



# Naval Medical Center San Diego Research Update

Defense Health Board  
San Diego 10 Feb 16

Head Clinical Investigations Dept,  
NMCS D 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 NMCS D/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: NMCS D - 158 (45% articles) – essentially stable last 4 years
- Cooperative Research and Development Agreement: (CRADA) 116 days (Average) process time; \$1M income
- IRB - largest in the Navy – nearly 300 active protocols; IRBNet suddenly D/c 30 Sept – closed Oct 2015
- No ACGME “scholarly activity” citations - 20 NMCS D Resident programs/ No research concerns pharmacy, psychology, and dental residencies



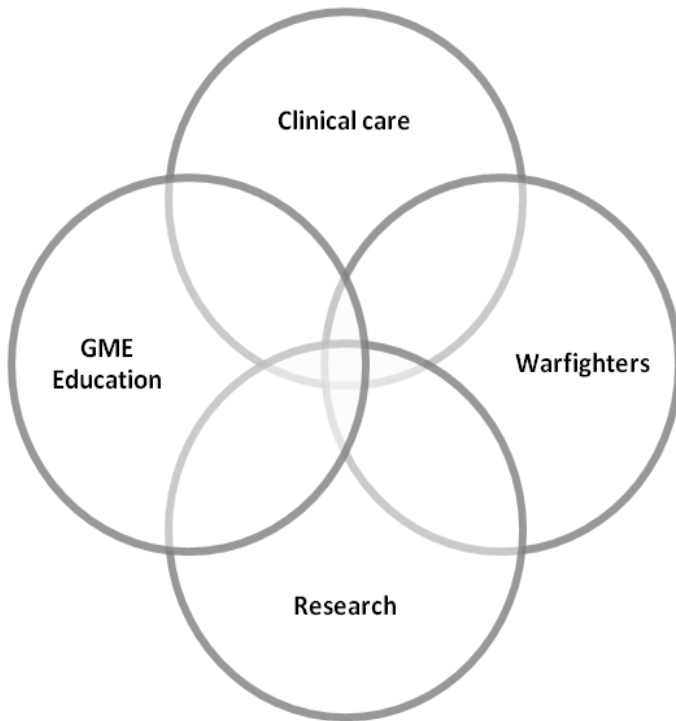


# NMCS D CID STRATEGY

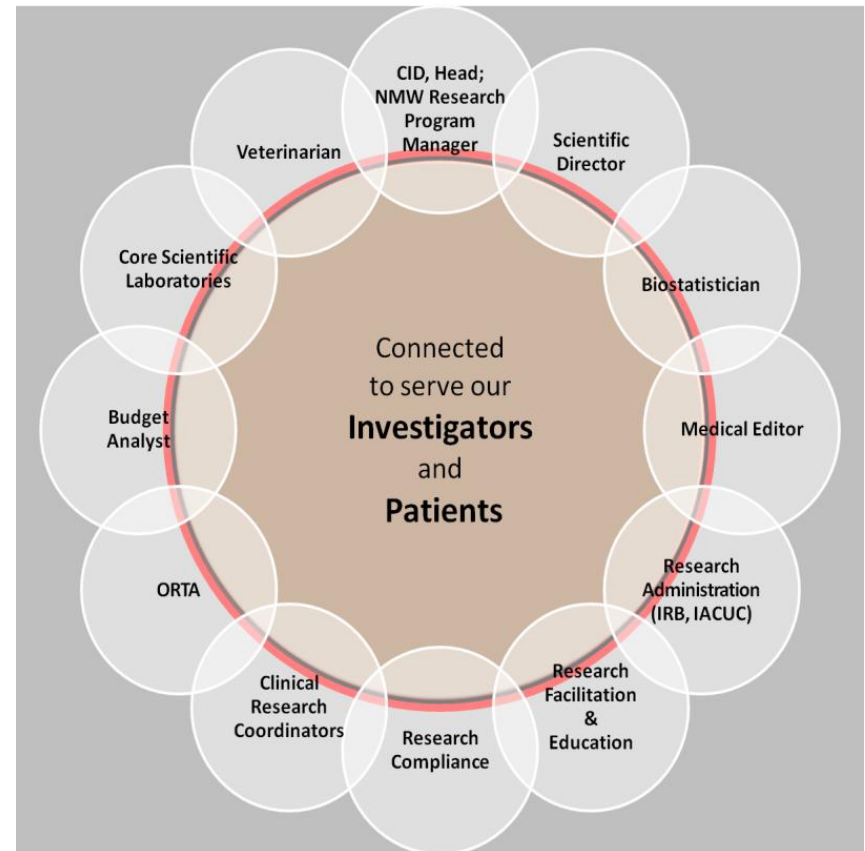


“Academic Excellence with Operational Relevance”

