MEMORANDUM FOR SGVT
ATTN: CAPT FAITH R. KELLY

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.

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

Warrior Medics – Mission Ready – Patient Focused
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) (SGS O&M); SRS 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. If 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/CRC. 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 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) 671-6795/3565, 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."

59 MDW FORM 3039, 20160628  
PREVIOUS EDITIONS ARE OBSOLETE  
Page 1 of 3 Pages
High-Fidelity Hemodynamic Waveform and Data Repository for Training Allied Health Personnel and Research

Eval of Exercise Response in a Young, High Risk Population: Submaximal Invasive Cardiopulmonary Exercise Testing (iCPET) in AD Soldiers
The abstract and poster presentation are approved. The author provided the needed documentation that her activity was approved through the BAMC IRB.

30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER
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Evaluation of Exercise Response in a Young, High Risk Population: 
Submaximal Invasive Cardiopulmonary Exercise Testing (iCPET) in Active Duty Soldiers.

Faith R. Kelly¹, James A. Watts¹, Terry D. Bauch², Joseph P. Murgo³, and Bernard J. Rubal¹
¹San Antonio Military Medical Center, ²Geisinger Medical Center, ³University of Texas Health Science Center at San Antonio

Background
- Clinical concerns raising suspicion for cardiovascular disease in active duty military require definitive evaluations to diagnose disease at an early stage given high risk occupation.
- There remains limited information for assessing left and right heart hemodynamic response during supine exercise in young adults in high risk occupations.

Objective
- Provide reference values for normal hemodynamic metabolic data in patients <40 years.

Methods
- A retrospective review of 4511 catheterization records between 1972-92 at Brooke Army Medical Center for active duty patients (ages: 19-40 years) in whom hemodynamic waveforms were obtained with multi-sensor high-fidelity catheters at rest and during supine submaximal exercise testing (53±12.6 watts).
- Metabolic data were obtained for direct Fick cardiac outputs.
- 42 met inclusion criteria with complete data available for review.

Results
- Submaximal exercise was associated with approximately fourfold increase in minute ventilation, O₂ consumption and CO₂ production (P<0.001).
- Heart rate, cardiac index, and stroke volume index increased 40±15 bpm, 3.7±1.4 L/min/M², and 23±18 ml/min/M², respectively (P<0.001).
- Pulmonary artery saturations fell from 77±3% to 55±7%, and the A-VO₂ difference increased from 3.8±0.5 to 8.3±1.5 ml/dl (P<0.001).
- The oxygen-uptake efficiency slope for submaximal exercise was 1,557±423.
- No change was noted in mRA pressure or pulmonary vascular resistance with a small (<1 mm Hg) increase noted in RVEDP (P=0.043).
- Mean pulmonary capillary wedge and LVEDP increased =214 mmHg (P<0.001) with pulmonary artery systolic, diastolic and mean pressures increasing 9±4, 4±3 and 6±3 mm Hg, respectively (P<0.001).
- Left ventricular dp/dt increased from 1,505±316 to 2,727±682 mmHg/sec and systemic vascular resistance decreased 37±128 dynes-sec-cm⁻⁵ (P<0.001).

Discussion
Clinical practice relies on the cardiologist’s ability to associate symptoms such as dyspnea with underlying cardiopulmonary processes.
Recent reviews of iCPET testing (Malhotra et al., Berry et al.) demonstrate the importance of iCPET testing with respect to prognosis and delineating underlying etiology of dyspnea in many patient populations such as heart failure.

Conclusion
This study provides insight into past practices of iCPET and furthers the understanding of metabolic and hemodynamic changes in a young population during supine submaximal exercise.
DEPARTMENT OF THE ARMY  
BROOKE ARMY MEDICAL CENTER  
3851 ROGER BROOKE DR.  
FORT SAM HOUSTON, TX 78234  

MEMORANDUM FOR: Bernard Rubal, Ph.D.  
FROM: Brooke Army Medical Center (BAMC) Institutional Review Board  
PROJECT TITLE: [408191-1] High-Fidelity Hemodynamic Waveform and Data Repository for Training Allied Health Personnel and Research  
REFERENCE #: C.2015.008d  
SUBMISSION TYPE: New Project  
ACTION: APPROVED  
APPROVAL DATE: February 11, 2015  
EXPIRATION DATE: February 11, 2016  
REVIEW TYPE: Expedited Review  

1. Congratulations! The Brooke Army Medical Center (BAMC) Institutional Review Board (IRB) reviewed and APPROVED your aforementioned protocol and supporting documents on February 11, 2015. The research is judged to constitute Minimal Risk. The protocol has been assigned control number C.2015.008d. Please refer to this designation in all correspondence.

Your protocol was reviewed for regulatory compliance under Expedited Review, in accordance with 32CFR§219.110(a) Federal Registry Categories (5) and (6). Applicable OHRP (under 45CFR46), FDA (under 21CFR§50 and 56) and HIPAA (45CFR§160 and 164) regulations were also consulted, as appropriate.

2. This submission has received Expedited Review based on the applicable federal regulation.
   a. The protocol is approved to enroll up to 4,500 records
   b. A waiver of informed consent has been approved IAW 32 CFR§219.116(d) for the entire study
   c. A HIPAA waiver has been submitted and approved.
   d. No funding is requested from the Department of Clinical Investigation.

3. All documents labelled *FINAL within the Designer Page and Board Documents sections of IRBNet are to be utilized throughout the course of this study.

4. A Research Monitor is not required; protocol is no greater than minimal risk.

5. You are required to report all unanticipated problems involving risks to subjects or others (UPIRSOs) and Serious Adverse Events (SAEs) to the IRB. Any unanticipated adverse events must be reported to the Human Protection Administrator within 24 hours by phone at (210) 916-2598 or (210) 916-0606 or by email at BAMC_IRB_AE@amedd.army.mil.

February 11, 2015
6. Protocol C.2015.008d will automatically expire on February 11, 2016. If you plan to continue beyond this date, the required continuing review progress report is due to the BAMC IRB at least six (6) weeks before this deadline. The IRB will attempt to assist you by sending a reminder; however, submission of the continuing review report is your responsibility. Failure to submit the report on time will result in the expiration of your protocol and a requirement to cease all research activities until the entire protocol can be resubmitted.

7. Please be sure to maintain all records in accordance with the terms set forth in your protocol. You are required to have all records, including informed consent and HIPAA documents, available for review by the IRB or other federal agencies.

8. Any changes to your protocol, including any changes in personnel, may not be made without prior IRB approval. Please forward a request for any changes, along with their rationale, to the BAMC IRB for review and approval.

9. Please inform the IRB when the protocol is completed or changes status and forward any significant findings.

10. Please ensure that you remain in compliance with BAMC Memo 70-1. Review and approval of abstract and/or manuscript submissions should be made through the Department of Clinical Investigation prior to any release. Contact Ms. Ileana King-Letzkus at (210) 916-2000 for additional details.

11. If at any time you have questions regarding your responsibilities as a Principal Investigator, please contact Lynn Platteborze at 210-916-9425 or lynn.s.platteborze.civ@mail.mil. On behalf of the entire IRB, we wish you much success with your research protocol. We look forward to reviewing the progress of your study in the coming months.

This document has been electronically signed in accordance with all applicable regulations, and a copy is retained within our records.