San Antonio Institutional Review Board (IRB)
Joint Base San Antonio and the University of Virginia

CONSENT TO PARTICIPATE IN RESEARCH

Principal Investigator: Dr. Gerald W. Talcott, PhD

Protocol Title: The Effectiveness of Text-Based Messaging Strategies for Preventing Subsequent Problematic Alcohol Use Among Technical Trainees in the US Air Force

Key Information: This section provides a one-page summary of the information outlined in this consent form. More information will be provided to you on the pages that follow.

Voluntary Participation	You do not have to take part in this research. It is your decision. You can also choose to stop participating at any time during the study.
Purpose	The purpose of this study is to examine the use of text messaging added to a standard, Command-directed Brief Alcohol Intervention (BAI) to prevent binge drinking and alcohol related incidents
Duration	You will be in this study from the beginning of Technical Training until we contact you 6 months after you have completed Technical Training.
Procedures	While you are in the study, you will be asked to complete a baseline questionnaire just prior to the BAI presentation. Your squadron will be randomly assigned to receive the BAI only or the BAI plus text messages to help you with your decisions about alcohol use. If you are assigned to the text messaging group, you will receive approximately 3-5 texts per week during the course of the study. The text messages will be sent through a mobile app. Regardless of which group you were assigned to, you will be asked to complete a follow-up questionnaire in-person at the end of Technical Training and a 6-month follow-up questionnaire on-line. When you complete the final 6-month questionnaire, you will be provided with information on how to receive a participation bullet for your Enlisted Performance Report.
Why might you want to participate in this research (benefits)?	Although there is no guarantee or promise that you will benefit from this study, your participation is important for the development of better methods to prevent problematic drinking that might result in unwanted alcohol related incidents that might impact your Air Force career.

Why might you choose not to participate in this research (risks)?	All study procedures involve only minimal risks to subjects. There are no major risks associated with completing questionnaires or participating in the BAI presentation. There is, however, the potential risk of loss of confidentiality; however, this study has been constructed to minimize that risk using anonymous identifier codes. In addition, your questionnaire data is securely transferred and stored electronically in a secure server at the University of Virginia.
What are the alternatives to participating?	Choosing not to participate in this study is your alternative to volunteering for the study.
Payment	You <u>will not</u> be paid for your participation in this study.

Contact the Principal Investigator with any questions: 210-292-3504; 1100 Wilford Hall Loop, Joint Base San Antonio, TX 78236 or gwt3a@virginia.edu.

1. **PROTOCOL TITLE:** The Effectiveness of Text-Based Messaging Strategies for Preventing Subsequent Problematic Alcohol Use Among Technical Trainees in the US Air Force

You may be eligible to take part in this research study. This form gives you important information about the study.

Please take time to review this information carefully. 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 participation in this study. 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, including the risks and possible benefits to you.

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

You do not have to take part if you do not want to. 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.

Your decision will not affect your eligibility for care or any other benefits to which you are entitled.

2. <u>WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?</u>

You are being asked to take part in this research study because you are an Air Force Technical Training student. The purpose of this research study is to learn better methods to help Airmen

prevent problematic drinking and Alcohol Related Incidents. Participation in the study is for 6 months after the completion of Technical Training. The duration of participation per visit is one hour for the initial data collection visit, 15 minutes each for the end of training and 6-month questionnaires.

There will be about 3000 people taking part in the study.

At the end of this research study the anonymous clinical results, will be shared through professional publications and presentations available to the general public, and through specific reports to military leadership and clinical providers There will be no names or identities of participants disclosed in any reports or publications.

3. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to review the information provided and ask any questions you have. If you provide consent to participate, you will qualify for the study based on your attendance in Technical Training. This is the only screening process as part of this study.

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

If you choose to participate in this study, you will be asked to sign this consent form. You will also be asked to provide your contact and demographic information, which will be kept separate from any answers or information you provide in participating in this project. You will as well as complete a baseline anonymous questionnaire, and generate your own unique code that will connect your future responses without sharing your identity. You will then receive the BAI presentation with your squadron. The BAI is not voluntary but participation in the study is.

At the end of the BAI presentation, you will be notified of which group your squadron was randomly assigned to: The BAI only group vs. BAI + texting group.

If you are randomly assigned to the **BAI only group**, you will not receive text messages. You will be asked to complete a follow-up questionnaire in-person at the end of Technical Training and then again online in 6 months.

If you are randomly assigned to the **BAI + texting group**, you will receive approximately 3-5 text messages per week during the study timeframe only. A mobile app will be used to send the text messages. You will be asked to complete a follow-up questionnaire in-person at the end of Technical Training and then again online in 6 months.

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

All study procedures involve only minimal risks to subjects. There are no major risks associated with completing questionnaires or participating in the BAI presentation. There is, however, the potential risk of loss of confidentiality; however, this study has been constructed to minimize

that risk using anonymous identifier codes and keeping your consent and information documents completely separate from your questionnaire responses. In addition, your questionnaire data is securely transferred and stored electronically in a secure server at the University of Virginia.