Research Projects Closest to Circles Intersection



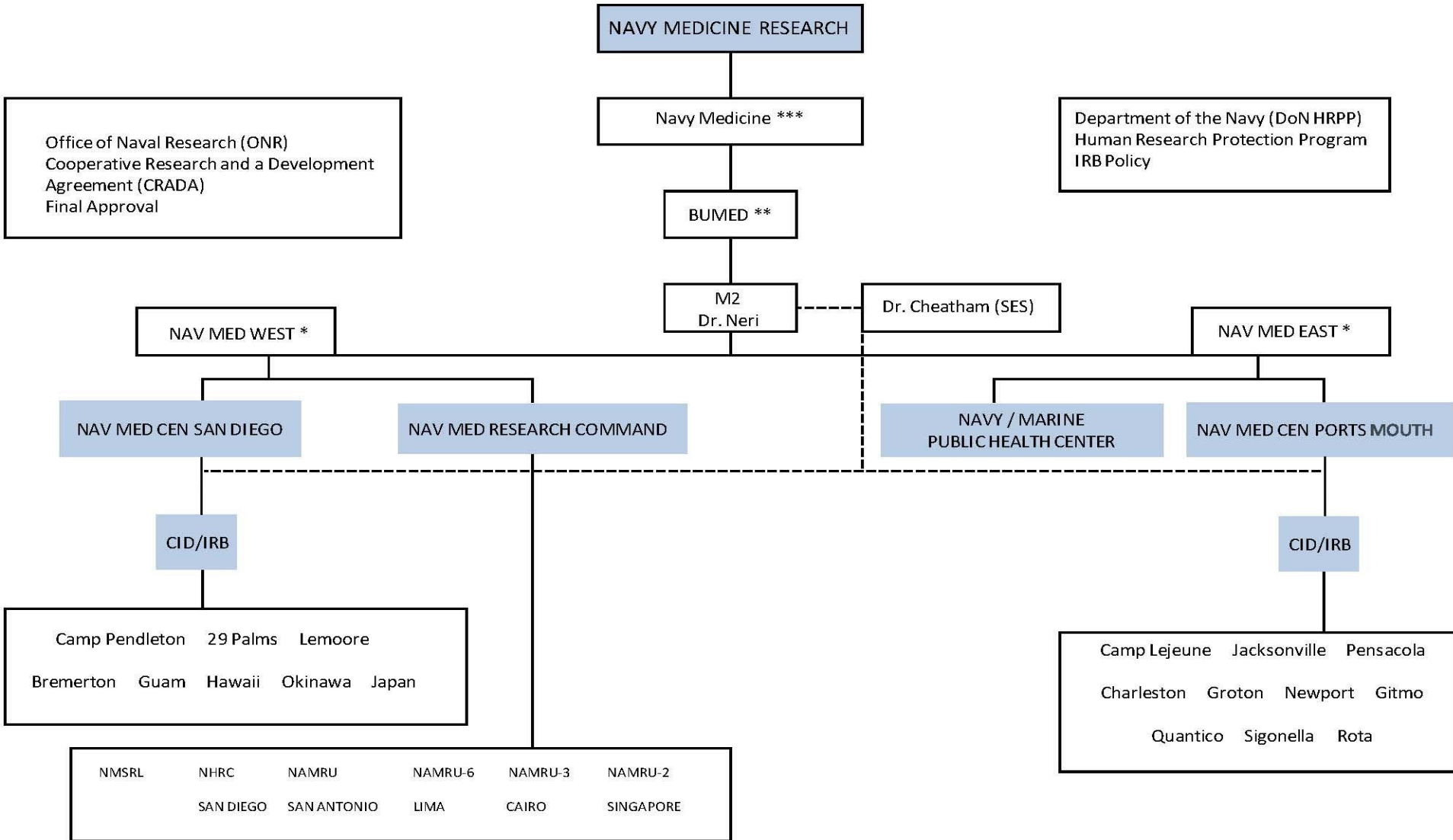
CID Research Team



CID supports the Commands mission of operational readiness, patient care, and medical education by facilitating scientifically sound research and publications.

