



DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS



31 MAY 2017

MEMORANDUM FOR SVGT

ATTN: CAPT. KAITLIN A. DUCKETT

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **Evaluating the impact of a tobacco cessation training for military medical providers in a primary care clinic** presented at/published to **San Antonio Military Health System & Universities Research Forum (SURF), San Antonio TX, 16 June 2017** in accordance with MDWI 41-108, has been approved and assigned local file #**17248**.
2. Pertinent biographic information (name of author(s) title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are a 59 MDW staff member, we can forward your request for funds to the designated Wing POC at the Chief Scientist's Office, Ms. Alice Houy, office phone: 210-292-8029; email address: alice.houy.civ@mail.mil.
4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

1. The author must complete page two of this form:
 - a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D; Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed Medical Research Program (CDMRP) ; Grants; etc.]
 - b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.
2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.
3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.
4. Attach a copy of your abstract, paper, poster and other supporting documentation.
5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.
6. On page 2, have either your unit commander, program director or immediate supervisor:
 - a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.
7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). **This should be accomplished no later than 30 days before final clearance is required to publish/present your materials.** If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.
8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.
9. Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. **Note:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.
10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DITC). See 59 MDWI 41-108, *Presentation and Publication of Medical and Technical Papers*, for additional information.
11. The Joint Ethics Regulation (JER) DoD 5500.07-R, *Standards of Conduct*, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. **If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review.** To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

For presentations before professional societies and like organizations, the 59 MDW Public Affairs Office (PAO) will provide the needed review to ensure proper disclaimers are included and the subject matter of the presentation does not create any cause for DoD concern.

If the sponsor of a conference or meeting is a DoD entity, an ethics review of your presentation is not required, since the DoD entity is responsible to obtain all approvals for the event.

If the sponsor of a conference or meeting is a non-DoD commercial entity or an entity seeking to do business with the government, then your presentation should have an ethics review.

If your travel is being paid for (in whole or in part) by a non-Federal entity (someone other than the government), a legal ethics review is needed. These requests for legal review should come through the 59 MDW Gifts and Grants Office to 502 ISG/JAC.

If you are receiving an honorarium or payment for speaking, a legal ethics review is required.

If you (as the author) or your supervisor check "YES" in block 17 of the Form 3039, your research or technical documents will be forwarded simultaneously to the 502 ISG/JAC legal office and PAO for review to help reduce turn-around time. If you have any questions regarding legal reviews, please contact the legal office at (210) 671-5795/3365, DSN 473.

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:

"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:

"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 40-401_IP :

"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS			
1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol) Kaitlin A. Duckett, Capt, O-3, SVGT	3. GME/GHSE STUDENT: ☒ YES ☐ NO	4. PROTOCOL NUMBER: FWH20170086E
5. PROTOCOL TITLE: (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.) Evaluating outcomes of a tobacco cessation training for military medical providers in primary care			
6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED: Evaluating the impact of a tobacco cessation training for military medical providers in a primary care clinic			
7. FUNDING RECEIVED FOR THIS STUDY? ☐ YES ☒ NO FUNDING SOURCE:			
8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: ☐ YES ☒ NO			
9. IS THIS MATERIAL CLASSIFIED? ☐ YES ☒ NO			
10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.? ☐ YES ☒ NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.			
11. MATERIAL IS FOR: ☒ DOMESTIC RELEASE ☐ FOREIGN RELEASE CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.			
☐ 11a. PUBLICATION/JOURNAL (List intended publication/journal.)			
☐ 11b. PUBLISHED ABSTRACT (List intended journal.)			
☒ 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.) San Antonio Military Health System & Universities Research Forum (SURF), San Antonio, TX, 16 Jun 2017			
☐ 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meeting.)			
☐ 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)			
12. HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED? ☐ YES ☒ NO ASSIGNED FILE # _____ DATE _____			
13. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC). DATE _____			
14. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)			15. DUTY PHONE/PAGER NUMBER
16. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.			
LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Duckett, Kaitlin A.	O-3 / Capt	59 TRS / SVGT	
b. Aycock, Chase A.	O-3 / Capt	59 TRS / SVGT	
c. Kalpinski, Ryan J.	O-3 / Capt	59 TRS / SVGT	
d. Marks, David E.	O-3 / Capt	59 TRS / SVGT	
e. Bailie, Jillian R.	O-3 / Capt	59 TRS / SVGT	
17. IS A 502 ISG/JAC ETHICS REVIEW REQUIRED (JER DOD 5500.07-R)? ☐ YES ☒ NO			
I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.			
18. AUTHOR'S PRINTED NAME, RANK, GRADE Kaitlin A. Duckett, Capt, O-3	19. AUTHOR'S SIGNATURE DUCKETT, KAITLIN A. 1523055557		20. DATE 12 May 17
21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE Ryan J. Kalpinski, Capt, O-3	22. APPROVING AUTHORITY'S SIGNATURE KALPINSKI RYAN J. 1411105721		23. DATE 30 May 17

