***NHMRC Human Research Ethics Application (HREA)***

*The* [*OREI website*](about:blank) *has information for QUT researchers.*

*The Human Research Ethics Application can be accessed at* [*https://hrea.gov.au/*](about:blank)

*The following document is a template for the proposal/protocol which is a HREA-required item for submissions.*

**Project description/protocol for human research**

**Guiding principles**

* the purpose of a research proposal/protocol is to provide the scientific and academic background and context of a research project
* not all headings or sub-headings in this template are relevant for each research project
* clinical trial proposals may use alternative protocol templates e.g. [SPIRIT statement](about:blank)
* use language that is understandable to non-technical reviewers.

**PROJECT DESCRIPTION/PROTOCOL**

**Title: The SAY (Sunscreen and Young Children) Study, Version 1**

1. **Project outline**

The purpose of this observational cross-sectional study will be to look at the beliefs and attitudes relating to the use of sunscreen and other sun protective behaviour in young children. The study will also look at barriers to the use of sunscreen and other sun protective behaviours in young children, will measure the amount of photoaging (wrinkling) and the amount of sunscreen applied to young child both before and after an intervention. The intervention will involve either daily text message reminders or the daily use of Suncayr stickers which will change colour when sunscreen needs to be reapplied.

1. **Project team roles & responsibilities**

* **Main Investigator:** Doctor of Philosophy Student Helen Ford
* **Other Investigator:** PhD Principal Supervisor Prof Dr Monika Janda (IBHI (Institute of Health and Biomedical Innovation) Theme Leader – Health Determinants and Health Systems, School of Public Health and Social Work, IHOP (Improving Health Outcomes for People) Research Group, Kelvin Grove Building Q Room 319, Queensland University of Technology
* **Other Investigator:** PhD Associate Supervisor: Dr Elke Hacker (Research Fellow, IHOP (Improving Health Outcomes for People), Institute of Health and Biomedical Innovation, Queensland University of Technology
* Helen Ford will be responsible for participant recruitment, obtaining consent, date collection, sample collection and data analysis. Prof Dr Monika Janda and Dr Elke Hacker will be responsible for overseeing and supervising all these stages of the research.

1. **Resources**

* **The resources necessary for the project to be conducted will be:**
* Sunscreen for use in the clinical room
* Sunscreen for use by participants at home
* Alcohol swabs and packaging
* Suncayr Stickers
* Text messaging service provider to enable daily text message reminders to be sent
* Clinic Room at IHBI for 4-5 months to conduct research with participants
* **Funding/support being sought or secured:** PhD student allocated funding from QUT, along with a $2,000 grant from QUT HDHS (Health Determinants and Health Systems) theme in IHBI.

1. **Background**

* **Literature review:**

Skin cancer is the most common type of cancer in humans (Alexander, 2012) and is a major public health concern (Robinson, Baker, & Hillhouse, 2012). Sun exposure during childhood is thought to be a major risk factor for skin cancer (English, Milne, & Simpson, 2005; Harrison, Saunders, & Nowak, 2007). However, it continues to be a major challenge to optimize the use of sunscreens, especially among children and adolescents (Quatrano & Dinulos, 2013). To make further progress in skin cancer development, the public has to be aware that avoidance of sunburns and sunscreen application is not enough to prevent skin cancer (Garbe, 2012) and that sunscreen application needs to involve a minimum quantity of sunscreen to reach the SPF. The prevention of melanoma has previously been found to significantly improve by targeting information directly towards the subpopulations of children and their parents (Lebbé et al., 2015). Based on these factors, it is timely for this study to focus on quantifying the use of sunscreen in young children and also the barriers or interrupters to sunscreen use in these participants.

**Significance of skin cancer globally and in Australia**

Of all cancers, melanoma is the one for which the incidence has increased the most worldwide in the last 20 years (Rat et al., 2014). In addition, the incidence of melanoma has increased in recent years faster than any other cancer (Salvio et al., 2011) and is continuing to increase (Moreno, Soria, Martínez, Martí, & Casanova, 2016). Melanoma also affects a relatively younger population and is notorious for its propensity to metastasize and for its poor response to current therapeutic regimens (Grimaldi, Cassidy, Leachmann, & Ascierto, 2014), including drug resistance (Mitchell & Leslie, 2013).

