*Uniformed Services University of the Health Sciences*
**CONSENT TO PARTICIPATE IN RESEARCH**
**Study Title:** *Optimizing a Multi-Modal Intervention to Reduce Health-Risking Sexual Behavior*
**Principal Investigator:** *Ryan Landoll, PhD, ABPP, Maj, USAF*

**Agreement to Participate in a Research Study**
**And Authorization for Use and Disclosure of Information**

You may be eligible to take part in this research study. This form gives you important information about the study. Please take time to carefully review this information. You should talk to the researchers about the research study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

**KEY INFORMATION:**

Faculty at the Uniformed Services University of the Health Sciences in conjunction with researchers at the Centers for Behavioral and Preventive Medicine at The Miriam Hospital and support from collaborators at United States Military Treatment Facilities (MTFs), including Naval Hospital Camp Pendleton, Camp Lejeune, Joint Base Elmendorf-Richardson, Joint Base Lewis-McChord, Keesler Air Force Base, Offutt Air Force Base, Fort Drum, Fort Jackson, and United States Naval Hospital Okinawa, are conducting this study to test a sexual and reproductive health intervention, the smartphone application ("app") *Mission Wellness*, they have developed. Participating in this study may take up to approximately three hours of your time over 3-5 sessions, including review of this form. As a part of this study you will be asked to complete several electronic questionnaires and go through the smartphone app *Mission Wellness*, the sexual and reproductive health application being tested as a part of this research study.

Potential benefits to your participation in this study include an increase in your knowledge of sexual and reproductive health and health-seeking behaviors. Potential risks to participating include feelings of discomfort or distress due to the topic of the study. The alternative to participating in this research study is to not participate. Participation in this research study is entirely voluntary. Your decision will not affect your future care at your local MTF or within the Military Health System. If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.


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Please tell the researchers if you are taking part in another research study.

**PRINCIPAL INVESTIGATOR:** Ryan Landoll, PhD, Maj, USAF; (Tel) 301-295-3185

**STUDY SPONSOR:** The Uniformed Services University of the Health Sciences sponsors this research. As the sponsor of this research is affiliated with the Department of Defense (DoD), the DoD may have access to your research data in accordance with DoDI 3216.02.

**SOURCE OF FUNDING:** This study is being paid for by a grant from the Uniformed Services University of the Health Sciences.

**LOCATION OF THE RESEARCH:** This research is being conducted by Family Medicine faculty at the Uniformed Services University of the Health Sciences (Bethesda, MD) in conjunction with researchers at the Centers for Behavioral and Preventive Medicine at The Miriam Hospital (Providence, RI) and with support from United States Military Treatment Facilities across the globe, including Naval Hospital Camp Pendleton (Oceanside, CA), Camp Lejeune (Jacksonville, NC), Joint Base Elmendorf-Richardson (Anchorage, AK), Joint Base Lewis-McChord (Tacoma, WA), Keesler Air Force Base (Biloxi, MS), Offutt Air Force Base (Bellevue, NE), Fort Drum (Watertown, NY), Fort Jackson (Columbia, SC), and United States Naval Hospital Okinawa (Okinawa, JP).

**DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS**: The Uniformed Services University of the Health Sciences, The Miriam Hospital, collaborating Military Treatment Facilities, and their affiliated research team members do not have any financial or personal conflicts of interest to disclose.

## WHAT IS THE PURPOSE OF THIS RESEARCH AND WHO WILL TAKE PART?

The purpose of this research study is to determine which aspects of the mobile behavioral sexual and reproductive health intervention (i.e., a smartphone application ["app"]) *Mission Wellness* are most effective at improving sexual and reproductive health outcomes of active-duty service members. It is expected that there will be up to 900 service members taking part in this study overall over a period of several years.

## WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

We have already asked you some questions to determine your eligibility to participate in the study. If you decide to participate in this study you will be asked to go through the smartphone app *Mission Wellness* on your personal mobile phone and complete several questionnaires



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electronically outside of the app. The app will include education on sexual and reproductive health, such as sexual and reproductive health knowledge, risk, behaviors, and consequences in the form of text, videos, images, games, and other interactive content. The app is supposed to help you better understand sexual and reproductive health and how your decisions can affect your sexual and reproductive health.

As a part of evaluating which parts of the app work best, participants in this study will be assigned different combinations of tasks (e.g., videos, games, images). This means that someone else who participates might receive more or less content – or tasks – to complete in the app than you. How much content you receive has nothing to do with any information you provide to us; it is entirely random. The app may take up to one hour to go through entirely, depending on how many tasks you receive in the app.

You will be asked to complete three electronic questionnaires outside of the app if you choose to participate. You will be asked to complete a questionnaire before using the app, within a week or so of completing the entire app, and 30-to-90 days after completing the entire app. The questionnaires will ask you questions related to your demographics, mental health, and sexual and reproductive health care, knowledge, and practices. Each questionnaire is anticipated to take approximately 20-30 minutes to complete.

At no point will your medical record be accessed as a part of this study. At the end of this research study research results about you will not be directly shared with you; they will be aggregated and published in a scientific journal.

Participation in this study is entirely voluntary. There is no penalty if you choose not to take part in this research study or if you leave the study before it is finished. However, if you will only be eligible to receive compensation for your participation in this study if you finish most or all parts of it.

## WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, there is a risk of feeling uncomfortable or distressed by the content of this study, or the discussion of sexual and reproductive health. If you feel uncomfortable or distressed by this study to the point that it is affecting your ability to live your life on a day-to-day basis, please contact the study team immediately.

You might feel like you have to take part in this study because you are in the military or because someone you know has endorsed it. This study is entirely voluntary, so your choice to participate is entirely and only your decision and not a requirement of being in the military.



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Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your research study records or other information researchers have stored about you. As described in the "Who Will See My Information (Privacy) And How Will It Be Protected (Confidentiality)?" section below, every effort will be made to protect your privacy and confidentiality.

While unlikely, there may also be other risks of taking part in this study that we do not yet know about.

## WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

The possible benefits to you as a research participant in this research study are an increase in knowledge of sexual and reproductive health and confidence in ability to perform health-seeking sexual heath behaviors (e.g., using condoms, getting tested for sexually transmitted diseases), which, overall, can lead to better sexual health. However, there is no guarantee that you will personally benefit from being in this research. Others may benefit in the future from the information learned during this study.

## VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You might feel like you have to take part in this study because you are in the military or because you receive care at one of the MTFs that is part of the study. However, as this study is completely voluntary, taking part in this study is not a requirement of your job or of being in the military.

You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled. However, please note that after all data has been collected, any documentation linking your identity to your data will be destroyed and after that time, it will not be possible to remove your data from analysis. You will be informed if significant new findings develop during the course of your participation in this research study that may relate to your decision to continue participation.

## ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

There are no costs to you for taking part in this research study.

## WHAT ARE THE ALTERNATIVES TO PARTICIPATING IN THIS RESEARCH?

Your alternative is not to participate in this research. There may also be other research studies in the community that you might participate in. Your decision to participate or to not participate will not in any way change your relationship with your healthcare providers.

## IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

If you participate in this research *off-duty*, you will be eligible to receive a $5 electronic Amazon gift card or redemption code after completing the questionnaire following use of the app and an additional $10 electronic Amazon gift card or redemption code after completing a follow-up questionnaire 30-to-90 days after use of the app. If you complete the follow-up questionnaire you will also be eligible to be entered in a raffle to win a $50 electronic Amazon gift card or redemption code.

## WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

It is your decision to be in the study. You are not required to participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If new information becomes available that might change your mind about whether you want to stay in the study the researchers will share this information with you as soon as possible.

The principal investigator of this research study may withdraw you from this research study at any time if it is determined to be in your best interest, if you are unable to comply with the procedures required, if the military mission prevents you from continuing, or if you no longer meet eligibility criteria.