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS		
1st ENDORSEMENT (59 MDW/SGVU Use Only)		
TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	24. DATE RECEIVED May 16, 2017	25. ASSIGNED PROCESSING REQUEST FILE NUMBER 17248
26. DATE REVIEWED May 31, 2017	27. DATE FORWARDED TO 502 ISG/JAC	
28. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: ☒ NO ☐ YES If yes, give date. _____ ☐ N/A		
29. COMMENTS ☒ APPROVED ☐ DISAPPROVED Presentation of IRB exempt determined study with appropriate disclaimers. Approved		
30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Kevin Kupferer/GS13/Human Research Subject Protection Expert	31. REVIEWER SIGNATURE KUPFERER KEVIN R. 1086667270 <i>(Digitally signed by KUPFERER KEVIN R. 1086667270 DN: cn=US, o=U.S. Government, ou=DoD, ou=PR, ou=USAF, ou=KUPFERER KEVIN R. 1086667270 Date: 2017.05.31 08:11:17 -0500)</i>	32. DATE May 31, 2017
2nd ENDORSEMENT (502 ISG/JAC Use Only)		
33. DATE RECEIVED	34. DATE FORWARDED TO 59 MDW/PA	
35. COMMENTS ☐ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED		
36. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	37. REVIEWER SIGNATURE	38. DATE
3rd ENDORSEMENT (59 MDW/PA Use Only)		
39. DATE RECEIVED May 31, 2017	40. DATE FORWARDED TO 59 MDW/SGVU May 31, 2017	
41. COMMENTS ☒ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED		
42. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Kevin Iinuma, SSgt/E-5, 59 MDW Public Affairs	43. REVIEWER SIGNATURE <i>(Digitally signed by IINUMA KEVIN MITSUGU 1296277813 DN: cn=US, o=U.S. Government, ou=DoD, ou=PR, ou=USAF, ou=IINUMA KEVIN MITSUGU 1296277813 Date: 2017.05.31 08:41:03 -0500)</i>	44. DATE May 31, 2017
4th ENDORSEMENT (59 MDW/SGVU Use Only)		
45. DATE RECEIVED	46. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL ☐ YES ☐ NO ☐ COULD NOT BE REACHED ☐ LEFT MESSAGE	
47. COMMENTS ☐ APPROVED ☐ DISAPPROVED		
48. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	49. REVIEWER SIGNATURE	50. DATE

16. AUTHORSHIP AND CO-AUTHORS

f. Russell, Brittany M.	O-3 / Capt	59 TRS / SVGT
g. Cassidy, Daniel G.	O-4 / Maj	59 MDOS
h. Little, Melissa	Civilian	University of Virginia
i. Talcott, Gerald W.	Civilian	University of Virginia



Evaluating the Outcomes of a Tobacco Cessation Training for Military Medical Providers in Primary Care

Katlin Duckett, M.S., Chase Aycock, M.A., Ryan Kapinski, Ph.D., Melissa Little, Ph.D., Daniel Cassidy, Ph.D., David Marks, M.A., Jillian Ballie, M.A., Brittany Russell, M.A., & G. Wayne Talcott, Ph.D.
United States Air Force & The University of Virginia



Abstract

- Opportunities to intervene with current tobacco users in the patient centered medical home (PCMH) are at once exciting and under-exploited.
- Military service members use tobacco products at a rate greater than that of their civilian counterparts, and corresponding reductions in health, productivity, and performance are harmful both for the service member, and for the military mission.
- While efficacious and effective, behavioral, pharmacotherapeutic, and multi-modal interventions for tobacco cessation are underutilized by both medical providers and patients. Previous research suggests that this is attributable to some combination of other-than-optimal clinician training and insufficient organizational support.
- It follows that improving clinicians' comfort with, and confidence in, their ability to discuss treatment options with patients will increase the percentage of tobacco users who ultimately will consent to, and derive benefit from, interventions that work.
- This study examined outcomes of a brief educational module consistent with the principles of motivational interviewing (MI), and designed to increase provider comfort with, and confidence in, their ability to discuss with patients the possibility of making a quit attempt.

Hypothesis

- The motivational interviewing (MI) intervention will significantly improve providers' comfort with, confidence in, and (self-reported) inclination to use tobacco cessation referral resources (including medications).

Methods

- Data derive from 14 providers working at a large primary care clinic on Joint Base San Antonio (Table 1).
- Researchers delivered a 1-hour, in-person training designed to increase provider comfort with, confidence in, and inclination toward use of a brief conversational strategy for tobacco cessation.
- Pre- and post-training questionnaires were used to assess utility of the training.

Figure 1. Provider Sentiment Regarding Tobacco Cessation Counseling

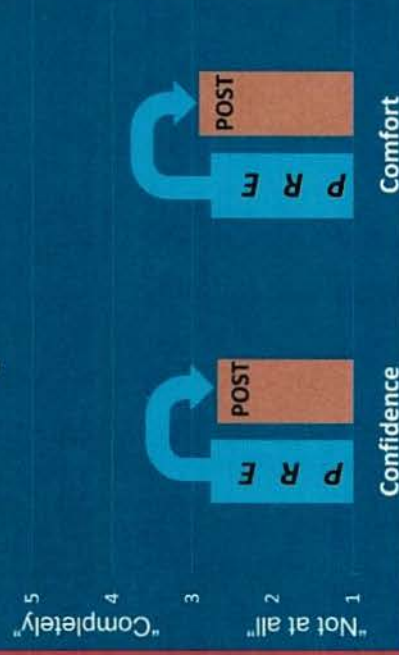


Table 1. Demographics

	M ± SD or %
Age	52.9 ± 16.21
Years Experience	13.1 ± 6.7
Female (%)	57.1
Provide smoking cessation resources at baseline (%)	85.7
Believed patients were receptive to conversations about tobacco use (%)	42.9

Findings

- Pre- and post-test values reflecting provider confidence and comfort in facilitation of a brief conversation with tobacco users not ready to quit were compared through paired samples *t* tests (Figure 1).
- There was no significant change in provider confidence from pre-test ($M=2.77$, $SD=1.01$) to post-test ($M=2.69$, $SD=.75$), $t(12)=-.291$, $p=.776$.
- There was no significant change in provider comfort from pre-test ($M=2.77$, $SD=.60$) to post-test ($M=2.92$, $SD=.64$), $t(12)=-1.477$, $p=.165$.

Conclusion

- Prior to administration of the training, 35.7% of participants were 'extremely confident' in their ability to facilitate a brief conversation with smoker not ready to quit, and more than half (57.1%) were 'very comfortable' with providing smoking cessation resources to such patients.
- Following the intervention, participants indicated similarly high levels of confidence and comfort.
- These data suggest that brief education is not, in itself, sufficient to improve provider confidence in, or comfort with, brief discussion of tobacco cessation with smokers not ready to quit.

Future Directions

- Research demonstrating the dose of training at which there exists a clinically meaningful shift in providers' comfort with, confidence in, and inclination to engage with tobacco users not yet ready to quit.
- Longitudinal assessment of provider behavior following such training, as a shift in behavior may manifest antecedent to attitudinal changes expressed in terms of purported comfort or confidence.

59th Medical Wing (59th MDW)
Institutional Review Board (IRB)
59th Clinical Research Division/SGVUS/(210) 292-7143
2200 Bergquist Dr, Bldg 4430, Lackland AFB, TX 78236-9908

23 May 17

FINAL IRB DETERMINATION - EXEMPT STUDY:

Determination Date: 12 May 17

Principal Investigator: Maj Daniel Cassidy/SGOWM

IRB Reference Number: FWH20170086E

Protocol Title: "Evaluating outcomes of a tobacco cessation training for military medical providers in primary care"

1. You may begin your study.

Your study, referenced above, was **determined** to be **EXEMPT** from research regulation 32 CFR 219 regarding the protection of human subjects, **Category 2** (32 CFR 219.101.b.2), by the 59th Medical Wing (59 MDW), via the *exempt review/determination process* by the 59th MDW Institutional Review Board (IRB) Chairperson or designee, based on 32 CFR 219.101(b). It has been determined your research activities, involving human subjects, all fit within one or more of the following exempt category:

32 CFR 219.101(b)(2) - Research involves the use of, interview procedures not involving children, survey procedures not involving children, AND the research is minimal risk, AND the information obtained will not be recorded so that the subjects can be identified directly or indirectly (through identifiers linked to the subjects e.g., codes).

2. ****Please note:** Your study has received a one-time exemption determination. You only need to contact the 59th MDW IRB in the future for the following reasons:

- You encounter an unexpected problem that could put your subjects or others at risk
- You intend to modify this study (submit an amendment to the usaf.ibsa.59-mdw.mbx.wing-crd-protocol@mail.mil to confirm the change does not affect the exempt status of your study)

The 59th MDW IRB must be notified immediately of any additional information or changes to the protocol that may affect its category and/or risk status.

3. You must comply with the information contained in the Form A Signature Sheet, e.g., Principal Investigator's Agreement. Protection of subjects' rights safety and welfare and responsibility for protecting PHI/PII and research data now fall on the investigator and their commander as the research is exempt from human research protection regulations.

4. The 59th MDW IRB no longer requires Status Reports and Final Reports for Exempt and Non-research/Non-human Research. The PI should notify the 59th MDW IRB of any publications/presentations resulting from a study outcome.

5. If funds were requested for your study, you will be notified by the 59th Clinical Research Division Resource Manager (292-7924) concerning the status of the requested funds. **YOU ARE NOT AUTHORIZED TO USE YOUR SECTION'S O&M FUNDS.**

6. IAW DoDI 3216.02_AFI 40-402, Enclosure 3, Section 3.a, this research will be reported to AFMSA/SGE-C and documented in subsequent IRB minutes. If SGE-C disagrees with the Designated Reviewer's determination, the research study may be temporarily suspended until resolution.

7. If you have any questions, the POC is Christopher Brown at 292-4012 or christopher.e.brown136.ctr@mail.mil. Please include your project title and reference number in all correspondence or inquiries.

GIBBONS.TH
OMAS.F.1128
005281

Digitally signed by
GIBBONS.THOMAS.F.1128005281
DN: c=US, o=U.S. Government,
ou=DoD, ou=PKI, ou=USAF,
cn=GIBBONS.THOMAS.F.1128005
281
Date: 2017.05.12 10:57:57 -05'00'

Thomas Gibbons, PhD;
Designated
Reviewer

Partners in a high-performance health system, dedicated to excellence in global care.

PROTOCOL FOR EXEMPT RESEARCH INVOLVING HUMAN SUBJECTS

Exempt research involving human subjects has very specific regulatory criteria and allows the research to be conducted under abbreviated and simplified rules established by the institution. There are six categories of minimal risk research, as defined in the federal regulations for protecting research subjects that do not require IRB approval. If the research falls into at least one of the qualified categories, as listed below, it may qualify for exemption [32 CFR 219.101(b)].

Title:	Evaluating outcomes of a tobacco cessation training for military medical providers in primary care (Include collaborating institution's protocol # in the title, if applicable.)
IRB #:	FWH20170086E

Principal Investigator (PI)	Rank / Civ Rating	Branch	AD/DoD Civ/ Ctr/Civilian	Dept/Base	Phone #	E-mail
Daniel Cassidy, PhD	Maj	USAF	AD	59 MDOS/ JBSA- Lackland	210-292-5968	Daniel.g.cassidy.mil@mail.mil
Co-PI (at Joint Site, if applicable)	Rank / Civ Rating	Branch	AD/DoD Civ/ Ctr/Civilian	Dept/Base	Phone #	E-mail
Ryan Kalpinski, PhD	Capt	USAF	AD	59 TRS/ JBSA- Lackland	210-292-5968	Ryan.j.kalpinski.mil@mail.mil

The research relevance of this protocol focuses on: (select one)			
☐ Diagnosis	☒ Treatment	☒ Medical Utilization/Managed Care	
☒ Prevention	☐ Medical Readiness	☐ Other: (if marked, explain the research relevance)	

FOR 59 MDW PERSONNEL ONLY			
Individuals must be covered under 59 MDWI 40-404 , <i>Managing Conflict of Interest in Research</i>			
CONFLICTS OF INTEREST:	Do you or any of your research staff have a potential conflict of interest to disclose? If unsure, read the below statement before proceeding.	☐ Yes	☒ No
If you answer YES above, you must complete the 59 MDW Form 14 – Financial Conflict of Interest Disclosure for each individual reporting a conflict and send it via <u>encrypted</u> email to the COI Manager for an official determination BEFORE PROCEEDING with this protocol application. The 59th Medical Wing Conflict of Interest Office can assist you with any questions you may have regarding conflicts of interest and the COI disclosure process. Contact the COI Manager with questions or for additional guidance at: 210-292-5885 or usaf.jbsa.59-mdw.mbx.chief-scientist-hrpp@mail.mil .			

