Measuring Real Time Decision-Making About UVR Protection

MSKCC NON-THERAPEUTIC/DIAGNOSTIC PROTOCOL

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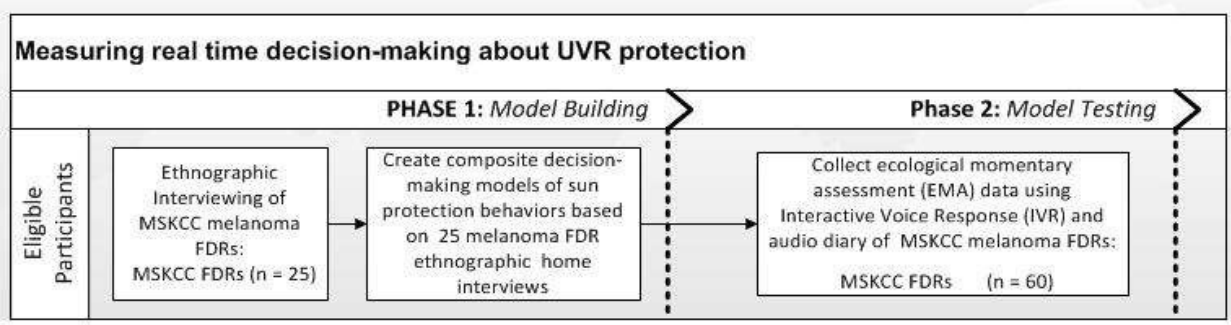
1.0 PROTOCOL SUMMARY AND/OR SCHEMA

Understanding how people make decisions about ultraviolet radiation (UVR) protection is critical to the development of melanoma risk reduction interventions, since UVR exposure is the primary modifiable risk factor for melanoma. Strategies available for UVR protection include consistent sun avoidance and shade-seeking, as well as use of sunscreen, clothing, and hats. However, individua Is at high risk for melanoma, including first-degree biological relative (siblings, children, or parents) are inconsistent in their UVR protection behaviors [22-24]. This behavioral inconsistency is significant for health outcomes since even a few episodes of sunburn can greatly increase skin cancer risk. Understanding the decisions that govern variations in UVR protection would greatly improve our ability to influence these behaviors. While extensive prior research has examined the role of individual differences (such as intentions, beliefs, and demographic differences) in average levels of UVR protection, this study will focus on developing a measurement strategy to capture within-person variability, or level of consistency, in UVR protection.

To understand UVR protection decision-making, we will use a mixed qualitative and quantitative approach dictated by ethnographic decision tree modeling (EDTM; [l, 2]). This mixed model approach is a well-established approach to elucidating the process of decision-making by identifying factors that groups of people use to make real-life decisions that has been used in anthropology, sociology, and psychology for 25 years. The central goal of EDTM is to uncover and validate the criteria that influence decision making about a particular task. EDTM is distinct from other mixed model designs because EDTM addresses cognition around decision making in particular, making it highly relevant to our study goals.

Using EDTM guidelines (described in greater detail on page 7), we will develop and establish the validity of decision models to explain daily decision-making about sunscreen use, shade-seeking, and UVR protective clothing use in melanoma first-degree relatives (FDRs). This study will involve two phases. In Phase I, we will conduct qualitative ethnographic interviews with 25 melanoma FDRs and generate a decision model for each UVR protection outcome for each rrelanoma FDR and then will construct a composite decision-making model incorporating findings across all 25 interviews for each of the three UVR protection outcomes (i.e., sunscreen use, shade-seeking, and UVR protective clothing use). Following this, in Phase II, we will establish the validity of the models using ecological momentary assessment ofUVR protection (over 14 summer days, at 1 pm and 5 pm daily) in 60 different FDRs of 60 different melanoma patients. We will report on the level of success of the decision-making models in predicting behavioral performance. We will also examine the influence of between- and within-person changes in melanoma threat and efficacy, drawn from Witte's Extended Parallel Processing Model [3], as well as satisfaction with UVR protection maintenance, drawn from Rothman's theory of health behavior maintenance [4-6] on the three major outcomes of the study (i.e., sunscreen use, shade-seeking, and UVR protective clothing use). We will recruit equal numbers of women and men, and of those who perceive high and low advantages of tanning, to both phases of the study. The study will increase our understanding of the decision-making context of behavioral maintenance of UVR protection, and dictate strategies to reduce behavioral inconsistency - and increasing maintenance - of UVR protection in those at risk for melanoma and the general population.



2.0 OBJECTIVES AND SCIENTIFIC AIMS

Specific Aim I *(Phase* I): To generate models explaining decision-making about four UVR protection behaviors (sunscreen use, shade-seeking, hat use, use of protective clothing) in melanoma FDRs.

Specific Aim II *(Phase II):* To examine theory-driven affective and cognitive predictors of UVR protection maintenance (sunscreen use, shade-seeking, hat use, and use of UVR protective clothing) assessed in real time.

3.0 BACKGROUND AND RATIONALE

Understanding behavioral patterns in UVR protection is critical to melanoma risk reduction. Melanoma accounts for about 70% of skin cancer deaths each year, making it the most fatal form of skin cancer [7]. Fortunately, risk factors for melanoma are relatively well-understood, as UVR delivered via sunlight is the predominant modifiable cause of melanoma, with approximately 65% to 90% of melanomas caused by UVR [8-11]. Accordingly, melanoma prevention recommendations inc Jude daily sun protection strategies such as sun avoidance in the middle of the day when UVR exposure is the highest, use of hats and clothing to block UVR exposure, and sunscreen use on exposed body parts [7, 12]. These recommendations are relevant to the general population, but even more important for those at high risk by virtue of their family history, a sun-sensitive phenotype (light skin and eyes, red hair) or other risk factors such as dysplastic nevus syndrome (the presence of many moles with irregular borders or coloring; [13]). Over and above cumulative UVR exposure, diverse *patterns* of UVR exposure, variations in the consistency with which some people engage in UVR exposure behaviors, lead to different levels of risk, which highlights the need to understand protection patterns with detail and nuance. For example, intermittent or recreational sun exposure, particularly beach and waterside activities, appear to increase risk much more than occupational exposure. Even in the context of regular sun protection a few UVR exposure episodes substantially increase risk [14-16].

UVR protection is inconsistently practiced among individuals at risk for melanoma. In national studies of UVR protection behavior, including the National Health Interview Survey [17] and the Behavioral Risk Factor Surveillance System [18], UVR protection is recalled cumulatively over large periods of time such as a year, with global indicators of usual behavior (such as "sometimes" or, "most of the time") used to indicate different types ofUVR protection. This is also true for intervention studies, where cumulative, global self-report strategies are used to indicate intervention outcomes [19]. Direct measures of UVR protection have also been used less-widely and include redemption of a sunscreen coupon on the beach [20], and direct visual inspection of the skin [19, 21]. Using the predominant, global retrospective measurement strategy, inconsistent UVR protection is the *norm* for individuals with a family history of melanoma [22-26]. For instance, Azzarella and colleagues [22] found that 47% of first-degree relatives of melanoma patients used sunscreen on their face inconsistently and 71% sought shade inconsistently (e.g.,

rarely, sometimes, often, more than half the time). Geller and colleagues [23] found that 46% of siblings of melanoma patients did not regularly use sunscreen. In a trial to improve early detection and prevention behaviors in melanoma siblings that included telephone motivational interviewing and tailored educational materials, 30% of siblings in control and treatment groups used sunscreen sporadically or not at all [24].

Decision-making has a potentially important role in cancer prevention behaviors, but has not been studied. Medical decision-making research has paved the way to an improved understanding about how people choose the best course of cancer screening, or cancer treatment [40, 41]. Useful decision aids have been developed to facilitate patients' deliberate analysis of the benefits and drawbacks of alternative medical courses of action that maximize satisfaction and minimize regret [42]. In contrast, research in decision-making about cancer prevention "is in its infancy" [43]. The emerging paradigm of naturalistic decision-making proposes that health-related decisions made outside the clinic setting, in naturalistic environments, necessarily entail evaluation of the ecological context where the decision is made [44]. In the context of cancer prevention, naturalistic decision-making may be quite important in the repeated assessment of a single behavioral option - such as whether to use sunscreen.

Daily assessment could also enhance understanding of the decision-making context for UVR protection. There is a substantial literature examining predictors of UVR protection (including seeking shade, sunscreen use, wearing sun protection hats and clothing) in those at increased risk for melanoma, all have examined between-subject factors. For example, increased use of UVR protection has been reported among women, younger individuals [26], those with higher education [22], and those without a prior recent history of tanning [23]. Attitudinal factors related to increased use of protection include higher risk perception for melanoma [38], optimism [39], self-efficacy for UVR protection [22, 25], and the perception of fewer sunbathing advantages, social norms about UVR protection, and higher benefits and reduced barriers for sunscreen use [25].

Yet given the inconsistency with which UVR behaviors are performed, there are likely important decision-making factors that vary within-person as well as between-person, that help dictate sociaL environmentaL and contextual variation in people's lives. Indeed, UVR protection utilized on family beach vacations may be different from what is utilized at soccer games or while walking a dog, and may differ based on the temperature, cloud cover, how rushed one feels in the morning, or might be based on the availability of clothing or sunscreen at any point in time. Understanding the basis of this variation may be useful in targeting interventions to encourage greater maintenance of UVR protection behaviors.

Ecological momentary assessment diary methods could capture information about daily patterns of UVR protection. Diary methods, in which research participants answer questions regarding their behavior or attitudes on their own without researcher involvement in real-time fashion, have been used extensively in sociological research to provide self-revealing records about day to day particulars of a person's life [27]. Qualitative and quantitative diaries are ecologically valid alternatives to global self-report questionnaires, as assessment points occur close to the time of the actual experience in the natural environment where it occurs. Paper and pencil diary methods have been used to examine UVR protection with general and high-risk populations [28-32], outdoor workers [33], and schoolchildren [34]. Diary methods have been validated against direct researcher observation [34] (in which the researcher is present with the participant and directly observes participant behavior), biological markers of sunscreen usage and UVR exposure [31], and questionnaires [30]. In individuals at high risk for melanoma, Brandburg and colleagues [28, 29] showed that diary methods showed less underreporting of sunbathing occasions and sunburns.

