



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

5 JAN 2017

MEMORANDUM FOR SGVU

ATTN: JOSHUA CALCOTE

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **Annual Report from the 59<sup>th</sup> Medical Wing Clinical Research Division (July 2015 – December 2016)** presented at/published to **DTIC & Hyper-Linked within the 59 MDW Clinical Research Division Knowledge Exchange Website** in accordance with MDWI 41-108, has been approved and assigned local file #**17021**.
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.

  
PAUL T. BARNICOTT, GS-15-DAF  
Deputy Director, Clinical Research Division

# 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 (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) Calcote, Joshua - Contractor, 59 MDW/SGVU	3. GME/GHSE STUDENT: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	4. PROTOCOL NUMBER: N/A
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.) N/A			
6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED: Annual Report from the 59th Medical Wing Clinical Research Division (July 2015-December 2016)			
7. FUNDING RECEIVED FOR THIS STUDY? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO FUNDING SOURCE:			
8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
9. IS THIS MATERIAL CLASSIFIED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> 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.? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.			
11. MATERIAL IS FOR: <input checked="" type="checkbox"/> DOMESTIC RELEASE <input type="checkbox"/> FOREIGN RELEASE CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.			
<input type="checkbox"/> 11a. PUBLICATION/JOURNAL (List intended publication/journal.)			
<input type="checkbox"/> 11b. PUBLISHED ABSTRACT (List intended journal.)			
<input type="checkbox"/> 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)			
<input type="checkbox"/> 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meeting.)			
<input checked="" type="checkbox"/> 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.) For posting onto DTIC and hyper-linked within the 59 MDW Clinical Research Division Knowledge Exchange website			
12. HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> 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 N/A			
14. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email) Calcote, Joshua C. - joshua.c.calcote.ctr@mail.mil			15. DUTY PHONE/PAGER NUMBER 210-292-7143
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 Joshua C. Calcote	Contractor	59 MDW/SGVU	
b. on behalf of Col Linda Steel-Goodwin			
c.			
d.			
e.			
17. IS A 502 ISG/JAC ETHICS REVIEW REQUIRED (JER DOD 5500.07-R)? <input type="checkbox"/> YES <input checked="" type="checkbox"/> 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 Dr. Joshua C. Calcote, Contractor		19. AUTHOR'S SIGNATURE <small>Signature required for DTIC release. Do not sign for DTIC release unless you are the author or have been authorized by the author.</small> STEEL, KEVIN E. 1162266558	20. DATE December 20, 2016
21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE Kevin Steel, Lt Col, USAF, MC Deputy Chief Scientist		22. APPROVING AUTHORITY'S SIGNATURE <small>Signature required for DTIC release. Do not sign for DTIC release unless you are the approving authority or have been authorized by the approving authority.</small> STEEL, KEVIN E. 1162266558	23. DATE December 21, 2016

**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 December 22, 2016	25. ASSIGNED PROCESSING REQUEST FILE NUMBER 17021
--	--	--

26. DATE REVIEWED December 27, 2016	27. DATE FORWARDED TO 502 ISG/JAC
--	-----------------------------------

28. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES:  NO  YES If yes, give date. \_\_\_\_\_  N/A

29. COMMENTS  APPROVED  DISAPPROVED  
Annual CRD report

30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Kevin Kupferer/GS13/Human Research Subject Protection Expert	31. REVIEWER SIGNATURE KUPFERER, KEVIN R. 1086667270 <small>Digitally signed by KUPFERER, KEVIN R. 1086667270 DN: cn=KUPFERER, ou=59 MDW/SGVU, ou=USAF email=KUPFERER, KEVIN R. 1086667270 Date: 2016.12.27 15:13:30 -0500</small>	32. DATE December 27, 2016
---	--	-------------------------------

**2nd ENDORSEMENT (502 ISG/JAC Use Only)**

33. DATE RECEIVED	34. DATE FORWARDED TO 59 MDW/PA
-------------------	---------------------------------

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
---	------------------------	----------

**3rd ENDORSEMENT (59 MDW/PA Use Only)**

39. DATE RECEIVED	40. DATE FORWARDED TO 59 MDW/SGVU
-------------------	-----------------------------------

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 IINUMA KEVIN MITSUGU.1296227 DN: cn=IINUMA, ou=59 MDW/SGVU, ou=USAF email=IINUMA, KEVIN MITSUGU.1296227@59 Date: 2017.01.04 18:21:47 -0500</small>	44. DATE January 04, 2017
--	---	------------------------------

