Title: Pilot Study on DNA Repair Activity in the Skin of Day and Night Shift Workers

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INFORMED CONSENT AND AUTHORIZATION

Pilot Study on DNA Repair Activity in the Skin of Day and Night Shift Workers

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WSU Staff Physician

Sponsor(s) name and address:
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Site where study is to be conducted:
Wright State Physician's Building- 2nd floor
725 University Blvd
Fairborn Ohio 45324

Phone number for subjects to call for questions:
(937) 245-7500 or 775-2463

Key Information Summary

The purpose of this consent form is to give you information about this research study. It is up to you to decide whether to take part in this study. If you choose not to participate your decision will not affect your current or future relationship with Wright State Physicians. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

The purpose of this study is to test how the skin of night shift workers responds to artificial sunlight (ultraviolet B radiation; UVB) at two different times of the day in comparison to normal day shift workers. After the skin biopsies are obtained, they will be brought to the laboratory to be exposed to UVB radiation and to measure UVB responses.

If you agree to be in this study the following will happen:

- Informed Consent: You will be asked to sign an Informed Consent form
- You will be asked to fill in a monthly calendar outlining your approximate work schedule for the past three (3) months
- 8 am: Two small round holes (5 mm, or 1/5 inch, which is the size of a pencil eraser) will be taken from an area of lower hip/buttock skin. If needed, a suture will be placed.
- 4 pm: The same procedure will be repeated from a region of lower hip/buttock skin on the opposite side of the body (left/right). If needed, a suture will be placed

Your participation in this study may be completed in one day and will involve the collection of skin punch biopsies at two time periods (around 8 am and 4 pm). If you need sutures, then you will be asked to return to the research office in 10-14 days for suture removal.

Potential risks:

- Skin Biopsies: Risk of allergic reaction to the local anesthetic lidocaine, risk of small scar at the biopsy sites, risk of wound infection at the biopsy sites, risk of bleeding from the biopsy site.

Additional information regarding all potential risks is listed on page 5.

You may not benefit by participating in this study. However, the information gained may be helpful to others.

The alternative to participating in this study is to not participate as it is not a treatment study.

Introduction and Background Information

The purpose of this consent form is to give you information about this research study. It will describe the purpose, procedures, benefits, risks, and discomforts of this study. The principal investigator (PI) and/or the study staff will discuss this study with you and explain everything in detail. Please ask them to explain any words or information that you do not clearly understand.

This study does not involve any particular diagnosis. The goal of this research study is to explore the effects of artificial sunlight (ultraviolet B radiation; UVB) on the skin of day and night shift workers. Sunlight exerts many effects on the body. We have evidence that skin responds differently to ultraviolet B radiation (UVB, which are the burning rays of sunlight) at different times of the day and that people who work night shifts may be less able to properly respond to UVB radiation than people who work a normal day shift. In fact, we feel that this difference in how the skin reacts to UVB may be why night shift workers are at a greater risk of developing skin cancer.

The study is being conducted at the Wright State Physicians Pharmacology Translational Unit under the direction of Dr. Jeffrey Travers, Principal Investigator. The study is being carried out with funds received from the National Institutes of Health. The total number of subjects will be up to 48 individuals (12 male and 12 female individuals that have worked primarily either day or night shifts in the past 3 months).

Purpose

This study is designed to test whether UVB (burning rays of sunlight) treatment of the skin will result in different responses in the morning and afternoon in people who work a day or night shift schedule.

Why am I being asked to participate in this research study?

You are being asked to take part in this study because you meet the criteria for this study.

- 18 to 40 years of age
- Male/Female
- Fair skin (Fitzpatrick types I and II)
- Able to comprehend procedures/risks
- Primarily work and are awake during normal daylight hours (6 am to 6 pm), or primarily work and are awake during night shift hours (6 pm and 6 am) or may work a mixture of these shifts over the past 3 months.
- Able to fill out a 3-month calendar of work schedule.

You do not meet any of the following exclusion criteria:

- Known photosensitivity (abnormal responses to sunlight)
- Currently on photosensitizing medications
- Diabetes Mellitus (sugar problems)
- On any hormonal agents (eg, birth control pills)
- History of abnormal scarring
- History of skin infections
- History of skin cancers
- History of sleep apnea or insomnia
- Known allergy to lidocaine local anesthetic numbing medicine
- Pregnancy or nursing
- Other serious health issues

Procedures

If you agree to be in this study, you will be one of up to 48 subjects who will be participating in this research locally.

You will be requested to do the following things:

Screening Period -31 to 0 Days (for females only)

If you are a female, you will have a screening period to ensure you are enrolled between days 20 and 30 of your menstrual cycle.

