MEMORANDUM FOR 559 THLS/SGOZ
ATTN: CAPT BRYANT J WEBBER

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **Athletic Trainer Integration in U.S. Air Force Basic Training** presented at **Military Health System Research Symposium Website** with MDWI 41-108, and has been assigned local file #16135.

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

**Warrior Medics – Mission Ready – Patient Focused**
<table>
<thead>
<tr>
<th>TO: CLINICAL RESEARCH</th>
<th>FROM: (Author's Name, Rank, Grade, Office Symbol)</th>
<th>GME/GHSE STUDENT:</th>
<th>PROTOCOL NUMBER:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bryant J. Webber, Capt, USAF, MC, 559 THLS/SGOZ</td>
<td>NO</td>
<td>2015051N</td>
</tr>
</tbody>
</table>

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.)

Athletic Trainer Integration in U.S. Air Force Basic Training

6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:

Athletic Trainer Integration in U.S. Air Force Basic Training

7. FUNDING RECEIVED FOR THIS STUDY? YES ☒ NO
FUNDING SOURCE: CDMRP

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.)
Military Health System Research Symposium Website

☐ 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)

☐ 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. 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
March 31, 2016

13. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)
Webber, Bryant J. (bryant.webber@us.af.mil)

14. DUTY PHONE/PAGER NUMBER
671-1087

15. AUTHORSHIP AND CO-AUTHORS (List in the order they will appear in the manuscript)

<table>
<thead>
<tr>
<th>LAST NAME, FIRST NAME AND M.I.</th>
<th>GRADE/RANK</th>
<th>SQUADRON/GROUP/OFFICE SYMBOL</th>
<th>INSTITUTION (If not 59 MDW)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Webber, Bryant J.</td>
<td>O-3</td>
<td>559 THLS/559 MDG/SGOZ</td>
<td></td>
</tr>
<tr>
<td>Esparza, Shandra D.</td>
<td>Ctr</td>
<td></td>
<td>Univ of the Incarnate Word</td>
</tr>
<tr>
<td>Fisher, Reid A.</td>
<td>Ctr</td>
<td></td>
<td>Univ of the Incarnate Word</td>
</tr>
<tr>
<td>Pawlak, Mary T.</td>
<td>O-3</td>
<td>559 THLS/559 MDG/SGOZ</td>
<td></td>
</tr>
<tr>
<td>Nye, Nathaniel S.</td>
<td>O-3</td>
<td>559 THLS/559 MDG/SGOZ</td>
<td></td>
</tr>
<tr>
<td>Tchandja, Juste N.</td>
<td>GS-11</td>
<td>559 THLS/559 MDG/SGOZ</td>
<td></td>
</tr>
</tbody>
</table>

I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401, JP, 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.

16. AUTHOR'S PRINTED NAME, RANK, GRADE
Bryant Webber, Capt

17. AUTHOR'S SIGNATURE
WEBBER, BRYANT J. 12701923

18. DATE
March 11, 2016

19. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE
Asha Mandhare, Major

20. APPROVING AUTHORITY'S SIGNATURE
MANDHARE, ASHA K. 11202491723

21. DATE
March 11, 2016

59 MDW FORM 3039, 20160218
PREVIOUS EDITIONS CURRENTLY IN USE CAN BE USED
ALL OTHERS ARE OBSOLETE

Page 2 of 3 Pages
The article is approved.

28. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER
Rocky Calcote, PhD, Clinical Research Administrator

29. REVIEWER SIGNATURE
CALCOTE ROCKY D 1179245644

30. DATE

31. DATE RECEIVED

32. DATE FORWARDED TO 502 ISG/JAC

33. COMMENTS ☒ APPROVED ☐ DISAPPROVED
(In compliance with security and policy review directives.) ☐ DISAPPROVED

34. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER

35. REVIEWER SIGNATURE

36. DATE

37. DATE RECEIVED
March 25, 2016

38. DATE FORWARDED TO 59 MDW/PA
March 29, 2016

39. COMMENTS ☒ APPROVED ☐ DISAPPROVED
(In compliance with security and policy review directives.) ☐ DISAPPROVED

40. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER
Christopher Carwile, TSgt/E-6, NCOIC, PA

41. REVIEWER SIGNATURE
CARWILE CHRISTOPHER STEW
ART: 1265472229

42. DATE
March 29, 2016

43. DATE RECEIVED

44. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL
☐ YES ☐ NO ☐ COULD NOT BE REACHED ☐ LEFT MESSAGE

45. COMMENTS ☐ APPROVED ☒ DISAPPROVED

46. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER

47. REVIEWER SIGNATURE

48. DATE
Athletic Trainer Integration in U.S. Air Force Basic Training

Bryant J. Webber, MD, MPH*; Shandra D. Esparza, EdD, ATC**; Reid A. Fisher, EdD, MS**; Mary T. Pawlak, MD, MPH*; Nathaniel S. Nye, MD*; Juste N. Tchandja, PhD, MPH*; Thomas L. Cropper, DVM; Sarah J. de la Motte, PhD, MPH, MA***

*59th Medical Wing, Joint Base San Antonio – Lackland, Texas
**Ilia Faye Miller School of Nursing and Health Professions, University of the Incarnate Word, San Antonio, Texas
***Injury Prevention Research Laboratory, Uniformed Services University of the Health Sciences, Bethesda, Maryland

Background
As the leading contributor to missed military training time and medical attrition from training, musculoskeletal injuries significantly affect operational readiness. Reducing injury morbidity among military recruits could minimize disruptions in the training pipeline, decrease the associated costs, and improve the health and fitness of individuals entering the armed forces. This project was designed to evaluate the operational and cost impact of embedding certified athletic trainers (ATCs) in a U.S. Air Force training squadron.

Methods
An athletic training room staffed by two ATCs was opened near the end of 2015 in the 323 Training Squadron of U.S. Air Force Basic Military Training, Joint Base San Antonio-Lackland, Texas. Musculoskeletal injury rates, time out of training due to injury, injury-based attrition rates, healthcare utilization for injury, and per capita injury-related costs were calculated for the intervention squadron and compared to two control squadrons without access to ATCs. This population-based intervention trial profited from extant random allocation of recruits into the three squadrons. Preliminary analyses for the first two months of the program (January 1 through February 29, 2016) were conducted for this abstract.

Results
A total of 2,239 recruits accrued 9,349 weeks of training in the intervention squadron, compared to 4,643 recruits and 20,075 weeks of training in the control squadrons. Intervention and control squadrons experienced similar injury rates (16.8 and 16.7 per 1,000 training-weeks, respectively; p=0.97). Recruits in the intervention squadron spent 46% (95% CI=36, 56%) more time out of training for an injury, as compared to the control squadrons, and were more likely to be discharged for injury (RR=2.64, 95% CI=1.07, 6.47). Utilization of out-of-squadron (i.e., non-ATC) healthcare settings—to include sick call clinic, urgent care, physical therapy, and orthopedics—for injury were lower in the control squadron (27.9 vs. 37.2 per 1,000 training weeks; p<0.001). Per capita, the intervention squadron experienced higher training costs ($340 vs. $214) and lower medical costs ($23 vs. $29) associated with injuries, for a net increased cost of $121 per recruit.

Conclusions
Embedded ATCs in U.S. Air Force Basic Military Training appear to reduce out-of-squadron clinical appointments and associated medical costs, but in light of increased attrition and time out
of training due to injury, the net financial impact is negative. This program is early in its implementation phase and analysis should continue to delineate the longitudinal impact of ATCs in a military training environment, such as the impact on graduation rates, physical fitness scores, and morale.

Disclosures
This project is funded by a Clinical Research Initiative grant from the Congressional Directed Medical Research Program (award #DM140461). 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.
COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA)

BETWEEN

University of the Incarnate Word

AND

59th MDW, Wilford Hall Ambulatory Surgical Center

FOR THE INVESTIGATION OF

"Athletic Trainer Integration in the U.S. Air Force Basic Training"

AGREEMENT NUMBER: 15-148-AFMS59-C15010

PROTOCOL INFORMATION:

CRADA TITLE: "Athletic Trainer Integration in the U.S. Air Force Basic Training"

AGREEMENT ADMINISTRATORS:

COLLABORATOR
Preferred Contact: Mr. Armando Saliba
Ph: 210-829-2754
E-mail: saliba@uiwtx.edu

Principal Investigator: Dr. Shandra Esparza
Ph: 210-832-2132
E-mail: sesparza@uiwtx.edu

Dr. Reid Fisher
Ph: 210-283-6446
Email: 210-283-6446

LABORATORY
Preferred Contact: Ms. Sherrilynne Cherry
Ph: 210-292-2570
E-mail: sherrilynne.cherry@us.af.mil

Principal Investigator: Bryant Webber, Capt, USAF, MC
Ph: 210-671-4087
E-mail: bryant.webber@us.af.mil

PREAMBLE
Under authority of the U.S. Federal Technology Transfer Act of 1986 (Public Law 99-502, 20 October 1986, as amended), COLLABORATOR and LABORATORY, described below, agree to enter into this Cooperative Research and Development Agreement (CRADA) according to the terms and conditions set in this Agreement.
The COLLABORATOR is The University of the Incarnate Word, on behalf of the School of Nursing and Health Professions, 4301 Broadway Street San Antonio, TX 78209, is duly organized, validly existing and in good standing under the laws of Texas. The COLLABORATOR is not a small business as defined in 13 CFR 121.101 et seq. of the Administrator of the Small Business Administration. Further, the COLLABORATOR is not directly or indirectly controlled by a foreign company or government (Executive Order 12591, Section 4 (a)) as of the effective date of this Agreement.

The LABORATORY is the Air Force Medical Service, as represented by the 59th Medical Wing, located at 2200 Bergquist Drive, Bldg 4550, JBSA Lackland, TX 78236-9908, is a Federal laboratory of the United States Department of Defense wholly owned by the U.S. GOVERNMENT whose substantial purpose is the performance of research, development or engineering.

DEFINITIONS:
“DATA” means all recorded information of any kind regardless of the form or method of the recording, including computer software.
“EXCLUSIVE LICENSE” means the grant by the owner of Intellectual Property of the exclusive right to make, use, or sell a patented INVENTION.
“GOVERNMENT” means the Government of the United States of America.
“GOVERNMENT PURPOSE RIGHTS” means the right of the GOVERNMENT to use, duplicate, or disclose DATA, in whole or in part, and in any manner, for GOVERNMENT purposes only, and to have or permit others to do so for GOVERNMENT purposes only.
GOVERNMENT PURPOSE RIGHTS includes competitive procurement, but does not include the right to have or permit others to use DATA for commercial purposes.
“INVENTION” means any INVENTION or discovery which is or may be patentable under Title 35 of the United States Code.
“INVENTION DISCLOSURE” means the document identifying and describing to organizational management the Making of an INVENTION.
“MADE” when used in conjunction with any INVENTION means the conception or first actual reduction to practice of such INVENTION. (15 USC 3703(b)).
“PARTY” means a signatory to this Agreement.
“PATENT APPLICATION” means U.S. or foreign PATENT APPLICATION, continuation, continuation-in-part, divisional, reissue and/or reexamination on any INVENTION.
“PROPRIETARY INFORMATION” means information that embodies trade secrets developed at private expense or business, commercial, or financial information that is privileged or confidential provided that such information: (a) is not known or available from other sources without obligations concerning its confidentiality; (b) has not been made available by the owners to others without obligation concerning its confidentiality; (c) is not already available to the receiving PARTY without obligation concerning its confidentiality; and (d) has not been developed independently by persons who have had no access to the information.
“SUBJECT DATA” means that DATA first recorded in the performance of the OBJECTIVE.
“SUBJECT INVENTION” means any INVENTION MADE through research, development, engineering, or other tasks performed under this Agreement pursuant to the OBJECTIVE.
"UNLIMITED RIGHTS" means the right to use, modify, reproduce, release, disclose, perform, or display DATA or Computer Programs in whole or in part, in any manner and for any purpose whatsoever, and to have or permit others to do so.
"TEST ARTICLE" means a drug, biological product or device, etc., which is subject to regulation under the Federal Food, Drug, and Cosmetic Act, 21 USC 301 et seq, as amended, as well as placebo.
"SPONSOR" means an organization or individual who assumes legal responsibility for supervising or overseeing this clinical trial.
"PROTECTED HEALTH INFORMATION" means patient-identifying DATA from medical records or attached to patient specimens, to be obtained prospectively or from stored medical records or specimens, that can be linked to Individual Human Subjects, either directly or indirectly through codes.
"ADVERSE DRUG EXPERIENCE" means an adverse clinical experience as defined under 21 CFR 310.305
"INVESTIGATOR'S BROCHURE" means a document containing all the relevant information about the drug, including animal screening, preclinical toxicology, and detailed pharmaceutical DATA. Also included, if available is a summary of current knowledge about pharmacology and mechanism of action and a full description of the clinical toxicities.

Article 1. OBJECTIVE: LABORATORY and COLLABORATOR have shared interests in improving diabetic healthcare in the DoD (OBJECTIVE). A Statement of Work (Appendix A) detailing tasks for both LABORATORY and COLLABORATOR is appended to the end of this Agreement. Should there be any conflicting terms between this Agreement and its Appendices; the PARTIES agree that the terms of this Agreement shall take precedence.

Article 2. DATA/proprietary INFORMATION: Each PARTY agrees that it will not disclose or use the other PARTY's properly marked proprietary INFORMATION without prior written consent except for the OBJECTIVE and as required by applicable law. It is COLLABORATOR's and LABORATORY's responsibility to properly identify all proprietary INFORMATION. Under 15 USC 3710a(c)(7)(B) the LABORATORY and COLLABORATOR mutually may agree to provide appropriate protection and restricted access to SUBJECT DATA generated under this Agreement against public dissemination or release under the Freedom of Information Act (FOIA) for a period of up to five (5) years after development of the information LABORATORY may provide DATA to COLLABORATOR that may be the subject of a PATENT APPLICATION which is protectable under 35 USC § 205.

Article 3. PUBLICATIONS: Publication and/or presentation of SUBJECT DATA is of prime interest to the LABORATORY and this Agreement shall not be interpreted to prevent or unreasonably delay publication and/or presentation of research resulting from the activities occurring under this Agreement. COLLABORATOR and LABORATORY agree to confer and consult to provide a reasonable review period, up to 30 days, prior to the publication or presentation of SUBJECT DATA regarding the collaboration to assure that no proprietary INFORMATION is released and that patent rights are protected. Publication and/or presentation will be delayed for a
reasonable time to afford protection, if needed. If the research is not published, the LABORATORY and COLLABORATOR shall provide a report of the research results to the other PARTY. Each Party agrees that the individuals named as principal investigators in this Agreement, or any individuals in the future who are identified as a principal investigator, will include each other as a coauthor in any peer-reviewed publication resulting from research carried out under this Agreement while the agreement is in force.

Article 4. REPORTS:
The PARTIES shall submit reports on the progress of the Cooperative Work as mutually agreed; and at minimum, final written reports shall be exchanged within 30 days of the expiration of this Agreement.

Article 4.1. TEST ARTICLE CLINICAL REPORTS AND PROVISIONS: Test Article Provision Not Applicable: COLLABORATOR will provide to LABORATORY without charge and on a schedule that will ensure adequate and timely performance of the research, a sufficient quantity of acceptably labeled TEST ARTICLE to complete the clinical trial(s) agreed to and approved under this CRADA. All ADVERSE EXPERIENCES, as defined in 21 CFR 310.305, that are either serious or unexpected, shall be reported to the SPONSOR as soon as possible following notification of the occurrence and as provided in the Protocol(s). Details about all such ADVERSE EXPERIENCES shall be communicated to the SPONSOR in writing via the appropriate form and as required by the Protocol(s). LABORATORY and COLLABORATOR, or their agents, may each file any required documentation related to TEST ARTICLE with the FDA. LABORATORY and COLLABORATOR expressly authorize and consent to allow each other or its authorized agent(s) access to, and/or to cross-reference, any documents filed with the FDA related to the TEST ARTICLE.

The PARTIES shall make all necessary SUBJECT DATA and Source Documents available to a regulatory authority or other governmental authorities, or the Institutional Review Board (IRB) for inspection or auditing. A PARTY shall immediately notify the other PARTY(ies) should it receive of an inspection, investigation or audit examination. The PARTY under examination shall share copies of any documents received from or provided to a regulatory authority or other governmental authorities with the other PARTY(ies).

In the event that PROTECTED HEALTH INFORMATION is to be shared among the PARTIES, each PARTY shall comply with all laws and regulations, including without limitation the regulations of the Health Insurance Portability and Accountability Act (HIPAA), governing the privacy and security of health information. COLLABORATOR will execute and abide by the terms of the attached Business Associate Agreement (Appendix B) addressing the handling of PROTECTED HEALTH INFORMATION. Each PARTY shall treat all PROTECTED HEALTH INFORMATION as protected from disclosure to the extent required by applicable law.

Article 5. WARRANTY:
The SPONSOR warrants that the TEST ARTICLE provided has been produced in accordance with the FDA’s current Good Manufacturing Practice set out in 21 CFR 210-211, and ICH QA7, and meets the specifications cited in the Certificate of Analysis and
INVESTIGATOR'S BROCHURE provided. No PARTY to this Agreement is presently subject to debarment or suspension by any agency of the GOVERNMENT. Should a PARTY be debarred or suspended during the term of this Agreement, the other PARTY(ies) shall be notified within thirty (30) days of receipt of a final notice. The notified PARTY(ies) may then elect to terminate this Agreement and any licenses and options granted under this Agreement. OTHER THAN THE AFOREMENTIONED, NO PARTY MAKES ANY REPRESENTATIONS NOR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESSED OR IMPLIED REGARDING ANY MATERIALS OR EQUIPMENT TRANSFERRED UNDER THIS AGREEMENT. THERE ARE NO EXPRESSED OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF ANY MATERIALS OR EQUIPMENT TRANSFERRED UNDER THIS AGREEMENT WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER RIGHTS.

Article 6. LIABILITY:
LABORATORY shall be liable for damage to any materials or equipment transferred under this Agreement resulting from LABORATORY's fault or negligence in accordance with Federal Law, excepting ordinary wear and tear occasioned by normal and ordinary usage. In no event shall LABORATORY be liable for such wear and tear associated with the usage of any materials or equipment transferred under this Agreement, or for loss, damage, or destruction prior to delivery of those materials/equipment/data to the LABORATORY. COLLABORATOR agrees to defend, indemnify, and hold harmless LABORATORY from any loss, claim, damage, or liability, of any kind, which may arise from COLLABORATOR's use, storage or disposal of any materials or equipment transferred under this Agreement. LABORATORY's entire liability is as stated in the Federal Tort Claims Act, 28 U.S.C. Section 2671 et seq. No PARTY shall be liable for the consequences of any force majeure that is beyond its reasonable control.

Article 7. TRANSFER AND DISPOSAL OF EQUIPMENT/MATERIAL:
The PARTIES agree that any materials or equipment transferred under this Agreement and related PROPRIETARY INFORMATION received by either PARTY, and any copies of information, shall remain the property of the providing PARTY. These items will be promptly returned, destroyed, or otherwise disposed of, at the termination of this Agreement in accordance with the directions of the providing PARTY. All requests and responses must be in writing. The materials or equipment transferred under this Agreement and information will be returned at no expense to the providing PARTY. All tangible property jointly developed under this agreement shall remain the property of the GOVERNMENT unless separately negotiated. The obligations of the PARTIES to transfer technology to one or more other PARTIES, provide technical information and reports to one or more other PARTIES, and otherwise perform under this Agreement are contingent upon compliance with applicable United States export control laws and regulations. In addition, where applicable, the PARTIES agree to fully comply with all laws, regulations, and guidelines governing biological select agents and toxins.

Article 8. INTELLECTUAL PROPERTY and DATA RIGHTS:
Each PARTY allows the other PARTY(ies) to practice its NON-SUBJECT INVENTION(s) to accomplish the OBJECTIVE. Except as expressly provided in this Agreement, no additional rights are provided to LABORATORY or COLLABORATOR under any pre-existing patents, PATENT APPLICATIONs, trade secrets or other intellectual property. LABORATORY has GOVERNMENT PURPOSE RIGHTS in any SUBJECT DATA or SUBJECT INVENTION MADE under this Agreement in performance of the OBJECTIVE and tasks. Each PARTY shall have the right to review and receive delivery of SUBJECT DATA generated by the other PARTY(ies), and SUBJECT DATA shall be delivered to the requesting PARTY within fifteen (15) days of the request.

Article 9. SUBJECT INVENTION LICENSE OPTION:
Each PARTY shall separately retain title to any SUBJECT INVENTION of its employees MADE in the performance of the OBJECTIVE and Statement of Work (Appendix A). Jointly developed SUBJECT INVENTIONS MADE in the performance of the OBJECTIVE and Statement of Work will be jointly owned by both PARTIES. Each PARTY shall notify the other of the receipt of any INVENTION DISCLOSURE regarding SUBJECT INVENTIONs occurring under this Agreement in accordance with the OBJECTIVE. COLLABORATOR has a non-exclusive, non-commercial, research use license to any SUBJECT INVENTION MADE by LABORATORY occurring under this Agreement in performance of the OBJECTIVE and tasks. LABORATORY gives COLLABORATOR the option, to be exercised within one hundred eighty (180) days after any filing of any type of PATENT APPLICATION claiming the SUBJECT INVENTION, of acquiring an EXCLUSIVE LICENSE in the GOVERNMENT’s rights in any SUBJECT INVENTION. The EXCLUSIVE LICENSE will be subject to a reasonable royalty. Any EXCLUSIVE LICENSE granted by the GOVERNMENT in an INVENTION is subject to the statutorily required reservation by the GOVERNMENT of a nonexclusive, irrevocable, paid-up license to practice the INVENTION or have that INVENTION practiced throughout the world by or on behalf of the GOVERNMENT. Unilateral termination of this Agreement may result in the termination of any EXCLUSIVE LICENSE or option thereto.

Consent must be obtained by all PARTIES to this Agreement for third-party contractors to be employed on behalf of either COLLABORATOR or LABORATORY, in performance of the OBJECTIVE; the contractors will retain their Bayh-Dole rights (35 USC 200 et seq.) unless otherwise agreed. COLLABORATOR consents to LABORATORY’s use of contractors in performance of the OBJECTIVE.

Article 10. NOTICES and AMENDMENT:
All notices will be sent to the Agreement administrators or their successors at the addresses shown in the PREAMBLE or other confirmed address. This Agreement can be amended only by a written amendment mutually agreed to and signed by the Agreement signatories or their successors.

Article 11. DURATION:
This Agreement will terminate on the earliest of the following dates:
(1) Upon thirty (30) days written notice by any PARTY to the other(s), or
(2) 42 months from the effective date of this Agreement.
Article 12. ENTIRE AGREEMENT, ASSIGNMENT, and DISPUTES:
This Agreement is the entire Agreement between the PARTIES concerning the OBJECTIVE and supersedes any prior understanding or written or oral Agreement related to the OBJECTIVE. This Agreement cannot be assigned without the prior written consent of the other PARTY(ies). The PARTIES agree that disputes shall be resolved by submitting the issue to the Director, Research, Development & Acquisition, Defense Health Agency or his designee for decision within 60 days of submission. The PARTIES may seek resolution in U.S. Federal Court or an alternative dispute resolution mechanism if the dispute remains unresolved after 60 days. The relationship of the parties to this Agreement is that of independent contractors and not as agents of each other or as joint venturers or partners.

Article 13. FUNDS: Article Not Applicable
It is agreed and understood that any materials or equipment transferred from COLLABORATOR to LABORATORY under this Agreement is/are furnished and the Agreement is entered into at no cost to the LABORATORY. If COLLABORATOR receives and accepts funds from LABORATORY in support of the OBJECTIVE, this Agreement is terminated and license terms of Article 9 are null and void. LABORATORY may discontinue performance under this Agreement if the funds provided by COLLABORATOR are insufficient or are not provided as specified. Funds that have not been obligated or expended at the conclusion of this Agreement shall be returned to COLLABORATOR.
COLLABORATOR agrees to pay LABORATORY the following fees/costs according to the schedule below: Not Applicable
Schedule: 
The funding amount is: Not Applicable Checks will be payable to: US Treasury
Schedule: 
Each check correspondence shall refer to LABORATORY CRADA number “DTTIS #”
Checks will be mailed to: COMPTROLLER
BASE
STREET
CITY, STATE ZIP

Article 14. TITLE:
Each PARTY shall retain title to all tangible property to which it had title prior to the effective date of this Agreement unless mutually agreed in writing.

Article 15. USE OF NAME OR ENDORSEMENTS:
Both LABORATORY and COLLABORATOR shall not use the name of the other PARTY on any product or service that is directly or indirectly related to this Agreement without the prior written approval of the named PARTY. Nothing herein is intended to preclude either party from acknowledging the existence of this Agreement or the relationship of the parties in reports of business activity.

Article 16. PUBLIC RELEASE OF THIS AGREEMENT:
Other than the funding information in Article 13, this Agreement is releasable to the public.

Article 17. EFFECTIVE DATE:
The effective date of this Agreement is the date of execution by the last to sign for the DURATION set in Article 11.
Article 18. GOVERNING LAW and SURVIVING PROVISIONS: All the Articles of this Agreement shall survive its termination.

Signatures on following page
Article 19. **SIGNATURES:**
Each PARTY shall execute a copy of this Agreement, each of which shall be deemed an original and all of which when delivered, by facsimile transmission, mail, or email delivery, together shall constitute one instrument.

Accepted for: **University of the Incarnate Word:**

I, the undersigned, am duly authorized to bind University of the Incarnate Word to this Agreement and do so by affixing my signature hereto. Entered into this 24th day of April, 2015.

By: [Signature]

**Name:** Douglas B. Endsley  
**Title:** Vice President of Business and Finance

Accepted for the Department of Defense **LABORATORY: 59th Medical Wing:**

I, the undersigned, am duly authorized to bind the LABORATORY to this Agreement and do so by affixing my signature hereto. Entered into this 23rd day of May, 2015 under 15 USC 3710a.

By: [Signature]

BART O. IDDINS  
Major General, USAF, MC, CFS  
Commander, 59th Medical Wing

**DATE:** 2 JUNE 2015

BY: [Signature]  
SHERRILYNNE CHERRY  
AFMS Technology Transfer Focal Point
Appendix

Statement of Work

"Athletic Trainer Integration in the U.S. Air Force Basic Training"

ARTICLE A—PROJECT DESCRIPTION

A.1. Study Problem: Unlike her sister services, the Air Force has not employed Certified Athletic Trainers (ATCs) in the Basic Military Training (BMT) environment. The Air Education and Training Command is currently considering hiring ATCs for multiple training platforms, but the evidence-base for ATCs in the military is not well-established. A scientifically robust, well-controlled study evaluating the impact of ATCs on military training injuries and their associated costs would provide an evidence base on which the U.S. Air Force—and its sister services—could define injury prevention policies. This will be accomplished by embedding ATCs in two squadrons and comparing their outcomes with two squadrons who will receive the current standard of care. Pre- and post-intervention surveys of musculoskeletal knowledge and morale will be provided to Independent Duty Medical Technicians (IDMTs) and Military Training Instructors (MTIs) in the four squadrons.

A.2. Study Purpose: Under this Agreement, the parties will conduct a clinical investigation related to injury prevention by embedding ATCs in BMT squadrons. Intervention results, if successful, can be easily disseminated to the entire U.S. Military as this project is designed to overcome the barriers unique to the military population and specific to injury associated with BMT. There will be 3 main goals: 1) Improve training and clinical outcomes in U.S. Air Force BMT by ATCs and thus enhancing prevention, diagnosis, and treatment of musculoskeletal injuries; (2) reduce the costs associated with musculoskeletal injuries by early recognition and intervention; (3) augment the morale, capabilities, and professional growth IDMTs and MTIs.