**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
-------------------	--

47. COMMENTS  APPROVED  DISAPPROVED

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



# **Status and Activities Report**

## **59th Medical Wing**

### **Clinical Research Division**

#### **JBSA-Lackland Texas**

#### **(July 2015-December 2016)**

Linda Steel-Goodwin, Col, USAF, BSC  
Director, Clinical Investigations & Research Support

Joshua C. Calcote, DrPH, Contractor, USAF  
Clinical Research Director Assistant, 59 MDW/SGVU

27 December 2016

## Table of Contents

<b>Mission Description .....</b>	<b>4</b>
<b>Significant Accomplishments Warranting Recognition .....</b>	<b>5</b>
- A Partner in Accreditation! .....	5
- Future Warrior Medics! .....	5
- The Highest Standards in Human Research! .....	5
<b>Evidence of Mission Support .....</b>	<b>6</b>
- Committed to Research! .....	6
- First-Class Training! .....	6
- VIP Tourist Destination! .....	6
- Joint Partnerships! .....	6
- Real-Time Information! .....	7
- Continuous Process Improvements! .....	7
<b>Demonstrated Professional and Technical Performance .....</b>	<b>7</b>
- Stellar program! .....	7
- Research Mentoring! .....	7
- Robust! .....	7
- Community Outreach! .....	8
- Modern Facility Upgrades! .....	8
- Accountable! .....	8
<b>Innovative and Creative Practices .....</b>	<b>9</b>
- Outstanding Support of Residents! .....	9
- Innovative! .....	10
- Supportive! .....	11
- Progressive! .....	11
- Productive! .....	11
- State-of-the-Art! .....	12
<b>Points of Contact .....</b>	<b>14</b>

## Table of Figures

Figure 1: An Operating Suite at CRD.....	4
Figure 2: GC Mass Spectrometer in the CRD Lab.....	4
Figure 3: Residents Practicing Surgical Techniques at CRD.....	5
Figure 4: Supportive Care in the CRD Operating Suite.....	5
Figure 5: Surgical Training at the CRD.....	5
Figure 6: Resident Operating the da Vinci Surgical System.....	5
Figure 7: Median Turn-Around Time Comparison of the 59 MDW IRB vs. AAHRPP Standards.....	6
Figure 8: Hyperbaric/Hypobaric Chamber at the CRD.....	7
Figure 9: David McGlasson, 2015 ASCLS Scientific Awardee.....	7
Figure 10: Residents Utilizing the da Vinci Surgical System.....	8
Figure 11: Sally Banfield, Lab Supervisor, Receiving a Quality Improvement Initiative Award.....	8
Figure 12: Leo Longoria Working on a Molecular Assay.....	11
Figure 13: Richard LaBoone Processing Blood Samples.....	11

# Status and Activities Report from the 59th Medical Wing Clinical Research Division (July 2015-December 2016)

## Mission Description

### *Vision Statement*

“Improve patient care through scientific inquiry, training, and education”

### *Mission Statement*

“To promote, conduct, and support clinical investigations and research that provide academic experience and training while meeting the needs of the Air Force Medical Service (AFMS)”

