Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: **A web-based intervention for cognitive behavioral therapy-based training to improve mental health in medical trainees**

Principal Investigator: Ginger Nicol, MD

Faculty Advisor: Ginger Nicol, MD

Research Team Contact: Justin Sanchez
Phone: 505-206-8314
Email: j.s.sanchez@wustl.edu

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

KEY INFORMATION

The first section of this document contains some key points that the research team thought you would find important. The research study is described in more detail after this section.

This is a research study conducted by Dr. Ginger Nicol having to do with interventions using online content to improve well-being in medical trainees. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not. Before you decide whether to be in this study, you may wish to consider other options that are available to you. For more information on opportunities to explore digital mental health content outside of participation in this study, please contact Justin Sanchez (j.s.sanchez@wustl.edu).

If you agree and sign this consent, you will be volunteering to participate in the research study. As a voluntary participant, your participation will last 4 months, during which time you will be asked to engage with the online intervention and periodically complete surveys. You will be asked to spend about 10-15 minutes per day, 5 days per week for the first 4 weeks reviewing online content for the intervention. After that, you will complete one survey per month (about 10-15 minutes each) for a total of 4 months. There is also the possibility we will invite you to complete an optional exit interview over Zoom after you participate, which would last about 20-30 minutes. This is a fully remote study, and you will not need to attend any in-person visits.

The main risks to you if you participate are emotional reactions as a result of the content of this study, which focuses on mental health topics including stress, burnout, and mood. There is also a possibility that confidential information may be accidentally disclosed.

You may or may not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because we hope it will guide the development of effective and accessible mental health interventions for medical trainees. There is no cost to you, and you will be paid up to $50 in Amazon gift cards for participating in the main part of the study, and potentially an additional $10 for

the exit interview. All of this information will be explained and is listed in more detail in this consent document. The research team must give you a copy of this signed consent document.

The rest of this document provides more details about the study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because of your current role/knowledge about/interest in medical trainee mental health.

The purpose of this research study is to determine the feasibility, acceptability, and efficacy of digital content to improve the mental health of medical trainees. We are developing this content in hopes of offering effective and accessible well-being resources to medical trainees.

WHAT WILL HAPPEN DURING THIS STUDY?

Participants will be randomized (1:1) to one of two evidence-informed, self-guided digital interventions: an interactive mobile mental health intervention (OptimalWork), or a curated, self-guided educational intervention (Radiolab). Both interventions are designed to take approximately the same amount of time: they both consist of about 20 modules, which can be completed at your own pace, with a suggested schedule of 5-10 minutes/day, 5 days/week for 4 weeks. To ensure equity, all participants will receive access to both interventions at different times in the study, although only the first will be required.

In addition to completing a digital intervention, this study involves completing a series of multiple-choice questionnaires / surveys (details below). These questionnaires can be filled out wherever is possible for you (for example: at home or in the office). In all of these questionnaires, you are free to skip any questions that you prefer not to answer.

You will receive periodic emails prompting you to complete the intervention content and surveys. These emails will contain a link to the relevant website and/or login info where you will be able to access the content. You will be paid up to $50 by gift card for being a volunteer participant. The procedures / timeline for the study are as follows:

- Upon enrollment, you will be emailed a link to complete a Baseline Survey, a Well-being Measures survey, and survey measuring challenge engagement (OptimalWork Inventory) (details below). Upon completing these, you will then be given instructions on how to complete one of two randomly-assigned interventions:
    - **Arm 1 (OptimalWork):** Includes 20 modules to be completed at your own pace (suggested schedule: 5-10 minutes of content per day, 5 days/week for 4 weeks). Each module is designed to take 5-10 minutes, and these include Tutorials (video content from Dr. Kevin Majeres explaining the concept of the day) and Best Practices (interactive sessions that incorporate user input to provide practical suggestions on how to apply the concept in daily life). These modules allow the user to control the playback speed (0.25 – 2x) and can be revisited at any time. Users are encouraged to practice a "Golden Hour" each week, in which one hour of their work is deliberately shaped as an opportunity to apply the principles from the MasterClass.

- **Arm 2 (Podcast Listening):** Includes 20 modules to be completed at your own pace (suggested schedule: 5-10 minutes of content per day, 5 days/week for 4 weeks). Each module consists of a selection from a podcast episode from Radiolab, a show that covers topics in science, philosophy, and more. These modules allow the user to control the playback speed (0.25 – 2x) and can be revisited at any time.

- You will be given Weekly Surveys (OptimalWork Inventory) for the first month (i.e., baseline and at the end of weeks 1-4), and a Feedback Survey upon completing the intervention after 4 weeks (see details below).

- You will be given Monthly Surveys (Well-being Measures) for months (i.e., at baseline and at the end of weeks 4, 8, 12, and 16).

- Eight weeks after enrolling in the study, you will be given access to the intervention (OptimalWork or Podcast Listening) that you were not assigned in the first month. This is to ensure equity in access to these interventions between groups; completion of the second intervention is not required as part of the study.