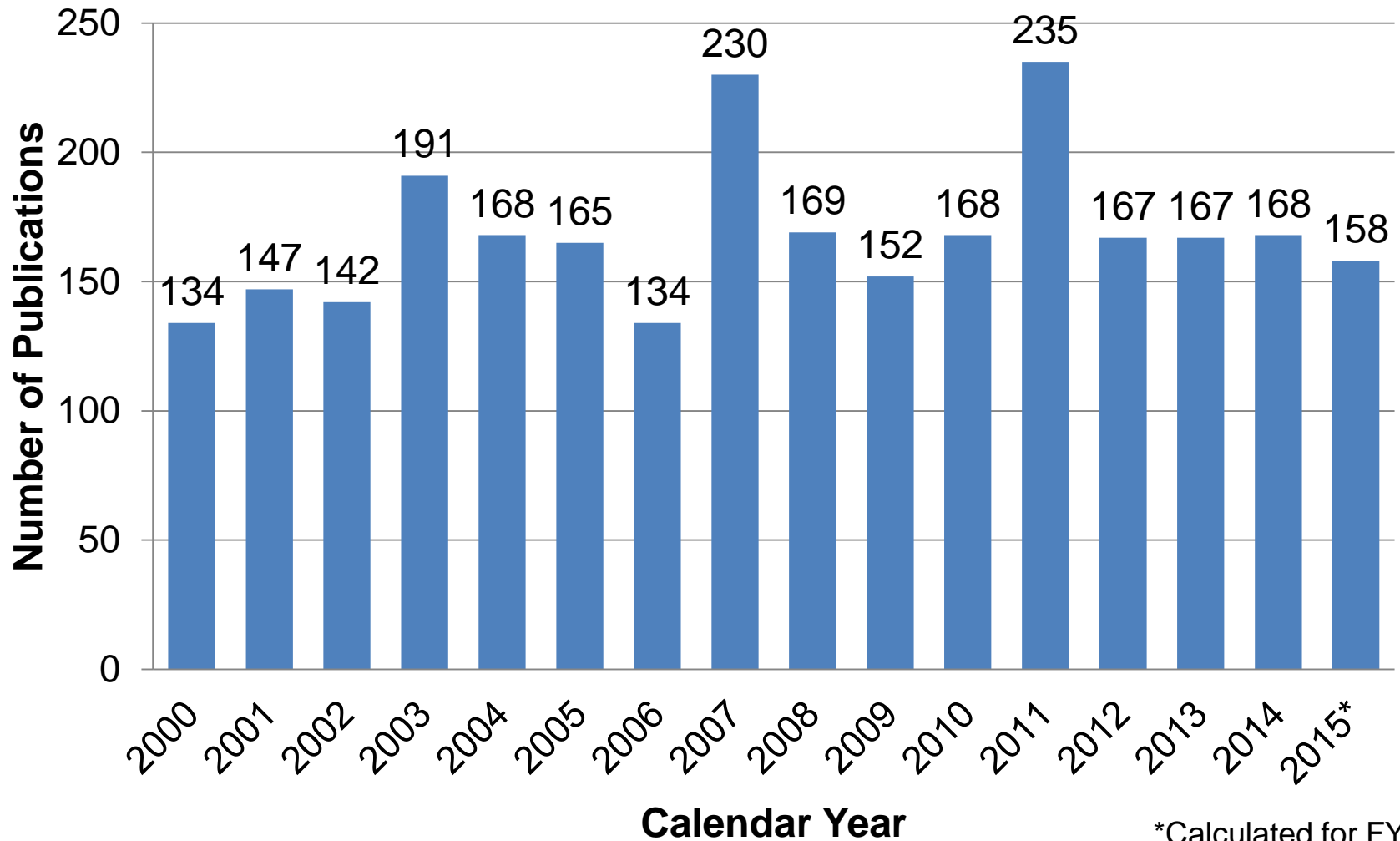


# Navy Medicine Research Reorganization October 2015





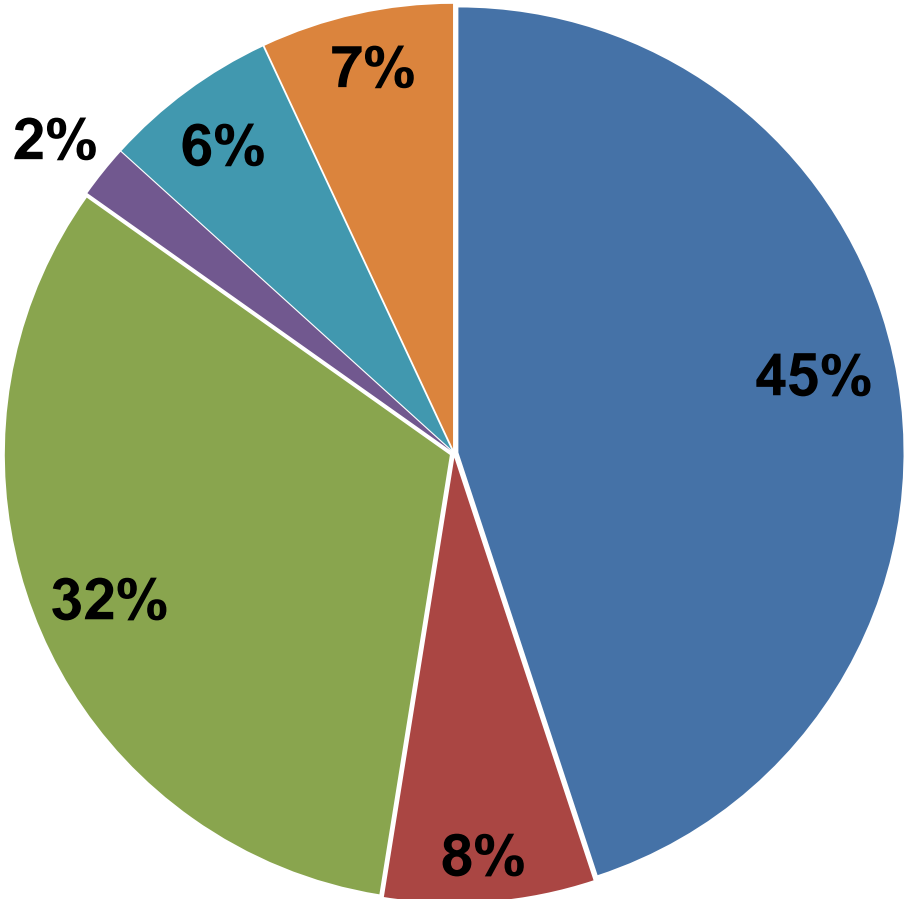
# NMCSD Academic Publications Submitted (2000-2015)