Over the µtst decade, the use of computerized diaries to collect data in real time has supplanted paper and pencil methods as the gold standard for diary methodology. This is due to documented problems with paper and pencil methods - including the risk of participants' reporting on their behaviors cumulatively rather than in real time, or at the end of the reporting period. Additionally, ecological momentary assessment (EMA) minimizes missing data by providing automatic skip-outs and audible prompts, and allows for accurate reporting of missing data by reporting time of completion [35] Adherence with these EMA methods is quite good, and appear to be highly dependent on training provided to participants (See Section 4.2 Intervention for the extensive training we provide to participants). In populations such as smokers, cancer patients, and pain patients using EMAs from three weeks to three months, adherence with "responding to auditory alerts," the most global measure of adherence, is in the range of 88-98% [35, 36].

In the current proposaL given our short assessment time frame (14 days), the fact that we are examining an asymptomatic, non-clinical population, and the extensive training regarding how to use the interactive voice response (IVR) system that we offer, we believe that the study will be quite feasible with relatively low levels of nonresponse to audible prompts, and low levels of missing data overall. To achieve the high rates of adherence reported in the literature, we will follow the seven recommendations proposed by experts in the field of ecological momentary assessment [37]: 1) Integrate compliance concerns throughout the study protocol and build in compliance feedback and prompts for participants; 2) adequate training of subjects on the IVR; 3) make the IVR user-friendly; 4) program reminders into the IVR; 5) efficient handling within the IVR of question branching to administer correct questions in correct order; 6) built-in "livability" features to ease incorporation of IVR into their daily lives, and; 7) emphasize participant accountability for the data through tracking of adherence. We will evaluate reasons for refusal and patterns of missing data in primary statistical analyses. Dr. Arthur Stone, an originator of EMA strategies and expert in methodological issues with EMA, has agreed to be a consuhant on our study and will provide input during the EMA questionnaire development, implementation of the Phase II study, and data analysis.

In addition to our use of the IVR data, we will also use audio narrative diaries to explore how first-degree relatives of melanoma patients make decisions regarding sun protection on a daily basis. Audio diaries are research µtrticipants' verbal narratives about behavior, attitudes, or beliefs (dictated by a study's research focus) that are captured when participants speak into a recording device. The sun protection questionnaire delivered through the IVR system will include a statement at the end that will instruct participants to verbally record their own narrative of their sun protection use for the assessed time-period (i.e., either from morning to approximately 12:30 pm, or from approximately 12:30 to approximately 5 pm). Participants will be able to speak directly into their phones to record their audio narratives. The voice direction delivered through the phone will instruct participants to share in their own words the methods of sun protection they used for the assessed time-period and to explain the reasons why they chose to use such methods.

Ethnographic decision-tree modeling (EDTM) is an ideal method to examine decision-making about UVR protection. EDTM is a mixed (qualitative and quantitative) research method specifically designed to elucidate the process of decision-making by identifying factors that groups of people use to make real-life decisions. For the past 25 years, EDTM has been used by anthropologists and psychologists to model decisions such as medical treatment decision-making [45, 46], including needle sharing decisions among drug users [47] and the decision to recycle beverage cans [48]. In her comprehensive book on this method, Gladwin [2] outlined the theory behind EDTM, that decision-making involves a serial consideration of options that maximize outcomes subject to constraints dictated by simplifying rules or heuristics in making everyday decisions [49], and reducing the cognitive demand of decisions.

In practice, EDTM guides development and validation of a formal decision tree of choice for a specific decision task The decision tree is comprised of an ordered set of "if then" decision rules that describe the principal considerations people use in making a choice for the decision task

EDTM involves two phases. The goal of the fast phase is to develop a composite decision model for a specific decision task This phase involves ethnographic interviews with individuals comprised of open-ended questions to understand the factors that influence their decision-making for that decision task After each ethnographic interview the researcher develops a decision tree for that research participant. When all interviews have been conducted, the researcher constructs a composite decision model for the decision task by grouping decision criteria used by the sample interviewed, and mapping their relationships in hierarchical order so that the flow of the 'if then' decision rules are predictive of choices in the sample. Reasons for performing the task come first in the hierarchical flow, with constraints for not performing the task coming second. Phase two involves model validation of the composite decision models generated in phase one. The composite model is tested using a new participant sample using a self-report survey that is based on the model; each question in the survey represents a criterion or decision factor. The goal of this phase is to quantitatively determine the sensitivity and specificity of the model.

Limitations of EDTM include the lengthy nature of the process and reliance on retrospective memory in model development. Strengths of the method involve the opportunity to develop a complex understanding of real-life decision making in a group of people, the sequential design that results in a quantitatively validated model of the decision-making context in question, and the ability of the model to explain when behavior is performed and avoided. EDTM is ideally situated to address applied research problems by pinpointing opportunities for intervention in real-world decisions in public health.

Health behavior theory may improve our understanding of the consistency ofUVR protection. Witte's Extended Paralle1 Process Model [3] offers an account of the conditions under which illness threat may lead to health protective behavior. In the context of heightened illness threat (severity and susceptibility beliefs) and heightened beliefs that they can overcome the threat (self-efficacy and response-efficacy), people will act to do so via health protective behavior, or "danger control." In situations where threat is high but people don't believe they can manage it, behavioral avoidance, or "fear control" will result as people work to reduce their feelings of threat rather than their chances of becoming ill. Beliefs related to threat control include self-efficacy, or confidence that one can perform the rehavior, and response-efficacy, or confidence that performing the behavior will protect against the health threat. Meta-analytic work examining this premise has found that pairing strong threat with high-self efficacy indeed maximizes behavior change [3]. In one of the only theories specifically addressing health behavior change maintenance, Rothman [50] has proposed and confirmed that satisfaction with the results of behavioral adoption - such as satisfaction with the results of smoking cessation or weight loss - determines whether individuals maintain health behavior over time [4, 5, 51].

We will examine these theory-based predictors - melanoma threat and efficacy, and satisfaction with UVR protection behavior - as between-subject and within-subject variables in this study. Accordingly, along with the most important decision factors, we will determine whether overall levels of these cognitive beliefs, or daily variations in these beliefs, are important in the maintenance of UVR protection over time in melanoma FDRs.

Study Significance. This is a measurement study aimed at understanding the discrete decision-making factors that dictate sun protection behavior on a daily basis. Given the clinical significance of even very few sunburn events, and the documented higher risk associated with some sun exposure contexts

(recreational) over others (occupationa l), new measurement strategies are needed in order to capture daily variation in sun protection, as well as the decision-making factors that dictate them. Accordingly, this new measurement strategy will be useful in assessing the impact of future intervention strategies that aim to increase the consistency of sun protection in higher and average risk individuals, and to address decision making factors that may set the stage for risky sun protection events.

An understanding of real time decision-making for UVR protection will provide a critical starting point to address the inconsistency with which those at high risk for melanoma practice this important cancer prevention behavior. Assessment of variations in daily decision-making about UVR protection will increase our understanding of the social and environmental context of behavioral maintenance of UVR protection, and will advance the development of novel interventions to reduce inconsistency in UVR protection in those at high risk for melanoma that can result in risky sunburns and intermittent high-doses of UVR. Decision-making models in cancer have been developed to address cancer treatment and screening decision-making; in contrast, research in decision-making about cancer prevention "is in its infancy" [43]. The study represents a novel first step in examining decision-making in cancer prevention, engaging with the complexities of measuring health decision-making in naturalistic settings where most health behaviors are performed [44]. The study also contributes to theoretical understandings concerning the processes by which health behaviors are maintained, or habituated, over time [50].

4.0 OVERVIEW OF STUDYDESIGN/INTERVENTION

4.1 Design

Overview Guided by EDTM, we will first build mode ls of decision-making about UVR protection using in-home ethnographic interviews with 25 melanoma FDRs (Phase I). We have chosen to interview 25 participants based on EDTM recommendations [1, 2]. We will build individual decision models for each UVR protection outcome for each melanoma FDR, and subsequently generate and composite decision models for the three primary outcomes (i.e., sunscreen use, shade-seeking, and UVR protective clothing use) representing the decision-making process and factors across the 25 melanoma FDRs interviewed. In Phase II, we will test the validity of each composite mode**1.** This will be completed using EMA data collection with 60 different melanoma FDRs who will report on their sunscreen use, hat use, shade-seeking, and use ofUVR protective clothing and decision-making regarding these outcomes via an Interactive Voice Response (IVR) system (described below) and audio narrative diaries. We will examine the validity of each model and examine the influence of theory-driven affective and cognitive predictors of UVR protection maintenance across time.

Although there are wide variations in sun protection recommendations worldwide, we will fo11ow the guide lines provided by the American Cancer Society. Their recommendations include: 1) limit direct sun exposure between the hours of 10 am and 4 pm; 2) if shade-seeking is not possible wear sun-protective clothing and hats, use sunscreen with an SPF of 15 or higher, and wear sunglasses that block UV rays when out in the sun.

4.2 Intervention

For each of the samples, we will use a screenmg questionnaire (See Appendix A) to identify melanoma FDRs. We will conduct purposive sampling [62] in order to ensure representation of melanoma FDRs with diverse approaches to UVR protection. Purposive sampling is a sampling strategy commonly used in qualitative research in which research participants are selected to participate based on some characteristic.

In Phase I of our study we will screen potential research participants according to whether they meet two criteria-participant gender, and their perceived advantages of sunbathing, given the importance of these factors in determining UVR behavior [26, 64]. Therefore, we will screen potential Phase I research participants according to their perceived advantages of sunbathing [63], to recruit equal numbers of those who perceive high versus low advantages of sunbathing. In Phase II we will only engage in purposive sampling for the gender criteria to ensure recruiting equal numbers of men and women. For Phase II only, we will additionally use the screening questionnaire (See Appendix A) to identify melanoma FDRs who report daily (weekday and weekend) outdoor activities due to vacations, retirement, leisure activities or work situations for inclusion to the study.

