



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

14 FEB 2017

MEMORANDUM FOR SGO7A

ATTN: LT COL EDWARD CHAMPOUX

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled The Evaluation of Serum Tryptase Levels After Subcutaneous Immunotherapy-Associated Systemic Reactions presented at/published to Harold S. Nelson Military Allergy/Immunology Symposium, Atlanta, GA, 2 March 2017 in accordance with MDWI 41-108, has been approved and assigned local file #17034.
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

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

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

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

1. The author must complete page two of this form:
 - a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D; Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed Medical Research Program (CDMRP) ; Grants; etc.]
 - b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.
2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.
3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.
4. Attach a copy of your abstract, paper, poster and other supporting documentation.
5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.
6. On page 2, have either your unit commander, program director or immediate supervisor:
 - a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.
7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). **This should be accomplished no later than 30 days before final clearance is required to publish/present your materials.** If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.
8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.
9. Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. **Note:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.
10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DTIC). 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) EDWARD CHAMPOUX, LT COL, O-5, SGO7A	3. GME/GHSE STUDENT: <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	4. PROTOCOL NUMBER: FWH20120105H
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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.)
Evaluation of Blood Tryptase and Histamine Levels in Allergic Systemic Reactions to Subcutaneous Immunotherapy

6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:
The evaluation of serum tryptase levels after subcutaneous immunotherapy-associated systemic reactions

7. FUNDING RECEIVED FOR THIS STUDY? YES NO FUNDING SOURCE: Surgeon General's Office

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.)
Harold S. Nelson Military Allergy/Immunology Symposium, Atlanta, GA, 2 March 2017

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 10 July 2014

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
20 Jan 2017

14. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email) Champoux, Edward, edward.champoux.mil@mail.mil	15. DUTY PHONE/PAGER NUMBER 210-292-5717
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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 Champoux, Edward	O-5/Lt Col	59th TRS/59 MDG/SGO7A	
b. Coop, Christopher A	O-5/Lt Col	59th MDSP/59 MDG/SGO5A	
c. Rans, Tonya S	O-6/Col	59th MDSP/59 MDG/SGO5A	
d. Wong, Priscilla H	O-4/Maj	56 MDOS/56 MDG/SGOMA	Luke AFB, AZ
e. Crisp, C. Howard	N/A	N/A	North Texas Allergy, Dallas

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 Edward Champoux, Lt Col, O-5	19. AUTHOR'S SIGNATURE CHAMPOUX EDWARD. 1012832229	20. DATE December 20, 2016
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21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE Christopher Coop, Lt Col, O-5	22. APPROVING AUTHORITY'S SIGNATURE COOP CHRISTOPHER ALBERT 1171111796	23. DATE December 20, 2016
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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 January 19, 2017	25. ASSIGNED PROCESSING REQUEST FILE NUMBER 17034
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26. DATE REVIEWED 6 Feb 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. _____ N/A

29. COMMENTS APPROVED DISAPPROVED
The author provided the requested Institutional Review Board approval letter for his project. The article 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 CALCOTE ROCKY.D.1178245844 DN: cn=Rocky.D. Calcote, o=59MDW, ou=CRD, email=rocky.d.calcote@59mdw.mil, c=US</small>	32. DATE
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2nd ENDORSEMENT (502 ISG/JAC Use Only)

33. DATE RECEIVED	34. DATE FORWARDED TO 59 MDW/PA
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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/PA Use Only)

39. DATE RECEIVED February 10, 2017	40. DATE FORWARDED TO 59 MDW/SGVU February 13, 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 Inuma, SSgt/E-5, 59 MDW Public Affairs	43. REVIEWER SIGNATURE IINUMA,KEVIN.MITSUGU.1296227 613 <small>Digitally signed by KEVIN MITSUGU.1296227 DN: cn=KEVIN MITSUGU.1296227, o=59MDW, ou=Public Affairs, email=kevin.mitsugu@59mdw.mil, c=US</small>	44. DATE February 13, 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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Title: The evaluation of serum tryptase levels after subcutaneous immunotherapy-associated systemic reactions

Authors: Edward Champoux, MD, Christopher Coop, MD, Priscilla Wong, MD, Tonya Rans, MD, and Howard Crisp, MD

Department of Allergy-Immunology, Wilford Hall Ambulatory and Surgical Center, Lackland Air Force Base, Texas

Introduction: Elevations in serum tryptase have been used to support the diagnosis of anaphylaxis but have not been measured systematically in patients who have systemic reactions (SRs) to immunotherapy (IT). 16 patients with SRs to IT were enrolled in the study.

Methods: Adult patients receiving immunotherapy to aeroallergens and/or venom and who experienced systemic reactions were recruited from December 2012 through November 2016. The severity of the reaction was graded according to the World Allergy Organization (WAO) Subcutaneous Immunotherapy (SCIT) Systemic Reaction Grading System. Total tryptase was obtained from stable patients an hour post-reaction. A second baseline tryptase level was drawn between 2-60 days after the reaction. Tryptase levels were measured using an immunofluorimetric assay (ImmunoCAP, Phadia, Uppsala, Sweden).