Australia has reported the highest rate of skin cancer (Langbecker et al., 2014; Lomas, Leonardi-Bee, & Bath-Hextall, 2012) and melanoma in the world (CancerCouncil, 2016a) at 529 cases per million adults (age-standardized) (Baade, Green, Smithers, & Aitken, 2011). It has been estimated that the Australian incidence rate of melanoma in 2008 among children aged 0-14 years was five cases per million population compared with two cases per million in Western Europe and Northern America (Baade, et al., 2011). Although data shows that skin cancer mortality rates have increased since 2000, recent trends in Australia suggest stabilization or slight decline among those under the age of 45 years in melanoma and non-melanoma skin cancer incidence rates (CancerCouncil, 2016e), which is thought to be due to public health campaigns targeting sun protection, such as ‘Slip, Slop, Slap’.

Melanoma is the most common cancer among 15- to 29-year-olds in Australia, while Non-Melanoma Skin Cancer (NMSC) is the most common and expensive cancer in Australia and places a high burden on the population, health care system and government (Fransen et al., 2012; Surdu, 2014). It is anticipated that NMSC will persist as the costliest cancer and place an increasing burden on Australia’s health care system (Fransen, et al., 2012). Therefore, further more work needs to be done to reduce the high incidence of NMSC and skin cancer in general.

**Skin physiology**

The epidermis is mainly made up of melanocytes and keratinocytes (CancerCouncil, 2016f). Melanocytes produce melanin, while there are several layers of keratinocytes, with the main viable layer composed of squamous cells and the lowest layer known as the basal layer (CancerCouncil, 2016f). Whist there are similarities, it is important to note that there are differences between adult and baby skin, as shown below in Figure 1. Babies and children have a thinner dermis than adults (Volkmer & Greinert, 2011), so the same amount of surface UltraViolet (UV) exposure may result in increased UV dosage and DNA damage to the cells that give rise to melanocytes than in older skin (Green, Wallingford, & McBride, 2011). A higher UV-exposure of these cells in childhood may enhance the skin cancer risk later in life (Morris, 2004).

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Figure 1 Differences between adult and baby skin (extracted from Centexbel 2016: http://www.centexbel.be/oeko-tex-and-human-ecology)

**Types of skin cancer**

Skin cancer includes both melanoma and keratinocyte cancer (Langbecker, et al., 2014). Ketatinocyte cancer generally refers to basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), although also includes other rare cutaneous neoplasms (Madan, Lear, & Szeimies, 2010). Cutaneous melanomas are classified into four types by histological appearance, as outlined below in table 1, however some melanomas are of unclassifiable histogenetic type. More broadly, skin cancer is classified as either melanocytic skin cancer (MSC) or non-melanocytic skin cancer (NMSC) (CancerCouncil, 2016f). The subtypes of each of these types of skin cancers are outlined below in the Table 1.

Table 1 – Types and sub types of skin cancers (Council).

|  |  |
| --- | --- |
| **Type of Skin Cancer** | **Sub Type of Skin Cancer** |
| **Melanocytic Skin Cancer**  **(MSC)** | Superficial spreading melanoma  (48.5% of MSC) |
| Lentigo maligna melanoma  (9% of MSC) |
| Acral lentiginous melanoma  (0.5% of MSC) |
| Nodular melanoma  (8.7% of MSC) |
| Unclassifiable histogenetic type MSC – including (but not limited to) malignant melanoma Not Otherwise Specified) NOS, balloon cell carcinoma, malignant melanoma regressing, amelanotic melanoma, malignant melanoma in junctional naevus  (33.4% of MSC) |
| **Non-Melanocytic Skin Cancer**  **(NMSC)** | Basal cell carcinoma  (30% of NMSC) |
| Squamous cell carcinoma (70% of NMSC) |

**Risk factors for skin cancer**

The Royal Australian College of General Practitioners has categorized the risk of developing skin cancer is categorised into average, increased and high risk, as shown below in Table 2.

