Participant Name: _____ Date: _____

Title of Study: Mindful Hand Hygiene to Reduce Infections Among Veterans While Enhancing Provider Well-Being – Nurse Intervention

Principal Investigator: Michael Todd Greene, PhD

VA Facility: LTC Charles S. Kettles VA Medical Center

Principal Investigator for Multisite Study: Michael Todd Greene, PhD

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the Department of Veterans Affairs Health Services Research & Development. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this study is to test an intervention focused towards promoting mindfulness among VA physicians and nurses. As part of this study specific hospital units have been randomly assigned to either receive the intervention or serve as a control group. You are being asked to participate in this study because the nursing unit on which you work has been assigned to receive the intervention.

Participation in this study is voluntary. You do not have to participate even if others in your unit choose to do so. If you choose to participate, you will be asked to complete some activities to promote mindfulness over the next month. This will include completing 3 online mindfulness education modules, attending at least one group discussion on mindfulness, and completing some study surveys.

This study is also being conducted with physicians separately. By doing this study, we hope to learn if this brief intervention will help improve mindfulness among VA physicians and nurses. Your participation in this research will last about 7 months total. The intervention period will last only 1 month. We will also ask you to complete 3 surveys over the next 7 months.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You may or may not personally benefit by taking part in this study. But by taking part, you could help us improve the mindfulness and wellness of future physicians and nurses. *For a complete description of benefits, refer to the Detailed Information section of this consent.*

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PI/SC Approval Date: 11/05/2021

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Participant Name: _____ Date:_____

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Principal Investigator: Michael Todd Greene, PhD

VA Facility: LTC Charles S. Kettles VAMC

Principal Investigator for Multisite Study: Michael Todd Greene, PhD

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

It will take 3-5 hours of your time over the next month. As with all research studies there is a risk of loss of confidentiality of your research data. However, we will take steps to protect you from these risks. *For a complete description of risks, refer to the Detailed Consent.*

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Michael Todd Greene, PhD at the LTC Charles S. Kettles VA Medical Center, Ann Arbor, MI. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is*:* Michael.Greene2@va.gov. You can also contact the project manager Karen Fowler at Karen.Fowler@va.gov, or (734) 845-3611.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

By conducting this research project, we hope to learn if a brief intervention is successful in improving clinician mindfulness.

HOW LONG WILL I BE IN THE STUDY?

Your individual participation in the project will take 7 months in total. This will include 1 month of the intervention. Intervention activities include completing 3 hours of online education modules and attending at least one 30 to 60-minute group discussion. We will also ask you to complete a 10-minute survey at baseline, at the end of the 1-month intervention, and again 7

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PI/SC Approval Date: 11/05/2021

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months from now. This entire research study is expected to take approximately 4 years for the researchers to complete.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

As part of this study, 2 nursing units from the LTC Charles S. Kettles VAMC have been randomly assigned to either participate in the intervention or serve as a control unit.

- Your unit has been assigned to the intervention arm of the study. All nurses from the intervention unit are being invited to participate in this voluntary study.
- This study is also being conducted at the Michael E. DeBakey VA Medical Center in Houston TX.
- Participation in the intervention will involve the following:
    1. Completing three 1-hour online educational modules on mindfulness
        - These online modules are offered by The Ohio State University Mind-Body Skills Training for Resilience, Effectiveness, and Mindfulness (STREAM) program.
        - You will be assigned a unique study code to access these modules.
        - Study staff will track which modules you complete using your unique study code. The Ohio State University STREAM program will not collect any personal identifiers.
        - We ask that you complete these modules during your personal time off-duty. If done off-duty, we can offer you $25 for each module you complete as a thank you for your time.
    2. Attending at least one 30 to 60-minute group discussion on mindfulness.
        - During the month of the intervention on your unit, the study team will organize several group discussions for intervention participants. You are asked to attend at least one of these discussions. You may attend more discussions if you choose.
        - The discussions will be offered at various days and times to be accessible to as many nurse participants as possible.
        - The discussions may be offered either in person or virtually using VA approved conferencing software.
        - The discussions will be led by co-investigators on this project who are serving as mindfulness champions.

