MEMORANDUM FOR ST
ATTN: DEBRA M NIEMEYER

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled Association for the Accreditation of Human Research Protection Programs (AAHRPP): Accreditation Overview (Updated Version) presented at/published to Provision of AAHRPP info briefing to Defense Health Board with MDWI 41-108, and has been assigned local file #16175.

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

*Reaccomplished due to originators request on 8 May 16. Originally signed 4/28/16.

Warrior Medics – Mission Ready – Patient Focused
### Processing of Professional Medical Research/Technical Publications/Presentations

<table>
<thead>
<tr>
<th>1. TO: CLINICAL RESEARCH</th>
<th>2. FROM: (Author's Name, Rank, Grade, Office Symbol)</th>
<th>3. GME/GHS ME STUDENT:</th>
<th>4. PROTOCOL NUMBER:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Debra M. Niemeyer, PhD, DAF, 59 MDW/ST</td>
<td></td>
<td>NA</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.)

NA

6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:

Association for the Accreditation of Human Research Protection Programs (AAHRPP): Accreditation Overview (Updated Version)

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.)

11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)

Provision of AAHRPP info briefing to Defense Health Board (Note: Please clear NLT 15 Apr 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

13. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)

LOPEZ, RAQUEL L; raquel.lopez.2ctr@us.af.mil

14. DUTY PHONE/PAGER NUMBER

292-2097

15. AUTHORSHIP AND CO-AUTHOR(S) 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>a. Primary/Corresponding Author</td>
<td>CTR</td>
<td>59 CRD (ST)</td>
<td></td>
</tr>
<tr>
<td>Dr. Josh Calcote</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Dr. Earl Grant</td>
<td>GS14</td>
<td>59 CRD (ST)</td>
<td></td>
</tr>
<tr>
<td>c.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f.</td>
<td></td>
<td></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, 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.

16. AUTHOR'S PRINTED NAME, RANK, GRADE

Debra Niemeyer PhD GS15

17. AUTHOR'S SIGNATURE

NIEMEYER DEBRA M. 1022593368

18. DATE

April 12, 2016

19. APPROVING AUTHORITY’S PRINTED NAME, RANK, TITLE

Markus Gmeulin, Col, Vice Commander

20. APPROVING AUTHORITY’S SIGNATURE

GMEULIN MARKUS P. 1087279329

21. DATE

April 14, 2016
### Processing of Professional Medical Research/Technical Publications/Presentations

**1st Endorsement (59 MDW/SGVU Use Only)**

<table>
<thead>
<tr>
<th>TO: Clinical Research Division 59 MDW/CRD</th>
<th>22. Date Received</th>
<th>23. Assigned Processing Request File Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>59 MDW/CRD Contact 202-7141 for email instructions.</td>
<td>April 15, 2016</td>
<td>16175</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>24. Date Reviewed</th>
<th>25. Date Forwarded to 502 ISG/JAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 April 2016</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>26. Author Contacted for Recommended or Necessary Changes:</th>
<th>27. Comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td>NO</td>
<td>APPROVED</td>
</tr>
<tr>
<td>YES</td>
<td>N/A</td>
</tr>
<tr>
<td>If yes, give date.</td>
<td>DISAPPROVED</td>
</tr>
</tbody>
</table>

### 2nd Endorsement (502 ISG/JAC Use Only)

| Printed Name, Rank/Grade, Title of Reviewer |
| COL LINDA STEEL-GOODWIN, USAF, BSC |

| Reviewer Signature |
| STEEL GOODWIN LINDA 110663583 |

| Date |
| April 15, 2016 |

### 3rd Endorsement (59 MDW/PA Use Only)

| Printed Name, Rank/Grade, Title of Reviewer |
| Heather Slawson, 1Lt, Assistant Staff Judge Advocate |

| Reviewer Signature |
| SLAWSON HEATHER M 151609267 42 |

| Date |
| 15 April 2016 |

### 4th Endorsement (59 MDW/SGVU Use Only)

| Printed Name, Rank/Grade, Title of Reviewer |
| Christopher Carwile, TSgt/E6, NCOIC, PA |

| Reviewer Signature |
| CARWILE CHRISTOPHER STEWART 1280477229 |

| Date |
| 26 April 2016 |

### Comments

- **APPROVED** (in compliance with security and policy review directives.)
- **DISAPPROVED**

The slide show contains the required disclaimer. Although the disclaimer language is not verbatim from the JER, it clearly conveys the intent of the JER. There are no conflict of interest issues with the presentation of this slide show.