At both 8 am and 4 pm (+/- 1 hr.):

After informed consent, you will be asked to fill in a monthly calendar outlining your approximate work schedule for the past three calendar months to allow evaluation of wake/sleep cycle. This consists of placing the approximate work shift (eg, 11PM-7AM) for each day worked in the past three months. Next, the areas to be biopsies will be marked and photographed (with any recognizable areas/buttocks shielded). The skin biopsies will be taken from a region of lower hip/buttock skin. For the **four** skin biopsies, the skin will be prepared in the usual sterile manner and anesthetized with 1% lidocaine with 1:100000 epinephrine. The lidocaine is a numbing medication and the epinephrine is used to decrease bleeding from the skin. The punch biopsy consists of cutting a round hole 5 mm (1/5 inch; the size of

a pencil eraser) across the top layer of skin. If needed, a suture will be placed. Wound care will be discussed and a sample of petrolatum ointment and band aids supplied. The biopsies will be taken to our laboratory, exposed to UVB radiation, and tested for various proteins and genes that we think are important in UVB responses. This process will be carried out at both 8 am and 4 pm on the same day using lower hip/buttock skin from opposite sides of the body. The 8 am visit will take less than 2 hours and the 4 pm visit should take less than one hour each time.

Suture Removal. If sutures were placed for the skin biopsies, then you would be scheduled to have them removed 10-14 days after their placement.

What Steps Are Being Taken to Reduce Risk of Coronavirus Infection?
The following steps are being taken to address the risk of coronavirus infection:

Screening: If you show potential symptoms of COVID-19 (fever, cough, shortness of breath, etc.) then you will NOT be permitted to participate in this study at this time.

Physical distancing: Whenever possible, we will maintain at least 6 feet of distance from you while conducting the study.

Mask/Covering: We will wear a mask and you will be required to shield your mouth and nose with a cloth face cover or mask during the study, even when maintaining at least 6 feet of distance. If you do not have a mask, one will be provided when entering the building. Tissues will be available to cover coughs and sneezes.

Handwashing: We will wash hands before/during examination or use a hand sanitizer. We will ask you to do the same.

Disinfecting materials: When feasible, we will clean and disinfect surfaces before your visit, using an EPA-registered disinfectant for hard materials and by laundering soft materials. Disinfected materials will be handled using gloves, paper towel, plastic wrap or storage bags to reduce the chance of re-contamination of materials.

Electronics: Alcohol-based wipes or sprays will be used to disinfect shared touch screens, mice, keyboards, etc. Surfaces will be dried to avoid pooling of liquids.

Potential Risks

1. Skin biopsies: risk of allergic reaction to the local anesthetic lidocaine, risk of small scar at the biopsy sites, risk of wound infection at the biopsy sites, risk of bleeding from the biopsy site.
2. There is also the potential risk of loss of confidentiality, but this will be minimized as samples will be labeled with numeric numbers --001, 002, 003 etc.
3. In addition, you may suffer harms that we have not seen before.

Benefits

You may not benefit by participating in this study. The information collected may not benefit you directly. However, the information may be helpful to others by providing us with an understanding of how the skin of night shift workers responds to artificial sunlight (ultraviolet B radiation; UVB) at two different times of the day in comparison to normal day shift workers.

Alternatives

This study is not a treatment study. Your alternative is to not participate.

Research Subject Costs

There will be no costs to you for any of the procedures or testing done as part of this research study

Compensation & Treatment for Injury

You will be paid for participating in this study. You will be paid for each completed visit as follows:

- $20 for Informed Consent
- $20 for completing a 3 month calendar of work shifts
- $25 for each of the two skin biopsies at 8 am
- $25 for each of the two skin biopsies at 4 am

If you complete all study visits, you will receive a maximum payment of $140.00. If you don't complete the study, you will be paid for the procedures you do complete.

If you are injured by being in this research study, Dr. Travers will arrange for you to get medical treatment. The most likely adverse reaction would be a biopsy site infection, which would manifest as increased pain and pus in the biopsy site approximately 4-7 days after the procedure. If that happens, Dr. Travers will provide you with a tube of the prescription antibiotic mupirocin ointment. If that is not effective, then, Dr. Travers will prescribe an oral antibiotic. You or your insurance company would be responsible for paying for the cost of the prescription oral antibiotic, but there will be no cost for Dr. Travers' services. If you are injured, there is no money set aside for lost wages, discomfort, disability, etc. You do not give up your legal rights by signing this form. If you think you have a research related injury, please call the research office at (937) 245-7500 or Dr. Travers at (937) 775-2463. Should an adverse event occur, please contact Dr. Travers who will provide treatment as outlined above.

