



**“A Conversation with the Department of
Defense: So You’re Engaged in Research
with the DoD – Now What?”**

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**Under Secretary of Defense
Personnel and Readiness**

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Outline

- What's Not New and What's New at DoD
- The Very Common Rule
 - Assurances
 - IRB Actions
 - Collaborations
- DoD Unique Requirements – Some Examples
- Vignettes: Applying DoD Policies and Procedures
- Conclusion
- The Secret to Success



What's Not New

- No new DoD policies for DoD-sponsored human research
- DoD policies and procedures have been harmonized
- Harmonized requirements are based in existing regulations (e.g., Common Rule, its subparts, DoD policies)



What's New: 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 Very Common Rule: Assurances

- All parties engaged in the research must be covered under a federally-approved assurance
- Need a federal assurance appropriate for the research
- Institution must receive notification from the DoD Component that their assurance is acceptable before initiating research
- Three basic options to ensure compliance with DoD policies



The Very Common Rule: Assurances (cont.)

- DoD Assurance for non-DoD Institutions
 - Typically used when the institution does not have an existing federally-approved assurance
 - Limited to DoD-sponsored research, and, at the moment, probably a single DoD Component



The Very Common Rule: Assurances (cont.)

- DoD Addendum to the DHHS Assurance (FWA)
 - Used for institutions with approved federal assurances from another DoD component or federal agency
 - Accepts the basic principles and procedures accepted by DHHS/OHRP
 - Identifies DoD policies not listed in the FWA
 - Each DoD Component sponsoring research has the authority to use the Addendum
 - Currently each Addendum is limited to a single DoD Component



The Very Common Rule: Assurances (cont.)

- Existing Federal Assurance + Additional DoD Oversight
 - Accepts the basic principles and procedures of the existing federally-approved assurance
 - Close Cooperation with the DoD Component Sponsor to ensure research is being approved and conducted in accordance with DoD policies and procedures



The Very Common Rule: Assurances (cont.)

- Institutional Agreement for IRB Review
 - Required when the IRB does not “belong” to the institution
 - Identifies the responsibilities of both parties
 - DoD template is similar to the DHHS/OHRP form
 - Becomes a part of the DoD Assurance or the DoD Addendum to the DHHS Assurance
 - Reviewed as part of the process to accept the institution’s assurance (or approve a DoD Assurance)



The Very Common Rule: Assurances (cont.)

- Individual Investigator Agreement
 - Extends the institution's assurance to researchers who do not "belong" to the institution and are not part of another institution with a federally-approved assurance
 - Identifies the responsibilities of both parties
 - May be reviewed as part of the process to accept the institution's assurance (or approve a DoD Assurance)



The Very Common Rule: IRB Actions

- IRB provides initial review and approval
 - Institution submits to DoD Component documentation of IRB approval, risk level, and expiration date
 - DoD may request additional documentation to verify compliance with federal policies (e.g., minutes related to the research and scientific review)
- Institution must receive notification from the DoD Component that the IRB review is acceptable before initiating research



The Very Common Rule: IRB Actions (cont.)

- IRB actions after initial review and approval
 - IRB shall review the research at least annually
 - Must determine appropriate time frame based on the research
 - Must review amendments to approved research
 - Institution shall submit to the DoD Component documentation of IRB continuing review
 - DoD may request additional documentation to verify compliance



The Very Common Rule: IRB Actions (cont.)

- Institution must receive notification from the DoD Component that human research protection requirements continue to be met
- IRB/institution shall ensure the DoD Component is notified of:
 - any suspension or termination of IRB approval of the research
 - any allegation of non-compliance with human research protections and the results of the investigation
 - any unanticipated problems involving risks to subjects or others



The Very Common Rule: 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 enrolling DoD personnel as subjects may require DoD review for human research protection requirements
- Institutional Agreement for IRB Review is required if a DoD IRB is the only IRB of record for the study



DoD Unique Requirements – Some Examples

- 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
- The presence of these unique risks can result in a protocol
 - Not meeting the exempt criteria or
 - Needing a research monitor



Vignette: Sock-it-to-You, Inc.