---

**59 MDW Form 3039, 20160218**

Prepared by 59 MDW 41-108

Previous editions currently in use can be used. All others are obsolete.
Association for the Accreditation of Human Research Protection Programs (AAHRPP): Accreditation Overview

Dr. Josh Calcote, CTR
Dr. Earl Grant, DAF
Clinical Investigations and Research Support
Clinical Research Division
Science and Technology
59th Medical Wing
4 March 2016
Disclaimer

The opinions expressed in this presentation are solely those of the author(s) and do not represent an endorsement by or the views of the United States Air Force, the Department of Defense, or the United States Government.
Accreditation Process

- **Self-Assessment** to identify gaps and make improvements

- **Submit Step 1** – an itemized, referenced document detailing how the organization meets each of the accreditation standards (~1,000 pgs.)
  - Reconcile issues identified by AAHRPP's Step 1 reviewer

- **Submit Step 2** and prepare for onsite evaluation by HRPP experts
  - Reconcile issues identified by AAHRPP's Site Visitors

- **AAHRPP Council review and determination** of accreditation status
  - Full Accreditation
  - Qualified Accreditation
  - Accreditation Pending
  - Accreditation Withheld
Accreditation Timeline

- Self-Assessment & Modification: 12-18 months (est.)
  - Submit Step 1 Application: 2-3 months
  - Site Visit: 1 month
  - Submit Step 2 App: 1 month
  - Site Response: 1 month
  - Report: 1 month
  - Council Determination: Quarterly Meetings - 4 per year
  - AAHRPP Review; Revise App: 2-4 months
Activities To-Date

1. Self-Assessment/Gap Analysis
2. Chartered a 59 MDW HRPP Steering Committee
3. Drafted HRPP Medical Wing Instruction (MDWI)
4. Drafted Institutional Conflict of Interest MDWI
5. Revised/Drafted new IRB Operating Instruction.
6. Revised/Drafted new IRB Forms/Templates/Checklists/Letters
7. Revised/Drafted new Investigator Handbook
8. Created new public HRPP webpage on 59 MDW website
9. Created new HRPP and Conflict of Interest Training modules
10. IRB Assessment and Feedback mechanism for QA/QI
11. Generated QA/QI metrics for IRB turnaround times
12. Drafted AAHRPP submission document (17 chapters)
The Way Forward

Create "HRPP Plan" (MDWI + Submission Document + IRB OIs)

- **Step 1:** Prepare Draft HRPP MDWI
- **Step 2a:** Domains prepare *Chs. 1-17* of AAHRPP Submission Document
- **Step 2b:** Incorporate Domain II IRB OIs into the Submission Document
- **Step 3:** HRPP Steering Cmte review of cover letter. **Start: 13 Jan 2016**
- **Step 4:** Receive comments/edits from Steering Cmte by: **1 Feb 2016**
- **Step 5a:** Submit HRPP MDWI for Wing approval. **Start: 14 Feb 2016**
- **Step 5b:** Submit all chapters and OIs to Steering Cmte. **ECD: Apr 2016**
- **Step 6:** Submit HRPP Plan for BOD review. **ECD: May 2016**
- **Step 7:** Submit HRPP Plan for 59 MDW/CC approval. **Target: Jun 2016**
- **Step 8:** After CC approval, submit AAHRPP Step 1 application. **ECD: Summer 2016**
Science & Technology

Warrior Medics – Mission Ready – Patient Focused

"Grow Medical Leaders, Drive Innovations in Patient Care and Readiness"