ACHIEVING EXCELLENCE IN DOD HUMAN RESEARCH PROTECTION PROGRAMS:
The Role of the Institutional Official

Using Alternative Models to Achieve Excellence in Your HRPP

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Outline

- What is an HRPP
  - Description of an HRPP
  - Key Elements of an HRPP
- HRPP Models
  - Optimizing Your HRPP Using Alternative Models
  - Criteria for Selecting a Model
- Conclusion

Description of an HRPP

- An integrated process where all the elements of an institution supporting or conducting human subject research work together to protect the rights and welfare of the subjects
- A collaborative effort of all who participate in the conduct, support, review, approval, or facilitation of human subject research
- The HRPP is not an office, committee, or an assurance

Goals of an HRPP

- Excellent policies and procedures that protect the rights and welfare of subjects
- Excellent quality of research by consistently applying high standards and practices
- Demonstrate the strengths of your institution's commitment to the protection of human research subjects

Key Roles in an HRPP

- Institutional Official (IO)
- Investigators and research team
- Division/Department Head
- Institutional Review Board (IRB) members
- Human Protection Administrator (HPA)
- IRB Office
- IO Advisors (legal, comptroller, DoD Component headquarters office, etc.)
- Contracting Office
- Privacy Office
- Research Integrity Office
- Security Review Office

Key Elements of an HRPP

- Institutional commitment to ethical research
- Education and training of all HRPP personnel
- Comprehensive review of research
- Scientific review (SR) of research protocols
- Managing conflict of interest
- Communication within and outside of the HRPP
- Monitoring and oversight of the research
- Recordkeeping and reporting
- Compliance with policies
- Continuous quality improvement of the HRPP

Key Elements of an HRPP (cont.)

- Institutional commitment to ethical research
  - Sufficient and skilled resources are necessary to support research in compliance with DoDD 3216.02
  - IO has the responsibility to ensure the proposed research has the required resources and is ethically conducted
- Education and training of all HRPP personnel
  - All HRPP personnel must understand their role in the HRPP and proficiently execute their responsibilities
  - IO has the responsibility to establish a comprehensive policy to ensure all personnel are competent

Key Elements of an HRPP (cont.)

- Comprehensive review of research
  - Research shall be approved and periodically reviewed in accordance with DoDD 3216.02
  - IO shall ensure that policies and procedures are followed and that personnel reviewing the research are valued for their contributions
- Scientific review of research protocols
  - Criteria-based review of a proposal to ensure that scientific knowledge or practice could be advanced
  - IO responsibility to ensure that policies and procedures require subject matter experts conduct a scientific review and that the IRB consider the scientific review

Key Elements of an HRPP (cont.)

- Managing conflict of interest
  - Addressing improper influence by an individual or the institution and take appropriate action
  - IO establishes policies to ensure possible conflicts with each research study are identified and creates a culture to appropriately address the conflicts
- Communication within and outside of the HRPP
  - Conveying information appropriately and in a timely manner to others
  - IO should ensure written policies and procedures are thorough and should incorporate protecting subjects into all the organization's actions

Key Elements of an HRPP (cont.)

- Monitoring and oversight of the research
  - Ensuring the conduct of the research is compliant with all elements of the HRPP, especially meaningful continuing review, adverse events, and new research
  - IO is responsible for ensuring the research departments and IRB office are conducting appropriate oversight
- Recordkeeping and reporting
  - Proof that the policies and procedures of the HRPP have been met
  - IO is responsible for ensuring documentation is complete and federal officials are appropriately informed

Key Elements of an HRPP (cont.)

