MEMORANDUM FOR SGVT

ATTN: MAJ RICHARD P DAVIS

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **Impact of the Group Lifestyle Balance (GLB) Program on Diabetes Prevention in the Military Health System** presented at **SURF Conference, San Antonio, TX 20 May 2016** with MDWI 41-108, and has been assigned local file #16115.

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 59 MDW staff member, we can forward your request for funds to the designated wing POC.

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

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Partners in a high-performance health system, dedicated to excellence in global care
Instructions to submit an approval request for
PROFESSIONAL MEDICAL RESEARCH PUBLICATIONS/PRESENTATIONS

1. Complete page two of 59 MDW Form 3039 (this form).

2. Print your name, sign and date the form in the author's signature block or use electronic signature.

3. Attach a copy of the WHASC IRB or IACUC approval letter for the research related study.

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 commander for review/approval.

6. On page 2, have your commander:
   a. Print their name, sign and date the form in the commander's signature block or use electronic signature.
   b. Contact the 59th CRD/Publications and Presentations Section at (292-7141) for instructions for submitting the request form.

7. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations and public affairs and forward you a final letter of approval or disapproval.

8. Once your manuscript, poster or presentation has been approved for public release you may proceed with your publication or presentation submission activities.

9. If your manuscript is accepted for scientific publication, please contact the 59th CRD/Publications and Presentations Section (292-7141). This information is reported to the 59 MDW/CC.

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

"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."
PROCESSING OF PROFESSIONAL MEDICAL RESEARCH PUBLICATIONS/PRESENTATIONS

TO: Clinical Research Division/SGVU
(59th CSPG/SGVU)
FROM: Richard P Davis/Maj/SGVT

PROTO COL NUMBER: FWH20130086H

PROTOCOL TITLE
A Retrospective Analysis of Outcomes from the WHASC DCOE Group Lifestyle Balance™ Program 2009-2013

1. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED
Impact of the Group Lifestyle Balance (GLB) Program on Diabetes Prevention in the Military Health System

2. IS THIS MATERIAL CLASSIFIED? ☐ YES ✓ NO

3. 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)

4. MATERIAL IS FOR (Check appropriate box or boxes for approval with this request.) (ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED)
☐ PUBLICATION/JOURNAL (List intended publication/journal)
☐ PUBLISHED ABSTRACT (List intended journal)
☐ POSTER (To be demonstrated at meeting/Name of Meeting, City, State, and Date of Meeting)
☐ PLATFORM PRESENTATION (At civilian institutions/Name of Meeting, State, and Date of Meeting)
☐ OTHER (Describe; Name of Meeting, City, State, and Date of Meeting)

5. WHO IS THE PRIMARY WHASC POINT OF CONTACT? (Last , First , M.I.) (Include email)
Davis, Richard P; Richard.p.davis56.mil@mail.mil
DUTY PHONE/PAGER No. 210-916-8589

AUTHORSHIP AND CO-AUTHOR(S) (List in the order they will appear in the manuscript)

- Primary/corresponding author
  Davis, Richard
  Maj 959 CSPS/SGVT
- Lewi, Jack
  COL 959 MCHE-MDE
- True, Mark
  Col 959 MDSS/ SGO5E
- Sauerwein, Tom
  GP-15 959 MDSS
- Wardian, Jana
  N/A 95 MDSS

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 MDW 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.

AUTHOR'S PRINTED NAME/RANK/GRADE
Richard Davis/ Maj/ O-4

COMMANDER'S PRINTED NAME, RANK
Mark W. True/ Col/ O-6

AMENDMENT INFORMATION

DATE

59 MDW Form 3039, 20131018
<table>
<thead>
<tr>
<th><strong>TO:</strong> Clinical Research Division</th>
<th><strong>1. DATE RECEIVED</strong></th>
<th><strong>2. ASSIGNED PROCESSING REQUEST FILE NUMBER</strong></th>
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<td><strong>3. DATE REVIEWED</strong></td>
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<td><strong>5. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES:</strong></td>
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<td><strong>6. COMMENTS</strong></td>
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The article is approved.

**PRINTED NAME, RANK/grade, TITLE OF REVIEWER**
Rocky Calcote, PhD
Clinical Research Administrator

**SIGNATURE OF REVIEWER**

**DATE**

**2ND INDORSEMENT (PA Use Only)**

**TO:** OFFICE OF PUBLIC AFFAIRS (PA)

**1. DATE RECEIVED**

**2. DATE FORWARD TO 59TH CSPG/SGVU**

**3. COMMENTS** □ APPROVED (In compliance with security and policy review directives) □ DISAPPROVED

**PRINTED NAME, RANK/grade, TITLE OF REVIEWER**

**SIGNATURE OF REVIEWER**

**DATE**

**3RD INDORSEMENT (SGVU Use Only)**

**TO:** 59 CSPG/SGVU

**1. DATE RECEIVED**

**2. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL**

□ YES □ NO □ COULD NOT BE REACHED □ LEFT MESSAGE

**3. DATE WRITTEN NOTICE OF APPROVAL AND CLEARANCE MAILED TO AUTHOR:**

**4. COMMENTS** □ APPROVED □ DISAPPROVED

**PRINTED NAME, RANK/grade, TITLE OF REVIEWER**

**SIGNATURE OF REVIEWER**

**DATE**

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59 MDW Form 3039, 20131018 (Supersedes WHMC IMT 3039, 20020301, V1) (Page 1 is Instruction Page) Page 3 of 3 Pages
IMPACT OF THE GROUP LIFESTYLE BALANCE (GLB) PROGRAM ON DIABETES PREVENTION IN THE MILITARY HEALTH SYSTEM

Maj Richard Davis, MD\(^1\); Col Mark True, MD\(^1\); COL Jack Lewi, MD\(^1\); Tom Sauerwein, MD\(^2\); Jan Wardian, Ph.D\(^2\)

\(^1\)Endocrinology Service, Department of Medicine, San Antonio Military Medical Center; \(^2\)Diabetes Center of Excellence, Wilford Hall Ambulatory Surgical Center

In 2014, 29.1 million Americans suffered from diabetes mellitus (DM). Additionally, 89 million Americans were pre-diabetic, 90% of them unaware. Current treatment costs of DM are estimated in excess of $245 billion. The Diabetes Prevention Program (DPP) demonstrated lifestyle intervention programs were effective. The GLB program translated the DPP curriculum into a 12 week group instruction for at risk patients. We implemented the GLB in a military universal access setting in 2009 to reduce diabetes.

