

CONSENT FORM

Career Enhancement Training Study Delivered Across Career Phases **Principal Investigator: Peter A. Wyman, PhD**

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate.

Key Information

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate or at any time.

- You are being asked to take part in this study because you are an Airman in Technical Training at Sheppard AFB and in a career field that supports the missions of Global Strike and Air Mobility Major Commands.
- Taking part in this study will last about one year.
- You will be asked to participate in one of two trainings starting today, complete a survey today, and another survey at 6 and 12 months. You will also have the option to receive text messages related to information you learned in the training and reminders by text to take the surveys.
- The most common risk of participating in the study is that some topics discussed in the trainings include common stressors and challenges, which could elicit stress and/or distress. Please see the “Risks of Participation” section in this consent form. The study team will discuss these risks with you.
- You might not benefit from being in this research study. A potential benefit might be that you learn about strategies for building strong relationships and managing stress and challenges in your Air Force career. This information could help you to improve your resilience and well-being.
- Being in this research study is voluntary – **it is your choice**. If you change your mind about participating, you may stop at any time.

Purpose of Study

This study is designed to learn about strengths that help with real-life challenges in the Air Force—what strengths help with the transition from civilian to military life and what strengths help Airmen get through the “ups and downs” that happen in military life.

This study compares two types of training for Airmen starting their careers, Wingman-Guardian Connect and Stress-Management. This study may help the Air Force offer programs to Airmen that will optimize their career goals, manage challenges of Air

Force to reduce stress, depression, and prevent some Airmen from becoming hopeless or even suicidal.

Description of Study Procedures

If you decide to take part in this study, you will be asked to complete a survey today before you start training and again at 6 months and 12 months. Your class, and 5-11 other classes will be randomly assigned (like a coin flip) to participate in either Wingman-Guardian Connect or Stress Management training. All training will take place with about 3-8 classes, so about 30-80 Airmen. All training will occur during unrestricted time, and no participant will miss class instruction time.

Wingman-Guardian Connect Training Description:

- Delivered by a certified facilitator from the Air Force and/or the University of Rochester.
- Covers skills to grow healthy relationships, emotional balance and other strengths that help Airmen make the most of opportunities during career transitions.
- The program includes approximately 6 hours of training spread over three days.
- You will be asked if you want to contribute to a strength-based video public-service campaign to share the program concepts with others in and outside the training group (other Airmen and USAF prevention personnel).

Stress Management Training Description:

- Group training delivered by University of Rochester research staff.
- Covers knowledge about the stress response system and techniques for reducing stress that can improve well-being and health.
- The program includes 2 hours of training in one day.
- You can choose to participate in a relaxation activity with other members of your class.

Text Messaging:

- Both trainings include informational text messages (approximately 1 per week) that reinforce training concepts and provide new information.
- Texts are computer-generated and not for texting interaction with trainers.
- Texts include short videos and quick polls that show how Airmen are using the skills.
- You may decide not to receive or send text messages with research study staff at any time, in person or by sending the research number a text message that says **“Stop Research Text”**. Your consent, and any request to stop email or text messaging, applies to this research study only.

Questionnaires

- You will complete a survey (~20 minutes), today, and again in 6 and 12 months (follow-up surveys completed in an off-duty context)
- You will be given a log-in ID to connect to the survey on a secure web-based platform located at the University of Rochester. IDs assigned to participants will be changed and replaced with random IDs before our research team receives data.
- Questions cover healthy career practices (e.g., having mentors), supportive relationships, the ability to manage common stressors of military occupational problems and life, and emotions and thoughts that can be challenging (i.e.,

depression, suicide risk, hopelessness). You will also be asked to name classmates who you trust and respect (we do not retain names).

- Questions about emotional health are answered on a separate secure site that does not store any personal information, as an added protection to your confidentiality. Graduation status (i.e., graduated, retrained, or separated) of members of your technical training class will be obtained from a squadron administrator 2-4 weeks after the scheduled completion of the course, and will be entered onto a secure, web-based site at the University of Rochester by research staff.

You will be asked to provide contact information, (personal email address and backup email if possible, and phone number), so you can be sent a URL to complete the follow-up questionnaires in 6, and 12 months in an off-duty context. If you agree to receive text messages, we will use the provided phone number.

Future Use of Information/Samples

Your information collected as part of this research will not be distributed or used for future research studies.

Return of Research Results

We will not be able to give you any individual results from taking part in the study. Survey responses are kept under an ID as noted in the Confidentiality section, and information from surveys about behavioral/emotional health will be stored separately and IDs will be removed before this data is sent to the research team.

Risks of Participation

(1) Some of the topics discussed during trainings include common stressors and challenges, which could elicit stress and/or distress. Training facilitators are qualified to note any distress and offer information on behavioral health resources available to you.

(2) You could disclose personal information and another participating subject could repeat that information out of the training context, resulting in a loss of confidentiality.