Table 2 – Skin cancer risk levels and characteristics (CancerCouncil, 2016d).

|  |  |  |
| --- | --- | --- |
| **Type of Skin Cancer** | **Risk Level** | **Risk Characteristics** |
| **Melanocytic Skin Cancer (MSC)** | Average | * Lightly pigmented skin |
| Increased – 2-5 x average | * Familial history of melanoma in a first degree relative (59, 70) * Fair skin, skin sensitive to sunburn, freckles, light eye colour, light or red hair * Aged >30 years (especially >50 years) * Solar lentigines (large, flat, pigmented irregularities) * Past history of keratinocytic skin cancer (especially if <40 years) * High level of UV exposure and episodes of sunburn during childhood |
| High –  >6 x average | * Multiple dysplastic naevi (atypically shaped moles) and * History of melanoma in themselves or a first-degree relative. |
| **Non-Melanocytic Skin Cancer**  **(NMSC)** | Average | * Fair to lighter than olive skin; and * <40 years |
| Increased – 2-5 x average | * Fair complexion, sensitive to sunburn skin, with freckles, light eye colour, light or red hair * Family history of skin cancer (59, 70) * >40 years * Male * Presence of multiple solar keratosis * High UV exposure |
| High –  >6 x average | * As for ‘Increased risk’; and * Previous history of non-melanoma skin cancer * Past exposure to arsenic * Immunosuppression |

Recognizing these risk factors and identifying high-risk groups are the first steps towards early detection of melanoma (Calianno, 2011). Of the risk factors for melanoma, exposure to sunlight and UV radiation (UVR) are the most significant (Saiag et al., 2015). In particular, it is important to maintain the focus on reducing sun exposure and increasing sun protection in infants and young children (Smith, Harrison, Nowak, Buettner, & Maclennan, 2013), particularly in regions of high UVR (Smith, et al., 2013), such as Australia.

Migration studies have examined the occurrence of melanoma among subjects according to their place of birth (Whiteman, Whiteman, & Green, 2001). Several studies conducted in Australia have observed rates of melanoma among British or Irish migrants considerably lower than that of native-born residents (Dobson & Leeder, 1982; Holman, Mulroney, & Armstrong, 1980; Khlat, Vail, Parkin, & Green, 1992; McCredie, Coates, & Ford, 1990; McMichael & Giles, 1988). Most significantly, there was a four-fold increased risk of melanoma among those living in sunny areas as children (Autier & Dore, 1998). Thus it is essential to provide effective sun protection during childhood as it a particularly susceptible time for UV exposure.

**UV exposure**

UV radiation plays a well-established role in photocarcinogenesis, increasing the development of common skin cancers in susceptible populations (Reddy & Gilchrest, 2011). It is classified as a human carcinogen by the World Health Organisation (Reddy & Gilchrest, 2011). In fact, UVR from sunlight has been identified as the cause of more than 95% of skin cancers in Australia (Armstrong, Hill, Elwood, & English, 2004; Makin, 2011).

However, there are conversely some positive effects of UV radiation. Whilst the most carcinogenic UVR wavelengths reaching the earth’s surface, are in the UVB range (290-315nm) (Reddy & Gilchrest, 2011), as shown below in Figure 4.2.5.5. This is the same wavelength required for vitamin D synthesis in the skin (Reddy & Gilchrest, 2011). Thus, there exists the dilemma of UVR being both the major cause of skin cancer and the best natural source of vitamin D (CancerCouncil, 2016b).

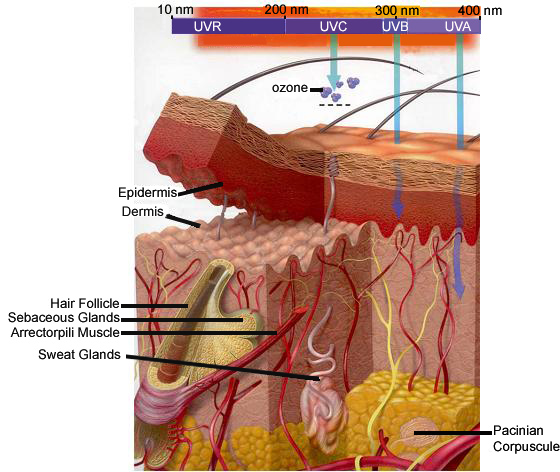


Figure 1 Most carcinogenic UVR wavelengths reaching the earth’s surface (adapted from Anatomical Chart Company, Illinois, K Kasnat, B Fairfax)

