MEMORANDUM FOR ST
ATTN: DEBRA M NIEMEYER

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled *Air Force Personalized Medicine Program Panel: Representative Research at the 59th Medical Wing San Antonio Military Medical Center* presented at/published to *SAMHS & Universities Research Forum (SURF), UTSA, San Antonio, TX 20 May 2016* with MDWI 41-108, and has been assigned local file #16202.

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) (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.

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   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 (59crdpuspres@us.af.mil). 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 MDWIPA) 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 MDWICC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DTIC). See 59 MDW 41-106, Presentation and Publication of Medical and Technical Papers, for additional information.

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"

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"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."

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"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."
1. TO: CLINICAL RESEARCH
2. FROM: Dr. Debra M. Niemeyer, Col-ret, GS-15, 59MDW/ST
3. GME/GHSE STUDENT: NO
4. PROTOCOL NUMBER: N/A
5. PROTOCOL TITLE: Air Force Personalized Medicine Program Panel: Representative Research at the 59th Medical Wing San Antonio Military Medical Center

6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:
Air Force Personalized Medicine Program Panel: Representative Research at the 59th Medical Wing San Antonio Military Medical Center

7. FUNDING RECEIVED FOR THIS STUDY? NO
8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES? NO
9. IS THIS MATERIAL CLASSIFIED? 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.? NO

11. MATERIAL IS FOR: DOMESTIC RELEASE
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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.)
   SAMHS & Universities Research Forum (SURF), UTSA, San Antonio, TX, May 20, 2016
11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)

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

DATE: 1-Jun-2016

13. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)
Sylvia, Victor L. victor.sylviactr@us.af.mil

14. DUTY PHONE/PAGER NUMBER
292-3513

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

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16. AUTHOR'S PRINTED NAME, RANK, GRADE
Debra Niemeyer, PhD, GS-15, DAF

17. AUTHOR'S SIGNATURE

18. DATE
May 9, 2016

19. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE
Col Brenda Morgan, Col, USAF, NC

20. APPROVING AUTHORITY'S SIGNATURE

21. DATE
May 9, 2016
The author attached her presentation. The presentation is approved.
San Antonio Military Health System

Joint Base San Antonio, Texas

Approved for public release; distribution is unlimited.

For questions contact the 59 MDW PA office, 210-292-7688.

Air Force Personalized Medicine Program Panel:

Representative Research at the 59th Medical Wing
San Antonio Military Medical Center

Dr. Deb Niemeyer, PhD, DAF
Chief Scientist

Dr. Vic Sylvia, PhD, CTR
Senior Scientist

59th Medical Wing
Wilford Hall, JBSA, TX
20 May 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.
Introduction

The Uniformed Services University of the Health Sciences and USAF Force Personalized Medicine and Advanced Diagnostics Program partnership seeks evidence to enhance support for the utilization of genetics, genomics, pharmacogenomics, proteomics, and bioinformatics tools to optimize prevention, diagnosis, early intervention and treatment strategies at the San Antonio Military Health System.

Panel members will describe studies in Disease Management providing evidence for the integration of personalized data into clinical decision-making, especially during the prevention and treatment of common yet complex disorders, to improve healthcare outcomes. Facility capabilities in support of military personalized medicine research will also be presented.
Panel Members

- Dr. Victor Sylvia (Moderator)
- Dr. Clifton Dalgard
- Maj Thomas Beachkofsky
- Dr. Thomas Gibbons
- LTC Lawrence Petz
- Dr Lisa Lott
Overview

• Strategic Alignment
• Strategic Priority and Objectives
• Program Portfolio and Implementation
• Panel Member Presentations
Obama pushes 'Precision Medicine Initiative'

David Jackson, USA TODAY  ·  11:22 p.m. EST, January 30, 2015

President Obama asked Congress on Friday to approve $215 million for a 'Precision Medicine Initiative' designed to help doctors tailor treatments to the individual characteristics of their patients.

White House Releases Proposed Precision Medicine Initiative Privacy Framework

7/17/2015 by Debra McCurdy | Reed Smith

Earlier this year, President Obama launched a high-profile "Precision Medicine Initiative" (PMI) to develop treatments, diagnostics and prevention strategies tailored to the individual genetic characteristics of each patient. On July 8, 2015 the White House released for public comment a draft document entitled "Precision Medicine Initiative. Proposed Privacy and Trust Principles," which provides broad guidance concerning: governance; transparency; reciprocity; respect for participant preferences; data sharing, access and use; data quality and integrity; and security within the context of the PMI. The principles include "strategies for engendering public trust and maximizing the possible benefits of a large national research cohort, while minimizing the risks inherent in large-scale data collection, analysis, and sharing." The White House is accepting public comments on the proposed principles through August 7, 2015.
A Service Strategic Priority

AFMS Vision—Trusted Care: “Our supported population is the healthiest and highest performing segment of the U.S. by 2025.”

AF Global Horizons Final Report: “The game changer for the Air Force is personalized health and performance.”


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**Personalized Medicine Program Transition**

Phase I (FY11-13): Research to Demonstrate Clinical Utility

Phase II (FY14-16): Transition of Research, Policy, & Bioinformatics Program Elements

Phase III (FY17+): Clinical Policy & Bioinformatics Integration
# Advanced Diagnostics, Personalized Medicine and Big ‘My’ Data

## Near Term (2019)
- Enhance Genetic Marker Research Data, Tissue and Specimen repository
- Elucidate biomarkers of enhanced risk of future diabetes and prediction of future disease.
- Evaluate and validate advanced diagnostic technologies, including automated nucleic acid extraction for complex matrices, DNA next gen sequencing and Real-Time Polymerase Chain Reaction (PCR) technology for RNA and DNA pathogens of both viral and bacterial etiology.
- Optimize molecular assays for PCR identification of MERS CoV, Coronavirus, pandemic Influenza A/H7N9 and other emerging/re-emerging disease threats of military importance, and FDA approval for diagnostic use.

