PROTOCOL TITLE: Helping All Children be Safe Outdoors with Sun Protection

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1.0 Protocol Title
Helping All Children be Safe Outdoors with Sun Protection

2.0 IRB Review History*
Approval of this research by the Northwestern University IRB has been obtained. This study has Northwestern IRB protocol ID STU00200215 and was approved on 2/18/2015. The Northwestern University Biomedical Research IRB can be contacted at (312) 503-9338 or irb@northwestern.edu.

3.0 Objectives

3.1 This novel research seeks to develop a multicomponent sun protection program that is feasible for family practice and pediatric clinicians to introduce with anticipatory guidance during well-child visits. The program will further be implemented through a sun protection read-along book in English and Spanish and weekly text message reminders. Electronic messaging is a powerful medium for communicating health information to underserved populations.

3.2 The sun protection program will enable behavioral change by caregivers and children of all ethnic and racial backgrounds. Testing the feasibility of delivering the intervention in a family medicine or pediatric practice will allow assessment of accrual and retention rates in a racially/ethnically diverse population, and lead the way to dissemination of good practice.

3.3 This proposal to improve sun protection of young children seeks to:

A) Deliver a short (13 pages) read-along book in English and Spanish for 2-6 year old children to read with their parent or caregiver, and text message reminders intended to change the knowledge, beliefs, intentions or behaviors of parents/caregivers and the for children under their care.

B) Obtain recommendations from an advisory committee of pediatric clinicians for implementing sun protection counseling with parents of well children 2-6 years old during the health care visit.

C) Perform a trial with randomization by clinic practice to either the intervention or control arm to examine whether a multicomponent sun protection educational intervention delivered over 4 weeks in summer enhances the use of sun protection among 2-6 year old children.

4.0 Background

4.1 Melanoma is the third most common form of cancer in adolescents and young adults in the United States. (Purdue 2008) Unprotected sun exposure, particularly during childhood, is an important contributing factor in the risk of developing melanoma later in life. (Whiteman 2001) The increasing incidence of melanoma among Latinos, the fastest growing segment of the population, approaches that among Whites. Melanoma incidence among US Latinos has increased at an annual rate of 2.9% in the last fifteen years, which is comparable to the 3.0% annual increase among Whites. (Ries 2007)
To address the rising incidence of skin cancers, including melanoma, the US Surgeon General recently issued a call to action. (U.S. Department of Health and Human Services 2014) At present, preventive health education intended to inform the public about melanoma has emphasized the risk of having “fair skin” or blistering sunburns. Ethnic minorities are often excluded from public health messages linking sun protection to prevention of sunburn and skin cancer. Latino and Black people display considerable diversity in skin pigmentation, which is also referred to as skin tone. Regardless of their skin tone, most Latinos and Blacks expect that the pigment in their skin is protective. The term, “people with skin of color”, is used to indicate racial and ethnic origins, especially people with multiracial ancestry; thus, the term refers to people who self-identify as Hispanic/Latino, Black, Asian or Pacific Islander, and Native American, Aleut or Eskimo. People with skin of color often do not perceive sunburn or skin cancer as a risk because they and their families lack experience with skin cancer or sunburn and with using sun protection.

Assessment of the risk of sunburn is based upon the subject’s self-report of ease of sunburn and tanning, known as skin phototype. (Table 1) While responses to the Fitzpatrick Skin Phototype (SPT) questions may be unreliable due to recall bias, subjective bias by clinicians and subjects, and lack of cultural sensitivity, the basic flaw is that the subject must have experienced sunburn in order to be able to answer the question. There has been a tendency to group all people of a similar ethnic group into a single category of SPT. The “gold standard” method of assessing skin pigmentation is reflectance spectrophotometry (RS). Skin pigmentation or melanin provides photoprotection and can be calculated as melanin index (MI). While those that are at risk to develop skin cancer have less melanin content (skin type I) than those at low risk (skin type VI), people with skin phototypes in the mid-range (III and IV) believe that their natural skin tone is protective against sunburns, thus, they fail to use sun protection.