**Overexposure to UVR during childhood**

Overexposure to UVR during childhood and adolescence is a major factor in determining future skin cancer risk (Armstrong, et al., 2004; Autier & Boyle, 2008; Khlat, et al., 1992; Whiteman, et al., 2001). Epidemiological research supports the possibility that sun exposure during childhood stimulates the initial mutational step in the development of melanoma (Armstrong, Grob, Stern, McKie, & Weinstock, 1997). Many previous studies have established that high levels of sun exposure and sunburns during childhood increase the risk of developing melanoma (Armstrong, et al., 2004; Autier & Boyle, 2008; Khlat, et al., 1992; Smith, et al., 2013; Tripp et al., 2016; Whiteman, et al., 2001).

The reduction of UVR exposure is the main strategy in order to prevent skin cancer (Crane et al., 2012; Garbe, 2012). Early childhood before the age of 6 years is regarded as a particularly vulnerable period of life (Crane, et al., 2012; Garbe, 2012). It is for this reason that this research project will focus on sunscreen use in young children aged between 2 to 6 years of age.

**Interrupters**

It has been well established that the sun’s UVR is the major cause of skin cancer (Reichrath & Reichrath, 2013). However, an important concept it that of ‘interrupters’ or factors that may interrupt the use of sun protection (Janda, 2016). Such interrupters include perceptions related to the need for sun exposure for vitamin D and also to the perceived toxicity of sunscreen.

**Vitamin D**

A safe threshold for UV exposure that results in maximal vitamin D synthesis without increasing skin cancer risk has not been established (Reddy & Gilchrest, 2011). Therefore, there needs to be a balance between excessive sun exposure (which increases the risk of skin cancer) and sufficient sun exposure to maintain adequate vitamin D levels (CancerCouncil, 2016c). In light of this, balancing the possible benefits and known harms associated with UV exposure represents a challenge not only for health experts but also for the general public (Youl, Janda, & Kimlin, 2009), so it timely that this study will seek information related to participants’ perceptions of this.

**Sunscreen toxicity**

There appears to exist a public perception that sunscreen could be toxic, and this forms another interrupter to sun protection. This is in spite of the fact that current evidence does not support an association between sunscreen use and melanoma, systemic toxicity or vitamin deficiency (Quatrano & Dinulos, 2013). Furthermore, there is no evidence that any of the filters used in sunscreens have harmful effects in children (Gilaberte & Carrascosa, 2014).

Thus it is important to de-mystify such ‘interrupters’, which this study will aim to do by providing recommendations post-study for sun exposure and protections and will aim to address any misconceptions of participants identified through questionnaires.

**Sunscreen and sun protection factor**

The Sun Protection Factor (SPF) was introduced in 1962 and has become a worldwide standard for measuring the efficacy of sunscreen products in shielding the sun’s ultra-violet radiation (UVR) and protecting the skin against sunburn (Reinau, Osterwalder, Stockfleth, & Surber, 2015). SPF is determined by applying sunscreen in an amount of 2 mg/m3 (Labeling and effectiveness testing; sunscreen drug products for over-the-counter human use; delay of compliance dates. Final rule; delay of compliance dates; request for comments, 2012), but in reality the amount of sunscreen applied has been found to be much lower than this at 0.5 mg/m3 (Kim, Oh, Lee, Choe, & Ahn, 2010). Therefore, further information needs to be provided to sunscreen users in order for them to use enough sunscreen to reach the SPF, which this study will aim to do by incorporating an intervention using instructions for applying sunscreen in the required amounts to reach the SPF.

**Previous studies and sun protection**

Although sunscreen application is the most common modality for sun protection, it has been found that many people do not use it correctly (Quatrano & Dinulos, 2013), even though regular sunscreen use during childhood and adolescence can significantly reduce lifetime incidence of skin cancer (Mortier et al., 2015; Quatrano & Dinulos, 2013), especially in populations at risk of NMSC and MSC (Reddy & Gilchrest, 2011; Robinson & Bigby, 2011). Emphasizing sun protection behaviours among young children may minimize sun damage and foster lifelong sun protection behaviours that will reduce the likelihood of developing melanoma (Ho et al., 2016).

