Informed Consent

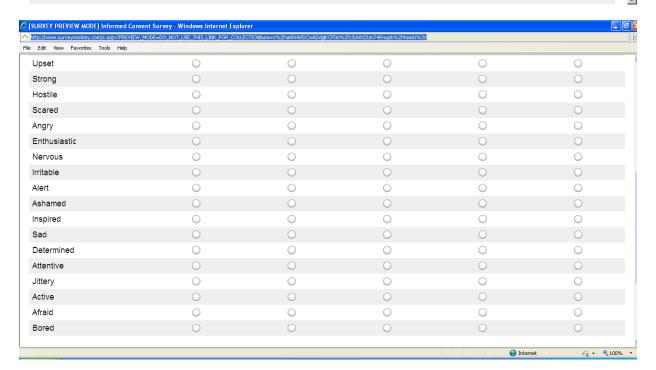
Exit this survey

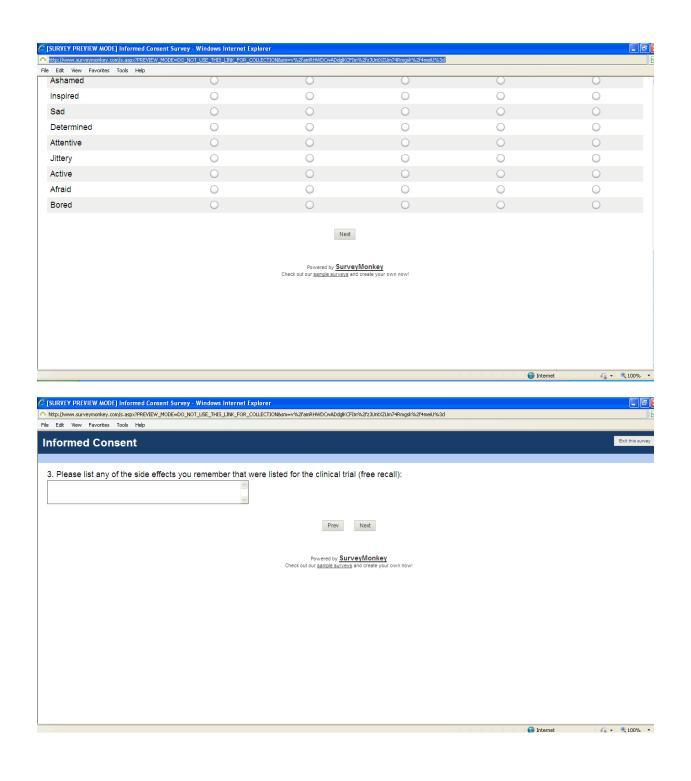
OMB No.: 0925-0645 Expiration Date: 12/31/2014

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.

- 1. 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





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3. Please check all of the side effects that were listed for the	aliniaal kviali	
Acne	Low blood counts	
Allergic Reaction	Low blood pressure	
Changes in kidney function	Metallic taste	
Changes in your vision	Nausea	
☐ Confusion and changes in mental status	Reproductive risks	
☐ Constipation	☐ Sore throat	
☐ Decreased appetite	☐ Staining of the teeth	
Depression	Sticky saliva	
☐ Diarrhea	☐ Sun sensitivity	
☐ Dry mouth	☐ Thinning skin	
☐ Heartburn	☐ Trouble speaking	
\square High levels of calcium in blood	☐ Unexplained stiff neck	
☐ Increased risk of hardened arteries	Unusually cold skin	
☐ Kidney stones	☐ Vomiting	
☐ Loss of skin pigment	Weakness	
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🕒 www.surveymonkey.com/s.aspx?PREVIEW_MODE=DO_NOT_USE_THIS_LINK_FOR_COLLECTION&sm=v%2famRHWDCwADdglKCFIm%2fzJUntXZUm74Rmgsk%2f4meiU%3d **Informed Consent** Exit this survey 4. True or False True False Participants may receive no benefit from participating in this study. Women who are pregnant may participate in this study. \bigcirc The purpose of the study is to determine whether cholecalciferol could help prevent skin cancer. Patients may choose whether they want to take Vitamin D. All participants in the study will receive Vitamin D. The entire study protocol will be completed within 8 weeks. \bigcirc The treatments in this clinical trial have been proven to be the best for prevention. Prev Next Powered by <u>SurveyMonkey</u>
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5. What organization is conducting this study?	
American Cancer Society	
National Cancer Institute	
Susan G. Komen for the Cure	
6. Who is the principal investigator for this study?	
Steven A. Palmer, M.D., Ph.D.	
○ Esther Weisen, M.D.	
○ Jonathan M. Rosenberg, M.D. Ph.D.	
7. Why is this study being conducted?	
For trial of a new preventive treatment	
For trial of a new medical device	
For medical students to practice techniques	
8. How will you be compensated for your participation?	
Patients receive \$100 per day for participation	
Patients are paid for participation on a sliding scale according to their income	
Patients receive \$300 total for participation	
9. The trial involves:	
A blood sample	
\sim	