Discussion: One patient had a reaction tryptase of 15.8 ug/L, with a baseline tryptase of 4.4 ug/L. Among the 15 other patients, the reaction tryptase ranged from 2.5-6.5 ug/L. Of these patients, 9 out of 16 returned for baseline tryptase levels, which ranged from 3.2-5.7 ug/L. Severity based on the WAO SCIT SR Grading System ranged from 1-2.

Conclusion: One patient out of 16 was observed to have an elevated total tryptase in our prospective cohort study of IT-associated systemic reactions. Tryptase appears to be of little clinical utility in evaluating mild SRs to IT; however, larger studies are needed.

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.

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.



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

22 Feb 2016

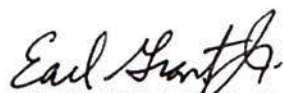
MEMORANDUM FOR Lt Col (Dr.) Edward Champoux, Principal Investigator

FROM: 59 MDW/SGVUC

SUBJECT: Human Research Protocol Compliance Assessment **FWH20120105H**
Evaluation of Blood Tryptase Levels in Allergic systemic Reactions to Subcutaneous Immunotherapy, (Investigator Files)

1. The 59th Clinical Research Division Quality Assurance and Education Branch conducted a post-IRB approval human research compliance assessment of the above-indicated protocol file 18 Feb 2016 at the Allergy/Immunology Clinic, WHASC. The documentation and mechanisms to ensure confidentiality, security, data management, and analysis of the protocol were determined to be appropriate. The protocol documents and Protected Health Information (PHI) were stored in a secure location inside an access-restricted area.
2. This minimal risk protocol is open to new participant accrual and has enrolled 18 subjects as of the 2015 progress report. This protocol successfully passed a previous compliance assessment 27 Jun 2013 [documents not previously found in the investigator's files were obtained by the former PI from the Protocol Office and filed appropriately]. Review of the principal investigator's protocol files, which included the original and amended versions of the protocol, 5 amendment submissions and IRB approvals, 3 progress report submissions and IRB approvals, 8 IRB-approved informed consent documents [ICDs] and HIPAA authorizations, other regulatory correspondence and documents, and five randomly-selected subject files, revealed several ICDs contained a blank line, i.e. volunteer's email, volunteer's phone. The principal investigator is reminded that when consenting subjects at enrollment to remind the subject to complete each line on the consent form or indicate "NA" for not applicable.
3. It was a pleasure meeting with you, Dr. Champoux. No additional items were noted and do not require any additional action at this time. If you have any questions or require additional information, please feel free to contact our office at (210) 292-7226 or jennifer.palmer.4@us.af.mil.


JENNIFER A. PALMER
Protocol Compliance Officer


EARL GRANT, JR., Ph.D.
Director, Quality Assurance & Education



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

FINAL IRB APPROVAL (FULL BOARD - MINIMAL RISK)

AUG 28 2012

Approval Date: 26 June 2012

Principal Investigator: Maj Howard Crisp/SGO5A

IRB Reference Number: FWH20120105H/IRBNet #377401-1

Assurance Number: FWA00001750 (Wilford Hall Ambulatory Surgical Center)

Protocol Title: "Evaluation of Blood Tryptase and Histamine Levels in Allergic Systemic Reactions to Subcutaneous Immunotherapy"

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). Additional items reviewed and approved by the WHASC IRB include:

- Informed Consent (ICD)
- HIPAA Authorization
- Standard of Care Sheet
- WHO Grading Sheet
- Letter of Support
- Data Collection Worksheet

2. Your study will be reviewed in **11 months for continuing review, based on its approval date, not to exceed 365 days**. It is the WHASC IRB's decision that this study will be terminated as of **25 Jun 2013**, unless you submit a continuing review report, using the most current template provided by the Protocol Office located on IRBNet. Your first progress report, which is a request for continuation of the study, will be due to the Protocol Office no later than **1 May 2013**. A continuing review report will be due every **11 months** thereafter, in order for the WHASC IRB to approve continuance of the study for another year. Upon completion of your study you must submit a final closeout report on IRBNet to the WHASC Protocol Office using the most current template.

3. All IRB approved documents have been uploaded onto IRBNet. It is the PI's responsibility to maintain all IRB approved documents. A recommended Table of Content (attached) is provided for the PI's use in maintaining copies of approved documents and correspondence in a new study binder. For more information on creating your new study binder, contact the WHASC Protocol Office at 292-4012 or 292-7143 (DSN 554) or 59crd_protocol@us.af.mil. The IRB approved documents uploaded to IRBNet include: Final Approval Letter, Original date-stamped ICD

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):

- Maj Howard Crisp, PI
- Lt Col Tonya Rans, AI
- Maj Kevin White, AI
- Mr. James Quinn, AI
- Lt Col Kimberly Johnson, AI

- Capt Michelle Bandino, AI
- Maj Tiffany Owens, AI
- Maj Daniel Steigelman, AI
- Maj Karla Adams, AI
- Maj Sandy Yip, AI
- Capt Scott Dickson, AI
- Maj Brett Coons, AI
- Capt David Rose, AI
- Mr. Robert Gomez, 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 protocol. All amendments 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 Ms. Elaine Turner at (210) 292-4012. Please include your project title and reference number in all correspondence or inquiries.

Rocky Calcote
ROCKY CALCOTE, PhD
WHASC IRB Administrator