It has also been found that the prevention of melanoma can be significantly improved by targeting information directly towards the subpopulation of children and young parents (Lebbé, et al., 2015). Another study used a multicomponent intervention using text-message reminder and distribution of read-along books and swim shirts and was associated with increased sun protection behaviours among young children (Ho, et al., 2016). Following on, this study will incorporate an intervention involving daily text-message reminder to participants to apply sunscreen.

In addition, it has been found that although most children with a family history of melanoma used sunscreen (79%), half experienced a recent sunburn (Glenn, Bastani, Chang, Khanna, & Chen, 2012). The mean sun protection level for the sample was similar to levels observed among average risk children (Glenn, et al., 2012). Therefore, efforts to reduce sunburn frequency and improve sun protection among these vulnerable children appear warranted (Glenn, et al., 2012). This study will aim to improve sun protection behaviours amongst children in general, and in particular, in this vulnerable group.

**Interventions**

Behavioural interventions to reduce exposure to UVR have been found to reduce the risk of skin cancer (de Vries et al., 2012). Additional data also demonstrated that educational campaigns emphasizing increased knowledge about melanoma and self-screening practices correlate with thinner tumours (Mitchell & Leslie, 2013). However, despite years of public education, sun-related behaviours are difficult to change and a recent survey showed low levels of sun protection (Vuong, Trevena, Bonevski, & Armstrong, 2014).

**Photoaging**

Photoaging of the skin is an adverse effect of UV exposure (Reddy & Gilchrest, 2011). Photoaging affects all skin phototypes, although lighter-skinned individuals are more severely affected (Reddy & Gilchrest, 2011). Broad-spectrum UV protection is a universally accepted preventive measure for photoaging (Reddy & Gilchrest, 2011). Following on, this study will incorporate photography of the back of the hand and forearm for the purpose of determining photoaging of each of the participants both before and after the study intervention.

**Text messages**

It has been found that text messages about skin cancer prevention and early detection are novel to induce behaviour change in young adults (Finch et al., 2015). The Healthy Text intervention was effective in inducting significant improvements in sun protection (Youl et al., 2015). Following on, text message reminders will be used for this study as an intervention.

**Sunscreen coverage measured using UV Camera**

This study will incorporate UV photography of the back of the hand and forearm of the participant to determine how much sunscreen coverage they have had during application.

**Instructions for sunscreen application**

Previous studies have found that although sunscreen is essential in protection of UV-induced damage and skin cancer prevention, inadequate application of sunscreen can decrease the actual efficacy of the sunscreen (Ou-Yang, Stanfield, Cole, Appa, & Rigel, 2012). In 2002, Schneider proposed the ‘Teaspoon Rule of Applying Sunscreen’, where one teaspoon of sunscreen is applied to the face/head/neck, a total of two teaspoons to the front and back torso, one teaspoon to each upper extremity, and two teaspoons to each lower extremity (Isedeh, Osterwalder, & Lim, 2013). It would therefore be useful to provide instructions on how much and how to apply sunscreen, which this study will use as an intervention

* **Rationale/Justification (i.e. how the research will fill any gaps, contribute to the field of research or contribute to existing or improved practice)**

Previous research has found skin cancer is the most common type of cancer in humans (Alexander, 2012) and that it is essential to provide effective sun protection during childhood (Autier & Dore, 1998), as overexposure to UVR during childhood and adolescence is a major factor in determining future skin cancer risk (Armstrong, et al., 2004; Autier & Boyle, 2008; Khlat, et al., 1992; Whiteman, et al., 2001). However, there is a clear gap in the literature regarding the thickness of sunscreen application in young children (2-6 year olds). This study will aim to address this gap by quantifying the use of sunscreen in young children, determine the barriers or interrupters to sunscreen use in these participants and evaluate the effectiveness of interventions involving text messages reminders to apply sunscreen or the use of Suncayr stickers that change colour when sunscreen needs to be reapplied.

