



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



22 JUNE 2017

MEMORANDUM FOR SGVT

ATTN: CAPT JOSEPH E MARCUS

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **Follow-up Evaluation of Air Force Blood Donors Screening Positive for Chagas Disease** presented at/published to **Military Health System Research Symposium (Florida, 27-30 Aug 2017)** in accordance with MDWI 41-108, has been approved and assigned local file #**17268**.
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

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 (59crdpubsres@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) Joseph Marcus, O-3, 959 CSPS	3. GME/GHSE STUDENT: <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	4. PROTOCOL NUMBER: FWH201700054N
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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.)
Follow up and outcomes of personnel screening positive for Chagas disease upon blood donation at JBSA-Lackland

6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:
Follow-up evaluation of Air Force blood donors screening positive for Chagas disease

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.)

11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meeting.)
Military Health System Research Symposium (Florida, 27-30AUG2017)

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	
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14. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email) Marcus, Joseph E, joseph.e.marcus3.mil@mail.mil	15. DUTY PHONE/PAGER NUMBER 210-220-7072
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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 Marcus, Joseph E	Capt	959 CSPS	
b. Webber, Bryant J	Maj	559 Trainee Health Squadron	
c. Cropper, Thomas L		Trainee Health Surveillance	
d. Wilson, Matthew C	Maj	559 Trainee Health Squadron	
e. Yun, Heather C	LtCol	959 MDOS	

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 Joseph E Marcus, Capt, USAF	19. AUTHOR'S SIGNATURE MARCUS JOSEPH E 1410684892	20. DATE 13JUN2017
21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE Kristen R Glass, Maj, USAF, MC	22. APPROVING AUTHORITY'S SIGNATURE GLASS KRISTEN R. 1246687419	23. DATE 20JUN2017

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 June 20, 2017	25. ASSIGNED PROCESSING REQUEST FILE NUMBER 17268
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26. DATE REVIEWED 21 Jun 2017	27. DATE FORWARDED TO 502 ISG/JAC
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28. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: NO YES If yes, give date. 21 Jun 2017 N/A

29. COMMENTS APPROVED DISAPPROVED
The author provided the required research determination authorization. The abstract is approved.

30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Rocky Calcote, PhD, Clinical Research Administrator	31. REVIEWER SIGNATURE CALCOTE ROCKY.D.1178245844 <small>Digitally signed by ROCKY D. CALCOTE DN: cn=Rocky D. Calcote, ou=59 MDW/CRD, email=rocky.d.calcote@us.af.mil, c=US Date: 2017.06.22 09:08:14 -0400</small>	32. DATE June 22, 2017
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2nd ENDORSEMENT (502 ISG/JAC Use Only)

33. DATE RECEIVED	34. DATE FORWARDED TO 59 MDW/WA
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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
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3rd ENDORSEMENT (59 MDW/WA Use Only)

39. DATE RECEIVED June 22, 2017	40. DATE FORWARDED TO 59 MDW/SGVU June 22, 2017
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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 IINUMA KEVIN MITSUGU.1296227 <small>Digitally signed by KEVIN MITSUGU IINUMA DN: cn=Kevin Mitsugu Iinuma, ou=59 MDW/PAA, email=kevin.iinuma@us.af.mil, c=US Date: 2017.06.22 09:27:11 -0400</small>	44. DATE June 22, 2017
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4th ENDORSEMENT (59 MDW/SGVU Use Only)

45. DATE RECEIVED	46. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> COULD NOT BE REACHED <input type="checkbox"/> LEFT MESSAGE
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47. COMMENTS APPROVED DISAPPROVED

48. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	49. REVIEWER SIGNATURE	50. DATE
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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 78236-5300

24 Feb 2017

FINAL DETERMINATION – NON-HUMAN RESEARCH

Determination Date: 24 Feb 2017

Project Lead: LTC Heather Yun/SG051

Reference Number: FWH20170054N

Project Title: Follow up and outcomes of personnel screening positive for Chagas disease upon blood donation at JBASA-Lackland

You may begin your project, as you would any other clinical or operational activity, with the approval and sponsorship of your leadership.