\*Calculated for FY 2015



# NMCS D Academic Publications Submitted FY 2015



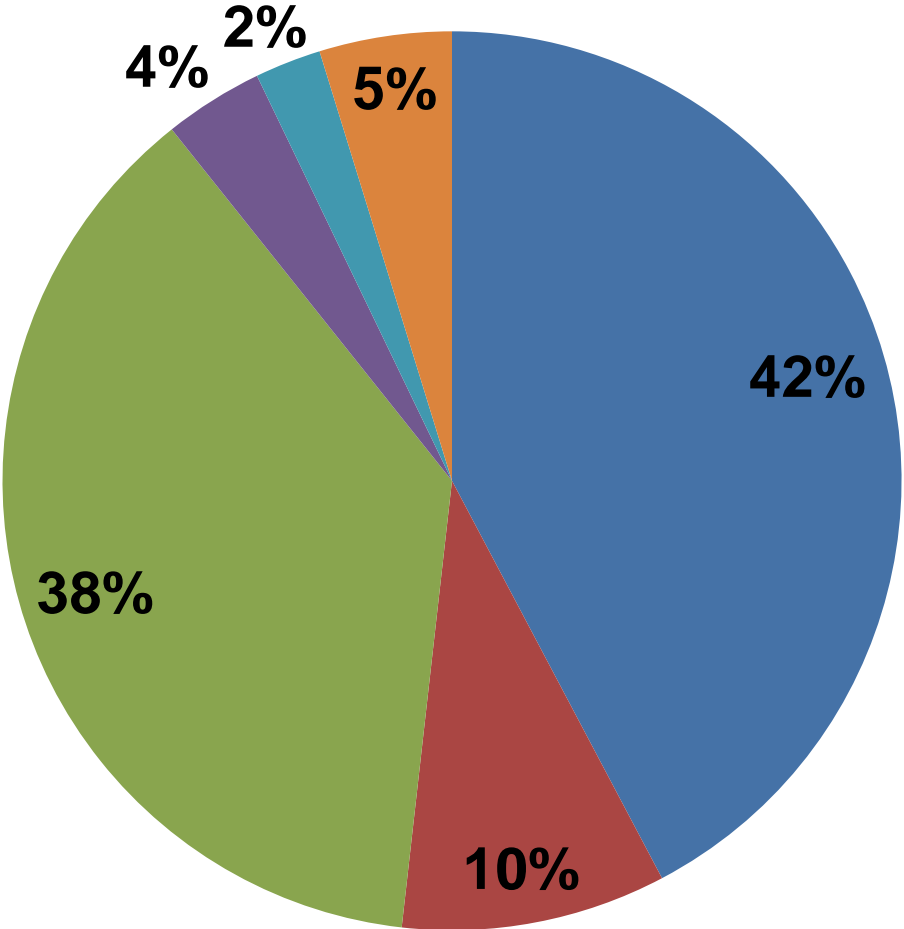
Total = 158

- Articles
- Book Chapters
- Case Reports
- Letters to the Editor
- Reviews
- Other\*