There may also be other risks of taking part in this study that we do not yet know about.

6. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

Although there is no guarantee or promise that you will benefit from this study, your participation is important for the development of better methods to prevent problematic drinking and Alcohol Related Incidents in the Air Force.

7. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

Choosing not to participate in this study is your alternative to volunteering for the study.

8. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

No, you will not receive any compensation for participating in this study. Those who complete the project will be provided a 'bullet' that may be used for evaluations and award packages, indicating your participation in a funded research project designed to assist your fellow Airmen.

9. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

10. WHO IS CONDUCTING THIS RESEARCH?

The University of Virginia in cooperation with the Air Force

11. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

The University of Virginia, the Institutional Review Board (IRB) (a committee responsible for protecting research participants), and the Department of Defense may have access to your research data in accordance with DoDI 3216.02. This would only be done to ensure proper oversight of the research team, or in extremely rare circumstances of negative outcomes. Your responses are not linked to your identity.

As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

12. SOURCE OF FUNDING:

National Institutes of Health

13. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Principal Investigator: Dr. Gerald W. Talcott, PhD, Col (ret), USAF
Phone: (210) 292-3504
Email: gwt3a@virginia.edu
Mailing Address: 59 MDOG/SGOWM, 1100 Wilford Hall Loop, Joint Base San Antonio – Lackland, TX 78236

14. LOCATION OF THE RESEARCH:

Research participants will be located at Joint Base San Antonio, TX, Sheppard AFB, Wichita Falls, TX and Keelser AFB, Biloxi, MS.

15. DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS:

There are no financial interests or other personal arrangements to disclose.

16. 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.

The research team will keep your research records. These records may be looked at by staff from the University of Virginia, the Institutional Review Board (IRB) (a committee responsible for protecting research participants), 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.

Procedures to protect the confidentiality of the data in this study include but are not limited to:

The research consent documents will be stored in a locked cabinet in a locked room. All research data including patient demographics will be kept in an electronic database, which will be encrypted, double password protected and the access will be restricted. The research data will be de-identified and any links to identifiable data will be destroyed as soon as possible after the study is complete. The research data will not be utilized for further research activity beyond the approved study methods without additional IRB approval.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

If applicable, 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 results. You can search this Web site at any time.

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

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. Should the research team be required to share any information about you in this rare circumstance, you will be informed. The research team will contact you using most recent information provided; it is important to keep the team informed of any changes to your contact information. It's important to note that in the 20 years that this research team has been conducting research with Airmen, we have never had a request for research data from medical or command authorities.

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.

The following 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:

- The study sponsor: National Institutes of Health
- The University of Virginia Institutional Review Board (IRB) and San Antonio IRB
- The University of Virginia research team and the Air Force

17. WHAT HAPPENS IF YOU ARE INJURED AS A RESULT OF THIS RESEARCH?

We do not anticipate any potential research-related injuries. If you think that you have a research-related injury, notify your Principal Investigator immediately at 210-292-3504 or via email at gwt3a@virginia.edu.

If you are injured because of your participation in this research and you are a DoD healthcare beneficiary (e.g., active duty military, dependent of active duty military, retiree), you are authorized space-available medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary. This care includes, but is not limited to, free medical care at DoD hospitals or DoD clinics.

Transportation to and from hospitals or clinics will not be provided or paid for by DoD. Unless you are covered by TRICARE, no DoD reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

18. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

You may withdraw your consent at any time and stop participating in this research study without affecting your eligibility for care or any other benefits to which you are entitled. Should you choose to withdraw, you must notify the research staff. Because your answers are anonymous, the research team may not be able to extract your responses previously provided from the larger collection of information as it would not be possible to determine your individual answers.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if he determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

19. VOLUNTARY PARTICIPATION:

The decision to take part in this research study is completely voluntary on your part. You will be informed if significant new findings develop during the course of this research study that may relate to your decision to continue participation.

20. CONTACT INFORMATION:

Principal Investigator (PI)
The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Dr. Gerald W. Talcott, PhD, Col (ret), USAF
Phone: (210) 292-3504
Email: gwt3a@virginia, gerald.w.talcott.ctr@mail.mil

Mailing Address: 59 MDOG/SGOWM, 1100 Wilford Hall Loop, Joint Base San Antonio, TX 78236

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:
San Antonio IRB (SA-IRB)
SA-IRB Office, Brooke Army Medical Center
ATTN: MCHE-ZQ, Department of Quality and Safety
3551 Roger Brooke Drive
Fort Sam Houston, Texas 78234-6315
Phone: 210-916-2598

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

A signed and dated copy of this document will be given to you.

21. LONG TERM USE OF DATA

Your data collected as part of this research will not be used for future research studies or given to anyone else for future research studies, even if all information that personally identifies you is removed.

SIGNATURE OF PARTICIPANT

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date