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: 11/05/2021

LSI Approval Date: 12/17/2021

LSI Verification Date: NA

- With your permission, we will audio record the group discussions to help analyze the data. With these recordings we can assess if the intervention is being delivered the same way across study sites.
- Study staff will ask for your verbal permission before beginning to record the group discussions. You can refuse to be recorded or ask to turn off the recorder at any time.
- The recordings will be transcribed for use in study analysis. Any names or identifiers will be removed from the transcript to protect your confidentiality. The recordings will be deleted once the transcripts have been verified.

3. Completing 3 study surveys.
   - You will be asked to complete a study survey at 3 time points – Baseline, in 1-month (after the intervention period), and in 7-months.
   - Each survey should take approximately 10 minutes to complete.
   - The survey will ask you questions about mindfulness and your well-being. You are free to skip any question you do not wish to answer.
   - The surveys can be completed either electronically, or on paper and returned using a postage-paid business reply envelope.
   - The surveys will be labeled with a unique study ID number. It will not include your name or any other personal identifiers to protect your confidentiality. Only study staff will have access to the file that would link your name to your study ID number.
4. Optional: As part of this study, we are encouraging participants to download a mobile application to your personal device designed to promote mindfulness. The application was originally developed by VA researchers and modified for use with clinicians specifically for our study.
   - Use of this mobile application is encouraged, but not required.
   - Similar to completing the educational modules, if you choose to use the application, you will be asked to enter a unique study code. The application will not collect any personal identifiers.

- This study is also being conducted separately with physicians from both the Ann Arbor VA and the Michael E. DeBakey VAMC in Houston TX. In total, we hope to enroll up to 120 nurses and 214 physicians into this study from both facilities.

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: 11/05/2021

LSI Approval Date: 12/17/2021

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- Study data from all participants in the intervention will be compared to those in the control arm in aggregate. Data from nurse and physician participants will also be compared.
- You will not be identified in any reports or papers from this study.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- As part of this study you are being asked to:
  - Complete 3 hours of mindfulness education modules during your off-duty time.
  - Participate in at least 1 group discussion on mindfulness
  - Complete your questionnaires as instructed.
  - Download and use an optional mobile application to promote mindfulness.
  - Ask questions as you think of them.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any study has possible risks and discomforts. The activities in this study may cause all, some, or none of the risks listed. Rare, unknown, or unexpected risks also may occur.

- There are no expected physical risks associated with this study.
- Some people get uncomfortable from being asked questions about their well-being. If, for any reason, you do not want to answer specific survey questions or you wish to leave a group discussion, you will be able to do so. Every effort will be made to provide an open and comfortable setting for the group discussions on mindfulness.
- Another risk is potential loss of confidentiality if the research data was breached. This risk is unlikely, and we will take steps to prevent this.
  - Your name and other identifying information will be kept in a separate limited-access file from your study data. For example, your name or any identifying information will not be included on the study surveys or in the group discussion transcripts.
  - Your study data will be stored on a secure VA server that only the study team can access.
  - If you choose to complete the study surveys electronically, it will be done using a survey program such as Qualtrics, which may store data outside the VA firewall. The survey will not contain any personal identifiers – only a unique study ID that

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: 11/05/2021

LSI Approval Date: 12/17/2021

LSI Verification Date: NA

only study staff can use to identify you. If you prefer, you can choose to complete the survey on paper instead of electronically.

- At the end of the study, the linking information will be removed from the survey and study transcripts to protect confidentiality.
- Risks associated with using the optional mobile mindfulness application are also minimal. If you choose to use this application, you will be asked to enter a unique study code into the application. The application may collect some data about you, such as how many times you access the application or what parts of the application you use. The application may also ask you some questions about mindfulness. No one outside this study will have access to the file that would link that information back to you. This mobile application and its data storage is VA approved and compliance with the VA Technical Reference Model.
- Data collected by the Ohio State University education modules will only include your unique study code and the date each module is completed. No personal information will be shared with the Ohio State University.