Phase 1

In-home interview with 25 melanoma FDRs. The in-home interview draws from an ethnographic, participant-observation research tradition which prioritizes collection of data in participants' home context [65], and has been suggested as the ideal strategy for model building in EDTM [1, 2].

The term "ethnographic" is an adjective derived from the word "ethnography," which refers both to a qualitative research methodological approach (i.e., doing ethnography) and a research product (i.e., developing an ethnography, a written account of a culture). Ethnography literally means "a study of a people," and this form of qualitative inquiry has served as the bedrock of the field of cultural anthropology since its inception. Ethnographic data collection can include a variety of observational techniques, such as participant observation (in which a researcher conducts fieldwork, lives among the people h/she is studying, and engages in their activities with them), and key informant interviewing (conducting interviews with individuals regarded as representative or highly knowledgeable of a culture). The common thread among diverse data collection techniques that can be regarded as ethnographic is that they aim to understand the broader context grounding individual behavior and beliefs, may be employed in the natural settings where such behavior occurs, and use exploratory methods to learn directly from individuals. The interviews that we conduct in Phase I of our study are ethnographic in that our interviews are semi-structured, with open-ended questions that allow the interviewer to be responsive to the participant's individual experience; and that we conduct the interviews in the home so that we may obtain a better sense of participants' sun protection behavioral habits and routines, and may see participants interact directly with their sun protection items as they describe their use of such items.

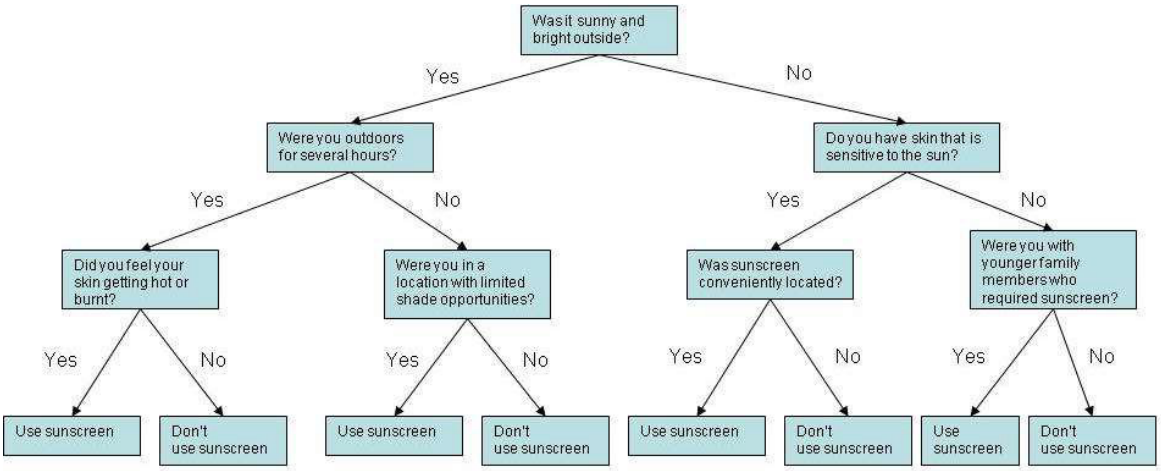
Ms. Shuk will conduct the interviews. The in-home interview will begin by completing the Informed Consent process. Following that, the interview discussion will be audio recorded using a digital voice recorder. The recordings will be uploaded to our secure network drives through 641 Lexington Ave offices or via remote VPN connection the same day when possible, or by the next day if the interviews were conducted in the evening. The interview content will be guided by our prior qualitative research with melanoma families, state-of-the-art strategies for ethnographic interviewing [65] and EDTM procedures [1, 2]. We will explore the following topic areas with each participant. (See Appendix B for full in-home interview guide):

- Sunscreen use and decision-making during most recent/one other recent sun exposure episode of at least 60 minutes or more;
- Protective clothing use and decision-making during most recent/one other recent sun exposure episode of at least 60 minutes or more;
- Seeking shade and decision-making during most recent/one other recent sun exposure episode of at least 60 minutes or more;

- Probes to tmderstand discrepancies in UVR protection behavior across sun exposure episodes;
- House tour to see locations in home where sun protection items are stored

The in-home interview will begin with a discussion of the participant's decision-making about sunscreen use and will subsequently consider decision-making about shade-seeking and use of UVR-protective clothing. We will frrst ask participants to recall the last time they were out in the sun for a period of 60 minutes or more during the summer months, whether they used sunscreen of SPF 15 or higher during this period of sun exposure, and to talk through the factors that led to their decision to use it or not. If participants did use sunscreen during this period of sun exposure, we will ask participants to lead us to the location in their home where they store their sunscreen, and if possible, to show us the sunscreen products that they used during this period of sun exposure. Having participants see their sunscreen products firsthand as they answer questions about their decision-making to use sunscreen may help to jog their memory regarding the key factors that influenced their use of sunscreen during the sun exposure episodes under examination (if participants are unable to locate the sunscreen items that they used during the sun exposure episode, we will still ask them to talk through their decision to use sunscreen and to answer the following questions regarding the broader context of their sunscreen use). We will also ask participants to "reenact" how they used sunscreen during the sun exposure episode. As participants describe the story of their sunscreen use, we will ask them where on the body they applied sunscreen, whether they reapplied sunscreen, the form of sunscreen that they used (e.g., spray, lotion, makeup/moisturizer with SPF) and its SPF level. It is likely that participants will share this information regarding their sunscreen use on their own without interviewer probing. Following exploration of participant's sunscreen use during their most recent period of sun exposure in the summer, we will ask them whether they sought shade or used sun protective clothing during the same sun exposure episode, and to describe the factors that led to their use or non-use of both sun protection methods. As we carried out with our examination of the participant's sunscreen use (as described in the procedure above), if participants did use sun protective clothing or used items to provide shade cover (e.g., sun umbrellas), we will ask participants to show us the clothing or shade items they used during the sun exposure episode, and to show us how they used the items. As before with our exploration of sunscreen use, if participants are unable to locate the clothing or shade items they used during the sun exposure episode, we will ask them to describe the reasons that influenced their use of both sun protection methods regardless.

Next, we will ask participants to recall a *second* period of sun exposure of at least 60 minutes or more during the summer, but a period where they were in a *different location* than the first period discussed earlier in the interview. We will again ask participants whether they used sunscreen, sought shade, and used sun protective clothing during this sun exposure episode and to describe the factors that led to their decisions for each behavior. If participants did engage in these sun protection methods and can recall the specific items they used, we will ask them whether the items used were different from the items used in the first sun exposure episode discussed in the interview. If they used different sun protection items (i.e., sunscreen products, sun protective clothing, or sun shade items) in the second sun exposure episode from the first sun exposure episode, we will ask participants to show us those items, and demonstrate how they used them during the second sun exposure episode. Open-ended probing will be used at "contrast" points, where we will request them to clarify the salient reasons for behavioral performance, followed by constraints that could lead to non-performance that may generalize to different behavioral choices across locations and situations. If there are inconsistencies in the participant's use of sun



protection (i.e., sunscreen use, shade-seeking, use of sun protective clothing) between the two sun exposure episodes discussed, we will ask them to explain the reasons that led them to use sun protection in one episode but not the other.

We finish the interview with a shadowing procedure, a common participant observation strategy in ethnographic research, in which the researcher instructs the research participant to perform a task, and then follows or shadows the participant as they perform the task. This procedure will consist of a house tour where the interviewer will ask the participant to show her all the locations inside or outside the home where s/he stores and applies the items they use for UVR protection, including sunscreen and clothing (e.g., bathrooms, closets, purses, bedrooms, garages, cars), and what outdoor areas are used for shade, if any.

The participants will receive $50 in cash for their time and effort on the study. Each in-home interview will be transcribed by RA Fisher Ink, an NYC-based transcription vendor, and will be used to generate the decision models. If any names are accidentally used in the audio recording, the transcribed version will only include the initials.

Generating the decision models. The primary goal of our analysis of the in-home interview data is to understand decision-making regarding consistent and inconsistent use of UVR protection in melanoma FDRs. In line with EDTM, we will construct three decision models, a tree representing ordered decision factors, one for each sun protection outcome. The decision models will present the ordered decision factors that dictate use versus nonuse of sunscreen, shade-seeking, and UVR protective clothing (See Figure below for an example). Each individual decision tree is a series of statements about the conditions leading to the selection of each alternative outcome. After the first interview, Ms. Shuk and Dr. Hay will meet to construct three decision tree models (sunscreen use, shade-seeking, UVR protective clothing use) for this participant. This will involve 1) sorting data segments into tentative categories; 2) mapping the flow and relationship between decision criteria, and 3) labeling and summarizing the content of each category. This will be repeated for each of the 25 interviews conducted. Subsequent to the development of the decision trees for each participant, the team will convene to form the composite decision models. Elyse Shuk, Drs. Hay and Burkhalter and consultants Drs. Mayer and Shoveller by telephone will meet to form the composite models for sunscreen use, shade-seeking, and UVR protective clothing use. Responses will be grouped to fonn decision criteria and arranged in a hierarchical order, structuring reasons *for* UVR

protection coming first, and the constraints *preventing* the action addressed next [l]. The ultimate goal is to maximize comprehensiveness and inclusiveness of the decision making context for each UVR protection behavior, while retaining participant natural language. As we analyze the individual decision trees to create composite models, we will consider the effects of gender as a determining factor in sun protection decision-making. We will evaluate whether commonalities exist within sun protection decision-making factors that seem particularly influential in shaping sun protection behavior among men and among women in our Phase 1 sample. The models will dictate the closed-ended questionnaire used (See Appendix C) in the IVR assessment where survey questions represent decision nodes from the mode I-building phase.

