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Informed Consent for Participation in Research

Study Title: Epidermal Sensors for Wireless and Enhanced Amputee Skin Tracking (E-SWEAT)

Protocol Number: 26923

NCT #: not yet assigned

Protocol is approved by NC State University IRB

Approval Period:

05/30/25 – 05/29/26

Updated on: 05/30/2025

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Consent Form

Title of Study: Epidermal Sensors for Wireless and Enhanced Amputee Skin Tracking (E-SWEAT) (eIRB # 26923)
Principal Investigator(s): Amay Bandodkar (ajbandod@ncsu.edu 919-515-0417)
Co Investigator: Ming Liu (mliu10@ncsu.edu 919-515-8541)
Funding Source: Department of Defense

What are some general things you should know about research studies?
You are invited to take part in a research study. Your participation in this study is voluntary. You have the right to be a part of this study, to choose not to participate, and to stop participating at any time without penalty. The purpose of this research study is to gain a better understanding of how the biomarkers in the sweat and skin temperature are affected by the pressure on the skin of the residual limb for below knee amputees. We will do this through 1) mounting a newly developed sweat sensor which is also integrated with pressure sensing and temperature sensing (not FDA approved) on your residual limb and 2) involving you into multiple activities to generate different load pressure on your residual limb and read from the sensor at the same time.

You are not guaranteed any personal benefits from being in this study. Research studies also may pose risks to those who participate. You may want to participate in this research because the collected information may benefit people with lower limb amputation by permitting more accurate evaluation of health of the residual limbs. You may not want to participate in this research because you might be exposed to the risk of fall, fatigue, potential skin injuries on the residual limb on other part of body due to pressure or high temperature, and identity leakage.

Specific details about the research in which you are invited to participate are contained below. If you do not understand something in this form, please ask the researcher for clarification or more information. A copy of this consent form will be provided to you. If, at any time, you have questions about your participation in this research, do not hesitate to contact the researcher(s) named above or the NC State IRB office. The IRB office's contact information is listed in the *What if you have questions about your rights as a research participant?* section of this form.

A lot of lower limb amputees uses medication to control the sweating on the residual limb. Because the experimental procedure of this study is designed to trigger sweating, we would recommend all participants to avoid sweating control medication for at least 48 hours before the experimental procedure. As mentioned during our initial screening, you need to check with your medical provide to verify whether it is OK for you to temporarily avoid these medication if you are using them.

The commonly adopted sweat control medications for amputees includes:
1) Antiperspirant with the brand names Drysol, Hypercare, Xerac AC, which can be got from drug stores without prescription.
2) Glycopyrronium with the brand name Qbrexza, which is a prescription medication.
3) Sofprionium with the brand name Sofdra. Which is a prescription medication.

What is the purpose of this study?

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The purpose of the study is to 1）test the effectiveness of a newly developed sensing system and 2) understand the relationship between pressure on the residual limb amputees and the biomarkers in the sweat and skin temperature. This relationship can be later used to identify areas, which are in high risk of pressure ulcer, a common problem for lower limb amputees.

How many people will be in the study?

There will be approximately 30 participants in this study.

Am I eligible to be a participant in this study?

In order to be a participant in this study, you must:

- Be 18 years or older
- Have a unilateral lower limb amputee (below the knee). The tibial length on the residual limb must be greater than half of the length of the tibial on the unaffected side
- Have an amputation that occurred over 2 years ago
- Have at least 1 year of experience using your prosthetic leg
- Have used the current socket for at least 6 months without a significant skin issue or major modification
- Be able to comfortably walk 6 mins (with prosthetic legs) without pausing to rest
- Be willing to come to NC State University's Centennial Campus to participate in research and be photographed while doing research activities

You cannot participate in this study if you do not meet the inclusion criteria or you

- Have acognitive or visual impairment that affects the participant's ability to provide informed consent or to follow simple instructions during the experiments
- Have any neuropathy observed on the residual limb
- Experience numbness, tingling, muscle weakness, and/or pain in your residual limb
- Weigh more than 300lbsDo not want to take photoes
- Are pregnant or plan to get pregnant
- Are allergic to latex, which is often contained in medical tapes.
- If you are using medication to control sweat on your residual limb, and your medical provider does not think that it is OK to avoid these medications for 48 hours.

