Naval Medical Center San Diego
Research Update

Defense Health Board
San Diego 10 Feb 16

Head Clinical Investigations Dept,
NMCSD Research Program Manager,
Navy Medicine West Professor of Medicine,
USUHS

The views expressed are those of the author and do not reflect the official policy or position of the Department of the Navy, the Department of Defense, or the United States Government.
Clinical Investigations Dept
NMCSD/NMW

Core Staff

- Dept Head; NMW Research Program Manager
- Scientific Director
- Director Animal Research
- Head Nursing Research
- Bio Statistician (0.5 FTE)
- Medical Editor
- Research Facilitator
- ORTA/CRADA/MOU
- IRB administrator
- IRB administrator
- Budget Analyst
- Executive Assistant

Vacant – Two IRB Administrators

Major Services and Products:

- Research facilitation; scientific design, promote publication
- Successfully process IRB/IACUC protocols
- Initiate and process CRADAs/MOUs/EPAs
- Facilitate collaborative relationships with major research centers/academic institutions
- Assist and disseminate CIP grants
- Organize and lead NMW Academic Research Competition

(MOU – Memorandum of Understanding)
(EPA – Educational Partnership Agreement)

Metrics

- Pubs submitted FY15: NMCSD - 158 (45% articles) – essentially stable last 4 years
- Cooperative Research and Development Agreement: (CRADA) 116 days (Average) process time; $1M income
- No ACGME “scholarly activity” citations - 20 NMCSD Resident programs/ No research concerns pharmacy, psychology, and dental residencies
CID supports the Commands mission of operational readiness, patient care, and medical education by facilitating scientifically sound research and publications.
Navy Medicine Research Reorganization October 2015

NAVY MEDICINE RESEARCH

Navy Medicine ***

BUMED **

Dr. Cheatham (SES)

NAV MED WEST *

NAV MED CEN SAN DIEGO

NAV MED RESEARCH COMMAND

CID/IRB

Camp Pendleton  29 Palms  Lemoore

Bremerton  Guam  Hawaii  Okinawa  Japan

NMSRL  NHRC  NAMRU  NAMRU-6  NAMRU-3  NAMRU-2

SAN DIEGO  SAN ANTONIO  LIMA  CAIRO  SINGAPORE

NAV MED EAST *

NAV / MARINE PUBLIC HEALTH CENTER

NAV MED CEN PORTS MOUTH

CID/IRB

Camp Lejeune  Jacksonville  Pensacola  Charleston  Groton  Newport  Gitmo  Quantico  Sigonella  Rota

Number of Publications

Calendar Year


134 147 142 191 168 165 134 230 169 152 168 235 167 167 168 158

*Calculated for FY 2015

Source: CID Medical Editor Database; Elisea Avalos, PhD
NMCSD Academic Publications Submitted FY 2015

Total = 158
- Articles: 45%
- Book Chapters: 32%
- Case Reports: 6%
- Letters to the Editor: 7%
- Reviews: 8%
- Other*: 2%

* Newsletters, dissertations

Source: CID Medical Editor Data Base; Elisea Avalos, PhD
NMCSD Academic Publications Submitted FY 2014

- Articles: 42%
- Book Chapters: 10%
- Case Reports: 38%
- Letters to the Editor: 5%
- Reviews: 4%
- Other: 2%
- Total = 168

* Newsletters, commentaries

Source: CID Medical Editor Data Base; Elisea Avalos, PhD
NMCSD Medical Editor Clearance Submissions by Department FY 2015

*Breast Health Center, Dental, Endocrinology, Family Medicine, GME, Laboratory, Medical Health, Nursing, Pathology, Patient Relations, Pharmacy, PM&R, Primary Care

Total products cleared FY15 - 514
NMCSD Articles Submitted for PAO Clearance by Department FY 2013-2015

*Breast Health Center, CID, Dental, Endocrinology, Family Medicine, General Surgery, GME, Laboratory, Medical Health, Nursing, Pathology, Patient Relations, Pharmacy, PM&R, Primary Care
NMCSD/NMW IRB Activity 2015

• Protocols
  Total IRB Approved studies – 264
  Total Tracked by NMCSD – 285 (includes IDCRP)

• Protocol Risk Level
  Greater than Minimal – 74
  Minimal Risk – 141
  Exempt – 34
  Unassigned – 15