Does this proposed research include the use of prisoners (including detainees)?	☐ Yes	☒ No
Is this proposed research FDA-regulated?	☐ Yes	☒ No

1. LOCATION AND SPONSOR

Collaborating Facilities: List participating facilities/other sites that may require separate HRPP or EDO determination.	☐ N/A
Wilford Hall Ambulatory Surgical Center, University of Virginia	
AF Sites Seeking Exemption Determination: Site name/POC and phone #.	☐ N/A
Wilford Hall Ambulatory Surgical Center/ Maj Cassidy 210-292-5968	
Study Sponsors:	☒ N/A

2. EXEMPT CATEGORY

Exempt Category: Select all categories that apply.	
☐	Category 32 CFR 219.101(b)(1): This research will be conducted in an established or commonly accepted educational setting, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☒	Category 32 CFR 219.101(b)(2)-(3): This research involves the use of: <i>(select all that apply).</i>		
	☐ Educational Tests (cognitive, diagnostic, aptitude, achievement) ☒ Survey Procedures Not Involving Children ☐ Interview Procedures Not Involving Children ☐ Observations of Public Behavior Not Involving Children ☐ Observations of Public Behavior Involving Children where the Investigator does not Participate in the Activities being Observed		
	Will you be collecting identifiable information?		☐ Yes ☒ No
	Choose One: ☒ Little or no risks exist: The nature of the information obtained in this study does not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation should any disclosure of the subjects' responses occur outside the research. ☐ Risks exist: The information obtained will <u>not</u> be recorded in such a manner that the subjects can be identified directly or through identifiers linked to the subjects (e.g., codes).		
☒	Category 32 CFR 219.101(b)(4): This research involves the collection or study of: <i>(select all that apply)</i>		
	☒ Existing Data ☐ Existing Documents ☐ Existing Records ☐ Existing Pathological Specimens ☐ Existing Diagnostic Specimens		
	Choose One: ☒ The information will be recorded by the investigator in such a manner that subjects <u>cannot</u> be identified directly or through identifiers linked to the subjects (e.g., codes). ☐ These sources are publicly available.		
☐	Category 32 CFR 219.101(b)(5): This research/demonstration involves the study/evaluation of: <i>(select all that apply)</i>		
	☐ Public benefit or service programs ☐ Procedures for obtaining benefits or services under those programs ☐ Possible changes in or alternatives to those programs or procedures ☐ Possible changes in methods or levels of payment for benefits or services under those programs		
☐	Category 32 CFR 219.101(b)(6): This research is a taste and food quality evaluation and/or consumer acceptance study that will involve: (1) the consumption of wholesome foods without additives; and/or (2) the consumption of a food that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the USDA.		

3. STUDY DESIGN

Purpose of Study: <i>List the broad, long-term objectives of the study. Use non-technical terms, as much as possible.</i> The purpose of the current project is to evaluate an intervention aimed at increasing medical providers' referrals to tobacco cessation resources and interventions.
Hypotheses, Research Questions, or Objectives: <i>State the specific hypotheses, research questions, or objectives you wish to test.</i> The following hypotheses will be tested: - Hypothesis 1 (H1) The motivational interviewing (MI) intervention will meaningfully improve providers' comfort with, confidence in, and (self-reported) inclination to use tobacco cessation referral resources (including medications). - Hypothesis 2 (H2) The MI intervention will meaningfully increase provider referrals to tobacco cessation resources.
Significance: <i>State the importance and health relevance of the research. State practical application(s). Significance is often demonstrated using numbers of patients affected, cost of care, impact on quality of life, etc.</i> In a 2014 AAAHC inspection, facilities in the San Antonio Military Health System facilities failed to provide adequate evidence of patient flow pathways which foster utilization of available tobacco cessation treatment efforts throughout the patient centered

medical home (PCMH). There is a tremendous need to design processes within PCMH to increase the likelihood of referral for and treatment of health-risk behaviors such as tobacco use. Such efforts are specifically pertinent in the military medical system as evidenced by a survey published by the U.S. Department of Defense (DoD) in 2011 in which 24% of military personnel reported currently smoking, compared to 19% of the civilian population.¹ This same survey found that 12.8% reported using a smokeless tobacco product in the last month, a rate four times that of the general population. Tobacco use among American service members is an important factor that can negatively influence military readiness, performance, and productivity with significant financial costs. It estimated the DoD spends an average of 1.6 billion treating tobacco related comorbidity among active duty military personnel (e.g. medical costs, hospitalizations).⁴ Tobacco cessation interventions, although readily available, are frequently underutilized by both medical providers and patients. This appears in part due to lack of effective clinician training, follow-up, and organizational support. Therefore, maximizing clinician training in tobacco cessation via interactive continuing education activities to increase use of interventions (e.g. prescription use, referral behaviors) is essential to reduce tobacco use in the military.^{2, 3}

Military Relevance: With regard to military needs and mission requirements, provide a brief justification for the research.

As above, there is a tremendous need to design processes within PCMH to increase the likelihood of referral for and treatment of health-risk behaviors such as tobacco use. Such efforts are specifically pertinent in the military medical system as evidenced by a survey published by the U.S. Department of Defense (DoD) in 2011 in which 24% of military personnel reported currently smoking, compared to 19% of the civilian population.¹ This same survey found that 12.8% reported using a smokeless tobacco product in the last month, a rate four times that of the general population. Tobacco use among American service members is an important factor that can negatively influence military readiness, performance, and productivity with significant financial costs. It estimated the DoD spends an average of 1.6 billion treating tobacco related comorbidity among active duty military personnel (e.g. medical costs, hospitalizations).⁴

Background and Review of Literature: Briefly describe the background leading to the present study. Critically evaluate existing knowledge and identify the gaps that the project is intended to fill.

Continuing medical education (CME) training is a common way for medical professionals to learn new skills or obtain information and didactic trainings are among the most common method of imparting these skills or information to medical professionals.³ Although didactic trainings are among the most common type of training, they are arguably not overtly effective in changing physician behaviors.^{2, 3, 5} Growing research indicates that engaging in interactive CMEs, can enhance the efficacy of CMEs, particularly for tobacco cessation information.^{3, 5} Effective interactive CMEs include use of participant feedback, provider reminders, personal involvement in training, and providing providers with educational materials.^{2, 5} We will provide an initial training for military medical providers on tobacco cessation medications, provide printed materials for their use with patients, and provided an educational follow-up. We will follow prescription trends for the months following each of these interventions in order to ascertain the efficacy of the training.

Bibliography: Cite 5-10 references (within the past 2-3 years) – more for complex studies.

1. Barlas, F.M., Higgins W.B., Pflieger J.C., Diecker K. (2011). Health Related Behaviors Survey of Active Duty Military Personnel. U.S. Department of Defense, TRICARE Management Activity, Defense Health Cost Assessment and Program Evaluation, and the United States Coast Guard 2013 [accessed 2016 Dec 13].
2. Bloom, B. S. (2005). Effects of continuing medical education on improving physician clinical care and patient health: a review of systematic reviews. *International journal of technology assessment in health care*, 21(03), 380-385.
3. Davis, D., O'Brien, M. A. T., Freemantle, N., Wolf, F. M., Mazmanian, P., & Taylor-Vaisey, A. (1999). Impact of formal continuing medical education: do conferences, workshops, rounds, and other traditional continuing education activities change physician behavior or health care outcomes?. *Jama*, 282(9), 867-874.
4. Department of Defense (2005). Armed Services exchange policy instruction 1330.09. Washington, DC, US. Available at <http://www.dtic.mil/whs/directives/corres/pdf/133009p.pdf>
5. Mazmanian, P. E., & Davis, D. A. (2002). Continuing medical education and the physician as a learner: guide to the evidence. *Jama*, 288(9), 1057-1060.

4. RESEARCH DESIGN AND METHODS**Research Design and Step-by-Step Methods:** State in detail how the research is designed to answer the hypotheses/research questions/objectives. Define what measurements (operational definitions – independent and dependent variables) the study will evaluate to answer the research questions/hypotheses/objectives.

The proposed study is quantitative in nature. Our research team will assess approximately 14 primary care providers at an outpatient military treatment facility, the CPT Jennifer M. Moreno Primary Care Clinic (Moreno clinic) on Joint Base San Antonio, Fort Sam Houston. The goal of this study is to investigate the effect of tobacco cessation training and receipt of associated materials for two hypotheses using the following methods:

- H1 – Anonymous self-reported survey data was collected before and after the motivational interviewing intervention.
- H2 – Utilization of tobacco cessation resources will be assessed before and after the MI intervention using the sources listed in 4.6.1.

a. Interventions, Observations, or Data Sought: Briefly describe what data (not the source of the data) will be observed or sought, or what interventions will be performed. For example, a chart review might seek "the blood-pressure taken at clinic check-in," or "the dose of drug X used to treat nausea." For an educational study, an example might be "Number of XYZ procedures performed by the residents and the corresponding test scores on the written examination."

We will use the following data to measure the stated outcomes:

- H1 – Provider’s self-reported comfort with, confidence in, and inclination to use tobacco cessation referral resources.
- H2 – Provider tobacco intervention behavior:
 - Prescription of FDA-approved tobacco cessation medications, as documented in the electronic medical records for each provider in attendance (will be pulled by the DHA using the National Provider Identifier number for each provider who participated in the intervention)
 - Referrals to the Freedom Quit Line which derive from a provider participate in this intervention
 - Referrals to the integrated primary care behavioral health providers
 - Referrals to the on-base tobacco cessation group

b. Data Collection and Processing: Briefly discuss who will collect the data and how it will be collected (structured medical record review, structured questionnaire, extracted from database). For record reviews, also describe how the data of interest will be identified for possible inclusion. For example “All charts will be manually screened at the end of each day for records of interest,” or “the database will be searched for all records with a diagnosis of chest pain.” All data gathered must be anonymous and not contain any personal identifying information that can be used to identify a subject.

We met face-to-face with the providers in the primary care clinic for the interventions. We explained the purpose of the interventions, entertained questions, and administered the interventions and surveys.

- H1 – Researchers met face-to-face with the providers. Providers completed anonymous pre- and post-intervention surveys as feedback for program development/evaluation purposes (See C. 4.6.1 and C 4.6.2).
- H2 -- We met face-to-face with the providers and explained the intervention and entertained questions prior to gathering provider tobacco intervention data (see C 4.6.1 and C 4.6.2).

c. Setting: Briefly describe the locations or institutions for the research subjects during the period of interest. Generally speaking, this is the location the raw data will first be generated by the subjects. For example, in a study of medical records it would be the physical location of the patients at the time of diagnosis or treatment. For educational studies list the location of the students at the time they will be studied, and for surveys, list the locations the survey will be targeted (e.g., “emailed to the subject’s home.”)

If Applicable, provide information on collaborative efforts with other researchers. Collaborative protocols should clearly delineate the responsibilities among the various institutions or groups. Example: Associates at the University of Texas will analyze blood specimens in their lab as their part of the study. (This does not include fee for services, gifts or grant support.) Provide a letter of support from the institution(s) outlining collaborative support.

Participants are primary care medical providers at the Moreno clinic.

d. Date(s): Specify the period of research interest. This should be the beginning and ending dates from which the raw data was generated. For record reviews, this is the inclusive dates of the medical encounters being studied. For educational and survey studies this is the period of subject involvement.

Oct 2016 – Oct 2018

e. Source of Research Material: Indicate how the research material(s) you plan to use meets the requirements of the Exempt category you selected above. (Insert "N/A" in this section for pure bench research studies – no human involvement). Identify the sources of research material you will use in your study. For studies using existing data/specimens, outline how you will collect data without recording patient identifiers or use codes.

- H1 – A brief, anonymous assessment survey before and after the original intervention was completed by providers in attendance.
- H2 – Provider utilization on tobacco cessation interventions will be gathered at time points of 3-months prior to the training, 3 months after the initial training was provided, and 3-months following the booster intervention (administered 3 months after the initial training) using a variety of sources (see 4.6.1).

Complete the table. Identify the sources of material obtained from individually identifiable living human subjects. Of the total number of procedures to be used, list the number obtained as standard practice and the number obtained for research purposes only. Include what existing database, records, or specimens will be used. Add rows as needed.

Source of Research Material per Participant (Procedures)	# Routine Care	# Research Driven	# Total Procedures
Pre-post intervention surveys	0	14	14
Prescribing pattern data from DHA (3 month periods)	0	3	3
Referral source data from Freedom Quit Line (3 month periods)	0	3	3
Total	0	20	20

If this is a primary record review, specify where the records are located or which systems they are stored on. Primary records are used for diagnosis, treatment, and form the legal medical record. They always contain patient identifiers.

N/A

If this is a secondary source, specify the database being used. Secondary sources contain extracts derived from primary records. They may or may not contain patient identifiers and this should be specified.

- DHA will generate provider prescription reports through Pharmacy Analytics Support and will be de-identified.
- Freedom Quit Line will provide referral sources for the specified periods of time.

If this is a survey or educational study, specify the instrument used to collect data. Attach a copy for IRB review.

N/A

For all record/database studies:

1. Attach a copy of the record abstracting worksheet or specify the data fields examined in the database, and
2. Include the statement: "Only records or database entries in existence at the time of study approval will be examined in this study. All data will be recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers or codes linked to the subjects."

f. Subjects: Briefly describe the sample population being studied. Specify if any special populations (e.g., pregnant women, children, military basic trainees, prisoners, detainees) are included or excluded. Of note, research on prisoners, including detainees, does not qualify under expedite rules. State any relationship the PI or AI has, had, or will have with these subjects (e.g., "some subjects were the PI's patients," or, "subjects are the AI's patients." NOTE: See 45 CFR 46, Subparts B-D; and 32 CFR 219.101(2)(i).