* **Research questions/aims/objectives/hypothesis**

This study has the following aims:

1. To measure the amount of sunscreen application amongst young children (2-6 year olds) by parents/caregiver and the children themselves.
2. To determine if providing an intervention of a daily personalised text message reminder to apply sunscreen is associated with the amount of sunscreen applied.
3. To determine if providing an intervention of a Suncayr sticker reminder to apply sunscreen is associated with the amount of sunscreen applied
4. To determine barriers to effective sunscreen use and how to overcome them.
5. To determine photoaging of participants before and after the intervention.

This study will test the following hypotheses:

1. First Hypothesis: The amount and self-reported frequency of sunscreen applied to young children (2-6 year olds) is below the amount required to reach the SPF of the sunscreen.
2. Second Hypothesis: The amount and self-reported frequency of sunscreen applied to young children (2-6 year olds) will increase with an intervention involving a daily personalised text message as a reminder to apply sunscreen.
3. Third Hypothesis: The amount and self-reported frequency of sunscreen applied to young children (2-6 year olds) will increase with an intervention involving Suncayr stickers as a reminder to apply sunscreen.
4. Fourth Hypothesis: Young children (2-6 year olds) whose parents/guardians apply sunscreen to them show less photoaging than those whose parents/guardians don’t.

The objectives of this study are to:

1. Determine if the amount of sunscreen used amongst young children (2-6 year olds) changes with an intervention involving daily text personalised text message reminders.
2. Determine if the amount of sunscreen used amongst young children (2-6 year olds) changes with an intervention involving the daily application of stickers to back of the hand of the young child as a reminder to reapply sunscreen.
3. Photograph the back of a hand and forearm of each participant in order to catalogue photoaging of young children participants.
4. Determine sun exposure behaviours, sun protections behaviours, barriers to sunscreen use and other potential factors that influence sun protection through a self-administered questionnaire completed by parents both pre- and post-intervention.

* **Expected outcomes: it is expected to be found that…**

1. **Project design**

* **Research project setting:** online questionnaire and 2 visits to the IHBI (Institute of Health and Biomedical Innovation) at QUT Kelvin Grove, 2 weeks apart.
* **Methodological approach:** 
  + Rationale for choices of method/s (tied to project aims/objectives): the method of data collection will be the least invasive to participants and cause minimal disruption to their day-to-day lives. The sunscreen data collection will be less prone to error as it will be conducted on QUT grounds in a controlled environment (a room in IHBI) and there will be far less opportunity for inaccuracies. The questionnaires will be completed online and recorded through RedCap, so there will be minimal opportunity for data errors as there will be no data entry required.
* **Participants:** 
  + Description and number
  + Inclusion and exclusion criteria
  + Sample size and statistical or power issues
* **Participant recruitment strategies and timeframes:** Participants will be recruited through QUT research distribution emails, QUT social media and also online media in Brisbane and print media in Brisbane (E.g. Brisbane Kids Magazine) once approval has been granted by QUT Ethics.
* **Approach/es to provision of information to participants and/or consent (as required in addition to that outlined in the HREA):**
  + If necessary, the type of consent provided to different participant groups, when and where, and any arrangements to confirm that consent: informed written consent will be given by the parents/guardians for their participation and also for the participation of their young child. Consent will be provided online through RedCap.
* **Research activities: What you are going to do?**
* Participant commitment: Participants will be asked to have access to a smartphone and/or computer to complete an online 20-30 minute questionnaire at the beginning and end of the study, one week apart. The questionnaire will look at the beliefs and attitudes relating to sunscreen and other sun protective behaviour in your young child. They will also be asked to visit to the Institute of Health and Biomedical Innovation (IHBI) at QUT Kelvin Grove with your young child on two separate occasions, one week apart. Participants and their young child be asked to their young child (after patch testing first), and the amount applied will be measured using alcohol swabs. They will also be asked to allow a non-identifiable photographic image to be taken of the back of the hand and forearm of your child, and to complete a sunscreen diary on how much and where sunscreen was applied during the one week course of the study.
  + Project duration: The recruitment and participation for the project is expected to run from late January 2018 (or when QUT Ethics approval is given) until June 2020.
  + Participant follow-up
* **Data collection/gathering: What information are you going to collect/gather?** 
  + Data collection/gathering techniques: Data will be collected by participants completing a baseline questionnaire (including eligibility and demographics questions) and then follow up questionnaire, both administered through RedCap. Both questionnaires will be able to be completed online. Data will also be gathered in person at IHBI (Institute of Health and Biomedical Innovation) at QUT Kelvin Grove.
* **Impact of and response to participant withdrawal:** participants are able free to withdraw without comment or penalty.
* **Data management:**