Phase 2

14-day IVR assessment and audio narrative diary. The fmal version of the Phase 2 IVR assessment survey has been developed from findings generated from analysis of the in-home interview data obtained in Phase I (see Appendix C). We have developed the content of the questionnaire that will be presented through the IVR telephone system from the outcome of our decision model development work in Phase 1 of the study. IVR is a technology that allows a computer to interact with humans via a phone. In this study, IVR will allow us to automate contacting our participants via telephone and allow them to respond to the assessment using their telephone keypad. The IVR system will be programmed to ask participants the assessment survey via prerecorded audio and direct them on how to answer the survey questions by pressing designated buttons on their telephone keypad.

The IVR and audio diary will be implemented using the MSKCC Web Survey Core Facility. The Core is an institutional resource to assist investigators in the creation of secure electronic surveys for use in research. It includes programmers to create study-specific surveys, and maintains servers for secure administration and storage of data. Core surveys are directly linked to the MSKCC Clinical Trials Research Database (CRDB), which is the institution's standard repository for secure storage of µitient study data. The server configuration and specifications for the web core are compliant with current standards for data safety and privacy and have undergone formal privacy and security review.

In generating the Phase 2 IVR assessment survey, we have translated each decision criterion identified in the four sun protection decision tree composite models generated in Phase 1 into a closed-ended question presented in yes/no format, so as to elicit from Phase 2 participants whether each decision criterion influenced their sun protection decisions during the assessed time period. For example, in our shade-seeking composite model we found that proximity to shade is a key factor dictating use of shade structures during outdoor activities. Accordingly, we developed a corresponding question "Was shade conveniently available? (yes/no)" and included this question on the IVR assessment survey to test the importance of this factor in the use of shade-seeking as a sun protection strategy. We have strived to phrase the closed-ended questions with key words and concepts identified in the decision criteria in the composite models [90].

During phase 2 recruitment, the study staff will record a series of choices (1_{s}\ 2^{nd}) of the 60 participants concerning when, during spring/summer months of2012 and 2013, they will be available for the 14-day assessment period and they will be in the continental United States. Eligible participants will be consented (in clinic or verbally over the phone) within a week of their 14-day assessment period. Once consented, the study staff will administer a short demographic questionnaire, provide training on the participant's data collection responsibilities during the 14-day period that includes what to expect, how to respond to the IVR, and answer any questions that they may have.

IVR and audio diary training. Each training session will last approximately 15 minutes and will be done over phone by the study staff. The purpose of the training session will be to orient and prepare participants

for daily use of the IVR over the duration of the 14 days of ecological momentary assessment sampling (See Appendix D). During the training call study staff will review a number of issues with participants, including: 1) that participants will receive 2 calls a day, one at approximately 12:30 pm and again at approximately 5 pm for each of the 14 days, starting on the 1st day of the agreed upon 14-day period; 2) that participants will be able to call the IVR system if they are unable to answer an outbound call from the IVR system for any assessment period-i.e., they will be able to call the IVR system by 1:30 pm to complete the morning assessment survey, and by 6 pm to complete the afternoon assessment survey; 3) the ID number and PIN that they will need to press on their phone keypads in order to complete a survey; 4) content of the IVR assessment survey, including a review of each question in the survey; 5) the numbers on their phone keypad that they will need to press in order to answer the survey questions; 6) that they should answer every question in the survey; 7) that the IVR system will prompt them at the end of each survey to record their own narrative describing their use of sun protection and associated decision making during the assessed time period; 8) that at the fmal assessment point they will be asked a number of questions to evaluate whether IVR prompts influenced their use of sun protection; 9) that study staff will call them a couple of times throughout the 2-week assessment to answer any questions they may have and to address any technological problems if necessary; and 10) provide the name and phone number of study staff that they can call if they have any issues throughout the 2-week assessment. The study staff will complete an "IVR Proficiency Checklist" (See Appendix D) with all participants to ensure that they have met all training goals, and training procedures will be repeated until proficiency is 100%.

Participants will also be trained in how to record their twice-daily audio narratives of UVR protection and decision-making. At the close of the IVR assessment survey, participants will be prompted to share in their own words their "story" of their UVR behaviors and related decision-making on that morning or afternoon. They will be instructed to not use their names in the recordings.

Participants will receive the following related technical support: 1) three proactive (i.e., research team calling participants) telephone calls to assist usage: 1 training and orientation prior to starting the 14-day period; 1 call a few days after the start of the 14-day period, and fmally 1 call towards the end of week two); 2) a hardcopy of the IVR training script they will receive by telephone from study staff (see Appendix D); 3) a hardcopy of the IVR assessment survey so that they will know the content of the assessment (see Appendix C); 4) an IVR response card that will contain the participant's 10-digit telephone number for the study and 4-digit PIN needed for completing the IVR assessment, and the telephone keypad numbers corresponding to the survey responses (see Appendix L); 5) an IVR sticker they can affix to their telephone that will contain the telephone numbers of the IVR system and study staff, and 6) a study telephone number to request assistance from study staff and/or to report technical problems.

Diary sampling procedure. Study participants will complete twice-daily assessments of their sun protection behavior and decision-making during the 14-day assessment period. Participants will be called twice a day at approximately 12:30 pm and approximately 5 pm by the IVR system using the primary telephone number provided by the participant at consent. They will not be able to influence or select the timing or content of assessments, which minimizes potential bias that occurs when participants initiate self-reporting [66]. If the IVR gets disconnected or the participant hangs up, the IVR will call them back and begin where it left off. If the participant does not answer an outbound call from the IVR system for any assessment period, they will have an opportunity to call the IVR system directly at 646-888-0720 to complete the survey corresponding to the outbound call that they missed. Specifically, they will be able to call the IVR system by 1:30 pm to complete the survey for the morning assessment period, and by 6 pm to complete the survey for the afternoon assessment period.

At each assessment session, they will be asked to respond to the question series using their telephone keypad. At approximately 12:30 pm they will be asked about their UVR protection and decision-making for the morning; and at approximately 5 pm, they will be prompted to complete this same assessment for the afternoon. At each time period after completing the IVR assessment, they will be prompted through the IVR system to record a brief (2-3 minute) description of their UVR protection strategies for that morning or afternoon. The IVR will allow a maximum of five minutes for the recording. The questions asking about sun protection use and decision making factors will follow a yes/no format to which they will respond using their telephone keypad. This format is a heavily-used, easy way to record health behaviors and decision-making factors consistent with EDTM. The IVR assessment survey will also include four closed-ended questions to assess: participants' perceived melanoma risk; perceived self-efficacy for following through with sun protection; beliefs about the effectiveness of sun protection in preventing melanoma; and level of satisfaction with decision to use/not use sun protection. Each assessment should require less than 10 minutes of the participants' time, keeping participant assessment burden low. Participants will have the option of being able to skip or refuse answering any questions they wish. Once the IVR has begun reading a question participants can interrupt the recording and move on by inputting their answer via the telephone keypad. The time at which participants complete the assessment will be electronically stamped on their assessment responses stored on the WEBCORE server. If the participant does not respond to the 1st call for each period (i.e., approximately 12:30 pm or approximately 5 pm), then the participant will automatically be called back up to 2 times within a one hour period. If the participant does not answer the 1st call for each period the system will leave the participant a voice mail message stating that they will be called back again shortly. If the participant does not answer the third follow-up call for a given time period the system will leave the participant a voice mail message stating that they will be called at the next assessment period. This same pattern will occur at the 5 pm assessment. Once the participant answers the call the IVR will not call again until the next assessment period. If the call is never answered, this assessment will not be ab le to be completed at a later time. However, the i:nrticipant will be able to call the IVR system directly to complete the survey if they miss an outbound call for any assessment period.

All IVR data, including the recorded voice narratives, will be stamped with date and time (in Eastern Standard Time) to verify compliance with the sampling procedure. To maximize compliance, the study team will call participants both once during the first week and second week of the assessment period to ascertain whether participants are experiencing any technological difficulties or challenges in completing the twice-daily assessments. We have soccessfully used these strategies in the past with lung cancer patients [57, 58].

Once i:nrticipants have completed their 2 week assessment, study staff will call participants within a week to thank them for their participation, and to complete a very brief program satisfaction survey (See Appendix N). During this final call staff will arrange to mail participants their $50 money order incentive for their time and effort on the study.

In the unexpected event that the IVR system experiences technical difficulties, our study staff will contact participants by phone to complete the assessments or send them paper assessments via mail or email to have them complete and mail back to us. The questions are the same as the IVR system. The participants' responses will be recorded on paper (see Appendix **P).** The data will be entered directly into an excel file and stored on the secure **H** file. We will merge it with the export files from the Webcore servers within the MSK firewall.

All study related materials may be emailed or mailed to participants.

5.0 CRITERIA FOR SUBJECT ELIGIBILITY

5.1 Subject Inclusion Criteria

- A first-degree biological relative (a child, sibling or parent) as per self report of an MSKCC follow-up surgical patient diagnosed with melanoma as per pathology report or clinician judgment;
- English-fluent; the surveys were designed and validated in English and are not currently available in other languages. Translation of questionnaires into other languages would require reestablishing the reliability and validity of these measures. Therefore, participants must be able to communicate in English to complete the surveys.
- 18 years of age or older;
- For Phase I *only:* FDRs who live within a 50 mile radius of MSKCC to make it feasible for Ms. Shuk to be able to arrive at each person's home for the in-home interview without the cost being prohibitive;
- For Phase I *only:* Can recall a period when s/he was out in the sun for at least one hour on a sunny day this past summer 2009.
- For Phase I *only:* Can recall a separate period whens/he was out in the sun for at least one hour on a sunny day this past summer 2009, buts/he was in a different location from the period referenced above.
- For Phase II *only:* FDRs who self-report at least 1 consecutive hour in the morning (dawn to 12:30pm) and 1 consecutive hour in the afternoon (12:30 - 5pm) of daily (weekend and weekday) outdoor activities on the screening questionnaire (Appendix A).