<table>
<thead>
<tr>
<th>Skin type: Erythema and Tanning Reactions to the First Summer Exposure (Fitzpatrick 1988)</th>
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<tbody>
<tr>
<td>I</td>
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<td>VI</td>
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4.2 Targeting 2-6 year old children for primary prevention of skin cancer will minimize sun damage and may foster lifelong sun–protective behaviors that will reduce the likelihood of developing skin cancer, especially melanoma. Parental beliefs about and involvement
in sun protection are important components of successful skin cancer prevention programs for children, especially young children. Parents control family resources and activities and the availability of sunscreen and protective clothing. (Buller 1995) Among US white children aged 6 months to 11 years, 43% experienced one or more sunburns within the past year, with sunscreen (62%) and shade (27%) being the most frequently reported protection methods. (Hall 2001) High sunburn rates among youth highlight the need for better education of parents and caregivers about appropriate sun protective behaviors. While sunscreen is a very convenient and the customary form of sun protection, sunscreen as the sole form of sun protection has some downfalls for the user including failure to protect some areas of the body, cost, messy application, and wearing off with physical activities like swimming. (Cokkinides 2006, Saraiya 2004, Mahe 2011, Banks 1992) Some parents apply sunscreen incorrectly or inconsistently, e.g. only after a child has experienced a painful sunburn. (Robinson 2000) The cost of sunscreen, especially in the setting of daily use and reapplication after swimming, can be expensive and unmanageable for families of lower socioeconomic status (SES). (Mahe 2011) Sun protective clothing provides sun protection when wet and a child can put it on, thus, providing consistent protection. (Harrison 2010) Sunscreens and sun protective clothing are effective in reducing the number of moles-precursors of and the strongest risk factor for development of melanoma—among children. (Gallagher 2000, Smith 2013) Sun protective clothing, including hats and swim shirts, as an additional and helpful form of sun protection for young children could be adopted by caregivers as a cost-effective and reliable method that could reduce the incidence of skin cancer in the future.

4.3 Family practice and pediatric clinicians recognize the importance of reducing sun exposure in young children and are able to counsel caregivers effectively; however, sun protection counseling is often associated with parental prompting, the child presenting with sunburn, or performing a summer camp physical (Cohen L 2012). Sun protection counseling by pediatric clinicians has been thought to be most effective when delivered with seasonal relevance, during the spring and summer months in northern latitudes. The American Academy of Pediatrics has acknowledged that skin cancer prevention is a matter of importance to clinicians and typically is “discussed on at least a few visits over the course of the relationship with a patient.” (Balk 2011)

Pediatricians have given bilingual read-along books to parents of Hispanic children 5-11 months old to promote literacy in Hispanic families (Golova 1999). Because healthcare providers are a trusted and important source of health information, having the pediatrician recommend and distribute the read-along book is expected to enhance the effectiveness of the intervention. By adapting the read-along book strategy to sun protection education, the strong, natural and immediate connection between parents and their children can be used as a catalyst to create a mutually supportive environment that effectively encourages both parties to develop the skills needed to make life-long sun healthy habits. Caregivers may participate in reading to/with the child. A caregiver is defined as a non-parental adult who assumes responsibility, at least part-time on a regular basis, for the care of at least one child, e.g. babysitters, grandparents, mother’s helpers, professional nannies, or other family members). Among low-income families, young children often are cared for by a grandparent or “auntie.”
5.0 **Inclusion and Exclusion Criteria**

5.1 Research assistants will screen potential participants for eligibility onsite prior to obtaining informed consent. Clinicians performing well-child visits may identify potentially eligible participants and notify the research assistants.

