Wearable Augmented Prediction of Burnout in Nurses: A Synergy of Engineering, Bioethics, Nursing and Wellness Sciences

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September 6, 2023

MAYO CLINIC

Name and Clinic Number

Approval Date: **September 6, 2023**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Wearable Augmented Prediction of Burnout in Nurses: A Synergy of Engineering, Bioethics, Nursing and Wellness Sciences

IRB#: 22-000447

Principal Investigator: William V. Bobo, M.D., M.P.H. and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part. Your current or future employment and medical care at the Mayo Clinic will not be jeopardized if you choose not to participate.
Research Purpose	The purpose of this study is to develop a technology to predict burnout in nurses by measuring workplace, psychological, and physiological factors experienced by nurses. You have been asked to take part in this research because you are employed as a nurse at Mayo Clinic.
What's Involved	Study participation involves wearing a smartwatch daily and completing surveys over the course of 12 months.
Key Information	The risks of this study are minor and include physical discomfort from wearing the smartwatch and emotional discomfort from answering survey questions.

	All data obtained from participants will be kept confidential and all study participant information will be kept in a secure, password-protected file. However, there is a potential risk that your information could be accessed by persons outside of the study team. You do not have to participate in this study. Information is being gathered for research purposes only with no direct benefit to you. There is no cost to participate, and you will be compensated for your time.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** William V. Bobo, M.D., M.P.H **Phone:** (904) 953-7286 Arjun P. Athreya, Ph.D., M.S. **Phone:** (507) 422-6073 Sherry S. Chesak, PhD, RN **Phone:** (507) 538-4875 **Study Team Contact:** Nursing Research Study Coordinator **Phone:** (507) 422-5523 **Institution Name and Address:** Mayo Clinic 200 First Street SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Why are you being asked to take part in this research study?

You are being asked to participate in this research study because you are currently employed by Mayo Clinic as a nurse and your primary work assignment is in a hospital-based unit.

We plan to have 360 participants total, 240 from Mayo Clinic in Florida and 120 from Mayo Clinic in Rochester.

Why is this research study being done?

The purpose of this study is to develop a technology to predict burnout in RNs by measuring workplace, psychological, and physiological factors experienced by nurses.

Information you should know

Who is Funding the Study?
The National Institutes of Health is funding this study.

How long will you be in this research study?

You will be in this study for 12 months. During this time, you will be encouraged to wear a smartwatch continuously except when charging the device.

What will happen to you while you are in this research study?

After you have consented to participate in this study, you will participate in a baseline visit with a member of our study team. This visit will take approximately 30-45 minutes and can take place by appointment at a research office, at your place of work (outside of your shift), by telephone, or virtually over Zoom.

At the baseline visit, you will be asked questions about you and your job role. You will also be given a smartwatch (Garmin Venu3 smartwatch – the Venu 2 Plus or Venu 3 – depending on market availability). Study staff will assist you with setting up the Garmin Connect app and enrollment in Fitabase through visuals in a printed manual.

Following the baseline visit, you will be asked to wear your smartwatch continuously except when charging it. While you are wearing your smartwatch, your measurements will be collected for the study. These deidentified data will be stored in a password protected database.

Every 3 months, you will complete surveys about burnout risk, depressive symptoms, quality of life, and diet. You will receive a notification from the Mayo Clinic Survey Research Center when it is time to complete your survey. You will be asked to complete the survey within 7 days of receiving it. We will also send out reminders via phone call, email, or SMS text services (Mayo Clinic CDH- Portal SMS services). We hope that you will answer all of the questions, but you can skip any questions you don't want to answer. The questionnaires will take about 30 minutes to complete.

Upon completion of the quarterly surveys, you will be invited to complete one additional survey called the Flourishing Index. Completion of the Flourishing Index is also voluntary, and it takes 5 minutes or less to complete. You will receive an additional remuneration for this survey.

What are the possible risks or discomforts from being in this research study?

There is a small risk of discomfort while you are in the study. You may find wearing the smartwatch to be uncomfortable. Some participants may feel negative emotions, anxiety, or fatigue when answering the survey questions.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

During this study, we will ask you to answer questions about your emotional health and depressive symptoms. The responses to the questionnaires in the application will not be actively monitored by study staff. If you experience depression, thoughts of suicide, or any other mental health concern please seek medical assistance immediately.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you don't follow the study procedures,
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used. You may withdraw consent for use of this data by contacting the study team in writing.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

What are the possible benefits from being in this research study?

You won't benefit from taking part in this research study. It is for the benefit of research. In the future, nurses may benefit from what we learn in this study.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

There are no costs or charges to you for participating in the study. The cost of the smartwatch will be covered by the study.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

If you are able to complete the entire study, you will receive $200. Upon completion of all 4 quarterly surveys, you will also be eligible to voluntarily participate in an additional survey called the Flourishing Index. If you complete the Flourishing Index, you will receive an additional $25. Payments will be issued about every 3 months following the completion of your surveys.

It is possible that you can also receive up to an additional $80 for wearing the watch 70% of the time or more as follows: $20 per quarter upon confirmation that at least 70% wear time for that quarter has been achieved while active in the study; ideally, the 70% or more wear-time payments will be distributed on the same schedule as your other remuneration payments mentioned above per Mayo Clinic policy concerning research payments.

If you are participating in the validation study period (only in Cohort-A participants willing to participate in the study for an additional 12 months), the study team will provide a quarterly token of appreciation for continued participation. This will be in the form of a coffee mug, or lunch tote, a little pouch, other similar items of limited value that may or may not be Mayo Clinic branded.

This will bring the total possible remuneration amount to $305 upon completion of all quarterly surveys, confirmed 70% or more wear-time, and the additional survey on flourishing.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name, address and Social Security number in order to issue a check for your study participation. If you receive research payments totaling $600 or more in a calendar year, a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

Will your information be used for future research?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information collected in this study, allowing the information to be used for future research or shared with other researchers without your additional informed consent.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

All study data will be accessed via password, and only study clinicians and research coordinators will be provided the passwords. All study datasets will be deidentified in accordance with HIPAA guidelines. Therefore, each study participant will be assigned a unique study subject ID number.

Data collected from smartwatches and psychological measures will be linked to each subject ID number. No protected health information will be entered into the study databases used for data analysis, such as subject names, addresses, telephone numbers, social security numbers, Mayo Clinic patient numbers, or any other data that could serve as identifiers.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and <u>not</u> employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records.

This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

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Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts forever, unless you cancel it.

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Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature