59th Medical Wing

59th Clinical Research Division
Research Day Briefing

Colonel Linda Steel-Goodwin
Director, 59 CRD
27 Oct 16

The views expressed in this presentation are those of the author and do not reflect the views of the DoD or its components.
Agenda

- 59th Clinical Research Division (59 CRD) Mission

1255 Wilford Hall Loop, Bldg 4430

- Organization
- Funding
- CRD Capabilities
- POCs
The 59 CRD provides centralized admin, technical, and scientific support and regulatory oversight and guidance to researchers in the development, performance, and dissemination of clinical investigations.

CRD directly supports wing readiness and certification training requirements for residents, fellows, nurses, allied healthcare professionals, and providers.

Four Focus Areas:

1. Clinical Investigation Support
2. Training
3. Support of RDT&E protocols
4. Research Subject Protection
   - Animal Subjects: IACUC – Institutional Animal Care and Use Committee
CRD Staff Expertise

1 – DVM, Board Certified American College of Lab Animal Medicine; Certified by American College of Veterinary Pathology

1 – PhD, Physiology/Biochem – Clinical Research Admin; Certified by Aerospace Medical Assoc; Certified in Hyperbaric Physiology

1 – ScD, Biostatistics/Epidemiology – Animal Research Admin

2 – PhD, Molecular Biology/Virology

1 – PhD, Chemistry

1 – PhD, Biochemistry

1 – PhD, Biology/Neurology

1 – DrPH, Public Health in Disease/Immunology/Occu. Health

1 – DHSc, Health Science; Licensed Physician Assistant

10 – Masters Degrees in various disciplines
Accessing CRD Funding (SG5 CIP Program):

- Funding Level: $15K-$30K … may fund at higher levels on a case-by-case basis; GME funding is 1-year money

- Part of Protocol Approval Process
  - PI asks for funding
  - 1st come, 1st served basis
  - Have quarterly targets, but they are not etched in stone

- Must have an Air Force Principal Investigator
  - Protocols may have Army/Navy AIs
  - Exception is Dental Post Graduate Program (WHASC Baseline)

- Baseline Cost covered for GHSE Publications, must request on Form 3039
Surgical Capabilities

Warrior Medics – Mission Ready – Patient Focused

Three operating room suites:
- General and vascular surgery
- Orthopedic
- Ophthalmic
- Maxillofacial/dental
- Microsurgery

DaVinci robotic surgical system

Radiology (digital)

C-Arm (3)

Fluoroscopy

Ultrasound
Research Capabilities

Warrior Medics – Mission Ready – Patient Focused

- Fully capable laboratory facilities
- Expanded Toxicology Capabilities
  - Highly specific
  - Medical Toxicology studies
  - Tandem Mass Spectrometer
- Molecular Biology/Genomics
  - Next Generation Sequencing
  - Real Time PCR
  - Multi-Plex Assays
- Cell Biology
  - Flow Cytometry
- Microbiology
- Coagulation and Hematology
- Scanning Electron Microscope

Clinical Laboratory
- Immunology
- Hematology/Chemistry

Instron Testing
- Determine fatigue, impact, and/or resistance of materials

Hyperbaric/Hypobaric Medicine
- Study aerospace physiology
CRD Website

59th Medical Wing
Clinical Research Division

Calendar

CRD Capabilities
Human/Non-Human Research
Clinical Research Division Points of Contact
Animal Research
Current Research
News

