FORM D – INFORMED CONSENT DOCUMENT

Volunteer Name:	

96th Medical Group
INFORMED CONSENT DOCUMENT
[Adult, Child (14-17 years of age)]

Title of Protocol:	Stress Management and Resiliency Training (SMART) for Family Medicine Residents at Eglin AFB
FWH #:	20190021H

INFORMATION ABOUT THIS CONSENT FORM: You may be eligible to take part in a research study. This form gives you important information about the study. You may be asked to sign your name in more than one place in this document, as needed. Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you may have for them. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand the procedures of the study and what the study is about, including the risks and possible benefits to you. If you are taking part in another research study, please tell the researchers or study staff.

VOLUNTARY PARTICIPATION: Your participation in this study is completely voluntary. If you choose not to participate in this research study or leave before it is finished, your decision will not affect your eligibility for care or any other benefits to which you are entitled. If significant new findings develop during the course of this study that may relate to your decision to continue to participate in the study, you will be informed.

PRINCIPAL INVESTIGATOR: The Principal Investigator (PI) is the researcher directing this study and is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is:

PI Name and Degrees:	Rank:	Branch:	Department and Base:
Laura Rhaney, MD	Capt	USAF	96 MDGFamily Medicine Residency

PURPOSE OF THIS STUDY (Why is this study being done?)**:** The purpose of this study is to identify if the practice of the Stress Management and Resiliency Training (SMART) program mindfulness decreases stress and increases resilience in family medicine residents. You are being asked to consider participation because you are a family medicine resident at Eglin AFB. This study will enroll approximately 35 subjects overall.

The SMART program specifically targets busy professionals who could very much use the benefits of mindfulness, but may not have a large amount of time to spend in training. The program uses techniques of joyful and kind attention, as well as a number of methods of interpreting the external world, which when practiced regularly in small increments can add up to increased quality of life.

PROCEDURES: If you decide to take part in this research study, you will be asked to sign this consent form. During your participation in this study, you will be asked to make approximately 4 visits with the study staff. As a research participant, you will undergo the following research-related procedures:

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SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY:

- Obtain your Informed Consent Document and HIPAA Authorization.
- We will record your name, age, gender, current email address, phone number, and Post Graduate Year (PGY) in training.

Study Procedures – as a participant, you will undergo the following **study-related procedures**:

Visit 1-Baseline (can be the same day as Screening Visit):

- You will be handed the following questionnaires in a plain manila envelope to complete prior to the SMART 1 Hour Session and will be asked to return them to the study staff:
  - Stress Scale
  - Mindful Attention Awareness Scale
  - Connor-Davidson Resilience Scale
- You will participate in the 1-hour SMART Program training conducted by the PI, who is certified to teach this method.

Visit 2-12 Weeks from Baseline:

- You will be handed the following questionnaires in a plain manila envelope to complete and will be asked to return them to the study staff:
  - Stress Scale
  - Mindful Attention Awareness Scale
  - Connor-Davidson Resilience Scale

Visit 3-12 Months from Baseline:

- You will be handed the following questionnaires in a plain manila envelope to complete and will be asked to return them to the study staff:
  - Stress Scale
  - Mindful Attention Awareness Scale
  - Connor-Davidson Resilience Scale

Your participation ends at 12 months.

RISKS OR DISCOMFORTS: There is a risk that you may experience psychological discomfort from group sharing. Additionally, there may be a risk of inadvertent breach of confidentiality.

WITHDRAWAL FROM THE STUDY: If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care and you will not be penalized or lose any benefits to which you would otherwise be entitled.

BENEFITS: There is no direct benefit to you for participating in this study. We hope the information learned from this study may help future residents increasing resiliency, decrease stress, increased ability to handle issues in both professional and personal life.

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COSTS: Will taking part in this study cost anything? The investigators have designed this study so that there is no cost to you to participate in this study other than what it will cost you to travel to the research appointments, beyond any scheduled standard of care appointments.

PAYMENT (COMPENSATION): You will not receive any compensation (payment) for participating in this study.

POTENTIALLY BENEFICIAL ALTERNATIVES TO STUDY PROCEDURES OR INTERVENTIONS: The only alternative is not to participate in this research study.

CONFIDENTIALITY OF RECORDS OF STUDY PARTICIPATION: Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C. § 552a, the Health Insurance Portability & Accountability Act of 1996, Public Law 104-109 (also known as HIPAA), and their implementing regulations. DD Form 2005, Privacy Act Statement- Military Health Records, contains the Privacy Act Statement for the records.

By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further the generalizable knowledge of medical science community. You will not be personally identified; all information will be presented as anonymous data.

Your records may be reviewed by the U.S. Food & Drug Administration (FDA), the Air Force, the DoD, other government agencies that oversee human research, and the 59 MDW Institutional Review Board.

A copy of this consent will be stored by the investigator in a locked cabinet in a locked room, as part of your research record. All research data will be kept in an electronic database, which will be double password protected, firewall-protected, encrypted, and access-restricted to people involved in this study. The research data will be coded. As soon as possible, any link between your identity and the research information will be destroyed which means research information about you will be permanently de-identified. Personal identifying information will be destroyed no later than at the closure of the study. The research information collected about you for this study will not be used for any additional research activity beyond what you have approved by signing this consent. The study staff advises that you protect your copy of the informed consent document. A breach of confidentiality could occur if you inadvertently lose this document or allow others to view the document. In the unlikely event that you experience a loss of confidentiality, the study staff will take appropriate action to assist you.

Complete confidentiality cannot be promised, particularly for military personnel, because information regarding potential UCMJ violations or concerns regarding fitness for duty may be reported to appropriate medical, law enforcement, or command authorities.

ENTITLEMENT TO CARE: In the event of injury resulting from this study, the extent of medical care provided is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries. Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations, and if you have questions about your rights as a research subject or if you believe you have received a research-related injury, you may contact the Director, 59 MDW Clinical Investigations Research Support Division, (210) 292-7069 or the Eglin Air Force Base

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Human Subject Research Protections Point of Contact, (850) 883-8834. If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

CONTACT INFORMATION:

****In the event of an emergency, dial "911" or immediately seek assistance at your nearest emergency room.****

Principal Investigator (PI): The principal investigators or research staff will be available to answer any questions concerning procedures throughout this study.

Location	Contact	Phone	Off-Duty Phone
Eglin Air Force Base	Capt Laura Rhaney	(612) 239-9763	(850) 883-9501

Institutional Review Board (IRB): The 59 MDW Institutional Review Board (IRB), the 59 MDW committee that reviews research on human subjects, will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer at 210-292-4683. You can contact the IRB by calling the Chairperson of the 59 MDW IRB at 210-916-8251, or by mail to IRB at 59 MDW/SCT, 1100 Wilford Hall Loop, Bldg 4430, JBSA Lackland, Texas 78236. If you have any questions about your rights as a research subject, research-related injuries or any other concerns that cannot be addressed by the PI, you can also contact the the Eglin Air Force Base Human Subject Research Protections Point of Contact, (850) 883-8834.

All oral and written information and discussions about this study have been in English, a language in which you are fluent. If you agree to participate in this research study, please sign this section. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:

- You have read the above information.
- Your questions have been answered to your satisfaction.
- Your consent to participate in this study is given on a voluntary basis.

A signed copy of this form has been given to you.

_____ _____

VOLUNTEER'S SIGNATURE **DATE**

_____

VOLUNTEER'S PRINTED NAME

_____ _____ (_____)_____-_____

ADVISING INVESTIGATOR'S SIGNATURE **DATE** **PHONE#**

_____

PRINTED NAME OF ADVISING INVESTIGATOR

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