A.3. Study Product: As the leading contributor to missed military training time and medical attrition from training, musculoskeletal injuries significantly affect the operational readiness of the U.S. Armed Forces. Reducing injury morbidity among military recruits would minimize disruptions in the training pipeline, decrease the costs associated with these disruptions, and improve the health and fitness of these individuals prior to graduating into active duty. This study has the potential to expand the multidisciplinary approach to musculoskeletal injury prevention, care, and rehabilitation by demonstrating the operational and fiscal value of embedding ATCs into training units. Should this study establish such an evidence base, the U.S. Air Force's Air Education and Training Command and other military services may expand the use of ATCs across various training platforms.
ARTICLE B—OBJECTIVES

B.1. CRADA Objective. The main objectives of this study are to: (1) Improve training and clinical outcomes in U.S. Air Force basic military training by embedding certified ATCs and thus enhancing prevention, diagnosis, and treatment of musculoskeletal injuries; (2) reduce the costs associated with musculoskeletal injuries by early recognition and intervention; (3) augment the morale, capabilities, and professional growth of IDMTs and MTIs.

B.1.1. The Air Force Activity and Collaborator desire to collaborate in research and development in support of the clinical investigation protocol to comprehensively test an intervention program in a specific military population. The results of the intervention program will determine the most efficacious method of improving military readiness and training.

B.2. Technology Transfer. This Agreement meets the statutory requirement of the Federal Technology Transfer Act in that it serves to transfer unique medical knowledge and military medical experience to the private sector. This knowledge transfer is critical to realizing the full benefits of other implementing technology transfer agreements between the parties related to this project.

B.4. Benefit to Air Force Mission. Musculoskeletal injuries are a leading cause of morbidity among U.S. military service members and trainees and therefore have a profound impact on current and future operational readiness. At Joint Base San Antonio-Lackland, over half of missed training time and nearly half of all medical attrition from U.S. Air Force basic training are attributed to musculoskeletal injuries. Reducing the rates of these injuries would have a threefold benefit for the military: improve the health and well-being of service members and trainees; save significant money from the associated medical and non-medical costs, including long-term disability costs; and enhance readiness by eliminating disruptions in the training pipeline. Common risk factors for injuries—such as inappropriate exercise type and intensity, musculoskeletal inflexibility and alignment abnormalities, and physical deconditioning—may be modifiable if addressed systematically by those with expertise in the field. This study seeks to determine if musculoskeletal injury rates and the associated costs may be reduced by embedding certified athletic trainers into two U.S. Air Force basic training squadrons. Each year, in addition to the 32,000 individuals who enter basic training, approximately 50,000 service members in the Air Force, Army, Navy, Marines, and allied forces train at JBSA-Lackland. Should the embedded athletic trainer model demonstrate improved musculoskeletal care of basic trainees, it could be extended to these training cohorts at JBSA-Lackland and to other military installations. Furthermore, by deploying prevention and treatment to the site of injury, and thereby preventing the number of patients waiting to be seen at the medical treatment facility, this intervention could improve efficiency of the medical treatment facility and enable better integration of medical and training line assets.
B.5. Benefit to Collaborator. The Collaborator will benefit by having access to military personnel, resources, and the knowledge gained by the study in determining effectiveness of an intervention program in a high risk population. It also develops a military-academia affiliation between JBSA-Lackland and the University of the Incarnate Word, an important San Antonio institution that has an expanding role in health professions education, and strengthens the relationship between the medical and military line communities at JBSA-Lackland. The investigative team is multi-disciplinary and includes a member of the basic military training command. The project includes mentors from the U.S. Army Research Institute of Environmental Medicine and the Uniformed Services University of the Health Sciences (though not in the role of associate investigators).

B.6. Estimate of Benefit. Air Force basic trainees are currently evaluated by IDMTs on the physical training pad or in the squadron dispensaries if they have musculoskeletal injuries or other basic complaints. Over half of the encounters with IDMTs are for musculoskeletal complaints, predominantly for pain of the lower extremities. IDMTs must follow pre-approved protocols for treatment. Trainees with more severe injuries, or who do not improve with IDMT treatment, are referred to a higher echelon of care at Reid. The ATCs would work alongside the IDMTs at the same facilities to provide musculoskeletal care, and they would do so within the same time period as the IDMTs. The only difference for the trainees in the intervention squadrons is that they would obtain a higher level of care. Essentially, the trainees would be treated like collegiate or professional athletes, who are typically evaluated by athletic trainers before seeing a physician. In our case, ATCs will provide three major clinical functions: (1) identify and evaluate trainees with gait issues or other musculoskeletal risk factors that predispose to injury; (2) diagnose and treat trainees with acute musculoskeletal issues and provide the appropriate disposition—i.e., to return to training, to provide immediate on-site treatment (such as taping or icing), or to refer to clinical care; (3) assist IDMTs and training instructors in providing basic life support during physical training, if needed. Finally, by being embedded in the squadrons, ATCs would become colleagues with the IDMTs and MTIs, which is why we would like to measure change in staff morale and knowledge of musculoskeletal injuries.

ARTICLE C—PARTIES AND OTHER PARTICIPANTS

C.1. Relationship of Parties. Collaborator’s personnel may work in Air Force Activity’s workplace, as necessary, to accomplish the goals of this Agreement. Each party will ensure that its own personnel participating in activities pursuant to this Agreement: (a) will comply with applicable workplace safety and training requirements appropriate for the individual’s duties; (b) will respect privacy and confidentiality of Protected Health Information (PHI) and Personally Identifiable Information (PII) encountered in the course of their duties; (c) will have appropriate privileges to fulfill their roles and have appropriate liability coverage if the individual is a health care provider; and (d) certify that they are qualified by training, education, and experience to fulfill their designated role in the research. When Collaborator’s personnel are working in Air Force Activity’s workplace, Collaborator’s personnel are considered part of Air Force Activity’s covered entity for the purpose of the Health Insurance Portability and Accountability Act (HIPAA). Disclosures of PHI or PII to such Collaborator
C.2. Other Participants. Not Applicable.

