ Bored |

## Recall

Please list any of the side effects you remember that were listed for the clinical trial (free recall):

_____

_____

**Please check all of the side effects that were listed for the clinical trial (actual side effects denoted with *)**

- ❑ Acne
- ❑ Allergic reaction*
- ❑ Changes in kidney function*
- ❑ Changes in your vision
- ❑ Confusion and changes in mental status
- ❑ Constipation*
- ❑ Decreased Appetite*
- ❑ Depression
- ❑ Diarrhea
- ❑ Dry mouth*
- ❑ Heartburn
- ❑ High levels of calcium in the blood*
- ❑ Increased risk of hardened arteries*
- ❑ Kidney stones*
- ❑ Loss of skin pigment
- ❑ Low blood counts
- ❑ Low blood pressure
- ❑ Metallic taste*
- ❑ Nausea*
- ❑ Reproductive risks*
- ❑ Sore throat
- ❑ Staining of the teeth
- ❑ Sticky saliva
- ❑ Sun sensitivity
- ❑ Thinning skin
- ❑ Trouble speaking
- ❑ Unexplained stiff neck
- ❑ Unusually cold skin
- ❑ Vomiting*
- ❑ Weakness*

## Recall and Comprehension

*True or False*

1. Participants may receive no benefit from participating in this study. **(true)**
2. Women who are pregnant may participate in this study. **(false)**
3. The purpose of the study is to determine whether cholecalciferol could help prevent skin cancer. **(true)**
4. Patients may choose whether they want to take Vitamin D. **(false)**
5. All participants in the study will receive Vitamin D. **(true)**
6. The entire study protocol will be completed within 8 weeks. **(false)**
7. The treatments in this clinical trial have been proven to be the best for prevention. **(false)**

*Multiple Choice*

1. What organization is conducting this study?
    a. American Cancer Society
    b. National Cancer Institute
    c. Susan G. Komen for the Cure

2. Who is the principal investigator for this study?
    a. Steven A. Palmer, M.D., Ph.D.
    b. Esther Weisen, M.D.
    c. Jonathan M. Rosenburg, M.D., Ph.D.

3. Why is this study being conducted?
    a. For trial of a new preventive treatment
    b. For trial of a new medical device
    c. For medical students to practice techniques

4. How will you be compensated for your participation?
    a. Participants receive $100 per week for participation
    b. Participants are paid for participation on a sliding scale according to their income
    c. Patients receive $300 total for participation

5. The trial involves:
    a. A blood sample
    b. A urine sample
    c. Both a blood and urine sample

**Risk Perception**

**If you enrolled in this clinical trial…**

1. how would you rate the risk of headache?

1 2 3 4 5 6 7

Very low Very high

2. how would you rate the risk of constipation?

1 2 3 4 5 6 7

Very low Very high

3. how would you rate the risk of nausea?

1 2 3 4 5 6 7

Very low Very high

4. how would you rate the risk of high levels of calcium in your blood?

1 2 3 4 5 6 7

Very low Very high

5. how would you rate the risk of kidney stones?

1 2 3 4 5 6 7

Very low Very high

6. how would you rate the risk of weakness?

1 2 3 4 5 6 7

Very low Very high

7. If you were to participate in this trial, how do you think your risk of headache would compare to that of other trial participants?

1 2 3 4 5 6 7

Much lower About the same Much higher

8. If you were to participate in this trial, how do you think your risk of constipation would compare to that of other trial participants?

1 2 3 4 5 6 7

Much lower About the same Much higher

9. If you were to participate in this trial, how do you think your risk of nausea would compare to that of other trial participants?

1 2 3 4 5 6 7

Much lower About the same Much higher

10. If you were to participate in this trial, how do you think your risk of high levels of calcium in your blood would compare to that of other trial participants?

1 2 3 4 5 6 7

Much lower About the same Much higher

11. If you were to participate in this trial, how do you think your risk of kidney stones would compare to that of other trial participants?

1 2 3 4 5 6 7

Much lower About the same Much higher

12. If you were to participate in this trial, how do you think your risk of weakness would compare to that of other trial participants?

1 2 3 4 5 6 7

Much lower About the same Much higher

13. If you were to participate in this trial, how vulnerable would you feel to headaches?

1 2 3 4 5 6 7

Not vulnerable at all Very vulnerable

14. If you were to participate in this trial, how vulnerable would you feel to constipation?

1 2 3 4 5 6 7

Not vulnerable at all Very vulnerable

15. If you were to participate in this trial, how vulnerable would you feel to nausea?

1 2 3 4 5 6 7

Not vulnerable at all Very vulnerable

16. If you were to participate in this trial, how vulnerable would you feel to high levels of calcium in your blood?

1 2 3 4 5 6 7

Not vulnerable at all Very vulnerable

17. If you were to participate in this trial, how vulnerable would you feel to kidney stones?

1 2 3 4 5 6 7

Not vulnerable at all Very vulnerable

18. If you were to participate in this trial, how vulnerable would you feel to weakness?

1 2 3 4 5 6 7

Not vulnerable at all Very vulnerable

19. If you were to participate in this trial, how worried would you be about headaches?

1 2 3 4 5 6 7

Not at all worried Very worried

20. If you were to participate in this trial, how worried would you be about constipation?

1 2 3 4 5 6 7

Not at all worried Very worried

21. If you were to participate in this trial, how worried would you be about nausea?

1 2 3 4 5 6 7

Not at all worried Very worried

22. If you were to participate in this trial, how worried would you be about high levels of calcium in your blood?

1 2 3 4 5 6 7

Not vulnerable at all Very vulnerable

23. If you were to participate in this trial, how worried would you be about kidney stones?

1 2 3 4 5 6 7

Not vulnerable at all Very vulnerable

24. If you were to participate in this trial, how worried would you be about weakness?

1 2 3 4 5 6 7

Not vulnerable at all Very vulnerable

**Behavioral Intentions**

1. If I was at high risk for skin cancer, I would participate in this trial.

1 2 3 4 5 6 7

Strongly disagree Strongly agree

2. This trial seems like a good option for those at high risk for skin cancer.

1 2 3 4 5 6 7

Strongly disagree Strongly agree

3. If my doctor recommended this option, I would participate.

1 2 3 4 5 6 7

Strongly disagree Strongly agree

## Satisfaction

If you were at high risk for skin cancer and were considering participation in a clinical trial, would the information in the clinical trial consent form have…

1. …provided you with adequate information? YES NO

2. …explained things in a way you could understand? YES NO

3. …answered questions or concerns you may have had? YES NO

4. …helped you make a decision about participation? YES NO

5. In general, how satisfied are you with the information provided in the consent form about the clinical trial?

| -2 | -1 | 0 | 1 | 2 |
|---|---|---|---|---|
| Very dissatisfied | | Uncertain | | Very Satisfied |