MEMORANDUM FOR ST/SGVUS
ATTN: DR. ANNEKE C. BUSH

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **What to Consider for Animal Research** presented at Resident Research Fundamentals Course (Gateway Club), JBSA - Lackland TX, 27 Oct 16 in accordance with MDWI 41-108, has been approved and assigned local file #16382.

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

Warrior Medics – Mission Ready – Patient Focused
**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:**
What to Consider for Animal Research

**FUNDING RECEIVED FOR THIS STUDY?** Yes [X] No

**DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES?** Yes [X] No

**IS THIS MATERIAL CLASSIFIED?** Yes [X] 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.?** Yes [X] No

**MATERIAL IS FOR:**
- [X] DOMESTIC RELEASE
- [ ] FOREIGN RELEASE

**EXPECTED DATE WHEN YOU WILL NEED THE ORO TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC:**

**DATE:**

**AUTHORSHIP AND CO-AUTHOR(S):** List in the order they will appear in the manuscript.

1. **LAST NAME, FIRST NAME AND M.I.**
   - a. Primary/Corresponding Author
     - Anneke C. Bush
   - b. 
   - c. 
   - d. 
   - e. 
   - f. 

**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**

**APPROVING AUTHORITY’S PRINTED NAME, RANK, TITLE**

**DATE**

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**59 MDW FORM 3039, 20160218**

**PREVIOUS EDITIONS CURRENTLY IN USE CAN BE USED**

**ALL OTHERS ARE OBSOLETE**

Page 2 of 3 Pages
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Contact 292-7141 for email instructions | **printer name**  
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| **22. DATE RECEIVED** | **31. DATE RECEIVED** | **37. DATE RECEIVED** | **43. DATE RECEIVED** |
| 11/1/2016 | | November 8, 2016 | |
| **23. ASSIGNED PROCESSING REQUEST FILE NUMBER** | **32. DATE FORWARDED TO 502 ISG/JAC** | **38. DATE FORWARDED TO 59 MDW/PA** | **44. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL** |
| 16382 | | November 14, 2016 | YES  
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| **24. DATE REVIEWED** | **33. COMMENTS** | **39. COMMENTS** | **45. COMMENTS** |
| | | X APPROVED  
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| **26. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES** | **36. DATE** | **42. DATE** | **48. DATE** |
| YES  
IF yes, give date. | | November 14, 2016 | |
| **27. COMMENTS** | | | |
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DISAPPROVED | | | |
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| 59 MOW FORM 3039, 20160218  
PREVIOUS EDITIONS CURRENTLY IN USE CAN BE USED  
ALL OTHERS ARE OBSOLETE  
Prescribed by 59 MDW 41-108 | | | |
59th Clinical Research Division
Wilford Hall Ambulatory Surgical Center

- AAALACI Accredited Vivarium
- 25K sq. ft. Facility
- 31K sq. ft. Paddock
- WHSC IACUC

CRD Capabilities

Animal Use Program

- Facility/Vivarium/Staff

Personnel

- (1) DVM - DACLAM, MPH
- (1) DVM - Certified by American College of Veterinary Pathology - 7 years Veterinary Pathology experience
- (1) PhD, Aerospace Physiology (IRB Administrator)
- (1) ScD, MHS Statistical Consultant/Epidemiology (IACUC Administrator)
- (1) Registered Nurse Anesthesia Specialist
- (1) PhD Chemist
- (1) PhD Biochemist (Director, Research QA/QI)
- (1) PhD Biologist with emphasis in Neurology
- (8) MS Degree - 10-30 years research experience
Personnel

- (1) Surgical Supervisor - 33 years OR experience
- (1) Biological Animal Technician - 20+ years OR experience
- (1) Instron/Hyper/Hypobarics Technician - 20+ years of medical veterinary experience
- (1) Certified Laboratory Animal Technician (AAALAS)
- (2) Certified/Registered Laboratory Animal Technologists (AAALAS)
- (5) Certified Clinical Laboratory Technologist
- (3) Active Duty Surgical Techs (4N1)
- (5) Civilian Surgical Techs
- (4) Active Duty Medical Admin Techs; (6) Civilian Admin Techs