Figure 1: An Operating Suite at CRD

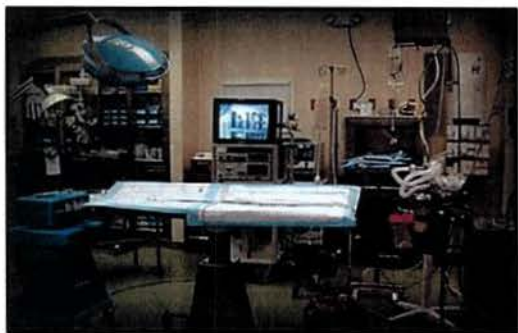


Figure 2: GC Mass Spectrometer in the CRD Lab



The 59th Medical Wing (59 MDW) Clinical Research Division (CRD) is a 60-man organization that executes the largest Air Force (AF) Clinical Investigation Program (CIP) which aims to improve the quality of healthcare for Department of Defense (DoD) beneficiaries by generating an atmosphere of scientific inquiry, promoting an academic environment of high professional standing, and providing a means to assist in the accreditation of graduate medical education and other allied health training programs. Accreditation committees consider research important in evaluating medical education and training programs. The CRD CIP is governed by DoD Instruction 6000.08, *Defense Health Program Research and Clinical Investigation Programs*, 22 January 2014. The CIP supports approximately 1,200 residents and fellows of the medical, dental, nursing, and biomedical science corps across 45 local training programs in the San Antonio area. Program purposes include regulatory oversight, subject protection, laboratory support for the development, performance, and validation of tests for clinical investigations, as well as, maintaining and administering surgical and procedural training protocols and providing guidance for research protocol generation in support of student scholarly activities.

The CRD also manages the execution of the CIP intramural Student Grant awards where the awardee is a 59 MDW Air Force military member. Under the CIP intramural grant award program, AF principal investigators compete with other AF CIPs for funding for medical studies,

analysis, and/or investigations conducted in local CIPs for the purposes of student research and/or program accreditation.

Figure 3: Residents Practicing Surgical Techniques at CRD



Figure 4: Supportive Care in the CRD Operating Suite



### Significant Accomplishments Warranting Recognition

- **A Partner in Accreditation!** The primary mission of the CRD is training. The CRD ensured 100% accreditation of 39 Air Force Graduate Medical Education (GME) programs in accordance with: Accreditation Council for Graduate Medical Education (ACGME) standards; Dental program on Joint Base San Antonio; and the Pararescue Training Protocol.

- **Future Warrior Medics!** CIP successes directly affected AFMS professions. CRD trainees include: nurses; physician assistants; surgeons; emergency medical technicians; independent duty technicians; and residents in all military healthcare fields.

- **The Highest Standards in Human Research!** The CRD helped establish the 59 MDW Human Research Protection Program (HRPP) and is supporting the 59 MDW effort to become the **first** DoD facility that is nationally-accredited through the Association for the Accreditation of Human Research Protection Programs (AAHRPP) – the premier accrediting body for human subjects protection programs. The HRPP was realigned to enhance the comprehensiveness and quality of human subjects protection at the 59 MDW and to directly increase the knowledgebase, diligence, and efficiency of 59 MDW Institutional Review Board (IRB) members and supporting staff. Consequently, the IRB currently achieves a 25-day turn-around time for reviewing and approving non-exempt research involving human subjects – a 156% quicker turn-around than the national average for other elite AAHRPP-accredited organizations.

Figure 5: Surgical Training at the CRD



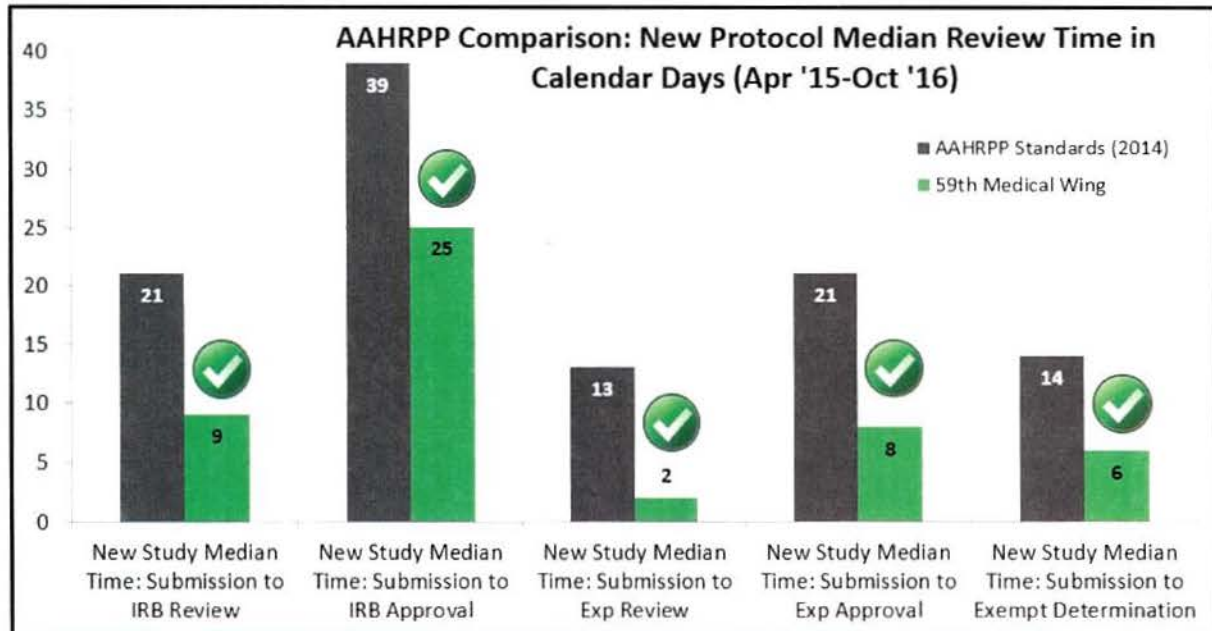
Figure 6: Resident Operating the da Vinci Surgical System