What will happen if you take part in the study?

If you agree to participate in this study, you will be asked to:

1. Review and complete this consent form
2. Fill out a general information survey, which is used to collect some basic information about you, including age, weight, reason of amputation and so on.
3. Complete 2 surveys
4. Conduct a 10-meter walking test to evaluate your walking speed
5. Conduct one 2 min walking trial and "up and go" test to evaluate the performance of your daily prosthetic usage.
6. Haveyour limb measured
7. Hold your leg while a researcher pushes a beam with rubber head to measure the stiffness of your skin on the residual limb. The maximum pressure will be less than 100Kpa and the peak pressure will not exceed 10 seconds to avoid any potential skin damage.

8. Put on no more than 5 sweat-temperature measurement sensors on your residual limb
9. Put on a pressure measurement pad on your residual limb
10. Conduct three tasks: bird-dog exercise, level ground walking
11. Wear a heated jacket (if it is needed)
12. Self monitor any discomfort during the experimental procedure
13. Complete a pain evaluation form at the end of the experimental procedure

The following procedures are experimental:

1. We will ask you to put on a fall protection suit from the Marine Anti-gravity System. The size of the suit will be selected to fit your body size. This system will help to prevent potential falls in the experimental procedure. Although the risk of fall is not high based on our protocol, we would like to ensure your safety.
2. You will sit down and take off your prosthetic socket and permit us to measure the length of your residual limb.
3. With the help of a certified prosthetist, we will identify five locations on your residual limb to mount our newly developed sweat sensors. To make sure that you are able to do self-monitoring, we will conduct touch sensitivity tests at the selected locations using a monofilament testing kit. If you have difficulty monitoring the pressure change at a given location, we will try to find an alternative.
4. We will take a picture of your residual limb before we put on the sensor system. The pictures will be compared with the pictures taken at the end of the experimental procedure to detect any potential skin damage.
5. You will clean the skin using commercially available soap, rinse with clean water, and dry using paper towel.
6. We will push a beam with rubber head towards your residual limb skin at five different locations. The push will be very short and you are not expected any pressure higher than 1 bar.
7. You will put the sensor on your residual limb at the locations, which have been identified. Then you cover them with medical tapes. We will help you in this procedure.
8. You will put on your socket and walk back-forth several times to make sure that the setup is comfortable. The certified prosthetist will check your socket fitting to make sure that it can function correctly.
9. You will be involved in two different tasks:
    a. Repeated quadruped alternate arm and leg (bird dog) exercises, which entails starting on one hand and a knee, lifting the arm and leg and holding them straight out. Using the unaffected side as the supporting leg, you will hold this position for 8 seconds, rest for 10 seconds, and repeat the 18 second cycle for 32 times. One two-minute break will be given every 8 cycles.
    b. Walk on the treadmill with your preferred walking speed for six minutes. You are allowed to use your hand to hold the rails to improve your balance. You can take a two minute break after three minutes' walking if you prefer.
10. You will meet these four tasks in a random sequence. After each task, you will take off the socket and liner, remove the sensors, clean your residual limb, take a 5 min break, and repeat the steps 6-9. If you feel discomfort on the residual limb, the experiment will be stopped immediately.