Withdrawing your consent to participate in this study will not remove de-identified information you have already provided to the research team.

## WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at:
http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2005.pdf.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This web site will not include information that can identify you. At most, the website will include a summary of results. You can search this website at any time.

The research team will keep your research records. These records may also be looked at by staff from the Institutional Review Board (IRB) and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

This form, which has your name on it, and any contact information you provide will be stored separately from any data that is collected in surveys. All study data from surveys and app use will be assigned a unique identification number, and will not be identified by your name or anything piece of information that people could use to identify you (e.g., your birthday). Surveys will be collected using secure software. All research files will be kept on servers at the Uniformed Services University of the Health Sciences and/or secure hospital servers at The Miriam Hospital. All information collected from surveys and interviews will be available to the investigators and research team members participating in this study at the Uniformed Services University of the Health Sciences and The Miriam Hospital. Those listed will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law. Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will de-identified.

For this research study, a Department of Health and Human Services (DHHS) Certificate of Confidentiality is in place to protect your privacy such as your name or other identifying information from being disclosed in any civil, criminal, administrative, legislative or other proceedings, whether at the federal, state or local level. The Certificate cannot be used to resist a demand for information from personnel of the U.S. Government that is used for auditing or

evaluation of Federally-funded projects or for information that must be disclosed in order to meet the requirements of the Food and Drug Administration (FDA). Further, the researcher is not prevented from disclosure for reporting matters such as family abuse, sexual assault, reportable communicable diseases, a participant's threatened violence to self or others, or as military regulations may require. You should understand that the Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

## USE OF INFORMATION

Data collected during this study will be stored for ten years following completion of the study. Data will have anything that might identify you removed; it will be de-identified—not personally identifiable. Information gained from your participation in this research study will be published in journals, discussed for educational purposes, and used generally to further science. Research that uses the information you provide may lead to the development of new inventions, products, or discoveries (some that might be patented and licensed); there are no plans to share any potential profits with you. You will not be personally identified; all information will always be presented as anonymous data. After all data has been collected from you, any documentation linking your identity to your data will be destroyed.

Data that we obtain from you for this study might be used for future studies, in the same area as the original study or it may be for a different kind of study. If we do so, data may then be used for future research studies or given to another investigator without getting additional permission from you. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

Any future research using your retained data will require a research protocol for the proposed study approved by an Institutional Review Board (IRB) (a committee responsible for protecting research participants) or other authorized official responsible for protecting human subjects of research. The data protections for privacy and confidentiality described in this consent form will apply to any future use of your stored data.

## CONTACT INFORMATION:

### Principal Investigator (PI)

The PI Dr. Ryan Landoll or a member of the Military Active-Duty Reproductive + Sexual Heath (MARSH) Research Program staff will be available to answer any questions throughout this study at: (301) 295-3185, 4301 Jones Bridge Rd, Bethesda, MD 20814

**Uniformed Services University of the Health Sciences Human Research Protection Program (HRPP) Office**

The HRPP Office Point of Contact (POC) and/or Human Protections Administrator (HPA) at USUHS will be available to answer questions or discuss concerns you may have about this research study at: (301) 295-3303, 4301 Jones Bridge Rd, Bethesda, MD 20814

**Institutional Review Board (IRB) Office**

If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Office at USUHS at: (301) 295-3303, 4301 Jones Bridge Rd, Bethesda, MD 20814

IF THERE IS ANY PART OF THIS DOCUMENT YOU DO NOT UNDERSTAND, ASK THE PRINCIPAL INVESTIGATOR OR A RESEARCH STAFF MEMBER BEFORE SIGNING THIS DOCUMENT. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

**SIGNATURE OF PARTICIPANT**

By signing this form, I voluntarily consent to participate in this research study. I agree that I have been provided time to read the information describing the research study in the consent form and have done so. I have been provided with the opportunity to ask questions, and all of my questions have been answered to my satisfaction.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date



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