5.2 Subject Exclusion Criteria

- First-degree relatives of melanoma patients who report never using UVR protection;
- Patients who provide consent for Phase I will not be eligible for Phase II.
- Any first-degree relative of a melanoma patient who already has a first-degree relative who consented to the study;
- Unable to provide informed consent.

6.0 RECRUITMENT PLAN

For each of the samples (Phase 1=25 FDR µtrticipants; Phase II=60 FDR participants) patients whose FDRs may be eligible for this study will be identified by a member of the patient's treatment team, the protocol investigator, or research team at Memorial Sloan-Kettering Cancer Center (MSKCC). Using clinic lists from the Department of Surgery Gastric/Mixed Tumor Services at MSKCC, study staff or a study investigator will do a medical chart review to identify patients who are melanoma patients. Study staff will then obtain permission from the attending physician to contact the patient about his or her FDRs' possible participation in this study. Once permission is obtained, the study staff will either approach the patient at their clinic appointment to provide a brief verbal introduction of the study along with a study brochure (Appendix E for Phase **1,** Appendix F for Phase 2) to the patient and any accompanying family members or mail them a letter (Appendix T) introducing them to the study and letting them know we will contact them about the study by phone in a few weeks.

If any first-degree relatives are present at the clinic appointment they will be given the consent form in addition to the brochure to read over. Once they have read the brochure and consent and are still interested, the study staff will administer the screening questionnaire (Appendix A). It will be administered prior to obtaining informed consent. The study staff will briefly explain the purpose of the screening questionnaire in determining if they are eligible for the study or not. They will make sure the FDR understands that completing the form is voluntary but that without completing it they will not be able to participate in the study. If an FDR is determined to be ineligible for study participation after administration of the screening instrument, s/he will be thanked for his or her time.

We will conduct purposive sampling [62] in order to ensure representation of melanoma FDRs with diverse approaches to UVR protection. Purposive sampling is a sampling strategy commonly used in qualitative research in which research participants are selected based upon some characteristic [91]. For Phase I of our study we will screen potential research participants according to whether they meet two criteria- participant gender, and their perceived advantages of sunbathing, given the importance of these factors in determining UVR behavior [26, 64]. Therefore, we will include screening assessment of perceived advantages of sunbathing [63] to recruit equal numbers of those who perceive high versus low advantages of sunbathing as well as equal numbers of men and women. In Phase II we will only engage in purposive sampling for the gender criteria to ensure recruiting equal numbers of men and women. For Phase II, we will additionally use the screening questionnaire (Appendix A) to only include melanoma FDRs who report daily (weekend and weekday) outdoor activities due to vacations, retirement, leisure activities, or work situations.

If the patient is not accompanied by an FDR at their clinic appointment but approves contact or we are contacting the patient by phone from the letter recruitment method, we will collect their identified FDR's contact information from the patient. Should a patient refer more than one FDR, we will ask them to identify them in order of preference for us to contact, based on their determination of who would most likely be eligible and who would most likely be willing to participate. We will then either contact the FDR by phone (including leaving a voice message), e-mail or by mailing the FDR a letter (Appendix G Phase I; Appendix **H** Phase II) and consent form. If a letter is mailed to them we will then follow up with a phone call to discuss the study, and complete the screening questionnaire by telephone. If the FDR states they did not receive a racket or if we have contacted them by phone and not sent a packet, we will offer to email them the consent. We will only contact one FDR at a time until they are determined to be ineligible, or refuse to consent. Once an FDR agrees to the home interview, we will not attempt to contact any other FDRs provided to us by that patient. If permission to contact the FDR is denied by the patient, the FDR will become ineligible for the study. We will ask the patient if they would be willing to provide a reason for their decision. This information will be obtained solely for the purpose of determining potential sample selection biases.

In the event that we have made several (up to 5) unsuccessful phone call attempts to prospective participants, we will mail a letter (Appendix I) to them indicating that they need to contact the study staff if they are interested in discussing the study. For FDRs who decline participation, we will ask if they would be willing to provide a reason for nonparticipation. This information will be obtained solely for the purpose of determining potential sample selection biases.

For phase I, the consenting professional will consent eligible FDR participants face to face at their home. The scheduling for the Phase I in-home interview will be arranged either in the clinic or over the phone by the study staff or Ms. Shuk.

For Phase II participants, the study staff began screening for eligible participants in the summer of 2011 with the expectation that the IVR system would be available to use and they could consent in 2011. Due to unexpected delays in the development of the IVR, we were not able to consent the potential FDRs whom we identified as eligible. We, therefore, asked each person's permission to contact them in the spring/summer of 2012 when they could enroll in the study. All 23 persons agreed to be contacted in the late spring of 2012 about enrolling in this study. At that time, they will be re-screened for eligibility and if interested, consented at that time. We will ask all potential participants to identify a 14-day period when they can participate in the study within the summer months of 2012. The participant will be told that they should expect to be consented to the study within a week prior to the start of this 14-day period. Depending on when period is, the potentia I participants can be consented either face to face in the clinic or verbally over the phone.

As of the end of summer 2012, we still had not completed recruitment and therefore will continue in the spring and summer of2013 when we expect to fmish as we only have 30 more FDRs to consent. We are going to mail patients in Spring 2013 a letter to introduce the study to them in hopes that this will help facilitate the recruitment process (as opposed to only approaching patients in clinic) in order to guarantee that we can complete recruitment by the end of summer 2013.

Throughout the recruitment process of both Phase I and Phase II, we will monitor and evaluate our progress toward meeting our recruitment aims of enrolling an equal number of men and women and an equal number of individuals who report high and low attitudes toward sunbathing into the study, and we will adjust our recruitment strategies accordingly if we are trending toward meeting our recruitment goals in one of these categories. For example, if we enroll IO men into Phase I of the study in succession, we will shift toward targeting enrollment of women into the study, to ensure that the Phase I study sample will include an equal number of men and women.

All participants will receive $50 in cash or money order for their time and effort on the study (see Appendix J Phase 1, Appendix K for Phase 2). There is no cost to study participants. Additionally, all participants will receive a packet of information on skin cancer prevention and screening from the NCI website (see Appendix M). Once the participant has completed the study, the research staff will ask if they are interested in participating in any similar studies. They will also be informed that they may be contacted during or shortly after their participation in the study to clarify an answer.

According to the 2008 Memorial Sloan-Kettering Melanoma Disease Management Team Database, the Gastric/Mixed Tumor Service anticipates following approximately 400 post-surgical patients diagnosed with melanoma, and 400 additional melanoma patients as new visits. Of these, 85% were diagnosed with clinically localized disease. In our pilot recruitment studies with melanoma FDRs, we find that 84% of melanoma patients are willing to refer an FDR for behavioral research studies (the remainder refuse or do not have eligible FDRs). We anticipate a conservative FDR participation rate of 80% based on prior studies evaluating daily diary assessment of UVR protection in a comparable high-risk population [28, 29]. We will accept only one family member participant per patient to exclude potential dependency in the data due to family membership. Thus for Phase I, we will have a patient pool of 228 that should result in 188 making a referral of an FDR Of these 188 FDRs, we anticipate 150 available FDRs available to meet our target participation of 25 FDRs. For Phase II we expect to have a patient pool of 285 that should result in 235 making a referral of an FDR. Of these 235 FDRs, we anticipate 188 available FDRs available to meet our target participation of 60 FDRs.

During the initial contact between the investigator/research staff and the patient and/or FDR, the patient and/or FDR may be asked to provide certain health information that is necessary for the recruitment and enrollment process. We will use the information provided by the patient, FDR, and/or medical record to confirm that the FDR is eligible and to contact the patient and FDR regarding the FDR's study enrollment. If the FDR turns out to be ineligible for the research study, the research staff will destroy all information collected on the patient and FDR during the initial conversation and medical records, except for any information that must be maintained for screening log purposes.

The recruitment process outlined presents no more than minimal risk to the privacy of the patients and FDRs who are screened and minimal PHI will be maintained as part of a screening log. For these reasons, we are seeking a (partial) limited waiver of authorization for purposes of (1) reviewing medical records to identify patients who are diagnosed with early stage, clinically localized cutaneous melanoma; (2) communicating with patients and FDRs regarding possible enrollment of the FDRs; (3) handling of PHI contained within these records and provided by patients and/or FDRs; and (4) maintaining information in a screening log of patients and FDRs approached.

7.0 ASSESSMENT/EVALUATION PLAN

Screening Questionnaire (Appendix A). This will include information to determine the eligibility of potential participants. Accordingly, the form will include information about potential participants' relationship to the index patient, gender, home geographical location, level of outdoor activities, use of sun protection and a seven-item measure of individuals' beliefs about level of agreement concerning advantages of sunbathing (1=strongly disagree to 6=strongly agree). This measure has been used in prior research and has good internal (alpha=.95) and test-retest reliability (r=.70, [63]). Participants scoring above the mean (4.0) identified in prior research will be designated as perceiving advantages of sunbathing; those scoring below the mean will be designated as not perceiving advantages of sunbathing for the purposes of stratification assignment. This will take about 5 minutes to complete.

Ethnographic Semi-Structured In-Home Interview -Phase I Only (Appendix B). The in-home interview guide will consist of several components. First, we will ask participants to recall the most recent time they spent outdoors on a sunny summer day for one hour or more. We will ask participants to describe how they made decisions whether to use three methods of sun protection: sunscreen with an SPF of 15 or higher, sun protective clothing such as a shirt with sleeves or a hat, and seeking shade or staying under an umbrella. Second, we will ask participants to recall another period when they spent time outdoors for at least one hour on a sunny summer day; we will ask participants to recall a period when they were in a *different* outdoor environment than the period just discussed. As before, we will ask participants to talk through how they made decisions to use the three methods of sun protection under examination (i.e., sunscreen with an SPF of 15 or higher, sun protective clothing such as a shirt with sleeves or a hat, and seeking shade or staying under an umbrella). If inconsistencies are present in the participant's sun protection behavior-using sunscreen, sun protective clothing, or seeking shade/staying under an umbrella-across the two sun exposure episodes reported, we will ask the participant to compare their use of sun protection across both episodes. The goal here will be to understand the reasons that led the participant to make different decisions to use sunscreen, and/or sun protective clothing, seek shade/stay under an umbrella across the two periods of time spent outdoors. We will ask a few demographic questions as well as ask each person's experience with different kinds of electronic equipment. We expect the interview to take about 90 minutes.