Participants are 14 medical providers employed at the Moreno clinic. The PI's and AI's have no conflicting relationships with the participants, nor do they intend to establish a conflicting relationship with the participants. All participation will be completely voluntary.

g. Inclusion/Exclusion Criteria: Describe the characteristics of the target subject population, including their anticipated age range and health status. If exclusion criteria are based on race, gender, or age for other than obvious reasons (i.e., disease state: sickle cell anemia, breast cancer, prostate cancer), specific justification for exclusion of these groups is required.

Participants are any credentialed medical providers at the Moreno Clinic. No exclusionary criteria are based on race, gender, or age.

Inclusion criteria include:

- Must be a medical provider capable of referring patients for tobacco cessation interventions.

There are no exclusionary criteria beyond the inverse of the inclusionary criteria.

5. HUMAN SUBJECTS PROTECTION

Recruitment and Consent Processes: Describe how subjects will be initially approached, recruited and the circumstances under which consent will be sought and obtained.

We were invited to conduct the aforementioned interventions at the Moreno clinic by the medical leadership with the stated goal of increasing tobacco intervention behavior. All data are archival in nature and de-identified when extracted by DHA for the purposes of these analyses.

- H1 – As part of the initial intervention in Oct 2016, anonymous surveys were administered to the 14 medical providers in attendance. The anonymous feedback does not include personally identifiable information.
- H2 – No personally identifiable information will be included in analyses or reports from the archival data gathered from DHA and therefore no informed consent is indicated.

6. DATA ANALYSIS

Data Analysis Plan: Describe what data (outcome measures) will be compared for each research question, and by what method (statistic or methodology, as appropriate). Be specific. Consult the statistician at the 59 MDW Clinical Research Division at 210-292-7295, as early as possible.				
- H1 – We will compare anonymous survey results (pre- and post- training) used paired-sample t-tests to determine the effectiveness of the training on provider confidence, comfort, and (self-reported) inclinations to utilize techniques for tobacco cessation interventions. - H2 – We will compare prescription patterns and referral behaviors before and after the tobacco cessation training and booster session using t-tests to assess whether the training and booster sessions (respectively) altered provider (tobacco cessation) behavior. - Descriptive statistics absent of personally identifiable and in aggregate information will be calculated for all data.				
Number of Records/Specimens: (if applicable)	# Used at 59 MDW	# Used at BAMC	# Used at	TOTAL
		14		14

7. LOCAL AND EXTERNAL SUPPORT SERVICES

Local and External Support Services: If local or external support services are required, attach the "Local and External Support Services Document" and a letter of support from each internal and/or external support service. If the proposed protocol is a joint institutional collaboration, letters for support services are required from each facility. Include only information on areas of support needed. If not applicable, state "None".
DHA, Freedom Quit Line, UVA

8. INTRAMURAL (GME) AND EXTRAMURAL FUNDING SUPPORT

Intramural (GME) and Extramural Funding Support: Specify source (e.g., CRADA, contract, cooperative agreement, Material Transfer Agreement, Technology Transfer Agreement, funding incentives for subject enrollment, gifts, grants, etc.) and amount, as applicable. If not applicable, state "None". If intramural (GME) or extramural funding support is required or is being provided for the study, attach a copy of the approved funding source document and fill-out the "Intramural and Extramural Funding Support Document".
None.

9. MEDICAL RESEARCH AREA

Select all that apply:

☐ Analytical Chemistry	☐ Anatomy	☐ Anesthesiology	☐ Biochemistry
☐ Cardiovascular Surgery	☐ Cardiology	☐ Cell Biology	☐ Dentistry
☐ Dermatology	☐ Dietetics	☐ Electrophysiology	☐ Endocrinology
☐ Emergency medicine	☐ Gastroenterology	☐ General Surgery	☐ Hematology
☐ Histology	☐ Immunology/Allergy	☐ Infectious Disease	☐ Microbiology
☐ Molecular Biology	☐ Neonatology	☐ Neurology	☐ Neurosurgery
☐ Nursing	☐ OB/GYN	☐ Occupational Medicine	☐ Occupational Therapy
☐ Oncology	☐ Ophthalmology	☐ Oral/Maxillofacial Surgery	☐ Orthopedics
☐ Pathology	☐ Pediatrics	☐ Pharmacology	☐ Physical Therapy
☒ Mental Health	☐ Radiology/Imaging	☐ Urology	☐ Wellness
☒ Other (specify): Prevention			

10. ATTACHMENTS

(EXAMPLES – Include as many as appropriate. Delete those that do not apply.)

- Form A – Signature Sheet
- Form I – De-identification Certification
- Local and External Support Services Document
- Intramural and Extramural Funding Support Document
- HIPAA and Consent Waiver and Alteration Form

6. PI Curriculum Vitae (dated in the last 12 months)
7. PI Copy of Certificate for IRB-approved Investigator CITI training