## Evidence of Mission Support

- **Committed to Research!** The CRD approved 140 new protocols from July 2015 to December 2016 comprising: 48 Human studies; 34 Non-Research projects; 21 Exempt studies; 10 External studies; and 27 Animal studies.

Figure 7: Median Turn-Around Time Comparison of the 59 MDW IRB vs. AAHRPP Standards (Apr 2015-Oct 2016)



- **First-Class Training!** The CRD has trained 2,200 personnel in human and animal research subject protection and 90 staff and residents in combat surgical techniques. CRD mentorship and training was provided to approximately 1,200 AFMS personnel with \$1,258,320 in CIP funding allocated to support research protocols in FY16 – a 28% increase in protocols funded over the previous year. CRD active participation in protocols produced 98 publications and 187 presentations in FY16 – a 12% increase in publications over the previous year.

- **VIP Tourist Destination!** The 59 MDW Clinical Investigations Facility received 1,000+ visitors, including Air Force Recruiters and university faculty from elite U.S. universities (e.g., Harvard, Stanford, etc.). CRD showcased ongoing joint research and USAF projects and the operationalization of molecular research and development systems that respond to real-world toxicology and disease incidents, thus, providing mission support opportunities for students with practical applications.

- **Joint Partnerships!** The CRD completed a new OMNIBUS 3 contract – a joint effort with the AF Office of the Surgeon General, the Naval Health Research Center, and Army Contracting. The OMNIBUS 3 was essential in acquiring critical contract labor for CRD support to infrastructure and awarded research grants. This one-year contract ensured 100% funds obligation and minimized delays in project and training execution throughout the fiscal year. A follow-on effort to establish a 5-year indefinite delivery/indefinite quantity (IDIQ) contract to support the CIP program has begun.

- **Real-Time Information!** The continuous, up-to-date information on the CRD website makes it the single-most important source for student research information, IRB and IACUC policies and instructions, information on laboratory capabilities, publications and presentations, and many other CIP-related topics. The website may be visited at:

<https://kx.afms.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/home.aspx>.

- **Continuous Process Improvements!** The CRD has on-going process improvements in research support efforts and communication of research support availability to 59 MDW residents and AF researchers. The most impactful process improvement in FY16 is the realignment and restructuring of all facets of the 59 MDW HRPP infrastructure in preparation for AAHRPP accreditation. Other important improvements include decreasing publications and presentations clearance times by half and establishing a program to fund GME publications. As a result, two (2) residents were approved for funding under this new program and had all their publication fees paid for by the CRD.

Figure 8: Hyperbaric/Hypobaric Chamber at the CRD

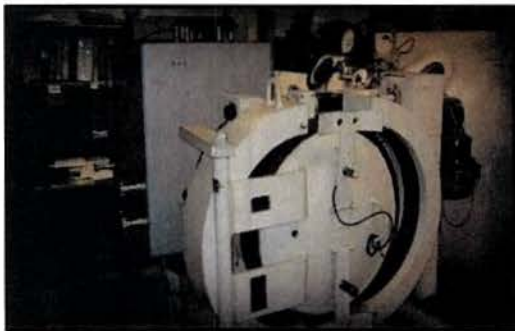
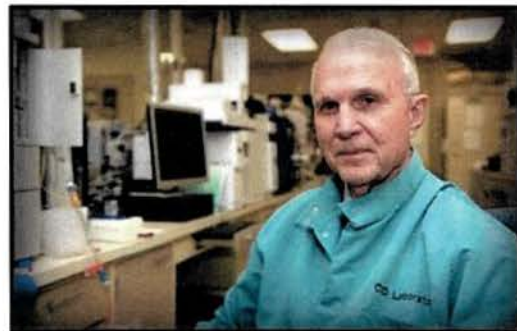