You will be reminded at the beginning and end of each group training session that content shared by individuals should not leave the group.

(3) The text messages and emails that are sent to you, which contain no personal information, could be accidentally seen by another person with physical access to your phone or computer, revealing your participation in the study. We advise you to use security passcodes on all devices to protect your privacy.

Clinical Trial

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 Web site will include a summary of the results. You can search this website for information related to this study by using this study's identification number NCT05967364.

Early Termination

If you decide to end your participation in the study before you complete it, that is your choice. The study team will not attempt to contact you in the future if you inform the study team that you wish to withdraw from the study.

Benefits of Participation

You might not benefit from being in this research study. The potential benefit to you from being in this study might be that you learn about strategies for building strong relationships and managing stress and challenges of Air Force life. This information could help you to improve your resilience, well-being, and career success.

Alternatives to Participation

You are free to not participate in the research or withdraw at any time.

New Study Information

If we discover any new information that might make you change your mind about continuing in the study, we will let you know.

Number of Subjects

Approximately 2,970 subjects will take part in this study.

Sponsor Support

The University of Rochester is receiving money from the National Institute of Mental Health to conduct this study. Dr. Peter Wyman, the Principal Investigator on this study, has a financial interest in the Connect Program that has been licensed to a commercial entity.

Costs

There will be no cost to you to participate in this study.

Payments

You will be paid \$50 for each follow-up survey completed (at 6 and 12 months) via Amazon gift cards that will be sent to you via email or text message. You can refuse payment if you chose.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will store all data (survey responses), phone numbers (for text messages) and email addresses digitally on a secure, password-protected server at the University of Rochester. Information about emotional health will be stored separately and IDs will be removed before data is sent to the research team. Data sent to Northwestern University under a data use agreement (DUA) for analysis will be deidentified and stored on a secure, password-protected server. Deidentified transcripts of the training will be sent to the University of Rochester from the USAF under a data use agreement (DUA) and will also be kept on a secure, password-protected server.

Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?

- The investigator will get your personal and medical information (only information provided on the surveys)
- Research records
- Records about text messages made as part of this research

Who may use and give out information about you?

- The investigator and the study staff
- URMC and Affiliates

Your information may be given to:

- The Department of Health and Human Services
- The University of Rochester
- Northwestern University
- The Sponsor; National Institute of Health

Why will this information be used and/or given to others?

- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

How long will this permission be valid?

This permission will last indefinitely. Records with personal information will be destroyed upon completion of the study.

May I cancel my permission to use and disclose information?

Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator. Upon receiving the

written notice, the research team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?

Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

No. There is a risk that your information will be given to others without your permission. Once your information is disclosed to the named entities or organizations listed above, it is possible that your medical information will be re-disclosed and will no longer be protected by U.S. federal privacy regulations.

The study is being supported by the DoD and DoD personnel will have access to study records to ensure subject safety and regulatory compliance.

Certificate of Confidentiality

The National Institutes of Health (NIH) issued a Certificate of Confidentiality (CoC) for this study. A Certificate of Confidentiality provides extra protection for you and any information collected from you as part of this study because it prevents us from disclosing this information in a lawsuit or legal proceeding. We cannot release your study information in a lawsuit or legal proceeding unless you provide your consent for us to do so. This is an extra layer of protection above the already existing protections in place for you and any information collected from you as part of this study. However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency funding this study requests the information. You should visit the NIH website at <https://humansubjects.nih.gov/coc/faqs> to learn more.

Use of E-mail and/or Text Messaging in Research

You have the option to receive communications about this study via email and/or text messaging, by indicating your consent at the end of this form. Text messages will contain information related to the training, reminders about coming surveys and possibly links to surveys. Emails will only contain reminders and links to surveys.

Email and/or text communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the study team. Your consent below indicates that you understand this risk. The University of Rochester is not responsible for any interception of messages sent through email or texting. Email communications between you and the study team may be filed in your research record.

You may decide not to receive or send text messages with research study staff at any time, in person or by sending the research number a text message that says "**Stop Research Text**". Your consent, and any request to stop email or text messaging, applies to this research study only.

Contact Persons

For more information concerning this research or if you feel that taking part in this study has resulted in any research related injury, emotional or physical discomfort please contact: Dr. Peter Wyman (Principal Investigator) at the University of Rochester (585-273-3372).

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

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Communication with the Study Team

YES (initial)	NO (initial)	<i>I consent to the use of <u>email</u> in this study. If yes, enter email address:</i> _____
YES (initial)	NO (initial)	<i>I consent to the use of <u>text messaging</u> in this study. If yes, enter phone number:</i> _____

SIGNATURES/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Subject Name (Printed)

Signature of Subject

Date**Person Obtaining Consent**

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

Name and Title (Print)

Signature of Person Obtaining Consent

Date