The data management for this study is outline in the document ‘SAY Study Data Management Plan’. Web-based questionnaires will be administered through Red Cap at http://apps.ihbi.qut.edu.au/redcap/index.php?action=myprojects.  Photographic images will be taken and recorded in a secure QUT Building (IHBI) and stored through the QUT network project folder for the SAY Study (U:\Health\PHSW\Projects\Young Children and Sunscreen).

The results form the alcohol swabs measuring sunscreen will be calculated in a secure QUT Building (IHBI) and stored through the QUT network project folder for the SAY Study (U:\Health\PHSW\Projects\Young Children and Sunscreen). Data will be stored in Red Cap at http://apps.ihbi.qut.edu.au/redcap.index.php?action=myprojects , which is on a secure server.

A secure project folder has been set up under QUT's U:\Health\PHSW\Projects\Young Children and Sunscreen.  Files saved under this drive are automatically backed-up nightly in two physical locations. Data will not be stored on flash drives, laptops, computers or external hard drives. Red Cap is automatically backed-up online and U:\ is automatically backed-up nightly in two physical locations.

Online those with secure logon (the research team) will be able to access the data in Red Cap.  The files in U:\Health\PHSW\Projects\Young Children and Sunscreen are only accessible if the individual has been granted approved access to that folder through IT. No data will be transmitted via email.  If data transmission occurs, it will take place electronically within established secure networks of Red Cap and QUT U drive.

All data will be kept for a minimum of 5 years as it is anticipated the data will result in a publication (not involving a clinical trial) for this project.  Consent forms related to the study will be kept for a minimum of 15 years. No special disposal requirements for this project. Data will be stored for 5 years, then securely destroyed through QUT. Data stored in U:\Health\PHSW\Projects\Young Children and Sunscreen will be made available to approved users as required. Date stored in Red Cap can be made available to other users through approval of a login to that project file path.

There are no plans for data sharing other than through dissemination of analysed data in conference presentations and peer reviewed publications. At this time, it is anticipated that the data will be shared only within the Improving Health Outcomes for People (iHop) research group with the QUT Faculty of Health, School of Public Health and Social Work.  This is for ethical, economic and intellectual property reasons.  The main route of sharing within this research group will be digitally through U:\Health\PHSW\Projects\Young Children and Sunscreen access and through Red Cap access.

* **Data analysis:** How will you measure, manipulate and/or analyse the information that you collect/gather?
  + Data from the baseline will be linked to the data collected in the 1 week follow up to allow for t-tests and paired t-tests. ANOVA analysis will be used to compare the different intervention groups.
  + Accounting for potential bias, confounding factors and missing information
  + Statistical power calculation

The previous study by Abbey Diaz showed… and it would be reasonable to expect a similar… for this study. Based on this, the

Sample size calculation:

Confidence level: 95%

Confidence interval: 5

Population: 150 (Abbey’s Study) (Standard Deviation)

Sample Size=108

|  |  |  |
| --- | --- | --- |
|  | ss = | Z 2\* (p) \* (1-p) |
|  |
| c 2 |

Where:

Z = Z value (e.g. 1.96 for 95% confidence level)    
p = percentage picking a choice, expressed as decimal   
(.5 used for sample size needed)  
c = confidence interval, expressed as decimal   
(e.g., .04 = ±4)

* **Data linkage:** What linkages are planned or anticipated?
* **Outcome measures:**

1. **Results, outcomes and future plans**

* **Plans for return of results of research to participants**
* **Plans for dissemination and publication of project outcomes:** it is anticipated that the results from this study will be published in 4 or 5 separate journal articles (one for each hypothesis).
* **Other potential uses of the data at the end of the project:** Data from this research could be used to drive future public health campaigns regarding skin cancer prevention.
* **Project closure processes**
* **Plans for sharing and/or future use of data and/or follow-up research** 
  + **Anticipated secondary use of data:** data from this research could be used as a comparative tool for future research in the same field.

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