Figure 9: David McGlasson, 2015 ASCLS Scientific Awardee



## Demonstrated Professional and Technical Performance

- **Stellar program!** The CRD was again granted full, continued Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) “**Emeritus**” status, marking 21 years of full accreditation. The animal research program and the CRD vivarium that houses five (5) different species for research and medical training have earned numerous accolades and commendations and developed best practices in the areas of maintaining accurate records and ensuring that personnel assigned to the Operations Branch are up-to-date on all required training and education.

- **Research Mentoring!** Mr. David McGlasson, winner of the 2015 American Society for Clinical Laboratory Science (ASCLS) Scientific Award, and the lab team led by Dr. Thomas Gibbons at the CRD instructed students on state-of-the-art laboratory practices and techniques.

- **Robust!** The CRD promotes and maintains a “bench-to-bedside” program of education, training, and research that leads to high-quality, cost-effective healthcare provided to the military beneficiary population. The CRD Laboratory Branch boasts exceptional and unique technological capabilities and provides a teaching environment that produces clinicians who conduct “cutting-edge” research that sets new standards for quality patient care. The lab’s molecular department now includes the capability to analyze the entire human genome. In

addition to molecular support, equally robust cell biology, hematology, chemistry, and microbiology departments provide support for research and clinical protocols.

- **Community Outreach!** Senior CRD staff members briefed over 220 students of the 59 MDW Gateway Academy across 11 different offerings of the “*What is Research?*” seminar. The CRD Operations Branch hosted and trained 80 students in human anatomy and over 220 students toured the CRD facility. The Operations Branch also hosted an intensive 3-day, live-animal trauma lab training for 119 Pararescuemen visiting from the 351st Battlefield Airmen Training Squadron, Kirtland AFB, NM. Trainees received 3,332 man-hours of training emphasizing life- and limb-saving procedures. The CRD also maintained 72 support agreements for research collaboration and funded two (2) protocols under the Regional CIP program at Offutt AFB and Wright-Patterson AFB: “*Centering Pregnancy (CP): A Randomized Controlled Study Designed to Evaluate Maternal/Fetal Outcomes, Breastfeeding Initiation and Maintenance, and Cost-Effectiveness after Participation in CP Compared to Traditional Prenatal Care in a Military Treatment Facility*”; and “*Brain Magnetic Resonance Imaging (MRI) and Neuropathological Effects of Hypobaric Exposure to 30,000 ft. and Hyperoxemic Exposure at Sea Level.*”

- **Modern Facility Upgrades!** The CRD is positioned to offer more diverse studies and advanced research projects with an upgraded vivarium. From July 2015 to December 2016, the CRD housed 49 sheep, 870 pigs, and 13 goats in a natural environment pasture and 49 rabbits and 6 ferrets in the vivarium. Facility improvements, valued at \$675,000, were awarded to the Army Corps of Engineers to improve the CRD facility HVAC system. The HVAC Upgrade Project will install pre-coolers and de-humidifiers for complete environmental control in the CRD facility and vivarium. Despite a localized roof fire, the project has proceeded on-time. Additional projects, valued at \$709,000, are in-progress to increase cooperative studies with full-time researchers and industry by upgrading animal caging facilities, strengthening and improving fencing at the outdoor animal facility, and upgrading flooring in the CRD facility to allow for more interior housing of large animals. The new projects commence January 2017 and are slated for completion by May 2017.

- **Accountable!** The CRD supported 211 IRB-approved projects, 51 IACUC-approved projects, and 92 non-research projects and maintains 100% accountability of annual continuation and final reports. The CRD supports publication clearance and submission to the DoD Defense Technical Information Center (DTIC).

