



Similarities & Differences in Interpreting & Applying Federal Regulations: Does the Funding Source Matter?

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The Common Rule?

- Even though the Common Rule is the same for the federal agencies, each agency follows different procedures to comply with the terms of the Common Rule
 - There are unique policies and procedures to implement the Common Rule regarding approving assurances and ensuring compliance for their sponsored research
 - Agency policies and procedures reflect the characteristics of the agency (e.g., leadership, culture, risk tolerance, mission, etc.)



What is Common?

- Agencies hold institutions accountable for the same basic requirements stated in the Common Rule
- The Common Rule identifies “what” the federal sponsor and engaged institution are required to do
- Agencies’ implementing guidance often identifies “how “ the Common Rule requirements will be met



DoD Implementation of the Common Rule

- DoD implements the Common Rule in DoD Directive 3216.02
- The DoD Component sponsor must notify the institution that it accepts the institution's:
 - “Not human subject research” or exempt determination
 - Federal assurance
 - IRB approval of the research (at initial review and continuing review)
- Director of Defense Research and Engineering approves DoD-sponsored research when “Secretary approval” is required



DoD Implementation of the Common Rule (cont.)

- Federal Assurance
 - FWA identifies Common Rule and DHHS requirements
 - DoD sponsor insures the institution is in compliance with the Common Rule and DoDD 3216.02
 - A DoD Assurance
 - A DoD Addendum to an existing federal assurance
 - Close communication and coordination plus an existing federal assurance
 - “Individual Investigator Agreement”



DoD Implementation of the Common Rule (cont.)

- IRB

- Membership and responsibilities are common
- Agreement between the engaged institution and an external IRB is common
- DoD sponsor insures the IRB review was compliant with the Common Rule and DoDD 3216.02
 - Accepting a letter from the IRB stating approval, level of risk, and continuing review date
 - May review the IRB process that led to the approval and determinations of risk and of the continuing review date



Some Unique DoD Requirements

- 10 United States Code 980 limitations on waiving informed consent
- Compliance with the Subparts B, C, and D
- Research greater than minimal risk requires a “Research Monitor”
- Many considerations in using DoD subjects
 - DoD review when using DoD personnel as subjects
 - Unique risks can result in a protocol not meeting the exempt criteria or needing a research monitor
 - DoD approval required for surveys of DoD personnel
- Session D3, “A Conversation with the DoD,” will fully discuss unique DoD requirements (Tuesday at 4:30 pm) 7



Conclusion

- DoD follows the same regulatory principles followed by DHHS and the other Common Rule Signatories
- Because of the DoD culture, organizational structure, and population, DoD has some unique implementing procedures and additional requirements to protect research subjects
- We want to work with you to get it right the first time
- The Secret to Success is to communicate early and often



Contact Information

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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>