\* Newsletters, dissertations



# NMCSD Academic Publications Submitted FY 2014



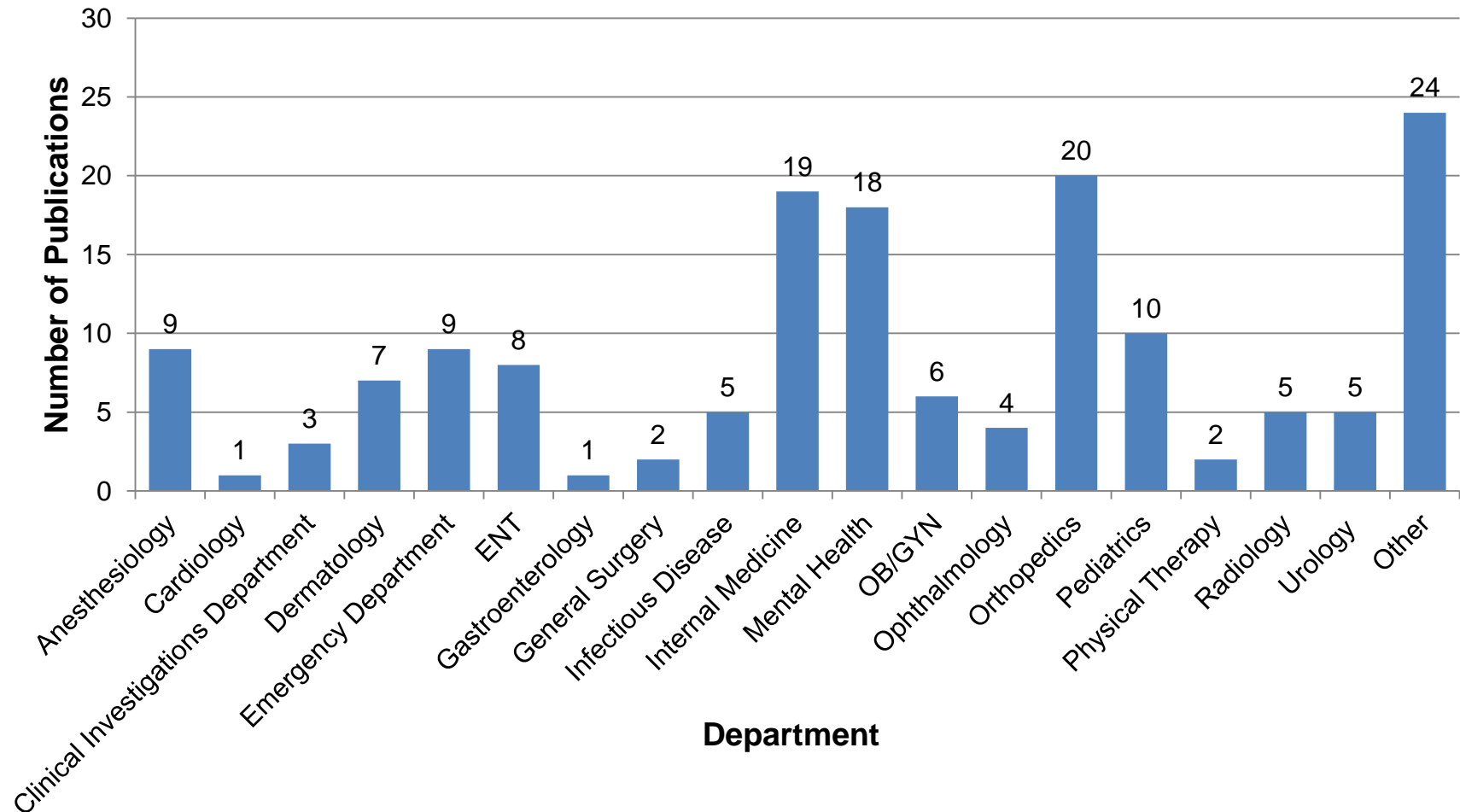
Total = 168

- Articles
- Book Chapters
- Case Reports
- Letters to the Editor
- Reviews
- Other

\* Newsletters, commentaries



# NMCS D 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

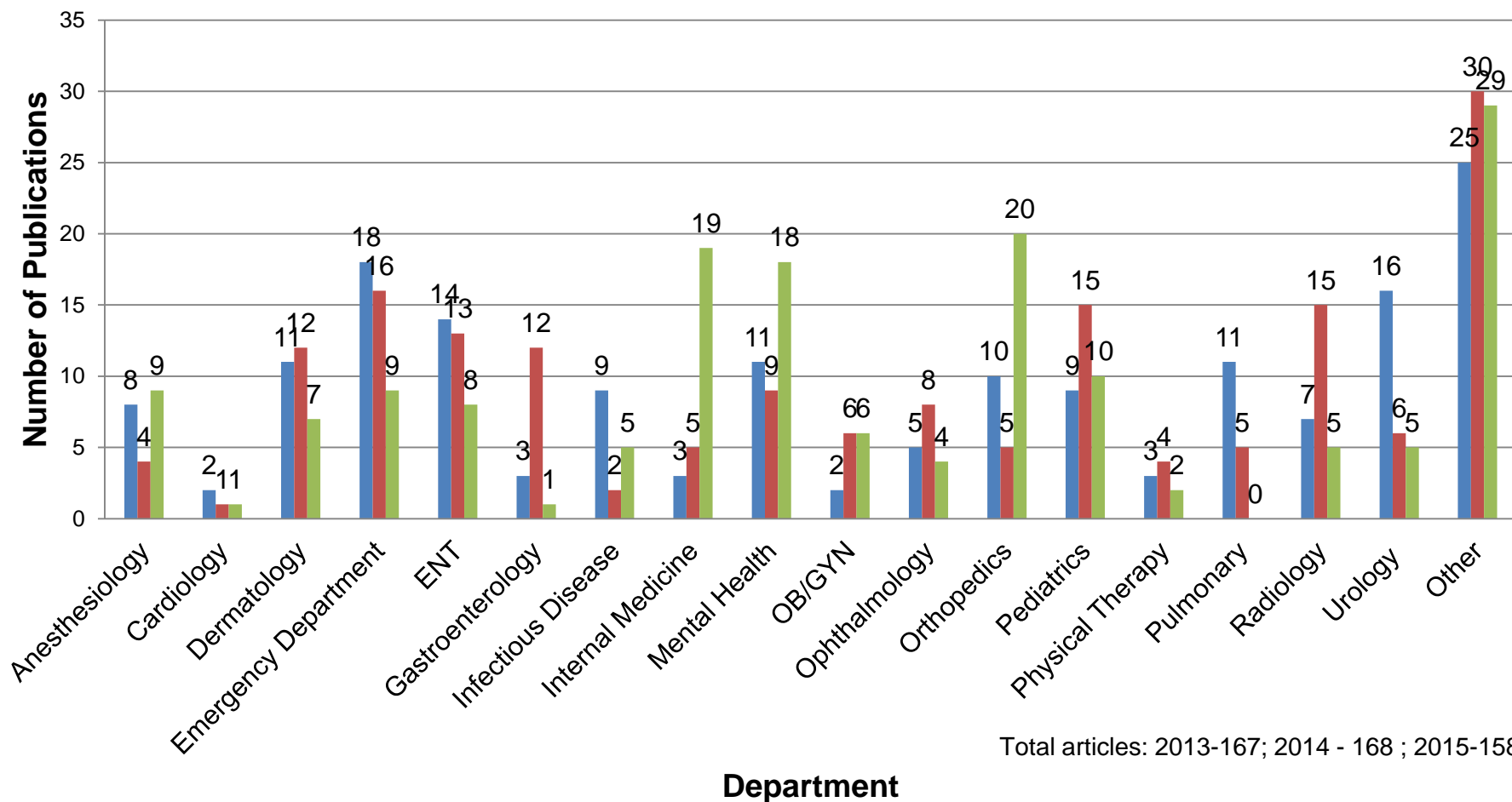
Total products cleared FY15 - 514





# NMCSA Articles Submitted for PAO Clearance by Department FY 2013-2015

■ 2013 ■ 2014 ■ 2015



Total articles: 2013-167; 2014 - 168 ; 2015-158

**Department**

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



# NMCS D/NMW IRB Activity 2015



- Protocols

Total IRB Approved studies – 264

Total Tracked by NMCS D – 285 (includes IDCRP)