Figure 10: Residents Utilizing the da Vinci Surgical System



Figure 11: Sally Banfield, Lab Supervisor, Receiving a Quality Improvement Initiative Award



## **Innovative and Creative Practices**

**- Outstanding Support of Residents!** Due to combined training efforts, the residents of the Wilford Hall Emergency Medicine Team won top national prizes. The CRD enables showcasing of research by clearing publications and presentations for the 59 MDW. From July 2015 to December 2016, **569** publications and presentations were cleared allowing for public recognition and preparing residents and staff for future national and international peer-reviewed presentations and award competition. During this period, 25 awards were garnered by authors supported by the CRD. Awards conferred include:

- Mr. David McGlasson, 59 MDW CRD: Won the **2015 Scientific Research Award** for his manuscript entitled, "Comparison of Six Dilute Russell Viper Venom Time Lupus Anticoagulant Screen/Confirm Assay Kits."
- Mr. David McGlasson, 59 MDW CRD: Won the **American Society for Clinical Laboratory Science's Scientific Researcher of the Year Award for 2015**. He earned the award for his manuscript, "Measuring Dabigatran with the Dilute Russell Viper Venom Confirm Assay in an Anticoagulation Clinic Population."
- Surgeon LCDR Ed Barnard, FCEM won **1<sup>st</sup> Place in the Young Investigator Category** for his work on "Selective Aortic Arch Perfusion for the Reversal of Hemorrhage-Induced Traumatic Cardiac Arrest in a Model of Non-Compressible Torso Hemorrhage" – MHRS, Aug 2015.
- CPT Amanda Laska, Lenz, B.L., Patterson, A.T., Brown, P.J., & Beachkofsky, T.M. won **1<sup>st</sup> Place Poster Presentation** for their work "Comprehensive Genomic Analysis of Cutaneous Adverse Drug Reactions" – Texas Dermatology Society Fall Meeting, San Antonio, TX, 30 Sept 2016.
- Dr. Shari Lawson, a surgical fellow with Lt Col Michael Davis' RESTOR group won **1<sup>st</sup> Place in Basic Science Award** for her presentation entitled, "Enzyme Triggered Drug Delivery for Graft Targeted Immunosuppression and Neuroregeneration after VCA".
- MAJ Karen Gonzalez-Torres, Oral and Maxillofacial Pathology Resident, won the **1<sup>st</sup> Place Award** from the International College of Dentists in the 2016 NPDS Research Competition.
- MAJ Karen Gonzalez-Torres, Oral and Maxillofacial Pathology Resident, won the **Chief of the Navy Dental Corps Award for Excellence**.
- Maj James Cullen (2015 Endodontics graduate) won the **2016 USUHS BoR Dental Award**.
- CPT Michael Segall, TORP Resident, won the **2016 Air Force Postgraduate Dental School (AFPDS), Marble Thesis Award**, given to the AFPDS resident with the best research manuscript from his graduating class.
- CPT Michael Segall, TORP Resident, AFPDS (2016), won the **2016 American Association of Orthodontists Joseph E. Johnson Table Clinic Award**.
- CPT Michael Segall, (2016 TORP graduate), won the **2016 AFPDS Marble Thesis Award for Outstanding Research Thesis**.

- LT Spencer Bjarnason, USN Endodontic Resident, won the **2<sup>nd</sup> Place Award** from the International College of Dentists in the 2016 NPDS Research Competition.
- CPT Christopher Lund, Comprehensive Dentistry Resident, APDS, Schofield Barracks, won the **3<sup>rd</sup> Place Award** at the Tripler Army Medical Center Bass Research Symposium from a field of over 60 entries.
- LCDR Bryan Rasmussen, Prosthodontics Resident, received the **3<sup>rd</sup> Place Award** from the International College of Dentists in the 2016 NPDS Research Competition.
- LT Christopher Ortiz, (USN), Periodontics Resident, NPDS (2016) received the **3<sup>rd</sup> Place Award** at the National Capital Region Continuing Dental Education Meeting for his table clinic titled: “*Multiple Applications of Amnion-Chorion Membrane.*”
- Col Howard Roberts, Professor of Comprehensive Dentistry, AFPDS, Keesler AFB, was awarded the **Thaddeus J. Weclaw Award** from the Academy of General Dentistry. The award is given to individuals who have served selflessly in education, organized dentistry, and in the dental profession. This award will be given to Col Roberts during the AGD Annual Session in June 2017.
- COL Van Ramos, Professor of Prosthodontics, APDS, Fort Gordon, was awarded the American College of Prosthodontists **2015 Bill B. Lefler Federal Services Award**. Col Ramos was also named the **Educator of the Year for DENCOM 2015**.
- COL Peter H. Guevara, Professor of Comprehensive Dentistry, APDS, Schofield Barracks was awarded the **2016 Dental Corps Chiefs Award for Excellence in Dental Education**.
- CAPT Robert Taft, Professor of Maxillofacial Prosthetics, NPDS, received the **NPDS Teacher of the Year Award** (10 June 2016).
- Col Chol Chong, Professor of Periodontics, AFPDS, received the **2016 AFPDS Outstanding Senior Educator Award**.
- Lt Col Dan Palazzolo, Associate Professor of Periodontics, AFPDS, received the **2016 Outstanding Educator Award** from the American Academy of Periodontology.
- Lt Col Cade Salmon, Associate Professor of Prosthodontics, AFPDS, received the **2016 AFPDS Outstanding Junior Educator Award**.
- Dr. John F. Johnson II was awarded the **Civism Award** for noteworthy accomplishments in service and education to the Naval Postgraduate Dental School.