5.2 **a) Inclusion criteria**

- Are at least 18 years old
- Is the parent of a 2-6 year old child attending a well-child visit
  - If the parent present is female, she may be pregnant
- Are able to read in English and/or Spanish at a 6th grade level or higher
- Are able to receive text messages

5.2 **b) Exclusion criteria**

- Is the parent of a child less than 2 or older than 6 years old attending a visit
- Unable to read in English and/or Spanish at a 6th grade level or higher
- Unable to receive text messages
- Unable to complete study procedures with eligible child
- Unable to return to clinic for a follow-up visit

5.3 Pregnant women are included in this research. This study is social behavioral in nature; it does not pose risks to an embryo or fetus. This research meets the criteria for Non-Federally Regulated Minimal Risk Research outlined in section 1.0 of HRP-412, Checklist for Pregnant Women. Furthermore, while children are not study subjects, this research meets the criteria for section 2.0 of HRP-416, Checklist for Children. No greater than Minimal Risk to children is presented in obtaining melanin index. There are no safety matters identified in the use of Mexameter MX18.

6.0 **Study-Wide Number of Subjects**

N/A. Please refer to 25.0, Local Number of Subjects

7.0 **Study-Wide Recruitment Methods**

N/A. Please refer to 24.0, Recruitment Methods

8.0 **Study Timelines**

8.1 An individual subject’s participation in the study consists of two visits, each 20-30 minutes in length. The first visit, or Baseline, may occur in conjunction with or be scheduled independently of the well-child visit. The second visit, or Follow-up, will take place four after the Baseline. The duration anticipated to enroll all study subjects is approximately six weeks, from May 18 to July 6, 2015. The four week follow-up visits will be performed at the study sites from June 18 to August 14, 2015. The estimated date for the investigator to complete primary analyses for this study is October 1, 2015.

9.0 **Study Endpoints and Statistical Analysis**
9.1 Change in the use of sun protection from baseline to 4 week follow-up by those in the control vs intervention groups is the primary endpoint. Secondary endpoints are the number of sunburns or irritation from the sun experienced by the child. Biologic confirmation of the parental report of sun protection will be obtained with spectrophotometry measurements of melanin index (means with 95% confidence intervals) in the sun protected upper outer arm vs the sun exposed forearm in controls vs intervention groups.

9.2 Statistical analysis

To test for attrition bias, participants who did not complete the study will be compared to participants who did complete on baseline measures. Chi-square tests will be performed for categorical variables (e.g., race) and t-tests will be performed for continuous variables (e.g., sunscreen use).

The primary outcome measure, use of sun protection behaviors on both sunny and cloudy days, will be assessed with two 2 (condition) by 2 (time) mixed measures analyses of variances (ANOVAs), one for the sunny day behaviors scale and one for the cloudy day behaviors scale.

Statistical differences between the different spectrophotometry measurements of melanin index for each Skin Phototype group will be analyzed via one-way ANOVA followed by Tukey’s post hoc test.

10.0 Procedures Involved*

10.1 This is a 12-week summer pilot study to determine the outcome of an educational intervention including the swim shirt provided to caregivers, the ability to recruit subjects, and the number of subjects lost to follow-up. Advocate Medical Group sites in Oak Lawn, IL and Park Ridge, IL have agreed to participate in the research. All physicians of these practices have appointments at Advocate Children’s Hospital. (Appendix. Letters of support) The racial/ethnic distribution of the Oak Lawn and Park Ridge population is 26% and 9% Hispanic, respectively; the remainder of the population in both locations is approximately 90% White. Given the target population, all subject study materials will be available in both English and Spanish. Research assistants (RA) involved on this project will be bicultural and bilingual in English and Spanish.

