



Taking an Active Role – Research Investigators

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Session Outline

- 1320 - 1335 Introduction
- 1335 - 1400 DoD Policy Update
 - Patty Decot
- 1400 – 1615* Keys to Success – A One-Way Trip Through the IRB
 - Colonel Scott Miller
 - Dr. Kathy O'Donnell
- 1630 Adjourn

* a 15 minute break will be taken about 1500



DoD Policy Update Outline

- “Harmonization Documents”
- Changes to DoD Directive 3216.02
- 10 USC 980 – Fact or Fiction
- Upcoming Defense Federal Acquisition Regulation Supplement (DFARS) Clause



Five “Harmonization Documents”

1. DoD Assurances for DoD Institutions
2. DoD Assurances for non-DoD Institutions
3. DoD Addendum to the DHHS Federal Wide Assurance (FWA)
4. DoD Individual Investigator Agreement
5. DoD Agreement for IRB Review



Three Options to Ensure Collaborators Have a Federal Assurance

- DHHS/OHRP Approved FWA
 - DoD Component may or may not use a DoD Addendum to the FWA
- DoD Assurance for non-DoD Institutions
 - Limited to DoD-sponsored research and probably a single DoD Component
 - Approved at the HQ Component Level
- Individual Investigator Agreement
 - Individual researchers can be brought under your institution's DoD assurance
 - Can be limited to the single study and approved at the institutional level



Three Options to Ensure Collaborators Have a Federal Assurance (cont.)

- “Pass through” contractors do not have to have an assurance if the contracts are written so that:
 - the engaged performer is required to comply with all federal policies;
 - DoD has the authority to approve research before it begins; and
 - DoD has access to all relevant documents for oversight



Economies when Collaborating

- IRB Staff Session is focusing on alternative models of IRB review
 - DoD Agreement for IRB Review specifies the responsibilities of the IO/institution and of the IRB
 - DoD Directive allows DoD institutions to rely on only federal IRBs
- Examples of other economies that can be shared
 - Scientific Review
 - Consultants to Investigators in preparing protocol and consent documents
 - Consultants to the IRB(s)
 - Subject/community input to Investigators & IRB(s)



Proposed Changes to DoDD 3216.02

- Less focused on medical research and more focused on non-specific human subject research
- Replace “Medical Monitor” with “Research Monitor”
- Update section about vulnerable populations
 - Clearly allow pregnant women to participate in survey research
 - Allow Heads of Components (e.g., IOs) to use their discretion to apply Subpart C criteria to subjects who subsequently become prisoners



Proposed Changes to DoDD 3216.02 (cont.)

- Address what the differences between DoD-supported and when DoD institutions are engaged in research, for example
 - Sharing information or data
 - Providing subjects or information to recruit subjects
 - Providing facilities or equipment
- Permit reasonable reliance on non-federal IRBs when collaborating
- Clearly identify which requirements in the Directive apply to Contractors
- Standardization of records retention



10 United States Code 980

Limitation on use of humans as experimental subjects

(a) Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless -

(1) the informed consent of the subject is obtained in advance; or

(2) in the case of research intended to be beneficial to the subject, the informed consent of the subject or a legal representative of the subject is obtained in advance.

(b) The Secretary of Defense may waive the prohibition in this section with respect to a specific research project to advance the development of a medical product necessary to the armed forces if the research project may directly benefit the subject and is carried out in accordance with all other applicable laws.



10 United States Code 980

Fact or Fiction?

The requirements of 10 USC 980 are unique to DoD (i.e., no other federal agency has these requirements).



10 United States Code 980

Fact.

The requirements of 10 USC 980 are unique to DoD.



10 United States Code 980

Fact or Fiction?

10 USC 980 applies only to human subjects involved in medical (clinical) experiments.



10 United States Code 980

Fiction.

10 USC 980 applies to all “research involving a human being as an experimental subject.”

“Experimental subject” is not defined in 10 USC 980, but it is defined in DoDD 3216.02, E2.1.3 as research involving “an intervention or an interaction with a human being for the primary purpose obtaining data regarding the effect of the intervention or interaction.”



10 United States Code 980

Fact or Fiction?

10 USC 980 does not apply to research that meets the exemption criteria in 32 CFR 219.101(b) (i.e., if the research is exempt from the Common Rule, then 10 USC 980 does not apply).



10 United States Code 980

Fact.

10 USC 980 does not apply to research that meets the exemption criteria in 32 CFR 219.101(b).



10 United States Code 980

Fact or Fiction?

10 USC 980 does apply to minimal risk research and does not allow altering the elements of informed consent or waiving the requirement to obtain informed consent as permitted under 32 CFR 219.116(c).



10 United States Code 980

Fact and Fiction.

10 USC 980 does apply to minimal risk research using experimental subjects. 10 USC 980 effectively eliminates the option to waive informed consent but is silent on the specific elements of informed consent.



10 United States Code 980

Fact or Fiction?

Since 10 USC 980 does not define “research intended to be beneficial to the subject”, the phrase can be broadly interpreted to mean beneficial to a class of persons represented by the subject and not just to the actual subject.



10 United States Code 980

Fiction.

10 USC 980 does not define “research intended to be beneficial to the subject”; however, the requirement must be interpreted that the research is intended to benefit the actual subject.



10 United States Code 980

Fact or Fiction?

10 USC 980 requires a subject's participation to result in direct benefit to the subject so placebo controlled studies are not permissible if the subject can not give consent.



10 United States Code 980

Fiction.

10 USC 980 does not prevent placebo controlled studies. There are ways to design the study that include the use of placebos and can provide direct benefit to the subjects.



10 United States Code 980

Fact or Fiction?

SECDEF has delegated the waiver authority under 10 USC 980 to the Heads of the DoD Components.



10 United States Code 980

Fact.

SECDEF has delegated the waiver authority under 10 USC 980 to the Heads of the DoD Components.



Upcoming DFARS Clause

- Defense Federal Acquisition Regulation Supplement (DFARS)
- Identifies the Common Rule and DoD requirements
- Before initiating research, must be notified by the DoD Component that it accepts the institution's:
 - Exempt determination
 - Federal assurance
 - IRB approval



The Secret to Achieving Excellence

Communicate, communicate, communicate!

- With the right people
 - DoD Component HQ Staff & IRB Members and Staff
 - The Contracting Officer & technical contract monitor
 - Research collaborators & Sponsors
- At the right time
 - Early! During the proposal & protocol development
- About the right topic
 - Common Rule, DoDD 3216.02, and your DoD Component regulations and requirements
 - Assurance requirements & other agreements
 - Research protocol requirements & templates



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>**