11. If the sweat sensor indicates that not enough sweat is generated during the experimental procedure, we will provide you a heated jacket, which is powered by a battery pack through an USB cable. To make sure that it will not overheat and cause damage to your skin, you will be required to put on a sweat hoody inside the heated jacket if you do not have at least two layers of clothes on your body. You have the flexibility to choose the temperature (three levels, 35, 45, and 55 degree), but we usually recommend the one with the lowest temperature.
12. After wearing the heated jacket, you are required to redo the last task, which failed to generate enough sweat. Then continue with the rest of the testing procedure described in step 9.
13. After all the activities, we will visually inspect your residual limb and take pictures to compare with the one taken in step 4.
14. The prosthetist will again check your socket to make sure that everything is OK.
15. We will ask you to fill a pain level evaluation form to identify any discomforts in the experimental procedure.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. law. This website will not include any information that can directly identify you, but it will include a summary of this study's results within a year after the study has completed. You can search the clinical trials website at any time to review this study's results once they are posted.

The total amount of time that you will be participating in this study is 4 hours.

Minimal Risk, Non-Invasive, Not Significant Risk Experimental Device

During the experimental procedure, we will adopt a newly developed sweat-temperature monitoring system. Although this system is not FDA approved, this sensor is with minimum risk and noninvasive. It is only about 30mmX3mmX0.5mm size and as flexible as your own liner. This system will be put on your skin under the prosthetic socket and we do not expect any abnormal pressure caused by the sensors. In this project, we will also evaluate the efficacy and safety of the sensor. We expect it to be minimal risk.

Recording and images

If you want to participate in this research, you must agree to be photographed. If you do not agree to be photographed, you cannot participate in this research

Risks and benefits

There are minimal risks associated with participation in this research. The risks to you as a result of this research include

- You are exposed to the risk of pressure ulcers. This risk is unlikely.
    - The risks from these activities are mitigated by
        - Procedures to ensure that you are able to conduct self-monitoring;
        - controlling the maximum load on the residual limb; The highest pressure is expected to be experienced in the walking task, which is identical to what you experience in everyday life.
        - instructions to monitor the pressure and stop the experiment when you do not feel comfort.
        - inspect any potential skin damage after the experimental procedure.

- You are exposed to very low risk of skin burning. This risk comes from that heated jacket may be used in the experimental procedure, which may cause higher than usual temperature on your skin.
    - This risk is mitigated by
        - provide you sweatshirts, so the heated jacket does not contact skin directly,
        - encourage your to select low temperature configuration; and
        - ask you to self monitor the temperature of their skin.
- You are exposed to low risk of fatigue and muscle soreness.
    - The risk from these activities are mitigated by
        - Control your total efforts by limiting the total testing time
        - provide you rests between tasks
        - permit you to end the experiments whenever you feel the fatigue.
- You are exposed to low risk of identity leak. This risk comes from these activities: screening and scheduling.
    - The risks from these activities are mitigated by
        - you will be given a code name, so your name is not linked with any saved data;
        - the name and contact information will be written down in a master list, which is locked in the PI's office and is accessible to PI only.
        - the W9 form and direct deposit setup is done using the standard procedure defined by NCSU and handled by the Department of Biomedical Engineering, the research team does not collect sensitive information, such as SSN or banking information;
        - the payment form will be transferred to the department immediately after the experimental procedure; and
        - destroying all the contact information, which are recorded on the master list, at the end of the project, by shredding.

There are no direct benefits to your participation in the research. The indirect benefits are: the amputee population as a whole might benefit from knowledge gained from the proposed study, because our careful designed study has potential to enable prosthetists to gain the capability to predict pressure ulcer development on the residual limb, improve the comfort of the prosthetic socket, and provide better user experiences for lower limb amputees.

Right to withdraw your participation

You can stop participating in this study at any time for any reason. To do so, just stop any research activity that you are doing or contact the PI , Amay Bandodkar (ajbandod@ncsu.edu and 919-515-0417), or the researcher, Ming Liu (mliu10@ncsu.edu and 919-515-8541). If you choose to withdraw your consent and to stop participating in this research, you can expect that the researcher(s) will redact your data from their data set, securely destroy your data, and prevent future uses of your data for research purposes wherever possible. This is possible in some, but not all, cases.