10.2 Baseline Visit and Randomization

Eligible parents will be offered inclusion, and a RA will obtain written informed consent. To ensure anonymity of response, each participant will be assigned a unique subject code upon consent. Only the subject code will appear on study materials. Parents will be asked to complete a short self-report questionnaire that can be completed in about 3 minutes. The survey will assess parental demographic information, history of sun sensitivity of the skin and skin cancer, in addition to the parents’ perception of their risk of developing skin cancer, child’s demographic information, and child’s sun sensitivity of the skin. (Appendix. Parent Self-Report Surveys) Parents who self-identify as Hispanic or
Latino on the self-report survey will be asked to complete a one-page acculturation instrument. (Appendix. Acculturation Measure) The RA will then take an instant, painless spectrophotometry reading of the melanin index (measurement of skin pigmentation) of child’s arm at three locations, as described in detail below. Block randomization will be done by day, e.g. all subjects accrued on Monday will receive the intervention and all subjects accrued on Tuesday will be assigned to the control group. This randomization assures that contamination of the control group will not occur when the intervention materials (read-along book and swim shirts) are distributed at the baseline visit. At intervention, RAs will distribute the read-along book, and swim shirt to the parents at the baseline visit. (Appendix. Anticipatory Guidance Tip Sheet, Read-Along Book) Parents in the intervention group will receive weekly text-message reminders to practice sun protection at 1, 2, 3, and 4 weeks post baseline visit. At the four week follow-up visit, parents in the control group will receive all materials of the educational intervention including swim shirts. Upon completion of the baseline visit, parents will receive a $20 Target gift card.

Follow-up Visit

Parents will be instructed to return with the child to the study site where consent was obtained. RAs will schedule the follow-up visits directly with the parents 4 weeks after the baseline visit; evening and Saturday appointments will be offered. Parents at both sites will be asked to complete a short follow-up self-report questionnaire. (Appendix. Parent Self-Report Surveys) RAs will then take a spectrophotometry reading of the melanin index of the child’s arm. Parents in the control group will receive anticipatory guidance tip sheet, read-along book, and swim shirt at this time. Upon completion of the follow-up visit, parents will receive a $50 Target gift card.

Melanin Index by Spectrophotometry

Skin pigmentation or melanin provides photoprotection and can be calculated as melanin index, MI. The “gold standard” method of assessing skin pigmentation is reflectance spectrophotometry (RS). Pershing et al performed seminal research comparing the area under the curve obtained by RS to profile the constitutive skin color with clinicians’ assessment of SPT. (Pershing 2008). The reflectance spectrophotometer Mexameter MX18 will be used in this study. A 2 cm² area of skin that is free of dermatologic disease will be determined by the trained RA. The probe of the portable reflectance spectrophotometer is lightly applied to the surface of the skin at three locations: right upper inner arm (natural skin color or constitutive pigmentation), right dorsum forearm (sun-exposed skin), and right dorsum upper arm (sun-protected skin when using the swim shirt).
10.3 The source records that will be used to collect data about the subjects are self-report questionnaires. They include the Baseline Self-Report, Control Follow-up, and Intervention Follow-up surveys. Research assistants will record melanin index readings in the designated space on the Baseline and Follow-up Self Report surveys.

10.4 The data that will be collected by self-report of the parent about themselves and about the child are listed below. The only follow-up will be four weeks after baseline; subjects will not be contacted after study completion.

- Melanin Index at baseline and follow-up visits via spectrophotometry measurement of child’s right upper inner arm, right dorsum forearm, right dorsum upper arm. Spectrophotometer measurement is the wavelength of the reflected light measured in nm. It represents the area under the curve for the all wavelengths of light, thus a reading will be expressed as (192 ±30, mean ± SD).
- Demographic information consisting of age, gender, education, annual household income, and race/ethnicity of the parent.
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- History of skin cancer and sun sensitivity of the skin of the parent
- Perception of parent’s risk of developing skin cancer
- Demographic information consisting of age and gender of the child
- History of sun sensitivity of the child with ease of sunburn and tanning
- Number of sunburns/skin irritation from the sun in the past month
- Use of sun safety behavior (wearing sunscreen, shirts with sleeves, hats with a brim, and sunglasses, and seeking shade) and duration of outdoor activities

11.0 Data and Specimen Banking

12.0 Data Management and Sample Size

12.1 The use of sun protection in those receiving the intervention vs the control group will be examined for correlation with 1) melanin index of child’s arm, 2) the history of skin cancer and sun sensitivity of the skin of the parent, 3) Perception of parent’s risk of developing skin cancer, 4) Demographic data of the parent, 5) Age and gender of the child, 6) Sun sensitivity of the child’s skin.

Spectrophotometry measurements of melanin index are presented as means with 95% confidence intervals.