Confidentiality

Total privacy cannot be guaranteed. We will protect your privacy to the extent permitted by law. If the results from this study are published, your name will not be made public. Once your information leaves our institution, we cannot promise that others will keep it private.

Identifiers might be removed from your identifiable private information (or/and identifiable biospecimens). After such removal, the information or biospecimens could be used for future research

studies or distributed to another investigator for future research studies without your (or your legally authorized representative's) consent.

FDA Clinical Trial Registry

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Use of Genetic Samples

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

You should also know that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Data Security

All conversations and procedures will take place in the Wright State Physician's building in the dermatology clinic in a private examining room. The data will be kept in the locked office of the PI. Samples and pictures from subjects will be coded by numbers as outlined above. Photos will not be of recognizable body parts or markings.

Voluntary Participation

Taking part in this study is completely voluntary. You may choose not to take part at all. If you decide not to be in this study, you won't be penalized or lose any benefits for which you qualify. If you decide to be in this study, you may change your mind and stop taking part at any time. If you decide to stop taking part, you won't be penalized or lose any benefits for which you qualify. You will be told about any new information learned during the study that could affect your decision to continue in the study.

Termination

The investigator, the Institutional Review Board (IRB) or the study sponsor has the right to stop this study at any point. The investigator may take you out of this study with or without your permission. Reasons why this may occur include:

- Failure to follow the instructions of the research study staff
- The study is cancelled
- The principal investigator believes it is in your best interest

Participation in Other Research Studies

You may take part in this study if you are currently in another research study. It is important to let the investigator know if you are in another research study.

Research Subject's Rights, Questions, Concerns, and Complaints

If you have any questions, concerns, or complaints about the research study you may contact the principal investigator, Dr. Travers, or the research office at (937) 245-7500 or (937) 775-2463.

If you have any questions about your rights as a study subject, questions, concerns or complaints, you may call the Wright State University IRB at (937) 775-4462 or irb-rsp@wright.edu. You may discuss any questions about your rights as a subject with a member of the IRB or staff. The IRB is an independent committee composed of members of the University community, staff of the institutions, as well as lay members of the community not connected with these institutions. The IRB has reviewed this study.

Authorization to Use and Disclose Your Health Information

State and Federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect the privacy of your health information. This section of the consent form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information (PHI) for this research study. **Please read this section of the consent form carefully.**

If you sign this document, you give permission to Dr. Travers and his Wright State Physicians Pharmacology Translational Unit research team to use or disclose (release) the following protected health information:

- Your medical records for past medical conditions and medications related to your skin conditions
- All information (research records and medical records) created during your participation in this research study

The research team needs this information to conduct the study. This is a study to test how the skin of night shift workers responds to artificial sunlight (ultraviolet B radiation; UVB) at two different times of the day in comparison to normal day shift workers.

To maintain the integrity of this research, you might not have access to any health information developed as part of this study until it is completed. At that point, you generally would have access to your health information.

Disclosure of your protected health information

If you sign this form, the researchers may share your health information during the conduct of the study with:

- Non-Wright State Physicians researchers or organizations working with Wright State Physicians researchers.
- Law enforcement or other agencies, when required by law
- WSU's Institutional Review Board (or other IRB of record), which oversees our research
- The sponsor (the organization paying for) of this research study: National Institute of Health (NIH)
- Representatives of government agencies in the United States and other countries (i.e. Food and Drug Administration and the Office of Human Research Protection)
- Other authorized Wright State University/Physicians Officials who oversee research and clinical care

The people listed above will use and share your health information to review the quality, safety, and results of the research and may also do additional research.

Please understand that these persons/organizations who may receive your health information may not be required by U.S. Federal privacy laws (such as HIPAA) to protect it and may share your information with others without your permission.

This authorization does not have an expiration date.
However, you can change your mind and cancel this authorization at any time. To cancel this authorization, you must write the study investigator listed at the beginning of this consent form.

If you cancel this authorization, you will no longer be allowed to take part in the research study. If you cancel this authorization, health information you had already allowed us to obtain may still be used and disclosed by researchers in order to maintain the integrity and reliability of the research, and to report any adverse (bad) effects that may have happened to you.

Right to refuse to sign this Authorization

You have the right to refuse to sign and give your authorization. If you do not sign this form, your non-research related treatment, payment or enrollment in any health plans, or your eligibility for other medical benefits at Wright State Physicians will not be affected in any way.

However, if you do not sign this form, you will not be able to participate in this research study.

Signature of Subject

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research and authorize the use and disclosure of my protected health information for this study. I will be given a copy of this signed and dated form.

_____ _____
Signature Date

_____
Printed Name

_____ _____
Signature of Person Obtaining Consent and Authorization Date

_____
Printed Name of Person Obtaining Consent and Authorization