- Compliance with policies
  - Internal evaluation of HRPP for compliance
  - IO is responsible for maintaining a process to evaluate compliance of the HRPP and take appropriate action
- Continuous quality improvement of the HRPP
  - Criteria-based program to strengthen the HRPP
  - IO is responsible for continuously seeking to identify short comings and provide guidance and resources to improve the HRPP

HRPP Models

Optimizing Your HRPP Using Alternative Models

- Alternative models exist to provide institutions' with key HRPP functions that may not reside within the institution
- Alternative models involve shared responsibilities and authorities
- Use of an alternative model can enhance an institution's HRPP performance
- An evaluation of the benefits and limitations of alternative models must precede choice of a model
- Alternative models can be enduring structures or situationally implemented

Common Models

- Institution relies upon its own internal IRB, scientific review, etc.
- Institution relies upon the IRB, scientific review, etc. of another institutions
  - For review of some protocols
  - For all protocols
- Institution relies upon a central IRB for review of specialty protocols
- Institution is part of group of institutions that form an IRB
- Institution uses some combination of options for IRB functions

Institution Relies Upon Its Own Internal IRB

U.S Air Force Academy (USAFA) relies on USAFA IRB

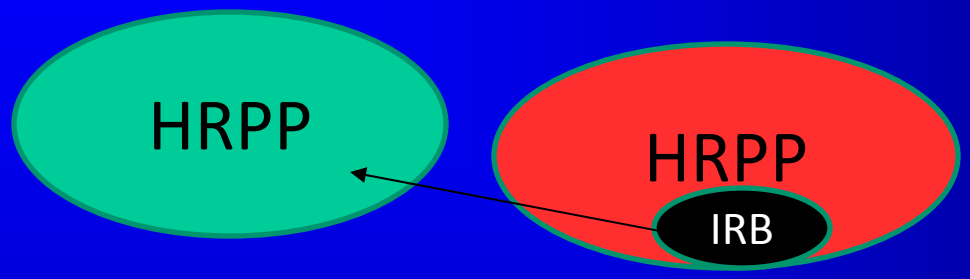
PRO

- Sufficient volume of research
- Able to fund adequate resources for IRB support operations
- Sufficient depth in SMEs to preclude COI for IRB members
- Desire to have IRB resources readily available and on site to staff

CON

- Small volume of research involving humans subjects
- Funding constraints
- Insufficient depth in SMEs to preclude COI for IRB members
- Geographic location limits likelihood of hiring HRP professionals

Institution Relies Upon the IRB of Another Institution



Naval Surface Warfare Center, Panama City, FL, relies on Naval Experimental Diving Unit IRB, Panama City

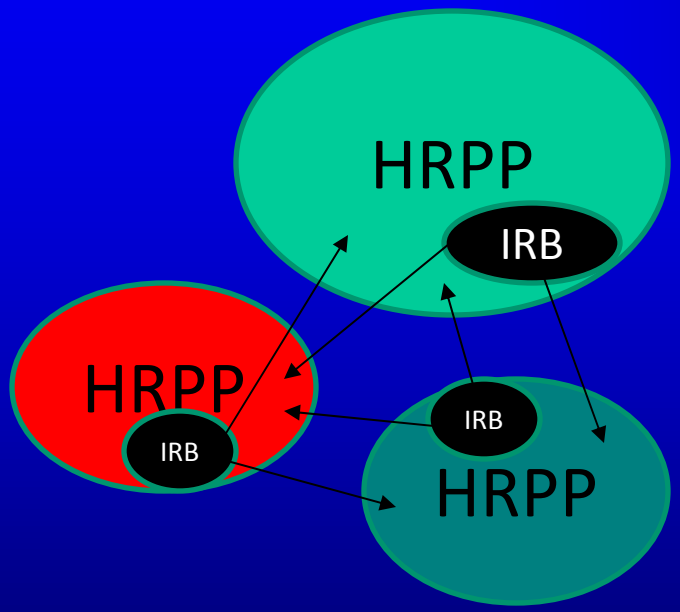
PRO

- Access to experienced, expert IRB
- Leveraging an existing infrastructure – decreased cost
- Limits potential for COI
- Larger volume review increases expertise of reviewers

CON

- Lack of knowledge of your institutional culture
- IRB resources not readily available for "drop in" or face-to-face consults
- IRB SME strength may not mirror your institution's
- May lose IRB "responsiveness" to your time sensitive needs
- IRB not part of your institution's culture

Institutions Relies Upon One Another's IRBs When Collaborating



US Army Medical Research and Materiel Command Laboratories/Institutes rely upon one another's IRBs- "reciprocity"