- **Innovative!** The *Non-Human Research Subject Blood Donor Initiative* designed by the CRD was presented at the American Association for Laboratory Animal Science (AALAS) National Meeting (30 Oct-3 Nov 2016; Charlotte, NC) and the Military Health System Research Symposium (MHSRS) National Meeting (15-18 Aug 2016; Orlando, FL) and chosen for the AFSO21 brief during the 2016 Unit Effectiveness Inspection (UEI). The Blood Donor Initiative resulted in a significant reduction in the number of animals required to support trauma-related protocols. Use of this protocol in other Clinical Investigations Facilities could drastically reduce the number of animals required to support trauma- and resuscitation-focused research resulting in a more viable research process with enhanced accessibility.

- **Supportive!** The CRD supported the “2016 Research Protocol Workshop,” multiple “Introduction to Clinical Research” training courses for ophthalmology residents, and “What is Research?” seminars for the 59 MDW Gateway Academy. These courses were available to all residents and staff in the entire San Antonio Military Health System and increased their knowledge of clinical investigations, training protocols, and the value of publishing. The CRD has enjoyed high demand for these training offerings, due in part to the popular comprehensive protocol writing techniques seminar.

- **Progressive!** The CRD presented their program to 15 members of the Defense Health Board who were investigating the ability of military research programs to: enhance Graduate Health Sciences Education (GHSE) training; facilitate clinical practice guidelines improvements; encourage utilization of new devices and drugs by clinicians; and improve the safety of patients.

- **Productive!** The CRD has a busy and productive staff working in Support, Laboratory, and Operations branches. Examples of activities include:

- The two-man pathology section processed and analyzed over 2,000 special histochemical and routine hematoxylin- and eosin-stained slides and performed over 220 necropsies on five (5) different lab animal species in support of 18 tissue preservation, ischemia-reperfusion injury, wound healing, homeostasis, and advanced trauma life support protocols providing superior lifesaving techniques to the Warfighter.

Figure 12: Leo Longoria Working on a Molecular Assay



Figure 13: Richard LaBoone Processing Blood Samples



- The Laboratory Branch:
  - Supported 32 research protocols utilizing an array of high-tech diagnostic and analytical laboratory devices.
  - Performed over 1,000 inflammatory marker analyses using single- and multi-plex technology in support of 12 research protocols.
  - Extracted and fragmented DNA from cultured colon tumor cells to facilitate IRB compliant Precision Medicine support to include human whole genome sequencing studies.
  - Researched and acquired equipment needed to perform whole genome, exome (DNA) and transcriptome (RNA) sequencing studies.