Home Tour - Phase I Only. The final piece of the in-home interview will be a brief house tour, in which we will ask participants to show the areas inside or outside their home where they store their sun protection

items. As participants present the sun protection items we will ask them if there are any other reasons why they may use or not use the item when they spend time outdoors. Seeing the items in front of them may prompt participants to remember details regarding the item's use. We expect the tour to take about 15 minutes.

Digital Voice Recorder. For Phase I, we will use a digital voice recorder to record the ethnographic in-home interviews.

Demographic Questionnaire (Appendix R). We will ask a few demographic questions once the participant has consented as well as ask each person's experience with different kinds of electronic equipment. We expect the questionnaire to take less than 5 minutes to complete.

Interactive Voice Response *(NR)* Diary Assessment - Phase II Only (Appendix C). The *NR* diary assessment survey will be modeled on the composite decision model for each assessed sun protection behavior (sunscreen use, shade seeking, hat use, use of sun protective clothing) that was developed in Phase I. For each assessment (at approximately 12:30 and 5 pm daily), participants will receive an IVR call to report their sun protection attitudes and behaviors for that morning or afternoon. The IVR assessment survey asks participants to report on the following: 1) whether or not they have used each of the following sun protection methods: sunscreen, hats, shade-seeking, and protective clothing; 2) the presence or absence of 21 decision criteria identified in Phase 1 to influence sun protection decision making; and 3) theory-driven affective and cognitive predictors.

In addition to answering questions about their sun exposure and protection through the IVR phone keypad, at the end of each assessment participants will be asked by the IVR to record an audio narrative diary that will capture their own thoughts about their sun protection choices during that assessed time period (i.e., either the morning or afternoon on a given day in the 14-day assessment period). The IVR will direct participants with the following instruction after participants complete the assessment at both approximately 12:30 pm and approximately 5 pm. "Please now speak into your phone to describe in your own words your use of sun protection during the time period(s) you have just reported on." After the instruction to record the audio narrative, the IVR will inform the participant the time at which they will receive their next call. Theory-driven affective and cognitive predictors will include perceived risk for melanoma and efficacy (UVR protection self- and response-efficacy) based on Witte's Extended Parallel Process Model [3]. We will assess these predictors at each assessment point, twice daily for 14 days. We have elected not to include melanoma severity in the assessment given that it is generally not found to be predictive ofUVR protective behaviors in melanoma FDRs [22, 25]. To measure perceived risk for melanoma we will use one established question that has been used in prior UVR protection studies with melanoma FDRs [22-26]: B) perceived absolute likelihood with verbal anchors (1 = no chance, 2 = unlikely, 3 = moderate chance, 4= likely, 5 = certain to happen),

Efficacy beliefs [72] will be assessed through two questions assessing the extent to which the participant feels capable of UVR protection in general (self-efficacy; 1="Not at all capable," 2="somewhat incapable," "3=somewhat capable," "4="extremely capable") and the extent to which the participant believes that UVR protection strategies can prevent melanoma (response-efficacy; l="Not at all effective," 2= "a little effective," 3= "moderately effective," 4= "extremely effective").

We will also assess satisfaction with UVR protection consistent with Rothman's theory of health behavior maintenance [50] via one question adapted to satisfaction with UVR protection based on Rothman's work on satisfaction with smoking cessation [4, 5]. Accordingly, we will ask "How satisfied are you with your

decision to engage in sun protection behavior this morning (or) this afternoon?" (1="Not at all satisfied," 2 for "a little satisfied," 3 for "moderately satisfied," 4 for "extremely satisfied.")

Within a week of completing the final IVR assessment on day 14, the study staff will call the participants to complete a brief program satisfaction survey consisting of 17 items to address any barriers to using the IVR. Additionally, in accordance with prior ecological momentary assessrrent research, the IVR will ask participants to self-report the extent to which the IVR prompting acted as a cue-to-action in their two-week assessment period of sun protection behavior. It is expected to take about 5 minutes to complete.

8.0 TOXICITIES/SIDE EFFECTS

Individuals may find it stressful to answer questions regarding their sun protection behaviors. The risk associated with answering these questions is expected to be minimal. Participants' level of distress will be carefully monitored by the research staff and by Dr. Hay. Participants may refuse any part of their participation, from answering questions that they find distressing, to refusing the home tour, or recording twice-daily audio narrative diaries through the IVR system. If a participant is significantly distressed, Dr. Hay or a covering attending will assess the participant and make an appropriate referral for clinical care if needed.

9.0 PRIMARY OUTCOMES

The following ultraviolet radiation protection (UVR) behaviors will be assessed as primary outcomes:

- Continuous sun avoidance and/or shade-seeking behavior
- Sunscreen use
- Use of UVR protective clothing
- Use of hats

Our first aim is to generate models explaining decision-making about three UVR protection behaviors (sunscreen use, shade-seeking, use of protective clothing) in melanoma FDRs. We will model daily decision-making processes for UVR protection through qualitative and quantitative research strategies. In Phase I, we will conduct in-home ethnographic interviews with 25 melanoma FDRs and generate a decision making model for each UVR protection behavior for each melanoma FDR, and subsequently construct a composite decision-making model for each of the UVR protection outcomes (i.e., sunscreen use, shade-seeking, and UVR protective clothing use) representing prominent decision making factors across all 25 FDRs interviewed. In Phase II we will establish the validity of the models via examination of daily decision-making about UVR protection using ecological momentary assessment via IVR (over 14 days in the summer/early fall, at approximately 12:30 pm and 5 pm daily) in 60 different melanoma FDRs from Phase I. As outlined in EDTM methodology, we will report on the level of success of the decision-making model in predicting uptake of each of the three UVR protection strategies.

Our second aim is to examine theory-driven affective and cognitive predictors of UVR protection maintenance (sunscreen use, shade-seeking, hat use, and use of UVR protective clothing) assessed in real time. We will examine the role of melanoma threat and efficacy beliefs in determining UVR protection maintenance drawn from Witte's Extended Parallel Processing Model [3], and will examine the role of satisfaction in UVR protection maintenance drawn from Rothman's theory of health behavior maintenance

[4-6]. We will examine both between-person and within-person changes in these predictors, as well as salient decision-making factors (Identified in Aim I), in predicting maintenance of sunscreen use, shade-seeking, hat use, and use of UVR protective clothing.

10.0 CRITERIA FOR REMOVAL FROM STUDY

Participants will be taken off study protocol under the following circumstances: 1) FDR voluntarily withdraws from study; 2) onset of severe cognitive impairment that makes participation in the study impossible, such as impaired ability to read or to provide accurate answers to the interviewer; 3) the participant expresses significant distress related to completion of the study assessments (the PI or a covering attending will refer the patient to clinical services if needed); or 4) if the study doctor believes it is in the participant's best interest to do so.

11.0 BIOSTATISTICS

Overview. This exploratory study is divided into two phases. Phase I involves in-home interviews of 25 participants to understand the factors that affect participants' decision-making about UVR protection (sunscreen use, shade-seeking, use of protective clothing). Qualitative data analyses will be carried out in Phase I to generate an Ethnographic Decision-Tree Modeling (EDTM) tree as described in Section 4.2. For example, a participant may be most likely to use sunscreen when it is a sunny day and when he/she is outdoors, at the beach, or at an outdoor sporting event. The participant may also state that he/she uses sunscreen whenever together with a young child, even though it may not be a sunny day.

In Phase II, we plan to recruit a sample of 60 melanoma first degree relatives (FDRs) and use IVR technology so that they can record their daily sun protection behaviors and decision criteria. The IVR system will call participants twice daily at approximately 12:30 pm and 5 pm for a period of 14 days. The participant will use their telephone keypad to answer a series of questions on their UVR protection behaviors, which will be four dichotomous, self-reported outcomes: sunscreen use, shade-seeking, hat use, and protective clothing use). The assessment will also address factors that affect UVR protection behaviors. These decision factors are based on the qualitative data we collected in Phase I. For example, we will ask participants to report the presence or absence of environmental factors (e.g., weather conditions), convenience/situational factors (e.g., availability of sun protection items), and social-interpersonal (e.g., activities engaged in). Data collected through IVR will generally be analyzed by Generalized Estimating Equations (GEEs) to explore the decision factors that promote or hinder the probability of UVR protection behavior.

Specific Aim I: To generate models explaining decision-making about three UVR protection behaviors (sunscreen use, shade-seeking, use of protective clothing) in melanoma FDRs.

Aim I will involve the EDTM methodology described in Section 4.2. Audio-recorded narrative data will be coded and summarized into an EDTM tree.

For example, decision factors such as convenience, weather, or social support for UVR protection may emerge as important factors. Because we are examining behaviors that involve highly complex interactions, we need to first understand the phenomenon more fully. Pertinent to Aim 1 is the use of descriptive statistics to summarize the sizes of the terminal decision nodes. Each node on the EDTM tree represents the pathway by which a person makes the decision to use or not to use UVR protection. The size of a terminal node in the EDTM tree represents the number of people who follow a specific decision

pathway. For example, we may fmd that many people do not use sunscreen if they do not find it before they leave home. In this hypothetical example, the decision factor of convenience trumps all other decision factors. We may therefore infer from the sizes of the nodes the importance of the corresponding decision pathways and specific decision splits. The most important advantage is that we will be better able to distinguish the factors that contribute to sunscreen nonuse from sunscreen use in order to separate the barriers from the facilitating decision factors.

Specific Aim II: To examine theory-driven affective and cognitive predictors of UVR protection maintenance (sunscreen use, shade-seeking, hat use, and use of UVR protective clothing) assessed in real time.