PRO

- Limits the number of IRBs (limits redundancy and turbulence)
- Eliminates the need for individual agreements on a case by case basis
- Promotes collaboration

CON

- Requires an agreement outlining shared responsibilities
- Requires policy outlining use criteria
- Potential for IRB shopping

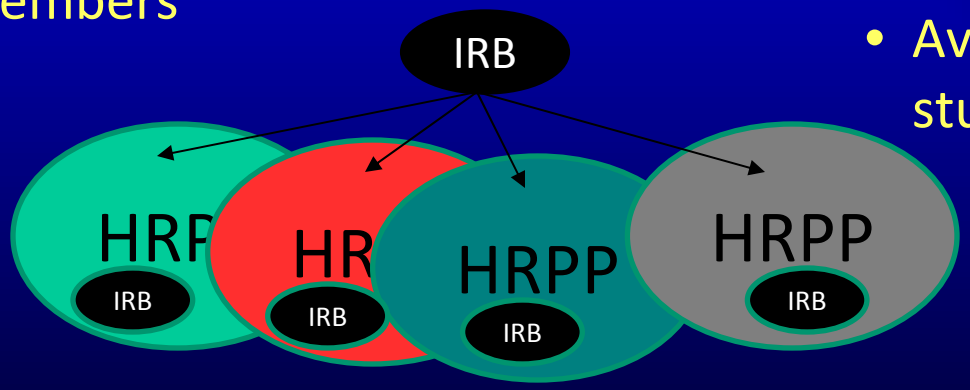
Institution Relies Upon a Central IRB for Review of Specialty Protocols

PRO

- IRB members possess SME
- Economy of review – decreased time, redundancy, turbulence
- Site costs are limited
- Limited potential for COI for IRB members