- Participation in this study will not have any impact on your VA employment. Only the study team will have knowledge about your participation. We will not share any information about your participation in this study with any of your VA supervisors.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include feeling less stressed and more mindful at work.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- Paper study documents, such as this consent form, will be stored in locked filing cabinets at the VAAAHS Center for Clinical Management Research offices.
- If you choose to complete the study surveys electronically, the responses will be stored on a survey program such as Qualtrics, which may be outside the VA firewall. The survey will not contain any personal identifying information to protect your confidentiality.

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: 11/05/2021

LSI Approval Date: 12/17/2021

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- The guided discussions will be audio recorded and transcribed by staff at the VA Ann Arbor Center for Clinical Management Research. The audio recordings will be deleted once the transcript has been checked for accuracy.
- Electronic study data will be stored on a secure VA server that only study staff can access.
- Data from this study will be combined with data from the Michael E. DeBakey VA Medical Center for joint analysis This analysis will occur at the Ann Arbor VA Center for Clinical Management Research, behind the VA firewall.
- You will not be identified in any reports or manuscripts on this study.
- By law, study records must be kept in a secure location for about six years after the study has ended, at which time they will be destroyed.

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

Health Information Portability and Accountability Act (HIPPA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name and address.

The research team may also need to disclose the information to others as part of the study progress. Others may include the following: Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office (GAO; Sponsors; Contractors, Affiliates as appropriate)l the VA Institutional Review Board, and the local VA medical facility Human Research Protections Program.

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: 11/05/2021

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Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will not have access to your research related health records. This will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility o you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VA employee in any way.

If you revoke this authorization, Michael Todd Greene, PhD and his or her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?

If you choose to complete the online educational modules outside of your normal work hours, you are eligible to receive a $25 gift card for each completed module. You could receive a maximum of $75 in gift cards if you complete all 3 of the mindfulness educational modules. There is no compensation for other study activities or for completing the educational modules during your normal work hours. When you complete a mindfulness module you will be asked to enter a unique study code. No other identifying information will be collected while completing the modules. Colleagues at The Ohio State University will then notify the project staff in Ann Arbor when a module is completed and what code was entered. The study team will then use that code to identify you as completing a module and will send you a $25 gift card. The gift card will either be provided to you in person where feasible or will be mailed to your home address by the project manager Karen Fowler from the VA Ann Arbor. If you have

FOR VA CENTRAL IRB USE ONLY

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any questions about the study gift cards, please contact the project manager Karen Fowler at Karen.Fowler@va.gov or (734) 845-3611.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

This study does not involve any expected physical risks. However, if you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call Ms. Karen Fowler at 734-845-3611.

DO I HAVE TO TAKE PART IN THE STUDY?

Taking part in this study is voluntary. If you don't want to take part, there is no penalty or loss of benefits to which you are otherwise entitled. Refusal to take part in this study will in no way influence your employment, ratings, subsequent recommendations, or academic progress.

You may discontinue taking part in this study at any time without any penalty or loss of benefits. If you leave the study early, the study team may continue to review the data already collected for the study but will not collect any more information.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions, concerns or complaints about the research study, you can contact member(s) of the research study team: Michael Todd Greene, PhD (Principal Investigator) can be called at (734) 936-4795 or Karen Fowler, MPH (Project Manager) at 734-845-3611 (email at Karen.Fowler@va.gov). If you have general questions about participating in research at the LTC Charles S. Kettles VAMC you can contact the Ann Arbor VA Research Office at(734) 845-3440.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

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Principal Investigator for Multisite Study: Michael Todd Greene, PhD

FUTURE USE OF DATA AND RE-CONTACT

Your data without any identifiers could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____ has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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Mailing Address