The general statistical paradigm for this Aim will be Generalized Estimating Equations (GEE) [83, 84] because of the repeated sampling of UVR protection behaviors and their predictors. Over a period of 14 days, each participant will generate a maximum of 28 assessrrents. Each assessment will yield 4 dichotomous outcome endpoints (sunscreen use, shade seeking, hat use and protective clothing). Additionally, each assessment will probe the decision factors, e.g., on environmental factors, convenience/situational factors, cognitive and social-interpersonal factors. For each outcome endpoint, we will fit a series of GEE models with a logit link. For example, we may fit the probability of stmscreen use as a function of weather (e.g., a dichotomous yes/no indicator of a sunny day). We will calculate the 95% confidence interval of the weather indicator on sunscreen use. The procedure will be repeated for other decision factors. We will use data visualization and graphs to summarize the 95% confidence intervals across decision factors, in the same exploratory procedures as outlined previously in O'Connor et al (2008).

Our exploratory GEEs approach is the most widely-used approach in the literature of intensive real-time data capture (aka Ecological Momentary Assessments, see Stone, 2009). Generally, these GEE models allow us to examme the extent to which each decision factor is associated with the health behaviors of interest. The repeated assessments will be clustered within persons. The working correlation structure will generally be fitted with an auto-regressive mode**1** because of the intensive daily assessments. The fmal number of covariates cannot be determined precisely at this time. However, care will be taken to minimize the number of confidence intervals to reduce concerns of multiple confidence intervals and to make the data more interpretable.

Power considerations.

We estimated the statistical power of a GEE model on sunscreen use. The GEE model has a single covariate (e.g., a weather indicator). An extensive literature search did not find prior data on UVR protection behaviors. However, we believe that an odds ratio of 1.55 is plausible and is not overly optimistic. A hypothetical example helps explain this 1.55 difference. Suppose on a given day, 30 people report that it is sunny and the other 30 report that it is not sunny. Then an odds ratio of 1.55 means that we will be able to detect a difference between 70% (21 / 30) and 60% (18 / 30) sunscreen use across the two groups. Our power calculation showed that a sample size of 60 would be adequate in detecting this 70% vs. 60% difference.

Our actual statistical power estimation was based on a more sophisticated Monte Carlo simulation approach [86] as we consider study attrition and missed assessments. Formulaic solutions for GEE power calculations were deemed inadequate for the current study because they do not apply (e.g., the present study involves no randomization to study arms [87, 88]). Our Monte Carlo simulation showed that, with a sample size of 60 melanoma FDRs, accounting for clustering effect, respondent attrition and missed assessrrents,

we will have 78% power to detect a 1.55 OR in a GEE predictor at a two-sided Type-I error rate of 0.01 (0.01 Type-I error to provide some control over multiple GEE models).

To account for correlated longitudinal sunscreen use data nested within study participants, we assumed in the power calculation an ARI correlation pattern with a 0.50 co-occurrence probability between two consecutive days of sunscreen use. This 0.50 co-occurrence probability was based on the expected co-occurrences if, at any given day, 21 of 30 respondents use sunscreen. We can use a simple 2x2 table to demonstrate that, with the fixed marginals at 21 on either day, the expected sunscreen use on both days is 15 persons (a joint probability of 0.50 = 15/30, below).

		Day 2	
		Use sunscreen (n=21)	No use (n=9)
Day 1	Use sunscreen (n=21)	15 (21*21)/30	6
	No use (n=9)	6	3

This 0.50 co-occurrence rate retween consecutive days of 0.70 sunscreen use translates into a tetrachoric correlation coefficient of 0.082 (by the commonprob2sigma() function in the R package bindata). We thus used a rounded 0.10 tetrachoric correlation between two consecutive days in our simulation of an ARI correlation matrix.

The simulations incorporated the following considerations of missing data. For rate of attrition, we assumed that 5% of the respondents will stop responding to the EMA assessments by the end of week 1, and 5% of the remaining respondents will be lost by the end of week Jwo. Thus, we assumed that we will retain 90% of the recruited respondents by the end of study period. Additionally, for any single assessment, there is a 30% probability that the assessment will be missing at random. We considered these missing data patterns because our prior LUCY data showed overall missing data patterns similar to these assumptions, so they are likely quite conservative given that LUCY subjects were quite ill.

Missing Data Analysis. Although we shall endeavor to obtain final evaluation data even for participants who discontinue the use of the hand-held device, we cannot rely on this and will use statistical methods appropriate when missing data may be informative. Data "missingness" may shed light on study features that affect feasibility. From our prior LUCY study we were able to attain a 89% completion rate for a 14-day period. This encouraging assessment completion rate notwithstanding, we will ascertain whether or not the number of completed IVR assessrrents differed between the sampling strata [78]. A significant difference will be evidence for missing not at random. For example, women may complete more assessments than rren do over the 14-day assessment period. If missingness is not at random, we will consider imputing the missing data using several missing data imputation techniques [79-81]. These techniques are appropriate for different data types, including continuous, dichotomous, and count data. Additionally, one recently published data imputation technique by Demirtas and Bedeker is especially suitable for dichotomous and/or ordered longitudinal missing data [82]. We will also consider the use of Pattern-Mixture Model to control for non-ignorable missing patterns. Pattern-Mixture Model assumes that participants can be grouped into a small number of implicit cohorts with different patterns of missing data. One such implicit cohort may include participants who miss only a handful of assessments. Conceivably, there may be a cohort of participants who miss a few consecutive days of assessments. Pattern-Mixture Model can statistically adjust for participants' missing data pattern in order to account for missing not at

random. The method models the typical trajectories ofresponses within each of these cohorts and combines results across cohorts to make overall comparisons between groups of individual participants. Thus, Pattern-Mixture Model corrects the potential statistical bias due to missing not at random, and may help identify subgroups that show the lowest response rate to the EMA. There is a SAS macro for Pattern-Mixture mode ling.

12.0 RESEARCH PARTICIPANT REGISTRATION AND RANDOMIZATION PROCEDURES

12.1 Research Participant Registration

Confirm eligibility as defmed in the section entitled Criteria for Patient/Subject Eligibility.

Obtain informed consent, by following procedures defined in section entitled Informed Consent Procedures.

During the registration process registering individuals will be required to complete a protocol specific Eligibility Checklist.

All participants must be registered through the Protocol Participant Registration (PPR) Office at Memorial Sloan-Kettering Cancer Center. PPR is available Monday through Friday from 8:30am-5:30pm at 646-735-8000. Registrations must be submitted via the PPR Electronic Registration System(http://pprQ. The completed signature page of the written consent/RA or verbal script/RA, a completed Eligibility Checklist and other relevant documents must be uploaded via the PPR Electronic Registration System

12.2 Randomization

Not applicable.

13.0 DATA MANAGEMENT ISSUES

Feasibility

According to the 2008 Memorial Sloan-Kettering Melanoma Disease Management Team Database, the Gastric/Mixed Tumor Service anticipates following approximately 400 post-surgical patients diagnosed with melanoma, and 400 additional melanoma patients as new visits. Of these, 85% were diagnosed with clinically localized disease. In our pilot recruitment studies with melanoma FDRs, we fmd that 84% of melanoma patients are willing to refer an FDR for behavioral research studies (the remainder refuse or do not have eligible FDRs). We anticipate a conservative FDR µtrticipation rate of 80% based on prior studies evaluating daily diary assessment of UVR protection in a comparable high-risk population [28, 29]. We will accept only one family member participant per family to exclude potential dependency in the data due to family membership. Thus for Phase I, we expect to have a patient pool of 228 that should result in 188 making a referral of an FDR Of these 188 FDRs, we anticipate 150 available FDRs available to meet our target participation of 25 FDRs. For Phase II we expect to have a patient pool of 285 that should result in 235 making a referral of an FDR. Of these 235 FDRs, we anticipate 188 available FDRs available to meet our target participation of 60 FDRs.

Data Management

Confidentiality of each participant's information will be protected with utmost care. Participants will be assigned an identification number that will be used for all study records. Participants will be identifiable solely by code number. The list of matching subject names and code numbers will be maintained in a locked file cabinet in a separate location in the Department of Psychiatry and Behavioral Sciences office at 641 Lexington Avenue, 7th Floor, New York, NY 10022. Completed research charts will be maintained in a locked file cabinet in a secured, locked office at the MSKCC Department of Psychiatry Research Offices. The data collected for this study will be entered into a secure database. Data management and statistical analysis will be done on a secured PC, licensed by the Department of Psychiatry and Behavioral Sciences. Data entry and analysis will occur in the MSKCC Deµirtment of Psychiatry and Behavioral Sciences office at 641 Lexington Avenue, 7th Floor, New York, NY 10022.

Once the participant completes an assessment using IVR, the data is stored on the MSKCC WebCore server. The data is stored using an ID number, not name. The data can be retrieved by accessing a web-based system with a login name and password (web address is http://webcore.mskcc.org). Each participant's data will be converted into an Excel file for ease of data checking and quality control A master file will contain all subject data and will be converted into a format amenable to data analyses. In the event that the *NR* system fails and we need to collect the data by phoning the participants, the data will entered manually into this same system regardless of whether we collect it by paper and pen first or enter directly into this web-based system. If we collect the data by paper and pen first, we will then enter it into this system and file the paper assessment in a locked file cabinet. Participants' audio narrative files will be stored on the MSKCC WebCore server as well. Web Core staff will upload the audio files to MSKCC's file transferring program for study staff to download and review.

13.1 Quality Assurance

Weekly registration reports will be generated to monitor participant accruals and completeness of registration data. Routine data quality reports will be generated to assess missing data and inconsistencies. Accrual rates and the extent and accuracy of evaluations and follow-up will be monitored periodically throughout the study period and potential problems will be brought to the attention of the study team for discussion and action.

Random-sample data quality and protocol compliance audits will be conducted by the study team, at a minimum of two times per year, more frequently if indicated.