ARTICLE D—TECHNICAL TASKS


D.1. The Air Force Activity agrees to use its best efforts and professional expertise to perform the requirements of this study in accordance with the Protocol and the terms and conditions of this Agreement. In the event that Air Force Activity uses sub-investigators, study coordinators, or contractors to perform any study-related services under this Agreement, Air Force Activity shall be responsible for ensuring the compliance of such individuals with the terms of this Agreement. In the event that Capt Webber becomes no longer affiliated with Air Force Activity, Air Force Activity shall provide written notice to Collaborator within fourteen (14) days of such departure. The Collaborator shall have the right to approve any new Principal Investigator designated by the Air Force Activity. The new Principal Investigator shall comply with the terms and conditions of this Agreement. In the event Collaborator does not approve such new Principal Investigator, Collaborator may terminate this Agreement in accordance with the provisions of this Agreement and Air Force Activity shall take all necessary steps to accommodate Collaborator's decision.

D.2. Air Force Activity will not conduct research Under this Agreement without a protocol approved by the Institutional Review Board (IRB) and Collaborator.

D.3. The Air Force Activity is equipped to undertake the study and Air Force Activity has agreed to perform the study on the terms and conditions set forth herein.

D.4. Air Force Activity will furnish the premises, facilities, utilities, furniture, and communication systems necessary for the study.

D.5. Air Force Activity will provide training, common access cards, e-mail with certificates, computer accounts, and installation access as necessary for Collaborator personnel to complete Collaborator's tasks associated with this Agreement.

D.6. Capt Webber, as the Principal Investigator, shall personally supervise the study and may not delegate this duty. The Principal Investigator may, however, delegate other duties to qualified personnel per protocol and regulatory requirements.

D.7. Air Force Activity agrees to use its best effort to provide appropriate responses to queries received.

D.8. Air Force Activity shall use its best effort to prevent unauthorized access to study data by maintaining physical security of computers and use ensuring Air Force Activity personnel maintain confidentiality of their passwords.

D.9. Air Force Activity will not make any payments or provide any funds, directly or indirectly, to Collaborator under this Agreement.
D.10. The Air Force Activity shall be responsible for reporting to relevant agencies any discounts, rebates and/or free product received from Collaborator, as required under Medicare, Medicaid or other applicable federal healthcare program rules, and for providing any other information requested by such agencies concerning the quantity or value thereof.

D.2 Collaborator

D.2.1. Collaborator shall insure that all personnel abide by applicable local command and USAF training, rules, regulations, and instructions.

D.2.2. Collaborator will inform Air Force Activity of name and title of Collaborator employees supporting this Agreement.

ARTICLE E—INTELLECTUAL PROPERTY

E.1. Background Technology. A designation of relevant Background Technology, if any, each party brings to this Agreement may be listed in this section, along with a detailed description or appropriate citation (e.g., patent number, software version, etc.) for each item and the type of intellectual property or other protection that applies (e.g., trade secret, copyright, patent or patent application, etc.).

E.2. No Effect on Rights of Background Technology. The designation of technology as Background Technology does not grant any rights in Background Technology to the receiving party other than to use the technology provided to the receiving party under this Agreement for the purpose of performing work Under this Agreement. Nothing in this Agreement shall be construed to otherwise alter or affect any rights of either party to any technology designated as Background Technology that exist or are modified outside this Agreement.


E.2.3. Air Force Activity Background Technology. None.

E.3. Marking of Background Technology. All Background Technology will be identified as such with a marking. For example:
[PARTY NAME] – BACKGROUND TECHNOLOGY

The right to use, modify, reproduce, release, perform, display, disclose or dispose of information revealed herein is restricted in accordance with CRADA No. FY-###-LAB-##.

This information shall be protected in accordance with 15 USC § 3710a(c)(7). Any information subject to this legend may only be reproduced or disclosed if authorized under the referenced agreement and every such reproduction or disclosure must also be prominently marked with this legend.

If you are not permitted to receive this information under the referenced agreement, you must immediately return it to an authorized representative.

Fig 1. Marking of Background Technology

E.4 Marking of Protected Information. All Protected Information will be identified as such with a marking. For example:

[PARTY NAME] – PROTECTED INFORMATION

The right to use, modify, reproduce, release, perform, display, disclose or dispose of information revealed herein is restricted in accordance with CRADA No. FY-###-LAB-##. This information shall be protected in accordance with 15 USC § 3710a(c)(7). Any information subject to this legend may only be reproduced or disclosed if authorized under the referenced agreement and every such reproduction or disclosure must also be prominently marked with this legend.

If you are not permitted to receive this information under the referenced agreement, you must immediately return it to an authorized representative.

Fig 2. Marking of Protected Information

ARTICLE F—DELIVERABLES

F.1. Property and Equipment. None.

F.2. Reports. Parties will prepare and exchange written reports, in a timely manner on the progress of their work, results obtained, and problems encountered. To the extent reasonable, further detail concerning the contents for the reports shall be provided upon request, if necessary, for the other Party to fully understand the results achieved. At a minimum, Principal Investigators will submit annual progress reports to the parties. Parties will prepare and exchange a final report within six (6) months after the completion of Research performed Under This Agreement, hereto, on the progress of their work, results obtained, and problems encountered, if requested. To the extent reasonable, further detail
concerning the contents of the report(s) shall be provided upon request if necessary for the other Party to fully understand the results achieved.

F.3. Other Deliverables. None.

ARTICLE G—MILESTONES.

G.1. This project is projected to require 36 months to complete.

