MEMORANDUM FOR SGOZ  
ATTN: CAPT MARY T PAWLAK

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval


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*
The Impact of Chagas Disease on Military Training in Texas

7. FUNDING RECEIVED FOR THIS STUDY? X YES □ NO FUNDING SOURCE: Air Force Medical Services Agency

8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES? □ YES X 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 X NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.

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.)
Additional Poster presentation: American Society of Tropical Medicine and Hygiene, Atlanta, GA, 13-17 Nov 2016

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
May 02, 2016

13. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)
Pawlak, Mary, T. (mary.pawlak@us.af.mil)

14. DUTY PHONE/PAGER NUMBER
671-8255

15. 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. Polak, Mary T. O-3 559 THS/559 MDW/SGOZ
b. Hall, Sallie 59 MDW/ST
c. Valtier, Sandra 59 MDW/ST
d. Daniels, Candelaria C. 59 MDW/ST

e. Cropper, Thomas L. 559 THS/559 MDW/SGOZ
f. Webber, Bryant J. O-3 559 THS/559 MDW/SGOZ

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.

17. AUTHOR’S SIGNATURE
Pawlak, Mary T. 1473946441

18. DATE
April 08, 2016

19. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE
Asha Mandhare, Maj, 559 TFS Flight Commander

20. APPROVING AUTHORITY’S SIGNATURE
Asha Mandhare 1120418753

21. DATE
April 08, 2016
If the primary authors and presenters are residents, fellows or post-docs/individuals with a doctoral degree within five years of graduation from a terminal degree they may be eligible for the Young Investigator Competition and if accepted in the poster session should ensure the poster conforms to the MFRS poster competition requirements especially any way they expect the IRB Clearance and date to be annotated on the poster.
If the primary authors and presenters are residents, fellows or post-docs/individuals with a doctoral degree within five years of graduation from a terminal degree they may be eligible for the Young Investigator Competition and if accepted in the poster session should ensure the poster conforms to the MIIRS poster competition requirements especially any way they expect the IRB Clearance and date to be annotated on the poster.
FINAL IRB APPROVAL (FULL BOARD - MINIMAL RISK)

Approval Date: 27 May 2014

Principal Investigator: Capt Bryant Webber/SGOZ

IRB Reference Number: FWH20140074H (IRBNet 402055)

Assurance Number: FWA000001750, Expiration: 12 Aug 18 (Wilford Hall Ambulatory Surgical Center) DOD Assurance #50007, Expiration: 8 Sep 16

Protocol Title: The Impact of Chagas Disease on Military Training in Texas

1. Your study, referenced above, is approved for one year as a MINIMAL RISK study by the Wilford Hall Ambulatory Surgical Center’s Institutional Review Board (WHASC IRB). This study was previously Conditionally Approved and this is notification that all stipulations have been met therefore the study may begin. Additional items reviewed and approved by the WHASC IRB include:
   - ICD
   - HIPAA Authorization
   - Individual Investigator Agreement (Dr. Daniels)
   - Letter of Support (341 Training Squadron)
   - Letter of Support (343 Training Squadron)
   - Letter of Support (59 MDW Laboratory Services)
   - Letter of Support (737 Training Group)
   - Letter of Support (FADL)
   - CAMD SOP 23.3
   - CAMD SOP 3.7
   - Form A-1
   - Form A-2
   - Master Key and Enrollment Case Report Form
   - Ombudsman Appointment Letter
   - CVs
   - CITI Training certificates

2. The expiration date on your new study is 27 May 2015. This is the date upon which the study is no longer approved, unless you submit a continuing review report, using the template provided by the Protocol Office which must be subsequently approved in no more than 365 days, as follows. The expiration date is based on this study’s approval date. The IRB will use the expiration date as a fixed anniversary date. This means if next year's IRB approval occurs within 30 days of expiration, the expiration date will remain the same. The study will be reviewed in approximately 11 months for continuing review. Your first progress report, which is a request for continuation of the study, will be due to the Protocol Office no later than 14 April 2015. A continuing review report will be due approximately every 11 months after each approval, in order for the WHASC/IRB to approve continuation of the study for another year. You must submit all publications and presentations for prior approval by the WHASC Public Affairs and Protocol Office. Upon completion of your study, you must submit a final closeout report to the WHASC Protocol Office.
3. IRB approved documents are in IRBNet and can be seen in Review Details. Following IRB review/approval, it is the PI’s responsibility to contact the WHASC Protocol Office at 292-4012 (DSN 554), within 30 days of notification to schedule a “New Study” start-up meeting. You will be given a study binder, the final IRB study approval letter, original date-stamped ICD, and any other IRB-approved documents needed for the study. Failure to schedule a “New Study” start-up meeting within the 30 day suspense will result in the study being suspended. It is the PI’s responsibility to maintain IRB approved documents in the new study binder.