Confidentiality, personal privacy, and data management

Trust is the foundation of the participant/researcher relationship. Much of that principle of trust is tied to keeping your information private and in the manner that we have described to you in this form. The information that you share with us will be held in confidence to the fullest extent allowed by law.

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Protecting your privacy as related to this research is of utmost importance to us. There are very rare circumstances related to confidentiality where we may have to share information about you. Your information collected in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety. In other cases, we must report instances in which imminent harm could come to you or others.

How we manage, protect, and share your data are the principal ways that we protect your personal privacy. Data that will be shared with others about you will be re-identifiable

> **Re-identifiable**. Re-identifiable data is information that we can identify you indirectly because of our access to information, role, skills, combination of information, and/or use of technology. This may also mean that in published reports others could identify you from what is reported, for example, if a story you tell us is very specific. If your data is re-identifiable, we will report it in such a way that you are not directly identified in reports. Based on how we need to share the data, we cannot remove details from the report that would protect your identity from ever being figured out. This means that others may be able to re-identify from the information reported from this research.

Future use of your research data

To help maximize the benefits of your participation in this project, by further contributing to science and our community, your Re-identified information will be stored for future research and may be shared with other peopleif you agree to the terms of the broad consent. The collected data will be shared at the National Institute of Mental Health Data Archive (NDA), a public accessible data archive. As the sponsor of the project, the Department of Defense will have access to collected data.

Compensation

For your participation in this study, you will receive $25/hour. If you withdraw from the study prior to its completion, you will get paid in the same rate with a minimum testing procedure 2 hours.

Emergency medical treatment

If you are hurt or injured during the study session(s), the researcher will call 911 for necessary care. There is no provision for compensation or free medical care for you if you are injured as a result of this study.

What if you are a student?

Your participation in this study is not a course requirement and your participation, or lack thereof, will not affect your class standing or grades.

What if you are an employee?

Your participation in this study is not a requirement of your employment, and your participation or lack thereof, will not affect your job.

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Sponsorship and funding

This study is funded by the Department of Defense (DoD) and the confidentiality section allows the DoD access to research records as a part of its human subjects protection oversight activities. This means that DoD is paying the research team for completing the research, DoD representatives will independently review and inspect the awardee's research, DoD representatives will prohibit research that is determined to present unacceptable hazards or is non-compliant with DoD regulatory requirements.

The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study. If you would like more information, please ask the researcher(s) listed at the top of this form about the funding and sponsorship.

Inventions and patents

Dr. Amay Bandodkar is an inventor of the sweat sensor that is part of this research being used. If the technology is licensed at NC State University, an innovation disclosure in Sophia (the Office of Research Commercialization database at the University) must state that the University and the inventor may benefit from the invention. If this patent or approach is successful at some point in the future, NC State University and Amay Bandodkar may receive financial benefits. If you would like more information, please ask the researcher(s) listed at the top of this form.

What if you have questions about this study?

If you have questions at any time about the study itself or the procedures implemented in this study, you may contact the researcher, Amay Bandodkar (ajbandod@ncsu.edu 919-515-0417).

What if you have questions about your rights as a research participant?

If you feel you have not been treated according to the descriptions in this form, or your rights as a participant in research have been violated during the course of this project, you may contact the NC State IRB (Institutional Review Board) office. An IRB office helps participants if they have any issues regarding research activities. You can contact the NC State University IRB office at IRB-Director@ncsu.edu, 919-515-8754, or fill out a confidential form online at https://research.ncsu.edu/administration/participant-concern-and-complaint-form/

Consent to participate

By signing this consent form, I am affirming that I have read and understand the above information. All of the questions that I had about this research have been answered. I have chosen to participate in this study with the understanding that I may stop participating at any time without penalty or loss of benefits to which I am otherwise entitled. I am aware that I may revoke my consent at any time.

☐ **Yes, I want to be in this research study.**

Name_____

Today's Date _____

☐ **No, I do not want to be in this research study.**

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Thank you for your consideration.