We retrospectively evaluated clinical outcomes for patients in our GLB program from 2009 to 2013. Objectives included analyzing demographic attributes of program completers and changes in metabolic surrogates of disease prevalence. Conditions of interest were prediabetes, obesity, and metabolic syndrome.

Adults ≥ 18yrs with a BMI ≥ 25 kg/m\(^2\), prediabetes, or metabolic syndrome (metS) were primary care provider and self-referred to GLB. Classes were offered Monday-Friday 730AM-430PM. Demographic data included gender, age, race, ethnicity, employment, education, military status, and family history of DM. Metabolic data included weight, height, waist size, blood pressure, A1C, glucose, and lipids. The GLB program was taught in the standardized fashion as previously described elsewhere. Updated participant metabolic data was collected at regular intervals during their participation.

During the five year study period, 704 patients attended the initial class. Baseline demographics: mean age 52 yrs, female 61%, Caucasian 61%, non-Hispanic 66%, college grad 39%, fully employed 50%, retired 33%, active duty 17%, and family history of DM 52%. Baseline metabolic means: weight 194.8lbs, BMI 31.7 kg/m\(^2\), BP 122/76mmHg, A1C 5.97% [0-5.6], TG 118mg/dL [0-150], LDL 107mg/dL [60-129], and HDL 54mg/dL [35-100]. Baseline prevalence: prediabetes 90.6%, obesity 56.1%, and metabolic syndrome 33.3%. Change from baseline was compared at the end of 12 weeks. Overall, 52% of all participants completed the program. GLB completers tended to be older and retired (\(p<0.05\)). A significant number of active duty military members (44.9%, \(p<0.01, n=53\)) dropped out of the program before the fourth week. Of
completers, 19.7% lost ≥ 5% of their body weight, 10.1% lost ≥ 7%. Blood pressure, A1C and lipids were mildly improved. Completers saw decreased rates of prediabetes 2%, obesity 9.3%, and metS 6.8% (p<0.02).

GLB was successfully implemented in a military health setting. Loss to follow-up was evident, but accurately reflects challenges in real-world program staffing and ongoing patient engagement. Significant beneficial changes were achieved, including weight loss and lower rates of prediabetes, obesity, and metabolic syndrome. Factors to improve GLB completion rates are currently under active investigation. Additional long-term studies regarding diabetes prevention following GLB participation are needed.

This project was sponsored by funding from the U.S. Air Force administered by the U.S. Army Medical Research Acquisition Activity, Fort Detrick MD, Award Number W81XWH-04-2-0030 and the Frank E. Rath/Spang and Company Charitable Trust.

The views expressed are those of the authors and do not reflect the official views or policy of the Department of Defense, or its Components.
MEMORANDUM FOR 959 CSPS/SGVT

ATTN: Major Richard P. Davis

FROM: 502 ISG/JA (Mr. Christenson)

SUBJECT: Ethics Review for Poster Abstract Approval Request (Major Davis)

1. This office is in receipt of a request for a legal review of a poster to be presented at the SURF Conference in San Antonio, TX by Major Richard P. Davis. The poster is legally sufficient.

2. FACTS: Major Davis plans to present the poster abstract titled "Impact of the Group Lifestyle Balance (GLB) Program on Diabetes Prevention in the Military Health System" at the SURF Conference in San Antonio, TX, on 20 May 2016.

3. LAWS AND REGULATIONS: DoD 5500.07-R, Joint Ethics Regulation (JER), section 3-305 lays out rules governing "Teaching, Speaking and Writing." Pursuant to the JER, if the presentation will "deal in significant part with any ongoing or announced policy, program or operation" of the Air Force, the presenter is required to include a disclaimer that states the "views presented are those of the speaker or author and do not necessarily represent the views of DoD or its Components."

4. ANALYSIS: Although the poster abstract does not "deal in significant part with any ongoing or announced policy, program or operation" of the Air Force, the information was obtained through military medical practice and Major Davis' affiliation with the Air Force may nevertheless be included in the abstract. Accordingly, and appropriately, he included the required disclaimer that the views presented are those of the authors and do not necessarily represent the views of DoD or its Components on the slide presentation. Although the disclaimer language included on the presentation is not verbatim from the JER, the language used is appropriate and clearly captures the intent of the language used in the JER. A Public Affairs review may be needed if it has not already been obtained. There are also no apparent conflicts of interest that would prohibit the presentation.

5. CONCLUSIONS: The poster abstract presented for review included the disclaimer that is required by the JER and as such, is legally sufficient. There are no apparent conflicts of interest. If you have any questions, please call me at 210-671-5792.

MARK E. COON, Major, USAF
Acting Chief, Civil Law

CONFIDENTIALITY NOTICE: This opinion contains attorney-work product and information protected under the attorney-client privilege, both of which are protected from disclosure under the Freedom of Information Act, 5 U.S.C. §552. Do not release this document without the prior consent of 502 ISG/JA.