4. Only investigators listed below are approved to participate in the study (e.g., obtain consent and to interact with and/or collect identifiable information on research subjects):

- Capt Bryant Webber, PI
- Sandra Vallier, PhD, AI
- Roger Bravo, RA/RC
- Lois Robinson, RA/RC
- Constance Kowat, RA/RC
- Michele Tavish, RA/RC

These are the only investigators identified by the WHASC IRB to have completed “IRB approved” investigator training. Any additions to this list must first be approved by the IRB by submitting an amendment, along with a copy of the investigator’s training certificate.

5. Your MINIMAL RISK study will be forwarded to the Surgeon General’s Research Compliance and Oversight Office (SGE-C) for information and concurrence.

6. The WHASC IRB must be notified immediately of any additional information, or changes to the approved protocol. All modifications to either the protocol or ICD must be reviewed and approved by the WHASC IRB prior to their inception.

7. You must comply with the information contained in the Certificate of Compliance.

8. 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.

9. If you have any questions, the POC is Mrs. L. Elaine Turner at (210) 292-4012. Please include your project title and reference number in all correspondence or inquiries.

JOHN R. EKSTRAND, COL, USA, MC
WHASC Authorized Institutional Official
Prevalence of Trypanosoma cruzi among U.S. Military Members Training in South Texas

Mary T. Pawlak, MD, MPH; Sallie Hall; Sandra Valtier, PhD; Candelaria C. Daniels, PhD; Thomas L. Cropper, DVM, MPVM, DACVP; Charles C. Tully, DO; Bryant J. Webber, MD, MPH

15th Medical Wing, Joint Base San Antonio - Lackland, Texas, USA; 2U.S. Army Public Health Command-Central, JBSA - Fort Sam Houston, Texas, USA; 3Defense Institute for Medical Operations, JBSA - Lackland, Texas, USA

Abstract

Vector-borne human Chagas disease is an emerging potential issue for personnel who work and live on Joint Base San Antonio (JBSA), Texas, where Trypanosoma cruzi-infected triatomine insects have been collected in abundance since 2013. This cross-sectional study, funded to enroll 3,000 subjects, seeks to determine the prevalence and seroprevalence of acute and chronic Chagas disease among sub-populations considered at highest risk for the disease. This includes U.S. Air Force students and military instructors who spend the majority of their time in the endemic field setting. After one year of enrollment (N=416 subjects), no positive cases have been identified. Current measures may be sufficient to prevent Chagas disease in this setting, although further enrollment is needed.

Methods

Study Design

Cross-sectional prevalence and seroprevalence study

Questionnaire

Participants were asked about their type and duration of field exposure, blood transfusion history, maternal living history, travel history, amount and type of outside exposure (camping, hunting), exposure to wildlife animals (raccoon, opossum, skunk, wood rats, deer, coyote, and feral hog), and history of bites by triatomines or unknown insects.

Laboratory Tests

- **Real-time Polymerase Chain Reaction (PCR):** Whole blood specimens were evaluated for presence of the T. cruzi parasite. Two multiplex TaqMan PCR assays were performed in parallel targeting highly conserved and representative T. cruzi genomic regions: nuclear minisatellite (TCZ), karnofsky or KDN, and small subunit ribosomal RNA (18S RNA) probe. A sample was considered positive if all three targets were positive.

- **Indirect Immunofluorescent Antibody (IFA):** Sera were evaluated for presence of human antibodies to T. cruzi antigens. Sera were serially diluted and placed on antigen-coated microscope slides, washed to remove unbound serum antibodies, stained with a fluorescein isothiocyanate-labeled anti-human IgG conjugate, and visualized through a fluorescence microscope. A sample was considered positive for titers of 1:32 or greater.