LARGEST by Volume
IRB in Navy by 100
protocols
Total “active” studies as of 1 Oct 2015: 264
Excludes other IRB approved studies: 5 USUHS Infectious Disease (IDCRP), 8 NHRC, 8 Satellite Sites
IRB Approved Protocols FY 2013-2015

Number of Protocols

Department

- Anesthesiology
- Branch Clinics
- Breast Health
- Cardiology
- Dermatology
- Emergency Medicine
- Family Medicine
- Gait Lab/PT
- Gastroenterology
- General Surgery
- Hematology/Oncology
- Infectious Disease
- Internal Medicine
- Mental Health
- Neurology
- Nursing Research
- OB/GYN
- Orthopedics
- Otolaryngology
- Pastoral Care
- Pediatrics
- Pharmacy
- Plastic Surgery
- Pulmonary
- Radiology
- Simulation Center
- Urology

[Bar chart showing the number of protocols approved in FY 2013, 2014, and 2015 for each department listed above.]
Average Process Time IRB Meeting Minutes FY 2015

Red line = goal 14 days
IRBNet system ceased 28 Sept
Cooperative Research and Development Agreements (CRADAs) and Amendments 2011-2015

CRADA Income per ONR
2011 - $102,193
2012 - $350,000
2013 - $695,691
2014 - $2,416,959
2015 - $1,088,773 *
*Unofficial

CRADA Income per ONR
Fiscal Years

Average # of Days

# of CRADAs and Amendments Initiated for FY

# of Executed CRADAs and Amendments (5 CRADAs and 13 Amendments)

# of Terminated CRADAs
Research Skill Sets

GME Division Head/Department Head/Program Director

Research Competent
Evaluate/Conduct

Study Design
Statistics
Writing
Ethics
Regulations
Immunology
Project Management
Fiscal
CID Major Accomplishments FY 15

• Academic Research Competition – 120 abstracts submitted – 60 posters/presentations selected. CDR Jeffrey Milligan, Psychiatry won entire Navy Clinical Staff Research Award for “Recent Sexual Trauma and Adverse Health and Occupational Outcomes Among Men Serving in the US Military”

• Military Health Research Symposium Presentations – 6 oral/4 poster presentations/ LT Cochran ortho resident selected New Investigator presentation to 1800 attendees.

• Nursing Research active engagement Command/Region – protocols from sleep apnea to oral history Hospital ship humanitarian missions. CDR King MHRS Poster honorable mention/RADM Hall Award Nurse Pub PTSD/Acupuncture

• $2.5M DoD grants:$1M FST TeamSTEPP/$1M OSA Pregnant/$.5M Hosp Ship

• MV22 Osprey fuselage to Strategic Operations for En Route Care research/development/training with BTSC (En Route Care Grant submitted)

• Stem Cell (mesenchymal) research project finalized San Diego Company

• DoNHRPP success inspect 1/27/15 – 100 page investigator manual revamped
Research Challenges

• Navy Cooperative Research and Development Agreement (CRADA) Template – 40 page document; restrictive IP language not supportive of clinical trials.

• IRBNet Replacement – sudden loss Sept 24 2015; Defense Health Agency (DHA) constructing new electronic IRB processing system.

• Data Sharing Agreement – DHA requirement for any use of AHLTA/CHCS information – 14 page request form requires Washington DC approval – 6 week process time requested. IRB approval required prior to submission.

• Navy Medicine Research Organization – maturation and refinement.

• Travel approval and funding for Research presentations and developmental collaborations.

• Civilian Hiring delays – local and BUMED issues; hiring process centralized in Norfolk VA.
Future Opportunities

• Culture Change research importance – level metrics (quantity/quality) across Navy and DoD – similar to clinical care and operational readiness. Immediately raises significance (fitness reports – providers/COs) and resource allocation (time/money/space).
  • Equal recognition for scholarly excellence (awards for publications) – similar to admin and collateral duties – not reduction in clinical time
  • High impact research – minimize Principle Investigator 2-4 yr rotation

• Education/skills increase – clinicians require formal skill sets: statistics, study design, epidemiology, writing – especially Dept Heads/Program Directors – minimum 1 year course; Masters Public Health/Clinical Research 2 year recommended.

• Standardize Research Process across DoD: All IRB forms, CRADAs – DHA Research, Development, and Acquisition Directorate mandate