G.1.1 Months 1 to 6: Devoted to securing approval by the WHASC Institutional Review Board; ordering supplies and equipment; hiring athletic trainers and an administrative clearance; obtaining security clearances, base access, computer and EHR access and credentialing for athletic trainers.

G.1.2. Months 7-30: Gather baseline survey data on IDMTs and MTIs; consent trainees entering squadrons and providing ATC services to consented trainees; tracking medical, personnel, and fitness data of intervention squadrons; and training IDMTs and MTIs

G.1.3. Months 31-36: Gather follow-up survey data on IDMTs and MTIs, data analysis, preparation of reports, and dissemination of results.
Date: 5 May 2015

TO: Capt Bryant Webber/SGOZ

Protocol Number: FWH2015051H. “Athletic Trainer Integration in U.S. Air Force Basic Training”

Introduced 28 Apr 15 as New Human Research at the 59th Medical Wing, Institutional Review Board (59th MDW IRB) at a convened meeting.

[Purpose of the study: (1) Improve training and clinical outcomes in U.S. Air Force basic military training by embedding certified athletic trainers (ATCs) and thus enhancing prevention, diagnosis, and treatment of musculoskeletal injuries; (2) reduce the costs associated with musculoskeletal injuries by early recognition and intervention; (3) augment the morale, capabilities, and professional growth of independent duty medical technicians (IDMTs) and military training instructors (MTIs).]

[Documents Reviewed: Protocol, ICD, HIPAA, Form A, Form A-2, Form F, IAIR with Univ of the Incarnate Word, C11, CV, Letter of Support 737 TRG Commander, Notification Letter, Survey Template, Texas Law_Title 3 Ch 451]

IRB Determinations:

This activity was determined to be considered not research as defined by DoD regulations at 32 CFR 219 and FDA regulations at 21 CFR 56. The Principal Investigator is not required to obtain IRB approval for this activity. The proposed activity is not funded by DHHS/DoD as research; while the activity is a systematic investigation to test a hypothesis and permit conclusions to be drawn, it is not designed to develop or contribute to generalizable knowledge; and the purpose is not to investigate the safety or effectiveness of a drug, medical device or biologic.

Since the IRB does not have regulatory oversight for this study, it is the investigator’s responsibility to validate the study’s scientific merit and design and to ensure the conduct of the study is upheld by the highest ethical standards, as required by the Wing. Should the investigator/evaluator require assistance in reviewing the scientific merit and design of the study, they should contact the Protocol Office. Protection of subjects’ rights, safety and welfare and the responsibility for protecting PHI/PII and research data, are the responsibility of the investigator and their commander, as well as the stakeholders that authorize the Program Evaluation.

In accord with DoDI 6000.08 any intramural funding of this study as research or as a clinical investigation may continue to be received or sought regardless of this IRB determination.

This study has received a one-time non-research determination. If the goals and/or activities of the project change during the course of the project, or if new activities are proposed that would constitute human subjects research, the principal investigator should re-contact with the Protocol Office, as required, so a regulatory expert may determine whether or not the revised plan involves human subject research activities.

Many revisions will be required for the study as currently written (as a research study) to become a proper Program Evaluation. This is the responsibility of the investigator/evaluator and the Wing. It is recommended the Principal Investigator obtain a copy of the “Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury – Program Evaluation Guide” to use as a reference when developing his Program Evaluation Study.

File this and any other IRB correspondence in your study binder
Continue to refer to the activity using the assigned Protocol number. However, the suffix must be changed from “H” for human research to “N” for non-research/non-human research.

While this activity is determined to be non-research, the responsibilities in Form A, Signature Sheet, in the “Principal Investigator’s Agreement” and the “Squadron Commander’s/Division Chief’s Certification” section will continue to apply during the life of this activity. All risk to subjects and the responsibility for protecting PHI/PII and research data will fall on the investigator and their commander. Should this activity be modified to a point that an additional regulatory determination may be necessary to consider whether human subject research is involved, the study must be resubmitted in its new form for a separate IRB determination. FOLLOW-UP: CLOSED

DELLA L. HOWELL, LtCol, USAF, MC
Chairperson, 59 MDW IRB
MEMORANDUM FOR 559 THLS/SGOZ

FROM: 502 ISG/JA

SUBJECT: Ethics Review for Presentation Approval Request

1. The abstract titled “Athletic Trainer Integration in U.S. Air Force Basic Training” was submitted for legal review. There are no apparent conflicts of interests and the abstract includes the required disclaimer. This abstract may be submitted for symposium consideration.

2. FACTS: The abstract titled “Athletic Trainer Integration in U.S. Air Force Basic Training” was submitted by Capt Bryant Webber. Capt Webber is a member of 559 THLS/SGOZ. Capt Webber plans to present this research at the Military Health System Research Symposium.

3. LAWS AND REGULATIONS: DoD 5500.07-R, Joint Ethics Regulation (JER), section 3-305 lays out rules governing “Teaching, Speaking and Writing.” If the abstract will include the service member’s rank or title and “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: The abstract deals “in significant part with any ongoing or announced policy, program or operation” of the Air Force. The author’s affiliation and/or rank will be included in the abstract, and the case study information was obtained as part of military medical practice. Capt Webber properly includes the required disclaimer that the views presented are those of the author and do not necessarily represent the views of DoD or its Components on the abstract. Any resultant poster, slide or oral presentation must also include the required disclaimer. A Public Affairs review will be needed if it has not already been obtained. There are no apparent conflicts of interest that would prohibit presentation of this research at this professional meeting.

5. CONCLUSION: The abstract presented for review included the disclaimer required by the JER. There do not appear to be any conflicts of interest. Any poster, slide or verbal presentation must also include disclaimer language. If you have any questions, please call the undersigned at 671-3362.

JESSE BOLANOS
Legal Intern

I concur.

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