- **Enzyme-linked Immunosorbent Assays (ELISA):** The Chagastest recombinant v3.0 assay (Wener Laboratories, Argentina) employs recombinant T. cruzi antigens to detect human IgG and IgM. Serum samples were incubated with the immobilized antigens, washed, incubated with goat anti-human IgG conjugated to horseradish peroxidase (HRP), and washed again. HRP substrates tetramethylbenzidine and hydrogen peroxide were then added. The reactions were stopped with 2 N sulfuric acid, which resulted in yellowish color. The colorimetric readings were taken at 450 nm in a plate reader (ref. wavelength, 650 nm). Cut-off, equivocal, reactive, and nonreactive values were defined as directed.

Oversight and Funding

This study was approved by the 5th Medical Wing Institutional Review Board. Funding was provided by the Air Force Medical Services Agency, Falls Church, Virginia, USA.

Results

**Population:**

- US Air Force students and military instructors at JBSA - Lackland and Camp Bullis
- Military instructors working in Basic Expeditionary Airmen Skills Training (BEASTS) at JBSA - Lackland, Medina Training Annex

**Laboratory Test Results:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Positive/Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>IFA</td>
<td>288/26</td>
</tr>
<tr>
<td>ELISA</td>
<td>408/0</td>
</tr>
<tr>
<td>PCR</td>
<td>405/3</td>
</tr>
</tbody>
</table>

**N=416 due to difficulty obtaining adequate blood samples in all situations.**

**Conclusions:**

- Chagas disease does not appear to constitute a significant public health risk during military field exercises at JBSA - Lackland, Texas.
- The lack of positive cases may be due to the effectiveness of current measures (e.g., use of bed nets and insect repellent) to prevent triatomine bites and/or the lack of exposure to aquatic transmission of T. cruzi.
- Since only 13.5% (N=416) of total participants have been enrolled, this research effort will continue to increase the statistical power of the results.

References


Acknowledgments

We thank Manuel Castiblanco, Arizma Heitl, David Hill, Samantha Hume, Constance Kowal, Jaime Mejia, Richard Mikolich, Louis Robinson, and Michelle Tavita at 59 MDW for their help drawing blood and conducting ELISA tests. President of the Military Medicine Society of America, Alejandro B. Elizondo, and Francisco Banuelos at USAF-Central for conducting IFA and PCR tests.

Disclaimer

The views expressed are the author's and do not reflect the official views or policy of the Department of Defense and its Components.
MEMORANDUM FOR 59 MDW  
ATTN: CAPT MARY T. PAWLAK  
FROM: 502 ISG/JA  
SUBJECT: Ethics Review for Presentation Approval Request (Pawlak)  

1. Capt Pawlak submitted a request for a legal review of a poster titled “Prevalence of Trypanosoma cruzi among U.S. Military Members Training in South Texas.” The author plans to present this research as a poster at the following meetings: Diseases in Nature on 25-27 May 2016 in San Antonio, TX; Military Health System Research Symposium on 15-18 August 2016, in Kissimmee, FL; and American Society of Tropical Medicine and Hygiene on 13-17 November 2016 in Atlanta, GA. This legal review is limited to the ethics issues regarding the presentation. The abstract contains the required disclaimer discussed below. The disclaimer must also be included on the poster. The abstract must also be submitted for Public Affairs approval. There are no conflict of interest issues with presenting this research at these events.

2. FACTS: Capt Pawlak plans to present her poster titled “Prevalence of Trypanosoma cruzi among U.S. Military Members Training in South Texas” at the above listed events.

3. LAWS AND REGULATIONS: DoD 5400.07-R, Joint Ethics Regulation (JER), section 3-305 lays out rules governing “Teaching, Speaking and Writing.” 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: The presentation does not "deal in significant part with any ongoing or announced policy, program or operation" of the Air Force, however, the abstract does address research done as part of the author’s military medical practice. Additionally, the presenter’s affiliation with the military will be included as part of the presentation. The author has 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. The disclaimer must be included on the poster. There are no apparent conflicts of interest that would prohibit the presentation.

5. CONCLUSIONS: The abstract presented for review included the disclaimer required by the JER. The disclaimer must be included on the poster.
6. If you have any questions, please call me at 210-671-5771.

VERNISHA N. FOSTER, Captain, USAF
Assistant Staff Judge Advocate

I concur.

ARLENE R. CHRISTILLES
Chief, Civil Law