In Phase I the in-home ethnographic interviews will be recorded using a digital voice recorder, with the permission of the participant. These digital audio files will be brought back to the Psychiatry and Behavioral Sciences offices and uploaded to our secure network drive the same day. In the event that they cannot be brought back same day (i.e. interview took place in the evening) the audio file will be uploaded to the secure network drive via VPN. Once the files have been safely uploaded to the secure network drive the file will be deleted from the recorder. The participant's name or any other personally identifying information will not be used in reports or publications of this study.

13.2 Data and Safety Monitoring

The Data and Safety Monitoring (DSM) Plans at Memorial Sloan-Kettering Cancer Center were approved by the National Cancer Institute in September 2001. The plans address the new policies set forth by the NCI in the document entitled "Policy of the National Cancer Institute for Data and Safety Monitoring of Clinical Trials" which can be found at: *http://www.cancer.gov/clink:altrials/conducting/dsm-guidelines/pagel*. The DSM Plans at MSKCC

were established and are monitored by the Office of Clinical Research. The MSKCC Data and Safety Monitoring Plans can be found on the MSKCC Intranet at: *http://smskpsps9/deptlocr/OCR%20Website%20Documents/Clinical%20Research%20Quality%20Assurance%20(CRQA)/MSKC<Y/o20Data%20and%20Safety%20Monitoring%20Planpdf*

There are several different mechanisms by which clinical trials are monitored for data, safety and quality. There are institutional processes in place for quality assurance (e.g., protocol monitoring, compliance and data verification audits, therapeutic response, and staff education on clinical research QA) and departmental procedures for quality control, plus there are two institutional committees that are responsible for monitoring the activities of our clinical trials programs. The committees: Data and Safety Monitoring Committee (DSMC) for Phase I and II clinical trials, and the Data and Safety Monitoring Board (DSMB) for Phase III clinical trials, report to the Center's Research Council and Institutional Review Board.

During the protocol development and review process, each protocol will be assessed for its level of risk and degree of monitoring required. Every type of protocol (e.g., NIH sponsored, in-house sponsored, industrial sponsored, NCI cooperative group, etc.) will be addressed and the monitoring procedures will be established at the time of protocol activation.

13.3 Regulatory Documentation

Participating site that are consulting and/or conducting specimen or data analysis should submit this protocol to their IRB according to local guidelines. Copies of any site IRB correspondence should be forwarded to MSKCC.

13.4 Audio Recordings

For Phase I, Ms. Shuk will be responsible for carefully handling all digital audio recorders and digital recordings (e.g. no cassette tapes) to ensure that all confidentiality procedures and HIPAA regulations are followed. All digital voice recorders will be stored in a locked file cabinet. When a research interview takes place, the interviewer turns on the recorder at the start of the interview. The interview will take place after introductions. The interviewer will avoid discussion of all protected health information on digital voice recordings.

When the interview is fmished, the interviewer turns off the recorder. The digital recorder should then be brought back to 641 Lexington Ave and uploaded to the shared H: drive in a restricted-access file. In the event that the interview takes places in the evening the digital audio file will be uploaded to the shared **H:** drive in a restricted-access file using VPN. Each digital audio recording is assigned and stored by a study ID, not name. Immediately after upload, the interview is deleted from the digital audio recorder.

For Phase II participants, we will instruct and emphasize to the participant not to include their name in the recorded audio diaries when we train the participants regarding use of the IVR before the assessment period commences. We will also instruct Phase 2 participants not to reveal the names of any other individuals in their audio diaries, but instead refer to other individuals by either "friend," "family member," or by some other role description as appropriate. The study staff will remind Phase 2 participants on both of these points during follow-up phone calls during the assessment period.

In-home interview digital audio recordings will be transcribed by the professional transcription service R. A. Fisher Ink. All files will be transmitted electronically to the transcription service through MSK's secure File Transfer System. Complete transcripts are transmitted electronically from the transcription service to the study staff via a JRSSword protected file transfer protocol (ftp). When the transcripts are received, the study staff downloads them to the departmental shared H: drive in a restricted-access folder. The transcription service does not share local drives over the internet, and all files are removed upon completion. A Business Associate Agreement (BAA) detailing these procedures will be signed by both the Principal Investigator for this study and the professional transcription service and stored in the research files. It will be specified to the transcriber that if any names are identified on the digital audio file that it should be transcribed as initials.

14.0 PROTECTION OF IRJMAN SUBJECTS

There are two main risks for participants in this study: 1) individuals may find it stressful to answer questions regarding their sun protection behaviors; and 2) breaches of confidentiality. Minimal risk of psychological distress is posed by study questions that ask participants to identify their current behaviors regarding sun protection. Reactions of participants in Phase 1 of the study will be observed during the in-home interview. The PI or a covering attending will follow up with participants who show signs of significant distress. Although participants may indirectly benefit from greater understanding of decision-making in relation to sun protection behaviors, there is no guarantee of benefit to participants based on study participation. There are no fmancial costs to FDRs for JRrticipating in this study. Participants in Phase I and participants in Phase II will each receive $50 in cash or money order for their time and effort on the study.

Participants will be informed that information collected during their participation in this study is considered confidential. To ensure confidentiality of data, all records will be identified by the participant's identification number, not by name, and will be stored in a locked secure area. All participants are provided a phone number in the informed consent that they can use if they are interested in receiving the overall results of the study.

A list matching participants' names and code numbers will be maintained separately and kept in a locked secure area in the Department of Psychiatry and Behavioral Sciences at 641 Lexington Avenue. Only the PT, Co-PT, and MSKCC research staff will have access to the records. Electronic data sheets and records will be maintained on MSKCC servers, with password protected log-on and secure back-ups per MSKCC IS SOP. Computer files will only be available to those granted permission to use the approved access code. All necessary precautions will be taken to ensure that there is no breach of confidentiality.

Participation in this study is entirely voluntary. All participants will be required to provide written or verbal informed consent that adheres to MSKCC guidelines. FDRs may decide not to participate in this study or to withdraw their consent to participate at any time during this study.

14.1 Privacy

MSKCC's Privacy Office may allow the use and disclosure of protected health information pursuant to a completed and signed Research Authorization form. The use and disclosure of protected health information will be limited to the individuals described in the Research

Authorization form. A Research Authorization form must be completed by the Principal Investigator and approved by the IRB and Privacy Board (IRB/PB).

14.2 Serious Adverse Event (SAE) Reporting

Only SAEs related to the protocol intervention will be reported to the IRB. Any SAE must be reported to the IRB/PB as soon as possible but no later than 5 calendar days. The IRB/PB requires a Clinical Research Database (CRDB) SAE report be submitted electronically to the SAE Office at sae@mskcc.org containing the following information:

Fields populated from CRDB:

- Subject's name (generate the report with only initials if it will be sent outside of MSKCC)
- Disease/histology (if applicable)
- Protocol number and title

Data needing to be entered:

- The date the adverse event occurred
- The adverse event
- Relationship of the adverse event to the treatment (drug, device, or intervention)
- If the AE was expected
- The severity of the AE
- The intervention
- Detailed text that includes the following
    - A explanation of how the AE was handled
    - A description of the subject's condition
    - Indication if the subject remains on the study
    - If an amendment will need to be made to the protocol and/or consent form.

The Pl's signature and the date it was signed are required on the completed report.

15.0 INFORMED CONSENT PROCEDURES

All potential participants will be informed as to their rights as volunteers in a research study. For both Phase I and II, if an FDR is not present with the patient in clinic, the study staff will collect contact information from the patient about their FDR to be able to contact their FDR. The study staff will then mail the FDR a study brochure and informed consent and then contact them to discuss the study and determine their interest in participating. For Phase I, the consenting will be done at their home, however, for Phase II it will be done within a week of their 14-day assessment period begim1ing. Depending on when this period is, participants can be consented either in clinic or verbally over the phone. If the FDR is present in the clinic with the patient, the study staff will determine their eligibility and, for phase I, arrange to have Ms. Shuk come to their house where the consenting will take place. The study staff will obtain 2 copies of the informed consent, one for the participant and one for the research record. The study staff or Ms. Shuk will arrange for a convenient time for the in-home interview and home tour for phase 1.

Before protocol-specified procedures are carried out, consenting professionals will explain full details of the protocol and study procedures as well as the risks involved to participants prior to their inclusion in the

study. Participants will also be informed that they are free to withdraw from the study at any time. All participants must sign an !RB/PB-approved consent form indicating their consent to participate. This consent form meets the requirements of the Code of Federal Regulations and the Institutional Review Board/Privacy Board of this Center. The consent form will include the following:

1. The nature and objectives, potential risks and benefits of the intended study.
2. The length of study and the likely follow-up required.
3. Altematives to the proposed study. (This will include available standard and investigational therapies. In addition, patients will be offered an option of supportive care for therapeutic studies.)
4. The name of the investigator(s) responsible for the protocol.
5. The right of the participant to accept or refuse study interventions/interactions and to withdraw from participation at any time.

Before any protocol-specific procedures can be carried out, the consenting professional will fully explain the aspects of µttient privacy concerning research specific infonnation. In addition to signing the IRB Informed Consent, all patients must agree to the Research Authorization component of the informed consent form.

Each participant and consenting professional will sign the consent form. The participant must receive a copy of the signed informed consent form.

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17.0 APPENDICES

APPENDIX A: PARTICIPANT SCREENING FORM
APPENDIX B: ETHNOGRAPHIC SEMI-STRUCTURED IN-HOME INTERVIEW GUIDE
APPENDIX C: IVR DIARY ASSESSMENT
APPENDIX D: IVR TRAINING TELEPHONE SCRIPT/MANUAL
APPENDIX E: STUDY BROCHURE: PHASE I
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APPENDIX G: PHASE I: INTRODUCTION LETTER
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APPENDIX L: EXAMPLE PHASE 2 IVR RESPONSE CARD & STICKER
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APPENDIX N: PROGRAM SATISFACTION SURVEY
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APPEND T: 2013 RECRUITMENT LETTER