12.2 The sample size is based on the use of sun protection, our primary outcome. Preliminary data obtained in the summer of 2014 show that 63% of caregivers of children 2-6 years old use some form of sun protection for the child. After counseling by pediatric clinicians, 20% used swim shirts. The sample size required to sensitively detect a 20% difference in using sun protection between the control and the intervention groups (63% vs. 83%) was 300 (150 in each group), assuming an alpha < 0.05 and power >= 0.8 in a two-tailed test. With 20% attrition based on the reported failure to keep appointments reported by these practices, 240 subjects will complete the study. This will adequately power the study for detecting 20% difference in sun protection use between the groups.

12.3 Subject medical information obtained as a result of this study is considered confidential and disclosure to third parties other than the principal investigator and the co-investigators is prohibited. All reports and communications relating to subjects in this study will identify each subject only by their initials and study identification number. To ensure subject confidentiality and anonymity of response, each subject will be assigned a unique subject code upon consent. Only this unique subject code will appear on study materials and an encrypted, password-protected database. Access to study access is restricted to authorized research staff, which is under the discretion of the principal investigator. The research files will be kept in a locked cabinet in a locked room within the Northwestern University Department of Dermatology research offices. Identifiable data will be kept separate from the case report forms and source documents. Data gathered as a result of this study are available to inspection on request by Food and Drug Administration or other government regulatory agency auditors, and the Northwestern University Institutional Review Board (IRB).
12.4 Collected data will be monitored and regularly undergo quality control. The role of one research assistant will be dedicated to collecting completed source documents from each site and entering data into the encrypted study database. The administrative research coordinator will perform routine data assurance by cross checking the paper surveys with the entered values.

13.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

N/A. This research is Minimal Risk to subjects.

14.0 Withdrawal of Subjects

14.1 The circumstances under which subjects may be withdrawn from the research without their consent are that they are 1) lost to follow-up or 2) unable or unwilling to complete study procedures.

14.2 It is anticipated that approximately 20% of consented subjects will fail to complete the follow-up. Subjects will be contacted by the research team to reschedule a missed visit. Once due diligence is completed via three unanswered phone calls, texts, or e-mails, the subject will be considered terminated from the research.

14.3 All data collected from terminated subjects will be excluded from the final data set.

15.0 Risks to Subjects

15.1 This research does not involve any physical risks other than what the subject and subject’s child would encounter in daily life. However, there may be minimal emotional discomfort in responding to survey items involving demographic information and history of skin cancer. Subjects will be informed that they may decline to respond to any of the survey items.

There are no anticipated adverse events associated with study procedures. To date, there are no safety matters identified in the use of Mexa meter MX18. This device has been utilized without issue in over 600 subjects collectively enrolled in prior studies.

16.0 Potential Benefits to Subjects

16.1 Subjects and their child may learn how to use sun protection effectively to prevent sunburns and reduce the likelihood of developing skin cancer. Subjects may also help the researchers learn better ways to present health information to patients in the future.

17.0 Vulnerable Populations

Subjects in the study may include employees (such as departmental staff with children). To avoid coercion, employees will be recruited for participation by study personnel that are not Advocate employees and therefore not managers of the institution.

18.0 Multi-Site Research

N/A
19.0 Community-Based Participatory Research

N/A

20.0 Sharing of Results with Subjects

20.1 Research assistants may inform the subject of their child’s individual melanin index readings.

21.0 Setting

21.1 The director of the Advocate Center for Pediatric Research, Denise Angst, PhD, RN, has committed to support this collaborative research. (Appendix. Letter of Support) Advocate Medical Group sites in Oak Lawn, IL and Park Ridge, IL have agreed to participate in the research. All physicians of these practices have appointments at Advocate Children’s Hospital. The clinical sites are:

- Advocate Children’s Hospital – Oak Lawn, IL
  - 4440 West 95th Street
  - Oak Lawn, IL 60453
- Advocate Children’s Hospital – Park Ridge, IL
  - 1675 Dempster Street
  - Park Ridge, IL 60068

21.2 Potential subjects will be identified at each clinic site. A flyer containing study information and research staff contact details will be placed in patient areas of the clinics. (Appendix. Study Flyer) In conjunction with well-child visits, pediatric clinicians may identify potential subjects and refer them to the onsite research assistants.

