



Date: *October 23, 2012*

To: Office of Management and Budget (OMB)

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Subject: Generic Sub-study, **Informed Consent and Incidental Emotion** under “A Generic Submission for Theory Development and Validation (NCI),” (OMB No. 0925-0645, Expiry Date 12/31/2014)

This proposal was previously submitted for OMB review the NCI IRB had completed their review. Attachment 2H demonstrates IRB approval.

Background/ Need and Use for Information

This proposed sub-study request plans to refine and validate a theory regarding the role of incidental emotional influences – that is, emotional influences not relevant to the decision but that may influence it nonetheless – on information processing in the context of clinical trial informed consent. Participants will watch an emotional movie clip (e.g., a scene from the Bodyguard or the Shining; **Attachment 2A**), and will then be instructed to read an informed consent document (**Attachment 2B**) as eye movements are monitored during the reading process. Finally, they will answer a series of questions about the informed consent process (**Attachment 2C**). This research will help to validate a theory concerning the potential role of incidental emotional influences on informed consent, and lead to further theory refinement. Specifically, the sub-study plans to examine whether a discrete emotion theoretical framework better predicts information processing in this context (compared to a valence-based approach).¹

The National Cancer Institute’s (NCI) Behavioral Research Program (BRP) is within the Division of Cancer Control and Population Sciences (DCCPS). The goal of BRP is to increase the breadth, depth, and quality of behavioral research in cancer prevention and control. BRP conducts varying programs of formative research to develop and validate cancer-related behavioral theories. This project will serve to examine behavior in the context

¹ For selected readings on incidental emotion, see **Attachment 2D**.

of informed consent in cancer clinical trials, which is an emerging scientific priority not only in DCCPS, but also in NCI's Office of Communication and Education (OCE). This NCI office is requesting that OMB review this sub-study, which describes a voluntary, low-burden, non-controversial, formative behavioral research project related to theory development and validation. Data collection for this project is authorized under 42 USC § 285 and 285a-1 (Section 410 and 412 of the Public Health Service Act).

This data will be collected in the Cognitive Testing Laboratory, within OCE. The project will be conducted as a collaborative effort between OCE and DCCPS. Recruitment and incentives for the project will be funded through DCCPS' global support contract, which supports (among other types of projects) new data collections. Labor for data collection will be provided by a post-baccalaureate CRTA within DCCPS.

While the methodology to sub-study 1 (**Self-affirmation and affect**), submitted and approved under this generic clearance, is similar, the underlying theoretical questions are quite different. As such, this sub-study will not duplicate current federal efforts.

Informed Consent and Incidental Emotion

It is predicted that individuals who have watched an anger-related movie clip will process information more heuristically than those who watched a fear-related movie clip, and that those who watch a neutral movie clip or sad movie clip will process information somewhere in between heuristically and systematically. These results would support a discrete emotion theory, by demonstrating that different negatively valenced states are associated with different outcomes. However, if all negative states systematically influence information processing in the same manner (compared to neutral), it would support an alternative explanation – valence emotion theory. Examining this hypothesis would allow us to refine and validate a discrete emotion framework in the context of clinical trial informed consent, and would set the stage for applied research examining real-world implications of these shifts in information processing.

Participants, Methodology, and Research Instrument

A convenience sample ($N = 240$), ethnically and racially representative of the local area in Rockville, MD will be recruited by Westat, both through their database of potential respondents and also through newspapers and craigslist (Advertisement, **Attachment 2E**), and will include mixed genders and ages. Enrolling 240 participants will allow for a final N of 200 participants; it is anticipated that data collection on approximately 40 participants will be incomplete, due to standard eye tracking equipment failure and non-trackable participants (i.e., participants with individual differences in eye features that are prohibitive for the collection of eye tracking data). 280 potential participants will be screened (**Attachment 2F**) in order to achieve a mix of genders, ages, and race/ ethnicities; $N = 280$ was identified as a reasonable number by Westat, a contractor with expertise in these types of recruitments.

Personally identifying information (PII) will be collected by Westat during the recruitment process; specifically, name, address, and telephone number will be collected in order to facilitate recruitment and reminders. PII will be stored on a password protected file on a

password protected computer in a locked office. After a participant is run through the study, PII will be destroyed.

The study will be completed in the Office of Market Research and Evaluation Lab, Office of Communications and Education, of the National Cancer Institute. Participation will take approximately 1 hour (based on pretests of 8 federal employees). Trained research staff will facilitate the one-on-one session for each participant. Participants will be reminded of their appointment via mailed letter (**Attachment 2G**). Respondents will be randomly assigned to one of four between-subjects movie conditions: anger, sadness, fear, or neutral. Respondents will watch one of four movie clips (**Attachment 2A**). They will then read a 9 page consent form that was an actual cancer clinical trial consent form used in the NIH Clinical Center (**Attachment 2B**). The Tobii Eye Tracker will record eye movements while the participants read the consent form. Eye tracking is an unobtrusive way to gather information about the online attentional deployment of the participant. The advantages of eye tracking over other means of assessing attention is 1) that the measure of gaze is taken while the participant is engaged in the task (i.e., online), rather than just after completing the task, and 2) eye tracking is a more direct measure of attention compared to other measures (e.g., dot probe tasks).

After reading the clinical trial consent form, participants will be asked to 1) indicate whether they would hypothetically participate in the clinical trial, and 2) recall the risk and benefit information presented in the consent form. Next, participants will respond to the risk perception and comparative risk questions (**Attachment 2C**). All questions will be administered via laboratory computer. Respondents will receive \$50 for participating. This incentive amount was determined by Westat, a contractor with substantial experience in carrying out this type of participant recruitment, and is based on standard remuneration rates for an hour-long study involving watching a video, reading a complicated 9-page consent form while eye movements are tracked, and completing a questionnaire for which thoughtful responses are needed. Additionally, this will remunerate participants for time and travel.

Analyses will involve examining correlations among study condition and eye tracking information (e.g., scanning vs. systematic engagement), intentions, risk perceptions, and satisfaction. Findings will be disseminated to relevant audiences –health psychologists/ public health researchers who capitalize on basic psychological science advances to understand real world phenomena such as clinical trial informed consent.

Other Considerations

The NCI Special Studies IRB approved this project on October 19, 2012 (**Attachment 2H**).

Burden

A total of 240 participants will complete the study and screener, which has an anticipated length of no more than 70 minutes altogether; thus, the total burden is estimated to be 287 hours. This effort will account for less than 5% of the total burden hours granted in the full generic OMB clearance package. To date, a total of 525 burden hours have been used of the 6,000 hours that were requested. Estimated cost to the Federal Government is \$3890 for staff

(estimated based on 3 FTE hours per week for 10 weeks and 200 total CRTA hours to run the study protocol), \$10,500 for recruitment; and \$12,000 for survey incentives (total \$26,390).

Estimates of Burden Hours					
Types of Respondents	Instrument	Number of Respondents	Frequency of Response	Average Time (Hours)	Total Hour Burden
General Public	Screener (Attachment 2F)	280	1	10/60	47
	Survey (Attachment 2C)	240	1	60/60	240
Total					287

List of Attachments

- 2A: Film Descriptions
- 2B: Consent Document
- 2C: Questionnaire (Word and Screenshots)
- 2D: Selected Readings
- 2E: Advertisement for Recruitment
- 2F: Screener
- 2G: Appointment Reminder Letter
- 2H: IRB Approval