Your project was determined on 24 Feb 2017 to be considered **not human research** as defined by DoD regulation **32 CFR 219 and FDA regulation 21 CFR 56**. Continued IRB oversight for this activity is not required. The proposed project does not include non-routine intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction, nor do the researchers obtain private, identifiable information about living individuals.

Since the IRB does not have regulatory oversight for your study, it is the investigator's responsibility to validate the study's scientific merit and research design and to ensure the conduct of the study is upheld by the highest ethical standards, as required by the Wing. Should you require assistance in reviewing the scientific merit and research design of your study, please contact the Protocol Office. Protection of subjects' rights safety and welfare and responsibility for protecting PHI/PII and research data now fall on the investigator and their commander.

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.

Your study has received a one-time 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, re-contact the Protocol Office, so that a regulatory expert may determine whether or not the revised plan involves human subject research activities.

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Thomas Gibbons, PhD

Designated Exempt Reviewer

Follow-up evaluation of Air Force blood donors screening positive for Chagas disease

Joseph Marcus¹, Bryant Webber², Leo Cropper², Matt Wilson², Heather Yun³

¹ Department of Internal Medicine, San Antonio Military Medical Center, JBSA-Fort Sam Houston, San Antonio, TX

² 559th Trainee Health Squadron, Wilford Hall Ambulatory Surgical Center, JBSA-Lackland, San Antonio, TX

³ Department of Infectious Disease Service, San Antonio Military Medical Center, JBSA-Fort Sam Houston, San Antonio, TX

Background: Human Chagas disease is caused by the protozoan parasite *Trypanosoma cruzi*, is endemic to South Texas, and has significant morbidity and mortality related to cardiac toxicity. Consistent with national guidance from the FDA Blood Products Advisory Committee, the Joint Base San Antonio-Lackland blood bank screens all first-time blood donors for *T. cruzi* infection, currently with a chemiluminescent immunoassay. Although there is a published, standardized approach for diagnosis and evaluation of Chagas disease in the United States, local adherence to this approach has not been studied.

Methods: A retrospective chart review was performed on all persons who screened positive for *T. cruzi* on blood donation at Joint Base San Antonio-Lackland from 2014-2016. Charts were reviewed to determine frequency and results of confirmatory testing. Chagas disease was considered confirmed on the basis of positive EIA and TESA testing from the CDC and/or two different positive serologic tests. Among those with diagnosed diseases, charts were further examined to review whether patients underwent the recommended workup of history and physical, EKG, and 30 second rhythm strip; outcomes of these evaluations were ascertained.

Results: Of the 23 patients who were identified, follow-up information was available on 22 (95.7%). Seventeen (77%) were military trainees and 18 (82%) were male. Patients had a mean of 2.5 (range 1-5) additional serologic tests, with 13 different combinations of confirmatory tests ordered, including 17 (77%) who had the initial screening test repeated. The mean time from positive screening test to first evaluation was 7 days, and from first evaluation to finalization of workup was 53 days; three patients completed their workup after transfer to another military installation. Two patients (9%), both from Texas, met criteria for Chagas disease. One of these was diagnosed with cardiomyopathy and underwent administrative separation from the Air Force. Both were offered treatment and declined. Eleven (50%) had Chagas disease excluded on the basis of two negative follow-up tests, and 9 (41%) had one negative follow-up test. All underwent history and physical, 15 (68%) had an EKG, and 5 (22%) had a 30 second rhythm strip. Fourteen (64%) were referred to infectious diseases.

Conclusions: Among a small cohort of active duty service members who screened positive for *T. cruzi* infection on blood donation, diagnostic workup and evaluation varied considerably. Opportunities exist to decrease heterogeneity and to improve evaluation of persons who screen positive in the future.

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

Words: (limit 500) 418