The clinic manager of each study site has completed a checklist to ensure consistency of protocol implementation and designation of a quiet, private space for study procedures. These areas may include exam rooms, partitioned areas of waiting room, or unoccupied office.

A total of four RAs will be dedicated to the study. Two RAs will be present at each site on pre-designated dates and times to conduct study procedures.

22.0 Resources Available

22.1 All members of the research team have completed and maintained current Human Subjects Protection Training, such as CITI and the Department of Dermatology compliance modules. The PI has over 25 years of clinical research experience, including multiple NIH-funded studies. The PI and research staff has personally met with the Director of the Advocate Center for Pediatric Research and with several pediatricians of the participating Advocate Medical Group sites to develop the current research.
Given the target subject population, all subject study materials will be available in both English and Spanish. The research assistants involved on this project are bicultural and bilingual in English and Spanish. The PI and research coordinator will oversee the research assistants. All research assistants are required to complete Human Subjects Protection Training and undergo study-specific training with the PI and research coordinator prior to interacting with potential subjects.

The sample size of the study population was determined from the number of collective well-child visits that occurred at the participating study sites in May 2014. Given that there were approximately 312 eligible children in one month at the study sites who met our inclusion criteria, extending the accrual over 6 weeks gives an anticipated 500 eligible subjects with 80% participation rate will give us 374 participants. With 20% attrition based on the reported failure to keep appointments reported by these practices, 240 subjects will complete the study. This will adequately power the study for detecting 20% difference in sun protection use between the groups. Based on these projections, it is feasible that the enrollment goal will be met within the agreed recruitment period.

This is a 12-week summer pilot study that will take place from May 18 to August 14, 2015. At least two research assistants will be present at each site on pre-designated dates and times to conduct study procedures.

The research will take place at the pediatric clinics of the Advocate Medical Group listed in 21.1. The clinic manager of each study site has completed a checklist to ensure consistency of protocol implementation. The PI and research coordinator will complete site visits prior to start of study to review action planning and complete training with participating staff. Each site will have a designated quiet, private space for study procedures, such as an exam room, partitioned area of waiting room, or unoccupied office.

There are no anticipated adverse consequences associated with the research. However, should a subject request medical or psychological resources, the PI and participating pediatric clinicians are available for debriefing.

The PI will ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions. The PI and research coordinator will train all individuals involved in study procedures and personally meet on a weekly basis to discuss study progress and review duties and functions as applicable. A continual, open dialogue among the PI, coordinator, and research assistants will be encouraged.

23.0 Prior Approvals

Approval by the Northwestern University IRB will be obtained prior to commencing the research.

24.0 Recruitment Methods

Potential subjects will be recruited at each study site over six weeks from May 18 to July 6, 2015. A flyer containing study information and research staff contact details will be placed in patient areas of the clinics. (Appendix. Study Flyer) In conjunction with well-child visits, pediatric clinicians may identify potential subjects and refer them to the onsite research assistants. The research assistants may recruit potential subjects while
they are waiting for an appointment. Potential subjects that express a willingness to participate will be referred directly to the onsite research assistants. The research assistants will then describe the study and answer any questions the potential subject may have. Should potential subjects be unable to complete the Baseline on the same day as their child’s well-visit, they will be instructed to schedule with the research assistants another date and time to return to the site and complete the Baseline.

24.2 Subjects will solely be recruited from the participating study sites: Advocate Children’s Hospital - Oak Lawn, IL and Advocate Children’s Hospital - Park Ridge, IL.

24.3 The pediatric clinicians and clinic managers at the participating study sites will be trained in the research protocol and will have knowledge of the inclusion and exclusion criteria. Any potential subjects that meet these criteria and express interest in participating in the research will be directed to the onsite research assistants. Should the research assistant not be present, the pediatric clinician and clinic managers will provide the potential subject with a study flyer and instruct him/her to contact the research staff for more information. Research assistants will keep a log of all potential subjects contacted.