- Protocol Risk Level

Greater than Minimal – 74

Minimal Risk – 141

Exempt – 34

Unassigned – 15

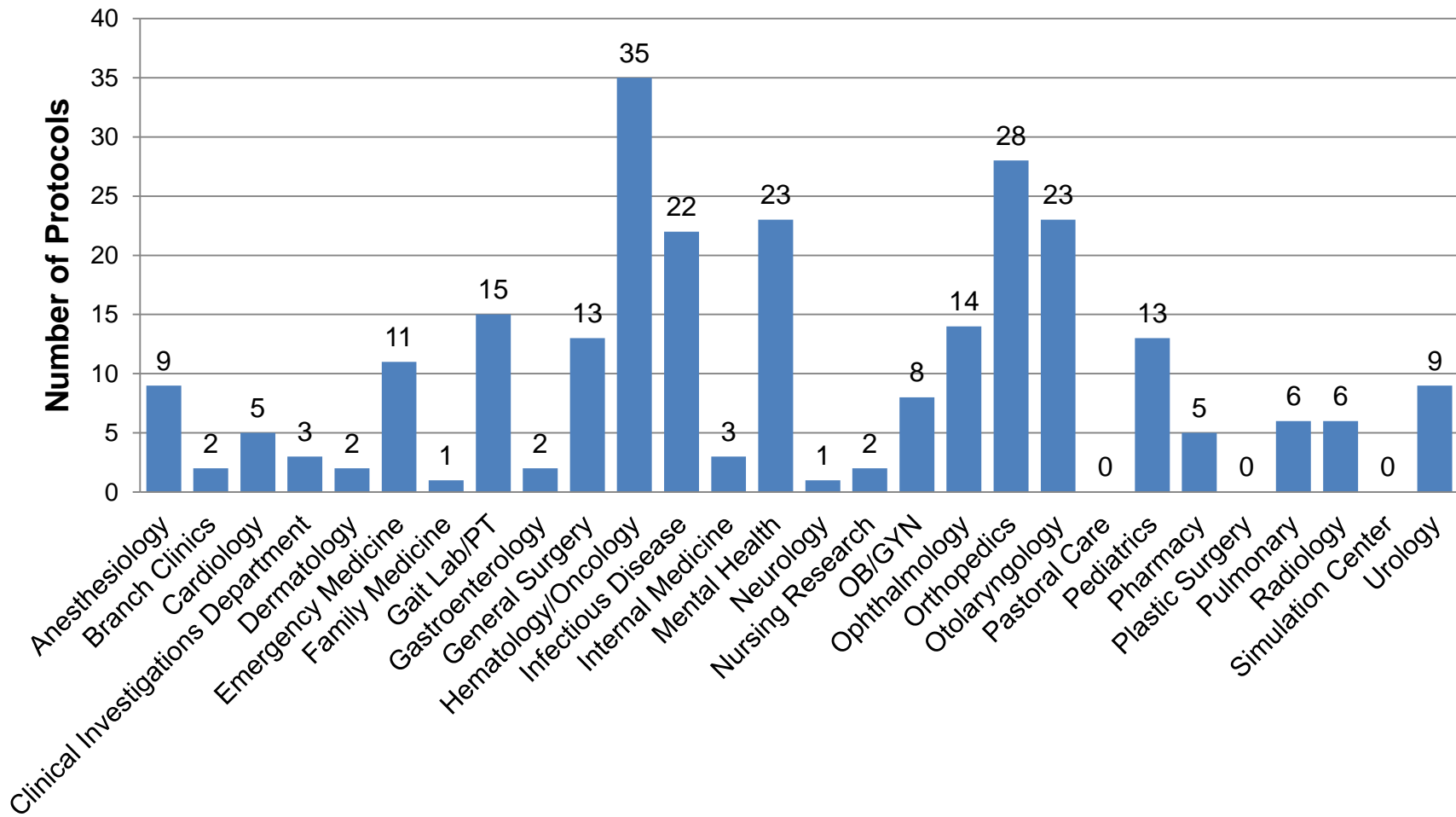
LARGEST by Volume

IRB in Navy by 100

protocols



# IRB Approved Protocols FY 2015



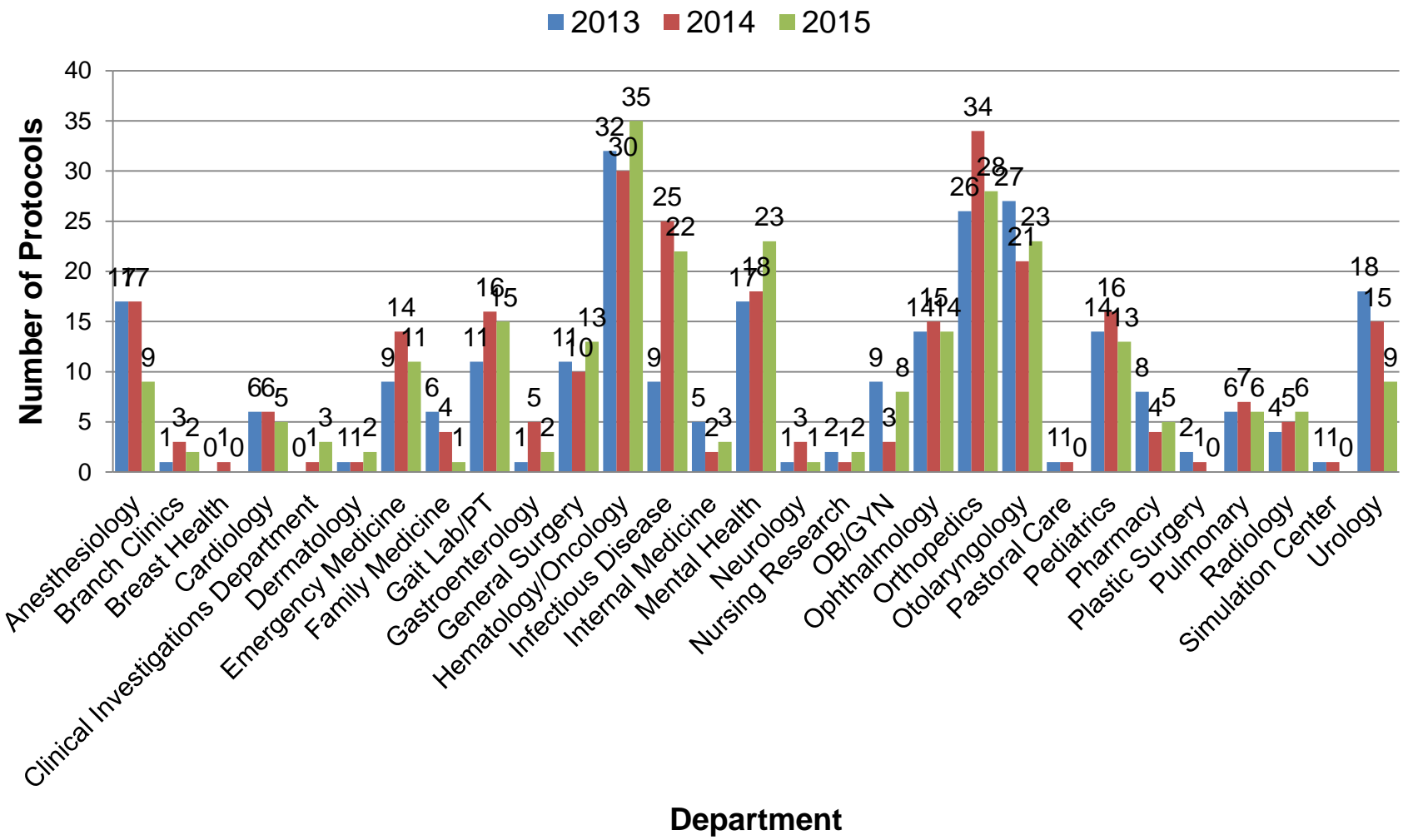
## Department

•Total "active" studies as of 1 Oct 2015: 264

•Excludes other IRB approved studies: 5 USUHS Infectious Disease (IDCRP), 8 NHRC, 8 Satellite Sites

