



HEALTH AFFAIRS

## OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, DC 20301-1200

### MEMORANDUM FOR RECORD

SUBJECT: Integration of Electronic Research Management Systems

As a result of ongoing fiscal concerns and acute budgetary pressures within the Department of Defense (DoD), on May 17, 2012, Dr. George Peach Taylor, Deputy Assistant Secretary of Defense for Force Health Protection and Readiness (DASD(FHP&R)), and Rear Admiral (RADM) Michael Mittelman, Deputy Surgeon General of the Navy, met to resolve differences between the FHP&R electronic management system, known as the electronic Institutional Review Board (eIRB), and the Navy IRB system, known as the Protections in Research Oversight Management Information System (PROMIS). Both systems were described in terms of their individual strengths and weaknesses. eIRB offers superior workflow management for IRBs and Institutional Animal Care and Use Committees (IACUCs) while PROMIS provides superior monitoring and oversight capability as well as metrics capture and reporting—all important attributes to IRB management. Dr. Taylor and RADM Mittelman decided that rather than maintain competing systems, the Military Health System (MHS) and Department of the Navy would move towards the creation of a single information technology solution, integrating the best attributes of both systems.

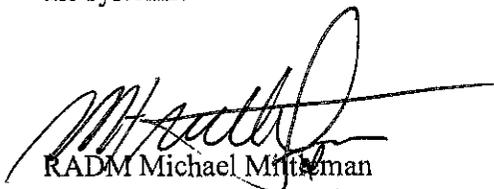
In brief, decisions reached during the meeting were to leverage the strengths of each system to supplement weaknesses and shortcomings on the other:

- Navy will leverage their existing feasibility study with IRBNet and planned funding to implement a bi-directional data sharing between the two systems thereby eliminating double data entry and facilitating adoption of both systems as an integrated workflow;
- The use of eIRB will continue as the preferred system for documenting new protocols at the IRB/IACUC level within MHS, with current funding efforts for eIRB continuing as scheduled;
- PROMIS will focus on and augment capabilities to enhance Command level management, regulatory oversight at multiple levels, provide metrics, and other DoD unique processes (e.g., Human Research Protection Official review for contract and grant reviews); and
- Arrive at a single, unified system based on the current PROMIS platform that serves all the needs of the user community (i.e., across DoD) without the need for duplicative data entry.

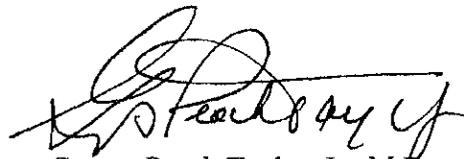
In order to accomplish the above, Health Affairs (HA) and the Navy have agreed to a single user steering committee that will be responsible to the entire user community.

While PROMIS undergoes modification and upgrade to support DoD MHS and non-MHS users alike, MHS IRBs and IACUCs will migrate to eIRB. Non-MHS IRBs may use either system. Using the steering committee, the PROMIS team will start customizing the system to perform headquarter oversight functions for each of the DoD Components. HA will serve as the first non-Navy Headquarters user.

Once the two systems are working together and providing stable efficient IRB and IACUC oversight and management, the Navy will determine the cost and timeline needed to develop a workflow management process that meets the requirements being performed by the eIRB. This proposal should be used to inform future decision-making regarding funding and development of the systems.



RADM Michael Mittelman  
Deputy Surgeon General  
of the Navy



George Peach Taylor, Jr., M.D.  
Deputy Assistant Secretary of Defense  
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