## Mid Term (2024)
- Demonstrate personalized treatment for diabetes, cardiovascular, pulmonary disease based on pharmacogenomic therapy.
- Place into practice genetic markers for musculoskeletal injuries and ailments to implement preventive measures in military field training sites.
- Rapidly characterize etiological pathogens of sepsis in support of same-day treatment-specific modalities.
- Leverage joint personalized medicine efforts to utilize biomarkers of physiological response to opioid use.
- Transition smartphone-based pathogen ID system to meet AF requirements for personalized medicine and infectious disease characterization.

## Far Term (2029)
- Produce a plug-and-play, closed system diagnostic array for emerging etiologic agent detection on ultra-small, rapid, ruggedized molecular detection platform.
- Assess autonomous field-forward microneedle acid extraction/sampling processing methods.
- Miniaturized, wearable, multiplexed immunoassay nano-arrays for multiple panels, to include toxins, viruses, bacteria, host immune biomarkers on Personalized Biometrics.
- Expand use of non-nucleic acid technologies to decrease diagnostic time to ID disease and disease susceptibility.
- Realize Big ‘My’ Data use for seamless individual health assessment & care.

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**POTUS Precision Medicine Initiative, OTSP Guidance, Global Horizons, AF/SG Advanced Diagnostics Initiative, AFMS CBA/ICL, 59MDW HRO Innovations**
Methods/tools (CPGs) for diagnosis, treatment and interventions using ‘Omics

FY13 FY14 FY15 FY16 FY17 FY18 FY19

Pharmacogenomic Risk Profile Application in a Clinical Setting

Optimization of Pharmacologic Cardiovascular Personalized Care Using Genomics-Based Risk Characterization

Reduce Time to Detection of Human Sepsis

Biomarkers to Predict Clinical Course

CBA: AFMS and MAJCOM Needs (Research Knowledge)

Decision Point
Milestone
Translational Event
TRL

O&M
RDT&E
JPC
SBIR
Other

1. Develop & Revise Clinical Practice Guidelines (CPGs): Personalized treatment for T2DM
2. CPGs: Variations in a patient's DNA used to predict individual's response to cardiac therapeutics
3. Provide universal standard sample and amplicon preparation protocol; point of care Sepsis testing tool
4. Develop algorithm based on biomarkers to predict therapeutic clinical response
## Personalized Medicine Program Portfolio

### Representative Extramural Projects

- **Coriell Institute:** Clinical Utility Study (CUS)
- **Johns Hopkins Applied Physics Laboratory (JHU-APL):** PC2 Program
- **Duke University:** Genetic Risk Testing & Health Coaching for T2D and CHD
- **Duke University:** Genetically Guided Statin Therapy
- **Duke University:** Implementation, Adoption, and Utility of Family History in Diverse Care Settings
- **Yale University:** Identification of Associations between Genetic Factors and Asthma that are Modified by Obesity
- **Nationwide Children's Hospital:** A Collaborative Translational Autism Research Program for the Military

### Representative Intramural Projects

- **Epigenetic Biomarkers of Stress at High Altitude Conditions**
- **711HPW Advanced Genomics and Technology Center Sequencing Validation**
- **Tele-genetics, Project ECHO within the AFMS**
- **Regenerative/Restorative Medicine Research Program**
- **Development of Human Mesenchymal Stem Cells for Treatment of Immune System Dysregulation in Neurological & other Diseases**
- **Immune Modulation of Poly/Trauma**
- **Characterization of High Mobility Group Box Protein 1 (HMGB1) as a novel early biomarker for injury severity and the coordination of patient evacuation**
- **Adverse Childhood Experience Serotonin Transporters and Telomeres: A Gene Environmental Interaction Study of the Risk of PTSD in Soldiers**
- **Biomarkers for Mental Illness and Recovery using Sleep as a Mediator: A Randomized Controlled Trial**
- **Characterization of the Proteomic Response to Hydrocodone: Plasma and Urine**
- **Genetic Epidemiology of Risk-Associated Single Nucleotide Polymorphisms (SNPs) of Type 2 Diabetes (T2D) Mellitus**
- **Pharmacogenomic Risk Profile Application for Clinical Setting**
- **Optimization of Pharmacologic CV Personalized Care Using Genomic-Based Risk Characterization**
- **Genetic Marker Repository**
- **Genetic & Epigenetic Biomarkers of Cutaneous Adverse Drug Reactions**
- **Predictors of Immune Status**

### PANEL PRESENTATIONS (update order as needed)

- **Population Genomics Innovation for Personalized Medicine in the Military**
- **Genetic & Epigenetic Biomarkers of Cutaneous Adverse Drug Reactions**
- **SAMHS / 59MDW Clinical Research Division Laboratory Capabilities and Supported Personalized Medicine Research**
- **SAMHS / BAMC Department of Clinical Investigations Laboratory Capabilities and Supported Personalized Medicine Research**
- **59MDW Center for Molecular Detection and Personalized Medicine Research of Military Significance**
Program Implementation

- Translate results into *Best Practice* and *Policy*
- Improve education for and support to Providers and Patients to integrate ‘Omics’ into Healthcare
- Establish relevance to Operational community
Success through Collaboration and Innovation...
Panel Member Presentations

“Prepare for the unknown by studying how others in the past have coped with the unforeseeable and the unpredictable”
-- George S. Patton

“Victory smiles upon those who anticipate the changes in the character of war...not upon those who wait until after those changes have occurred.”
-- Giulio Douhet

“The true sign of intelligence is not knowledge but imagination”
-- Albert Einstein