

# Human Research Protection Program



Office of the Under Secretary of Defense (Personnel and Readiness)

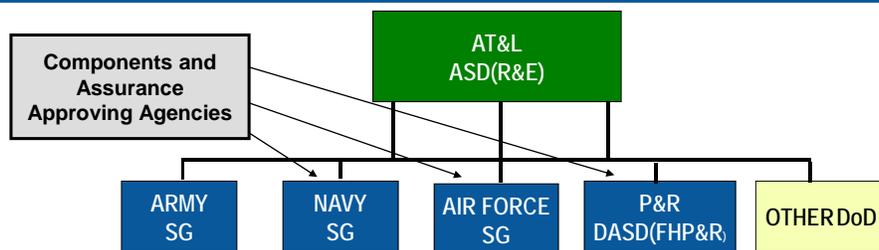
Force Health Protection & Readiness Programs,  
Office of the Assistant Secretary of Defense (Health Affairs)

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## DoD Research Oversight



**AT&L:** Under Secretary of Defense for Acquisition, Technology and Logistics

**ASD(R&E):** Assistant Secretary of Defense for Research and Engineering

**P&R:** Under Secretary of Defense for Personnel and Readiness

**DASD(FHP&R):** Deputy ASD for Force Health Protection and Readiness

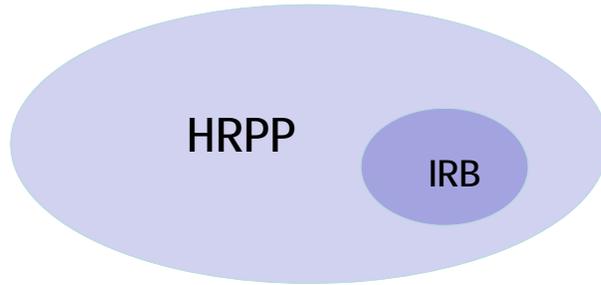
**SG:** Surgeon General

**Assurance:** Written agreement from research institutions assuring research will be conducted according to the rules and guidelines



## Overview of Human Research Protection Program (HRPP)

- A Human Research Protection Program (HRPP) is an integrated process where all the elements of an institution supporting or conducting human research work together to protect the rights and welfare of human subjects



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## Elements of DoD HRPP



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## DoD HRPP: Human Subjects Research Protocol Numbers

### FY2010 Open Human Subjects Research Protocols

| DoD Component    | Intramural                      |                             | Extramural                      |                             |
|------------------|---------------------------------|-----------------------------|---------------------------------|-----------------------------|
|                  | Intramural non-exempt protocols | Intramural exempt protocols | Extramural non-exempt protocols | Extramural exempt protocols |
| Army             | 2002                            | 484                         | 2536                            | 273                         |
| Navy             | 1414                            | 372                         | 113                             | 9                           |
| AF               | 520                             | unknown                     | 40                              | 10                          |
| USD(P&R)         | 400                             | 230                         | 150                             | 50                          |
| DARPA            | 0                               | 0                           | 64                              | 5                           |
| DTRA             | 0                               | 0                           | 2                               | 0                           |
| USSOCOM          | 0                               | 0                           | 5                               | 0                           |
| USCENTCOM        | 49                              | 9                           | 0                               | 0                           |
| NSA              | 0                               | 0                           | 20                              | 5                           |
| NGA              | 0                               | 0                           | 5                               | 0                           |
| SOLIC            | 0                               | 0                           | 10                              | unknown                     |
| USJFCOM          | 0                               | 0                           | 5                               | unknown                     |
| <b>DoD Total</b> | <b>4368</b>                     | <b>1095</b>                 | <b>2950</b>                     | <b>352</b>                  |



### HRPP Process Improvement Initiatives: Past, Present and Future



## DoD HRPP: Issues

- Stove-piped regulatory compliance oversight structure
- DoD unique requirements
  - Collaborative research with non-DoD or non-Federal institutions challenging
- Component unique requirements and processes
  - Collaborative research within DoD can be challenging
  - E.g., training requirement, templates
- Compliance responsibility is institution centric
  - Collaboration often means multiple IRB reviews

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## HRPP Harmonization: Past

- Templates
  - Assurance acceptable to all components
- Agreements
  - Institutional Agreements for IRB review
- Training requirements
  - Role based common requirements across DoD
- Topic specific central IRB pilot

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## Central IRB: Infectious Disease Clinical Research Program (ID CRP)

- **Agreement between Surgeons General and DASD(FHP&R) for centralized process for infectious disease research**
  - Central IRB (at Uniformed Services University) with representatives from sites
  - Central administrative support with local research coordinators
  - HQ oversight mechanism for visibility and coordination across Services
- **Highly successful in overcoming stove-piped regulatory system**
  - ID CRP implementing research now that would have been impossible before
- **Success is due to the program, not the central IRB alone**
- **Defense Centers of Excellence are currently chairing a working group to examine feasibility of expanding the concept to other research areas**

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## Harmonization Present: e-Research Management Tool

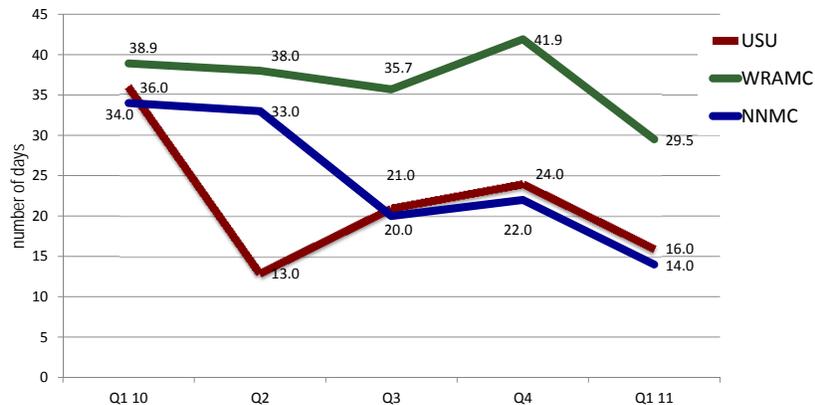
- **IRBNet Demonstration project: National Capital Area FY 08-09**
  - WRAMC, NNMC, MGMC and USUHS
  - DDEAMC and NMC-SD joined
- **FY10 gained ASD(HA) support**
  - Expanded to 19 institutions in FY11
- **Force Health Protection Integrating Council approved central governance plan and implementation MHS-wide in July 2011**
  - Central program management office at USU
  - Funded proportionally by users
- **Business Intelligence (BI) capability under development**

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## e-Research Management Tool: Efficiencies

### DMRN Expedited Review Cycle Time Improvement: 2010-2011



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## e-Research Management Tool: Value Added

- **IRB process improvements**
  - Every step in the process can be measured
- **Animal protocols (IACUC)**
- **Publication clearance**
  - E.g., processing time reduced from 30 to 14 days
- **Any committee process requiring coordination**
- **HQ level data mining**
  - Enterprise-wide process harmonization
  - Real time data access

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## Harmonization Future: DoD HRPP Strategic Vision

- **Reduce stove-piped process**
  - Support researchers and foster translational research
  - Regional home administrative infrastructure concept approved by the Senior Military Medical Advisory Committee (SMMAC) in March 2011
- **Expand central IRB concept**
  - Initiative approved by the SMMAC in March 2011
- **Implement electronic research management tool**
  - Measure and improve processes
  - Harmonize templates and processes MHS-wide
  - Expand DoD-wide

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## Protecting Human Subjects – A Shared Responsibility



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