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## A Conversation with the Department of Defense (DoD)

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**Human Research Protection Program**

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**Under Secretary of Defense  
Personnel and Readiness**

**Assistant Secretary of Defense  
Special Operations and Low Intensity Conflict**



# Proposed Defense Federal Acquisition Regulation Supplement (DFARS) Clause

- Published in the Federal Register on October 27, 2008, for public comment  
(<http://edocket.access.gpo.gov/2008/E8-25562.htm>)
- Comment period closed December 26, 2008
- Imposes no new rules
- Only identifies the existing requirements in the Common Rule and DoD policy



# Outline

- Three Basic Requirements of the Common Rule
  - Determinations
  - Federal Assurance
  - IRB Actions
- DoD Unique Requirements – Some Examples
- The Secret to Success
- Conclusion



# Three Basic Requirements: #1 Determinations

- Three Questions:
  1. Is the activity research?
  2. Does the research involve a human subject?
  3. Is the human subject research (HSR) meet one of the exemption criteria?
- Institutional policy should specify who makes these determinations
- DoD sponsor, usually, will need to concur with the determinations before allowing the activity to start



# Three Basic Requirements:

## #2 Federal Assurance

- The institution must have a federal assurance acceptable to the sponsor appropriate for the research in question...
- DoD sponsor will:
  - Work with the institution to approve a DoD Assurance
  - Recommend the institution obtain an FWA with DHHS/OHRP
  - Accept an existing FWA
- Additional available tools
  - Researchers not “covered” under an assurance can be covered by an assured institution using an **Individual Investigator Agreement** Form
  - **Institutional Agreement for External IRB Review**
  - Existing FWA may be augmented with a **DoD Addendum**



# DoD Addendum to the DHHS Assurance (FWA)

- One of many methods that can be used to inform institutions (Institutional Officials and IRB Chairs) about DoD requirements (not listed in their DHHS FWA)
- Used for institutions with approved federal assurances from another federal agency
- Accepts the basic principles and procedures accepted by DHHS/OHRP
- DoD is instituting a single DoD Addendum that can be accepted DoD-wide
- Not a required DoD form



# Three Basic Requirements:

## #3 IRB Actions

- IRB Review and Approval
  - Institution submits to DoD Component Sponsor documentation of IRB approval, risk level, and expiration date
  - DoD may request additional documentation to verify compliance with federal and DoD policies (e.g., minutes related to the research and scientific review)
- IRB Continuing Review
- Same notifications as to OHRP (e.g., suspensions non-compliance, unanticipated problems)



# Collaborating

- Collaborating institutions are encouraged to use economies for IRB review
  - Local context can be provided to the IRB
  - Performing institutions remain responsible for oversight and execution of research conducted by their investigators
- Research recruiting DoD personnel or using DoD data or specimens may require DoD review for human research protection requirements (this does not mean DoD IRB review)
- Institutional Agreement for IRB Review is required if a DoD IRB is the IRB for the study



# DoD Unique Requirements – Some Examples

- DoD Directive 3216.02
- 10 United States Code 980 limitations on waiver of informed consent
- DoD requires documentation of exempt determinations, including the justification or rationale
- DoD applies protections in Common Rule Subparts B-D
  - Director of Defense Research and Engineering approves DoD-sponsored research when “Secretary approval” is required
- Research greater than minimal risk requires a *Medical Monitor*



# DoD Unique Requirements – Some Examples (cont.)

- Risks unique to DoD employees not present for civilians:
  - Participation in drug studies (prescription or non) can jeopardize the deployability of certain personnel
  - Personal conduct standards for DoD personnel holding a security clearance are high; problems can cause a loss of clearance and jeopardize their job
  - Duty to Report certain actions such as substance abuse, violence, sexual conduct
  - Because of the unique population and demographics, anonymity cannot always be afforded
- Presence of these unique risks can result in a protocol
  - Not meeting the exempt criteria or
  - Needing a *research* monitor



# The Secret to Success

- **Communicate, communicate, communicate!**
  - With the right people
    - DoD Component Headquarters Staff
    - The technical contract monitor
    - Research collaborators
  - At the right time
    - During research proposal development
  - About the right topic
    - Assurance requirements
    - Other research protocol requirements



# Conclusion

- DoD has the same basic requirements as DHHS and the other Common Rule Signatories
- Because of the DoD culture, organizational structure, and population, DoD has additional requirements to protect research subjects
- Let's work together so we can get it right the first time



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**The DoD policies and links to the DoD  
Components' policies can be found at  
<http://www.dtic.mil/biosys/org/hu.html>**



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- **Thank you....**
- **Questions?**