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O Patients receive \$300 total for participation
9. The trial involves:
○ A blood sample
○ A urine sample
○ Both a blood and urine sample
Som a stood and anno sample
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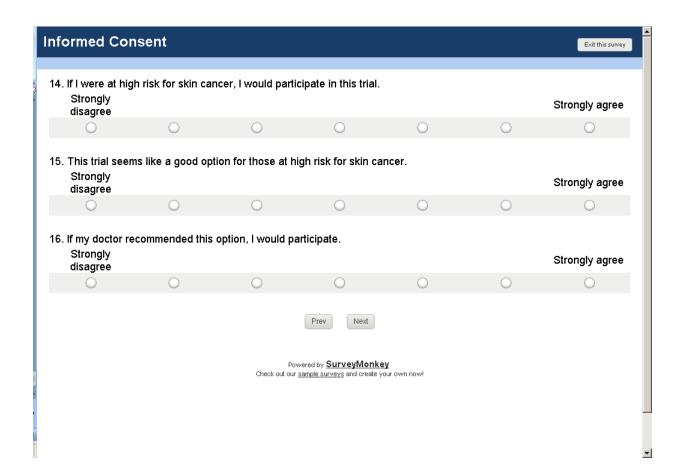
ı	nformed Consent						Exit this	survey
	10. If you enrolled in this clinical trial							
		Very low						Very high
	how would you rate the risk of headache?		\circ	\circ	\circ	0	0	
	how would you rate the risk of constipation?		\bigcirc	\bigcirc	\bigcirc	\bigcirc		
	how would you rate the risk of nausea?	\circ	\bigcirc	\circ	\circ	0	0	
	how would you rate the risk of high levels of calcium in your blood?	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc	
	how would you rate the risk of kidney stones?	\circ	\bigcirc	\circ	\bigcirc	0	0	
	how would you rate the risk of weakness?		\bigcirc	\bigcirc	\bigcirc	0	0	
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11. If you were to participate in this trial	Much lower			About the			Much higher
how do you think your risk of headache would compare to that of other trial participants?	0	0	0	same	0	0	0
how do you think your risk of constipation would compare to that of other trial participants?	\circ	0	0	0	\circ	0	\circ
how do you think your risk of nausea would compare to that of other trial participants?	0	0	0	0	\bigcirc	\circ	\circ
how do you think your risk of high levels of calcium in your blood would compare to that of other trial participants?	\circ	0	0	0	0	\bigcirc	\bigcirc
how do you think your risk of kidney stones would compare to that of other trial participants?	\circ	0	0	\circ	0	0	0
how do you think your risk of weakness would compare to that of other trial participants?	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc	\bigcirc
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nformed Consent							Exit	this survey
12. If you were to participate in this trial	Not							
	vulnerable at all							Very nerable
how vulnerable would you feel to headaches?	0 (0	0	\circ	\circ	0)	\bigcirc
how vulnerable would you feel to constipation?	O (0	\bigcirc	\bigcirc	0)	\bigcirc
how vulnerable would you feel to nausea?	0 (0	0	\circ	\circ	0)	\bigcirc
how vulnerable would you feel to high levels of calcium in your blood?	0 (0)	\bigcirc
how vulnerable would you feel to kidney stones?	0 (0	0	\circ	\circ	0)	\bigcirc
how vulnerable would you feel to weakness?	0 (0	0	\bigcirc	\bigcirc	0)	\bigcirc
13. If you were to participate in this trial,	Not at all worried							Very worrie
how worried would you be about headaches?	\bigcirc	C	(0	\circ	\circ
how worried would you be about constipation?						\bigcirc	\bigcirc	
how worried would you be about nausea?	0) () (0	0	\circ
how worried would you be about high levels of calcium in your blood?								
how worried would you be about kidney stones?	0					0	\bigcirc	\circ
how worried would you be about weakness?	\bigcirc							



Informed Cor	nsent					Exit this survey
17. If you were at clinical trial conse	high risk for skir	n cancer and were	considering partic	ipation in a clinic	cal trial, would the	information in the
ciii iicai tiiai conse	, il ioiii iiave				YES	NO
provided you v	with adequate inf	formation?			0	0
explained thing	gs in a way you	could understand?	•			0
answered que	stions or concer	ns you may have l	nad?		0	\circ
helped you ma	ake a decision at	oout participation?				0
	w satisfied are y	ou with the inform	ation provided in th	ne consent form	about the clinical	
Very dissatisfied			Uncertain			Very satisfied
			0			
			Prev Done			
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