24.4 A flyer containing study information and research staff contact details (i.e. phone number and email address) will be placed in patient areas of the clinics.

24.5 Upon completion of the first visit (Baseline), subjects will receive a $20 Target gift card. Upon completion of the second visit (Follow-up), subjects will receive a $50 Target gift card.

25.0 Local Number of Subjects

25.1 The total number of subjects to be accrued in this study is 300.

25.2 There will be 150 subjects randomized to the intervention group, and 150 subjects randomized to the control group. It is estimated that 60 subjects will be lost to follow-up.

25.3 There is a 20% attrition based on the reported failure to keep appointments reported by the participating sites. It is anticipated that 240 subjects will complete the study. This will adequately power the study for detecting a 20% difference in sun protection use between the groups.

26.0 Confidentiality

26.1 Subject medical information obtained as a result of this study is considered confidential and disclosure to third parties other than the principal investigator and the co-investigators is prohibited. All reports and communications relating to subjects in this study will identify each subject only by their initials and study identification number. To ensure subject confidentiality and anonymity of response, each subject will be assigned a unique subject code upon consent. Only this unique subject code will appear on study materials and an encrypted, password-protected database. Access to study access is restricted to authorized research staff, which is under the discretion of the principal investigator. The research files will be kept in a locked cabinet in a locked room within the Northwestern University Department of Dermatology research offices. Identifiable
data will be kept separate from the case report forms and source documents. Data gathered as a result of this study are available to inspection on request by Food and Drug Administration or other government regulatory agency auditors, and the Northwestern University Institutional Review Board (IRB).

27.0 Provisions to Protect the Privacy Interests of Subjects

27.1 This research includes provisions for protecting the privacy of potential and current subjects. All study procedures will take place in a designated quiet, secluded area of the pediatric clinic. The sole physical measurement of this research, melanin index, will be performed in a private setting. The research team will make every effort to address the questions and concerns of potential and current subjects. Furthermore, the research team will ensure interactions with potential and current subjects are not overheard.

27.2 This research includes steps to make subjects feel at ease. To reduce the sense of intrusiveness a subject may experience in response to survey questions, subjects will be informed that they may decline to provide any information they do not wish to disclose. The information being collected is limited to only the minimum amount of data necessary to accomplish the research purposes.

27.3 The research team will only be permitted to access study-related, subject-reported information. Under no circumstances will the research team access subjects’ medical records or other sensitive information.

28.0 Compensation for Research-Related Injury

N/A. This research is Minimal Risk to subjects.

29.0 Economic Burden to Subjects

N/A

30.0 Consent Process

30.1 Informed consent will be obtained. The consent process will take place in a quiet, private space of the clinic, i.e. exam room, partitioned areas of waiting room, or unoccupied office. A waiting period is available between informing the prospective subject and obtaining consent. In this case, time will be arranged for a follow-up discussion to help the prospective subject further understand the details of participation in the research and their subject rights. The research team will follow the consent process as outlined in SOP: Informed Consent Process for Research (HRP-090).

Other than English, Spanish is understood by prospective subjects and representatives. This research anticipates enrolling subjects that do not speak English. To ensure that the oral and written information provided to those subjects will be in subjects’ preferred language, the onsite research assistants are bicultural and bilingual in both English and Spanish. The Spanish language will be used by research assistants in obtaining consent and communicating any relevant future research information. All study materials (i.e. consent form, surveys, educational materials) will be available in English and Spanish and provided to the subjects in English and/or Spanish.
31.0 Process to Document Consent in Writing

The research team will follow the SOP: Written Documentation of Consent (HRP-091).

32.0 Drugs or Devices

N/A

33.0 Glossary of acronyms

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<th>Acronym</th>
<th>Meaning</th>
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<td>ANOVA</td>
<td>analysis of variance</td>
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<td>SD</td>
<td>standard deviation</td>
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<td>melanin index</td>
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34.0 References