Accreditation/Assurances

Animal Program

- Association For Assessment And Accreditation of Laboratory Animal Care International (AAALAC) Accredited
  - Last Visit - 15 June 2016 (Due Every 36 Months)
  - CRD hailed as a “A Best Practice Site”
  - “Emeritus Status” for 21 consecutive years (no major findings)
- PHS Assurance
  - Only Air Force Facility with OLAW (PHS) Assurance
  - Allows us to accept PHS funding for clinical investigations

Site Visits

- Animal Research Protection Program Compliance SAV – Bi-Annual by AF Medical Support Agency/SGE-C
  - SAV Pending – TBD FY17
- AAALAC – triennial accreditation site visit
  - 15 June 2016

Animal Use Program

- Facility/Vivarium/Staff
- IACUC – Institutional Animal Care & Use Committee
**Subject Protection**

**Program Responsibilities**

- Protection of Animal Research Subjects/IACUC
  - Set animal use policy
  - Review, modify, approve/disapprove all animal use protocols
  - Ensure training for all personnel working with animals

**IACUC Requirements**

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**Institutional Animal Care and Use Committee**

- IACUC must follow PHS Policy on Humane Care and Use of Laboratory Animals and the Animal Welfare Act USDA Title 7, Ch 2131, 9 CFR parts 1-4
- DoD 3216.01 Use of Laboratory Animals in DoD Programs
- Accreditation by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC)
- Reports directly to the Institutional Official (IO)
- Second Level Review at SG level

**IACUC Responsibilities**

- Responsible for the Oversight and Evaluation of the Institution's Laboratory Animal Care and Use Program
  - Review the institution's program for Humane Care and Use of Animals
  - Inspect all the institution's animal facilities semi-annually
  - Submit reports of IACUC evaluations to the IO
  - Review concerns involving care and use of animals
  - Make recommendations to the IO regarding any aspect of the program
  - Review and approve, require modifications (to secure approval) or withhold approval of activities involving animals (research or training protocols)
IACUC Responsibilities (cont.)

- Review and approve, require modifications (to secure approval) or withhold approval of proposed significant changes (protocol amendments)
- Suspend an activity involving animals
- Ensure personnel who use or care for animals are properly trained
- Ensure there is an adequate Occupational Health and Safety Program

• Bottom line: the IACUC is responsible for all aspects of the institution's animal care and use program

Animal Use Program

- Facility/Vivarium/Staff
- IACUC – Institutional Animal Care & Use Committee
- Investigators

Animal Research Protocol Requirements

- PIs and AIs must complete the Animal Care and Use courses located on the AAALAS Learning Library prior to doing animal research
- PIs must consult the CRD veterinarian, Dr. Dawn Harris, for assistance in protocol development prior to submission to the IACUC
- Templates are available from the protocol office staff

Animal Research Protocol Requirements

- Standard DoD Animal Use Protocol
  - May have facility specific language
  - Cover sheet with Signatures
  - Non-technical synopsis
  - Literature reviews
    - Search for duplication of effort
    - Search for alternatives to painful procedures
  - Study Hypothesis, design, statistical review
  - Veterinary considerations including pain management and study endpoints
  - Table of qualifications of investigators
Animal Research Protocol Life Cycle

- IACUC Submission Deadlines
- Pre-review process
- IACUC review and approval
- Second level approval, if applicable
- Funding and scheduling
- Annual Reviews
- Triennial de novo review
- Final Report

Points of Contact

- Col Linda Steel-Goodwin, Division Chief & Institutional Official 292-7068
- Dr. L. Dawn Harris, DVM, MPH, DACLAM Laboratory Animal Medical Officer 292-2771
- Dr. Anneke Bush, ScD, MHS, IACUC Chair 292-7295
- Mrs. Maria Dominguez 292-6095
- Ms. Jessica Mercado 292-2977
- Ms. Rachel Montez 292-4683

Questions?

"If we knew what it was we were doing, it would not be called research, would it?"
- Albert Einstein