- Developed/selected epigenetic molecular assays to investigate potential biomarkers of PTSD development and optimized GHSE precision medicine clinical investigation utilization of Pyrosequencing to elucidate biomarkers which predict susceptibility to PTSD.
  - Provided critical chemistry, hematology, and coagulation laboratory support for research involving new methods to treat potentially survivable deaths on the battlefield using balloon occlusion of the aorta and abdominal aortic junctional tourniquet.
  - Provided over 5,000 laboratory tests essential for animal physical welfare checks and surgical procedures to ensure healthy population of subjects and guarantee the best quality care and optimal research results.
  - Enhanced teamwork amongst branches to optimize support of clinical investigation by performing validation of i-STAT and ABL Blood Gas Analyzer to determine accuracy and precision of pH, pCO<sub>2</sub>, pO<sub>2</sub>, and lactate measurements obtained during point-of-care testing.
  - Supported study of resuscitation strategy for pediatric patients who suffer from blasts and penetrating trauma by performing over 1,000 laboratory procedures and generating/analyzing data that helped to determine effects of hemorrhage and the irreversible threshold of organ injury in children.
  - Validated labor-intensive, time-consuming, precision-driven Fluorescent In-situ Hybridization (FISH) and Immunocytochemistry (IHC) procedures to verify emerging evidence regarding predictor of genomic and proteomic MYC and BCL-2; retrospective review of Diffuse Large B-Cell Lymphoma and Burkitt's Lymphoma – presents a potential application to optimize treatment strategies.
  - Conducted four (4) concurrent disinfection and sterility studies for surgical and dental appliances with the goals of understanding/optimizing effective cleaning of devices and maximizing longevity of dental and surgical equipment.
- The CRD maintains the following: three (3) fully-functioning operating suites that include microsurgical capabilities; a DaVinci robotic training suite; a hyperbaric/hypobaric chamber; two (2) Instron material testers; and radiology and imaging capabilities, including ultrasound, digital film, and fluoroscopy. The surgery suites have conducted 14,000 hours of surgery and 1,300 hours of post-operative care.

- ***State-of-the-Art!*** The CRD procured the following tools for GHSE research from July 2015 to December 2016:

- \$285,000 worth of pathobiology equipment (digital gross imaging station, slide scanner, and updated necropsy suite lighting), thereby significantly improving efficiency, quality of data, and safety.
- Innovian Surgical Data Management System: this system allows for establishment of electronic medical records for research subjects. It is interfaced with anesthesia equipment and allows for automatic capture of all research-related vital sign data and will provide an electronic record of all pre-surgical, surgical, and post-surgical procedures on research subjects. The Innovian system is an important component necessary to provide

anesthesia support to over 10 readiness-training protocols, 52 active research protocols, and 780 surgical cases. The System is needed in order to interface with nine (9) Draeger Fabius GS Anesthesia units and CS700 Patient monitors to provide a distributed solution that permits comprehensive data management for CRD staff and investigators. The goal for use of Innovian Anesthesia is to contribute to more effective data management and medical care throughout CRD surgical suites. This system makes it much easier for CRD to illustrate regulatory compliance, eliminate human error, and establish and maintain master records of all the critical activities within the CRD research environment. The system was installed and operational on 1 Sept 2016.

- The Illumina NEXTSeq Human Genome Sequencing System was received to support four (4) GHSE protocols that have been approved for human genome sequencing. The system went live during the 4<sup>th</sup> quarter of 2016. Molecular capability has been increased to include Real-Time PCR, Pyrosequencing, Sanger Sequencing, Next Generation Sequencing, MicroArray, and full genome sequencing. High interest has been generated within the GME community to perform genomic investigations; several protocols have been approved and a number of new protocols are being prepared for submission. This is a high growth area for the CRD.

**Points of Contact**

<b>Linda Steel-Goodwin, Colonel, USAF, BSC</b> Director, Clinical Investigations & Research Support	<b>292-7069</b>
<b>Mr. Paul Barnicott</b> Deputy Director, Clinical Investigations & Research Support	<b>292-5687</b>
<b>TBD</b> NCOIC, 59th Clinical Research Division	<b>292-4673</b>
<b>Dr. Rocky Calcote</b> Clinical Research Administrator (Human)	<b>292-5203</b>
<b>Dr. Anneke Bush</b> IACUC Chair/Clinical Research Administrator (Animal) Biostatistician	<b>292-7295</b>
<b>Dr. Earl Grant, Jr.</b> Director, Quality Assurance and Education	<b>292-5146</b>
<b>Dr. L. Dawn Harris</b> Laboratory Animal Medical Officer (Chief Veterinarian) Operations Branch Chief (Surgery/Vivarium)	<b>292-2771</b>
<b>Dr. Thomas Gibbons</b> Laboratory Branch Chief	<b>292-7363</b>
<b>LTC Christine Christensen</b> Chief, Veterinary Pathology	<b>292-6589</b>
<b>Ms. Rachel Montez</b> Support Branch Chief Supervisor, Office of Research Protocol Support	<b>292-4683</b>
<b>Mr. Todd Brown</b> Supervisor, Surgery Branch Surgical Research Coordinator (OR Scheduling)	<b>292-7157</b>