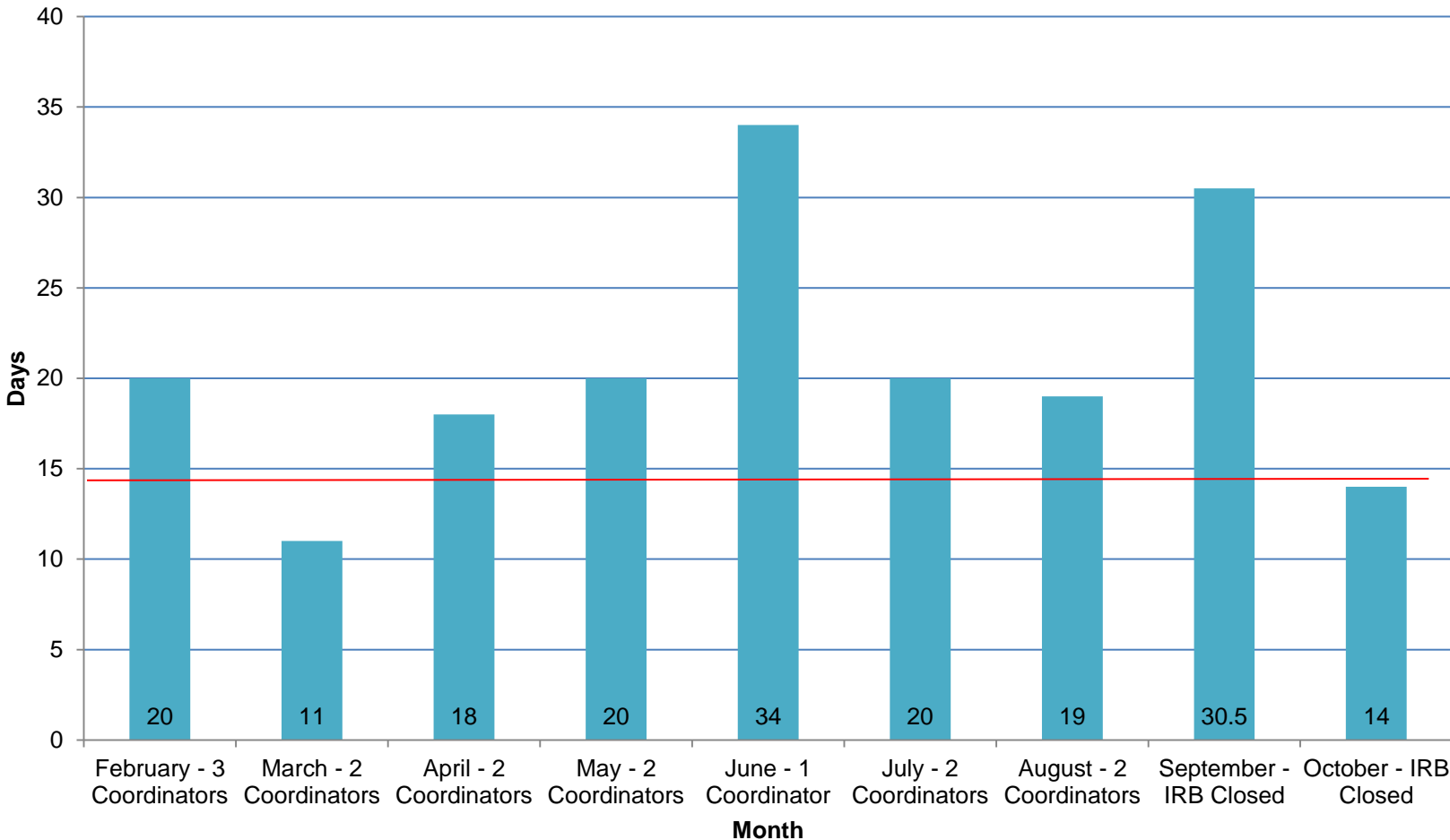


# IRB Approved Protocols FY 2013-2015





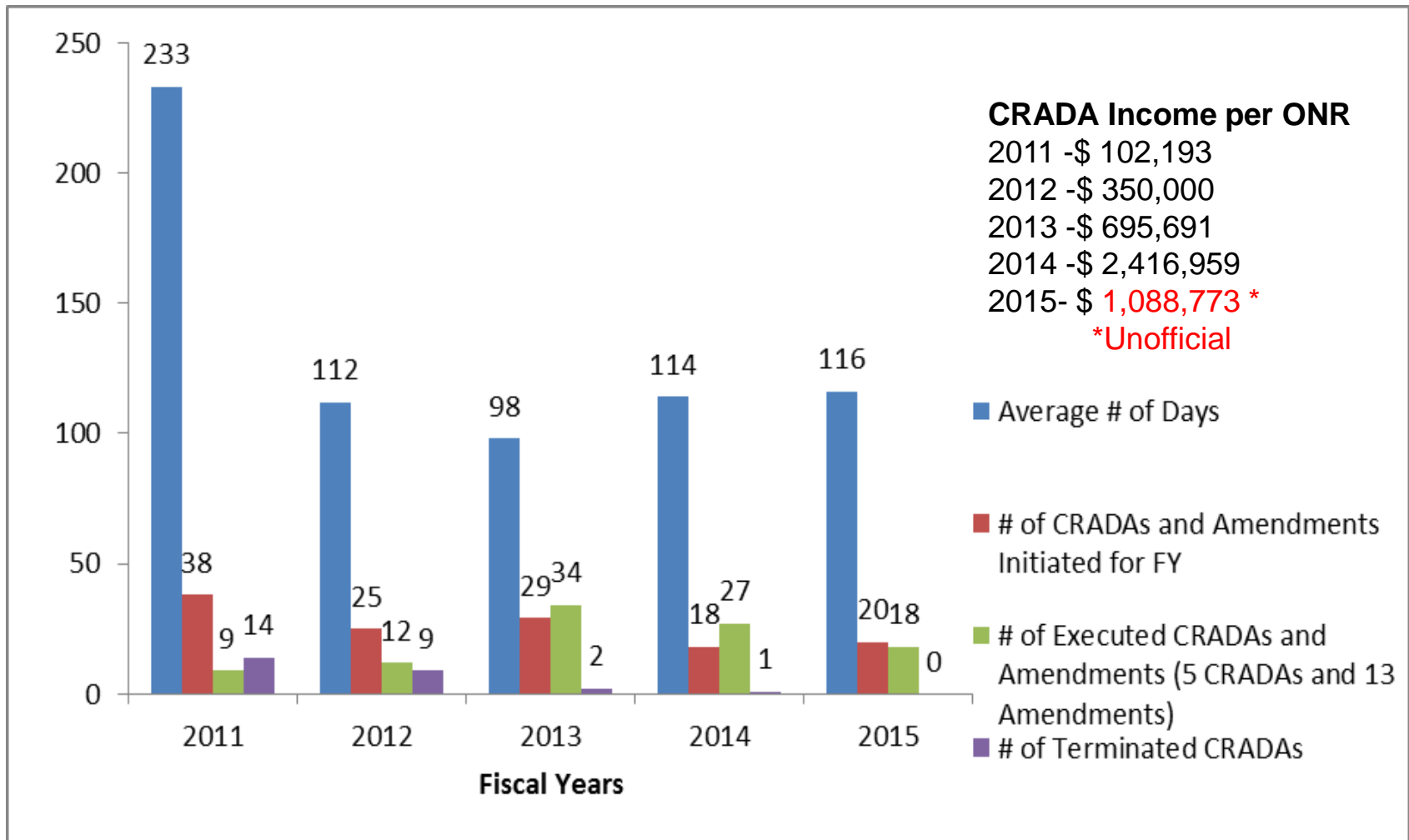
# Average Process Time IRB Meeting Minutes FY 2015



Red line = goal 14 days  
IRBNet system ceased 28 Sept



# Cooperative Research and Development Agreements (CRADAs) and Amendments 2011-2015





# 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 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