Survey Details

- **Details about the Baseline Survey**
  - About 5-10 minutes of time to answer 14 multi-choice questions
  - This survey will ask about demographic information, your current school situation and clinical duties, and utilization of WUSM health and mental health services.
- **Details about the Monthly Survey – Well-being Measures**
  - About 5-10 minutes of time to answer 42 multi-choice questions
  - These questions will focus on sleep, stress, burnout, emotional response (mood) and support. These results will be analyzed as the Primary Outcome for this study.
  - If you have not yet completed the Monthly Survey, you will receive a reminder email within 5 days.
- **Details about the Weekly Survey – OptimalWork Inventory**
  - About 5-10 minutes of time to answer 24 multi-choice questions. Responses will be analyzed as a Secondary Outcome in this study.
  - These questions will focus on challenge engagement across domains of ideals, mode of working, work-life harmony, and relationships.
  - If you have not yet completed the Weekly Survey, you will receive a reminder email within 2 days.
- **Details about the Feedback Survey**
  - About 5-10 minutes of time to answer 8 questions. Responses will be analyzed as a Secondary Outcome in this study and help guide the development of future digital well-being interventions.
  - These questions will ask you to rate your satisfaction (multi-choice, 6 questions) with different aspects of the intervention, and optionally to provide qualitative (free-text, 2 questions) feedback on your experience with the intervention.

<u>Audio Recording/Video Recording/Photographs</u>

One aspect of this study involves making audio and video recordings of you. This pertains only to the optional exit interview portion of the study. These recordings are made so that transcriptions can be

made and submitted to qualitative analysis to identify barriers and facilitators to implementing these kinds of interventions among medical trainees. Access to recordings is limited to a select number of study staff involved in the transcription process, and recordings will be destroyed once a de-identified transcription is made and the original is deemed no longer necessary.

While all recordings are stored in a confidential manner, please be aware that it may be possible to identify you from your voice recording. While all video recordings are stored in a confidential manner, please be aware that the recording will likely contain information that would identify you.

As the audio and video recordings are only relevant to the optional exit interview portion of the study, you may still enroll in the study without being recorded.

I give you permission to make **audio recordings/ video recordings** of me during this study.

_____ Yes **_____ No**
Initials **Initials**

Will you save my research data to use in future research studies?
As part of this study, we are obtaining data from you. We would like to use this data for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding the mental health needs of medical trainees. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you for use of your data. By allowing us to use your data you give up any property rights you may have in the data.

We will share your data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or commercial sponsors of research. We may also share your data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your data for future research you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

HOW MANY PEOPLE WILL PARTICIPATE?
Approximately 100 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?
If you agree to take part in this study, your involvement will last for approximately four months (16 weeks), with most of the involvement taking place in the first four weeks. There will be no in-person

visits or contact, however if needed you will be offered the chance to connect with a member of study staff who will talk with you over the phone and offer additional resources if appropriate.

Study Timeline (total events: 9)

- **Baseline:** Baseline Survey, Well-being Measures, OptimalWork Inventory (15-30min.)
- **Weeks 1-4:** Complete Intervention (20 modules: 15-20 min/day, 5 days/week, 4 weeks)
- **Week 1:** OptimalWork Inventory (5-10 min.)
- **Week 2:** OptimalWork Inventory (5-10 min.)
- **Week 3:** OptimalWork Inventory (5-10 min.)
- **Week 4:** OptimalWork Inventory, Well-being Measures, Feedback survey (15-30min.)
- **Week 8:** OptimalWork Inventory, Well-being Measures (10-20 min.)
- **Week 12:** Well-being Measures (5-10 min.)
- **Week 16:** Well-being Measures (5-10 min.)

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

You may experience emotional reactions as a result of surveys in this study. These surveys focus on mental health topics, including stress, burnout, and mood, so you may feel uncomfortable as a result of these questions. Note that you are free skip any questions you prefer not to answer.

Breach of Confidentiality

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because we hope it will guide the development of effective and accessible mental health interventions for medical trainees.

WHAT OTHER OPTIONS ARE THERE?

If you wish to know more about opportunities to explore digital mental health content outside of participation in this study, please contact Justin Sanchez (j.s.sanchez@wustl.edu).

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study.

You will be asked to provide your social security number (SSN) for payment purposes only. You will be paid $10 per main time point for completion of research activity. There are 5 main time points: baseline, 4 weeks, 8 weeks, 12 weeks, and 16 weeks, for a total of $50. You will be paid by gift card. To receive payment, you must complete the questionnaires at the given time points. If you do not complete the questionnaire, you will not be paid for those time points you do not complete.

WHO IS FUNDING THIS STUDY?

The Health Resources and Services Administration (HRSA) is funding this research study. This means that Washington University is receiving payments from HRSA to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from HRSA for conducting this study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those listed below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities
- The Health Resources and Services Administration (HRSA)
- Partner corporations / developers of digital mental health interventions.
- University representatives to complete University responsibilities
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.
- Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will have all data collected as part of the study coded with a unique study identification number, rather than using your name or other personally identifiable information. A master list linking the identification number and your email address will be kept separately from where data are stored. All databases are password-protected on secure servers.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify. Similarly, there will be no penalty for you as a student if you choose not to participate.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Justin Sanchez at 505-206-8314 or email j.s.sanchez@wustl.edu. If you feel that you have been harmed in any way by your participation in this study, please contact the Principal Investigator: Dr. Ginger Nicol at nicolg@wustl.edu.

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 07/01/25.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)