MINDFULNESS DURING CORONAVIRUS

Informed Consent Form to Participate in Research
Rebecca E. Wells, MD, MPH, Principal Investigator

You are invited to participate in a research study. The purpose of this research is evaluate the effects of mindfulness activities on stress and anxiety related to COVID-19. Participation in this study will involve completing a brief survey, undergoing a brief guided mindfulness session led by the study investigators, and completing a brief survey after the session, all lasting about 30 minutes. Repeat mindfulness sessions and surveys may occur in the future as well. The mindfulness sessions may be pre-recorded or may be live. The live sessions will be recorded and may be made publicly available. I understand and give my permission for release of photographic, video, or audio recordings from these sessions for purposes of research and education. I understand that once this information is released, it may no longer be protected by state or federal confidentiality laws and may be re-disclosed.

All research studies involve some risks. A risk to this study that you should be aware of is a breach of confidentiality. There is the possibility that you may benefit from participation in this study.

Your participation in this study is voluntary. Other relaxation or mindfulness activities are available outside of the study. You will not lose any services, benefits, or rights you would normally have if you choose not to participate. You may discontinue participation at any time without penalty.

Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Rebecca E. Wells, MD, MPH. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** demographic information and your stress and anxiety levels. We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information on a password protected computer.

Your information may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products. Some of the people, agencies and businesses that may receive and use your health information are the Institutional Review Board; representatives of Wake Forest University Health Sciences; representatives from government agencies such as the Office of Human Research Protections (OHRP), and similar agencies in other countries. Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from

this study unless there are photographs or recorded media which are identifiable.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Rebecca Wells, MD, MPH that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Rebecca Wells, MD, MPH
[redacted]

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 Web site at any time.

By completing the surveys and participating in the mindfulness session, you are agreeing to take part in this study.