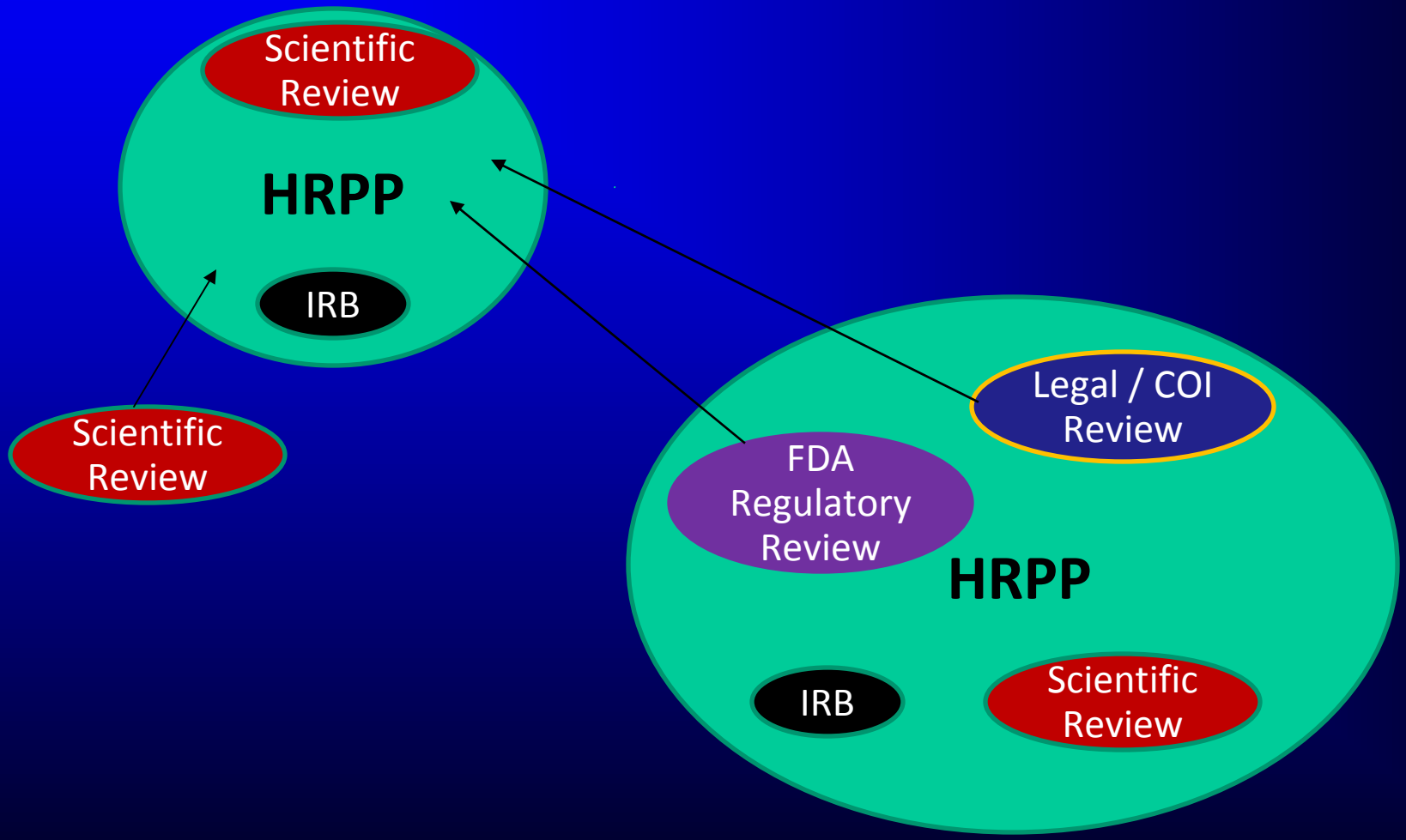
CON

- Central IRB resources must be fully resourced
- Lack of knowledge of your institutional culture
- Limited options for protocol modification
- Available for small number of studies



Army, Navy and Air Force Medical Centers rely on the Infectious Disease Clinical Research Program (IDCRP) IRB for IDCRP studies conducted at these sites. IDCRP funded by NIH.

Alternative Models for Other HRPP Functions



Important Considerations When Deciding Upon Your Optimal HRPP Model

In-House

- Funding to ensure adequate human resources, space, equipment, training, etc.
- Sufficient in-house workload to support investment
- Expert human subjects protection resources readily available
- Density of SMEs to avoid conflicts of interest in IRB members
- Desire for this process to be local for a variety of reasons (culture, responsiveness, availability, etc.)

Shared Function

- Access to independent review
- Access to expert, efficient, and adequately resourced human research protection regulatory review process (e.g., legal, SR, FDA regulatory)
- Infrastructure costs borne by another institution
- Larger volume review increases expertise of reviewers
- Higher quality operation than could be supported locally

Concerns Regarding Use of Shared Models

Risk

- Lack of familiarity with institution, scientific concerns
- Knowledge of local context
- Lack of responsiveness, ready availability
- Real-time protocol writing consultation availability
- Visibility of study records, notification of problem situations and approval status
- Confusion regarding who is responsible for what activities

Mitigation

- Selection of IRB with appropriate expertise and experience
- Site visits by IRB or other function supporting institution, provision of local context information in protocol packets, membership on the IRB
- Specify terms of working relationship in MOA (e.g., completeness of submission and feedback, turn around time, volume of protocols)
- Specify mechanisms for record sharing and reporting
- FULLY Specified MOA outlining each party's responsibilities

Where Do You Go for Assistance or Information?

- Start with your Component's HQ POC for human research protection programs
  - Knowledge of resources within and outside of the Component
  - Knowledge of the strengths and weaknesses of Component IRBs
  - Has your success as a priority
- ODDR&E is also a resource for DoD policy and process and for information within and outside of the DoD Components

Conclusion

- You are responsible for optimizing the performance of your institution's HRPP
- HRPPs consists of several key functional areas
- You must provide or obtain sufficient and skilled resources for your HRPP
- You may choose from a variety of alternative HRPP models in your quest to optimize and improve the performance of your institution's HRPP
- Your Component HQ Human Research Protection Office can assist you in learning more about your options in employing alternative models