Sock-it-to-You Inc. has developed a sock that not only stays dry after 24 hours of wear, but also keeps feet toasty warm in the winter and cool in the summer. Currently the socks cost \$20/pair to manufacture. Sock-it-to-You asks the local Military Reserve Unit to wear the socks during their next weekend drill.

The consent form, under compensation, reads:
“As a volunteer, you may keep the pair of socks you wore during the weekend. In addition, you will be paid \$10 for completing the survey after you return home.”



Vignette: Chill Out, Inc.

Chill Out, Inc. has developed a new personal, portable cooling device that will allow the warfighter to comfortably operate in any hot environment even in full battle gear. They want to test the effectiveness of this device during the upcoming Annual Wargame Exercise. Data collection includes participant surveys, physiologic data, weather data, and individual and unit effectiveness.

Chill Out has received the Exercise Director's permission to equip two Red Teams with their device and compare the effectiveness with two Blue Teams, the control group. To inform the subjects of DoD approval, Chill Out wants to give the Teams a letter from the Exercise Director at the recruiting session. Since all the exercise teams will be at the pre-Wargame briefing, Chill Out has asked the Exercise Director to introduce the study and have time during the briefing to recruit the four teams.



Vignette: Mountain Air, Inc.

Military personnel who have physically demanding jobs when working in the high mountains of Afghanistan take several days to adjust to the lack of oxygen at this altitude. Mountain Air, Inc. has a portable altitude chamber (simulates high-altitude environmental conditions) large enough to allow personnel to sleep and exercise inside of their chamber. Mountain Air wants to develop an exercise program that would allow soldiers to spend the 24 hours prior to a mountain excursion in the altitude chamber in order to acclimate to the mountain environment.

Under contract to the DoD, Mountain Air is proposing to collect physiological and survey data on soldiers working in the mountains and on civilian subjects living in their altitude chamber in the US. Mountain Air has received permission from the Commander of the Army unit in Afghanistan to recruit soldiers as subjects. Mountain Air's IRB has approved the research and sent the Commander a letter from the IRB Chair stating their FWA # and that the protocol has been approved.



Vignette: Wonder Drugs, Inc.

Wonder Drugs, Inc. has developed a new drug to reduce the degree of hemorrhage in trauma patients; the drug must be given within one hour of the trauma. Wonder Drug wants to conduct part of the FDA-approved Phase III study in DoD trauma centers. The double-blind, placebo-controlled study will be conducted with minor and adult patients.

The drug/placebo will be administered in addition to the standard of care. If the patient or Legally Authorized Representative (or parent of minors) can not consent within the one-hour time frame, the patient will not be enrolled.



Vignette: Impressive Research Credentials, Inc.

Impressive Research Credentials, Inc. (IRC) has been awarded a contract from the DoD to study Post Traumatic Stress Disorder (PTSD) among wounded warriors returning from combat. IRC develops a survey which will be mailed to potential participants. Some of the questions are sensitive and potentially incriminating, but the surveys are returned directly to the IRC where they are immediately transcribed, the survey is destroyed, and the data are stored in a secure database.

In the consent form, IRC reassures potential participants that they may answer freely because IRC is gathering the data, not the DoD. The consent form concludes with, “Your responses will be kept confidential and the data from this survey will be used for exclusively statistical purposes.”



Vignette:

Anti-Alcoholic Center (AAC)

DoD awards a contract to the Anti-Alcoholic Center (AAC) to gather data for a new program to prevent alcohol abuse in military families with deployed spouses. In conjunction with interviews on drinking, AAC will use its standard surveys:

- The Alcohol Screening Test, which includes questions such as, “Have you ever been in physical fights while drinking?” and “Have you ever been arrested while drinking?”
- A quality of marriage index on issues such as sex and careers
- Psychological screening tools

Subjects will include active duty personnel and their spouses. AAC will collect identifiers to refer subjects in need of follow up (e.g., for treatment of alcohol abuse, depression, or anxiety) to mental health professionals. As per their usual operating procedures, AAC will obtain a Certificate of Confidentiality from NIH to protect subjects from risks related to mandated release of the sensitive information gathered in this research.



Conclusion

- DoD follows many of the same principles followed by DHHS and the other Common Rule Signatories
- Because of the DoD culture, organizational structure, and population, DoD has additional requirements to protect research subjects
- We want to work with you to get it right the first time



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



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