https://kx2.afms.mil/kj/kx8/ClinicalResearchJBSALackland/Pages/home.aspx
<table>
<thead>
<tr>
<th>Department</th>
<th>Contact Person</th>
<th>Phone Number</th>
<th>Email Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB/IACUC Protocol Office</td>
<td>Ms. Rachel Montez</td>
<td>292-4683</td>
<td><a href="mailto:Rachael.Montez@us.af.mil">Rachael.Montez@us.af.mil</a></td>
</tr>
<tr>
<td>IRB/IACUC Protocol Office</td>
<td>Rachael Montez</td>
<td>292-4683</td>
<td><a href="mailto:Rachael.Montez@us.af.mil">Rachael.Montez@us.af.mil</a></td>
</tr>
<tr>
<td>Laboratory Services Branch</td>
<td>Dr. Thomas Gibbons</td>
<td>292-7363</td>
<td><a href="mailto:Thomas.gibbons@us.af.mil">Thomas.gibbons@us.af.mil</a></td>
</tr>
<tr>
<td>Publications and Presentations</td>
<td>Dr. Rocky Calcote</td>
<td>292-5203</td>
<td><a href="mailto:rocky.calcote.1@us.af.mil">rocky.calcote.1@us.af.mil</a></td>
</tr>
<tr>
<td>Publications and Presentations</td>
<td>LTC Michele Thompson</td>
<td>292-6589</td>
<td><a href="mailto:michelle.thompson.8@us.af.mil">michelle.thompson.8@us.af.mil</a></td>
</tr>
<tr>
<td>Human Studies</td>
<td>Dr. Dawn Harris</td>
<td>292-2771</td>
<td><a href="mailto:linda.harris@us.af.mil">linda.harris@us.af.mil</a></td>
</tr>
<tr>
<td>Animal Studies</td>
<td>Dr. Dawn Harris</td>
<td>292-2771</td>
<td><a href="mailto:linda.harris@us.af.mil">linda.harris@us.af.mil</a></td>
</tr>
<tr>
<td>Animal Scheduling</td>
<td>Mr. Todd Brown</td>
<td>292-7709</td>
<td><a href="mailto:todd.brown.9@us.af.mil">todd.brown.9@us.af.mil</a></td>
</tr>
<tr>
<td>Animal Studies</td>
<td>Mr. Todd Brown</td>
<td>292-7709</td>
<td><a href="mailto:todd.brown.9@us.af.mil">todd.brown.9@us.af.mil</a></td>
</tr>
<tr>
<td>Research Education/Post-Approval Monitoring</td>
<td>Dr. Earl Grant</td>
<td>292-5146</td>
<td><a href="mailto:earl.grant.1@us.af.mil">earl.grant.1@us.af.mil</a></td>
</tr>
<tr>
<td>Research Education/Post-Approval Monitoring</td>
<td>Ms. Jennifer Palmer</td>
<td>292-5819</td>
<td><a href="mailto:jennifer.palmer.1.ctr@us.af.mil">jennifer.palmer.1.ctr@us.af.mil</a></td>
</tr>
<tr>
<td>Animal Scheduling</td>
<td>Mr. Todd Brown</td>
<td>292-7709</td>
<td><a href="mailto:todd.brown.9@us.af.mil">todd.brown.9@us.af.mil</a></td>
</tr>
<tr>
<td>Research Education/Post-Approval Monitoring</td>
<td>Ms. Jennifer Palmer</td>
<td>292-5819</td>
<td><a href="mailto:jennifer.palmer.1.ctr@us.af.mil">jennifer.palmer.1.ctr@us.af.mil</a></td>
</tr>
<tr>
<td>Tours/Contracts/Concerns/Facilities Access</td>
<td>Chief – Col Steel-Goodwin</td>
<td>292-7068</td>
<td><a href="mailto:linda.steel_goodwin.1@us.af.mil">linda.steel_goodwin.1@us.af.mil</a></td>
</tr>
<tr>
<td>Tours/Contracts/Concerns/Facilities Access</td>
<td>Chief – Col Steel-Goodwin</td>
<td>292-7068</td>
<td><a href="mailto:linda.steel_goodwin.1@us.af.mil">linda.steel_goodwin.1@us.af.mil</a></td>
</tr>
<tr>
<td>Tours/Contracts/Concerns/Facilities Access</td>
<td>Deputy Chief – Paul Barnicott</td>
<td>292-5687</td>
<td><a href="mailto:paul.barnicott.1@us.af.mil">paul.barnicott.1@us.af.mil</a></td>
</tr>
</tbody>
</table>
Thank You!
MEMORANDUM FOR SGVUS
ATTN: COL LINDA STEEL-GOODWIN

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval


2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.

3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.

4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

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

Warrior Medics – Mission Ready – Patient Focused
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 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/ICC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DTIC). See 59 MDW 41-108, Presentation and Publication of Medical and Technical Papers, for additional information.

11. The Joint Ethic Regulation (JER) DoD 5000.07-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)] [presenters(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 40-402.2."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 40-401.1P:

"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."
TO: CLINICAL RESEARCH

FROM: (Author's Name, Rank, Grade, Office Symbol)

GME/GHSE STUDENT: N/A

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.)

TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:

FUNDING RECEIVED FOR THIS STUDY? NO

DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES? NO

IS THIS MATERIAL CLASSIFIED? NO

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.? NO

MATERIAL IS FOR:

DOMESTIC RELEASE

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

HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED? NO

EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC DATE

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

STEEL-GOODWIN, LINDA linda.steel_goodwin.1@us.af.mil

AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.
a. Primary/Corresponding Author
STEEL-GOODWIN, LINDA COL 59 MDW/SGV

b.
c.
d.
e.

IS A 502 ISG/JAC ETHICS REVIEW REQUIRED (JER DOD 5600.07-R)? NO

I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401-1P, 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.

AUTHOR'S PRINTED NAME, RANK, GRADE

STEE L-GOODW IN, COL

APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE

NIEM WER, DEBRA M. 1022603567
1st ENDORSEMENT (59 MDW/SGVU Use Only)

<table>
<thead>
<tr>
<th>TO: Clinical Research Division</th>
<th>24. DATE RECEIVED</th>
<th>25. ASSIGNED PROCESSING REQUEST FILE NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>59 MDW/CRD</td>
<td>Oct 2016</td>
<td>16348</td>
</tr>
</tbody>
</table>

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

29. COMMENTS □ APPROVED □ DISAPPROVED

The presentation is approved.

30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER

Rocky Calcote, PhD, Clinical Research Administrator

31. REVIEWER SIGNATURE

CALCOTE ROCKY D. 01176245844

32. DATE

2nd ENDORSEMENT (502 ISG/ISG/ISG/ISG 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

October 19, 2016

40. DATE FORWARDED TO 59 MDW/SGVU

October 19, 2016

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

INUMA KEVIN MITSUGU 1296227 813

44. DATE

October 19, 2016

4th ENDORSEMENT (59 MDW/SGVU Use Only)

45. DATE RECEIVED

46. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL

□ YES □ NO □ COULD NOT BE REACHED □ LEFT MESSAGE

47. COMMENTS □ APPROVED □ DISAPPROVED

48. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER

49. REVIEWER SIGNATURE

50. DATE