Achieving Excellence in DoD Human Research Protection Programs: The Role of the Institutional Official

An IO's Role in Collaborative, Contracted, and Supported Human Subjects Research

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Federal Policy

- Common Rule applies to "..all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department…" (32 CFR 219.101(a))
- Common Rule addresses cooperative research, "..each institution is responsible for safeguarding the rights and welfare of human subjects…" and "may enter into a joint review arrangement…for avoiding duplication of effort" (32 CFR 219.114)

When the Common Rule Applies

- If you are supporting human subject research, you may not always be conducting (engaged) in human subject research
- If you are engaged in human subject research, you are
  - Supporting human subject research
  - Involved in the conduct of the human subject research by obtaining:
    - Data about the subjects through intervention or interaction with them;
    - Identifiable private information about the subjects; or
    - The informed consent of human subjects for the research

Outline

- Collaborating with Another Institution
- Supporting Research with Funding
- Supporting Research (other than Funding)
- Other Types of Collaboration or Support

Research Collaborations in DoD

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DoD Components with HRPPs

Collaboration within Your Component

- When planning on conducting human subject research at multiple sites, consider
  - Assurances – all institutions engaged in human subjects research need to be covered
  - IRB review - think economy—think **one**
  - Protocol - think economy—think **one,** with site specific addenda
  - Check out the process(es) - ask questions
  - Communicate - up and down chain of command
- Are other written agreements needed?

Be Proactive - Do Your Homework Upfront

Collaboration Across DoD Components

- This is very similar to within a DoD Component with the added responsibility to ensure that the requirements of multiple Components are met
- There are some differences in the way Components meet requirements
- It is often a good idea to work through the Component headquarters offices to understand their requirements
  - Each Component is operating under a different, but similar, Component regulation implementing DoDD 3216.02
  - Deferral of headquarters-level review to a single Component is encouraged

When Engaged in Research, Who is Responsible?

- Some responsibilities can be shared or delegated
  - Scientific review
  - DoD IRB review - DoD institutions may rely on other DoD IRBs
  - Submission for FDA review
  - Agreements - these shared and delegated responsibilities should be established in writing
- Some responsibilities cannot be delegated
  - Assurances - all investigators must be covered
  - Command approval
  - Oversight of the execution of research
  - Training

Advantages to Collaboration

- Multiple sites with access to larger subject pool
- Single review (IRB, scientific, HQ, etc.) provides:
  - Use of the most appropriate experts
  - Faster turnaround
  - Reduced workload for reviewers
  - Less turbulence with multiple and possibly conflicting comments
  - Single and simpler reporting requirements

Research Collaborations with Institutions Outside of the DoD

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Collaborating Outside of DoD: The Check List

- Assurance
  - Ensure all collaborating personnel are covered under a federal assurance
  - Individuals can be covered under an Individual Authorization Agreement
- Reviews (IRB, scientific, etc.) - there are many ways to streamline this process
- Protocol development - there are ways to achieve a single protocol

Collaborating Outside of DoD: The Check List (cont.)

- Oversight of the Research
  - Ensure you know your institution's responsibilities under the terms of your agreement and/or protocol
  - You are responsible for your investigators' actions and for research conducted at your institution
  - Keep the communication open with the other institution from concept to final report of the research protocol

Collaborating Outside of DoD: The Check List (cont.)

- Early Planning
  - Get all IRB offices, IOs, and your Component Headquarters Office involved early to brainstorm efficiencies and prevent delays
  - Call ODDR&E if you need help
  - Communicate up and down and sideways
  - Agreements should be written and identify who is responsible for what

Funding Human Subjects Research: Grants, Contracts and other Agreements

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US Army Medical Research and Materiel Command

DoD Human Subjects Protection Regulations Apply

- 32 CFR 219 or "Common Rule"
  - Applies to research conducted or supported by DoD
- DoDD 3216.02
  - Applies to "research that is supported by a DoD Component through a contract, grant, cooperative agreement, or other arrangement"

Defense Acquisition Regulations

- Defense Acquisition Regulations System, 48 CFR 207, 235, 252; Defense Federal Acquisition Regulation (DFAR) Supplement
- Effective 29 July 2009 to address regulatory requirements for protection of human subjects involved in research
- Requires DoD Component to identify Human Research Protection Official (HRPO) in their Human Research Protection Management Plan responsible for oversight and execution of the requirements in the clause
- Contains clause for use in contracts involving human subjects in research to inform contractors of their responsibilities

Funding Extramural Research: DFAR Clause

- Applies to solicitations and contracts that include or may include research involving human subjects (even if it may be exempt from 32 CFR 219)
- Applies to awards by any DoD Component <u>regardless of mission or funding program element code</u>
- Does <u>not</u> apply to use of cadaver material

DFAR Clause

- Holds contractor responsible for overseeing execution of the research
- Requires prime contractor to include clause in subcontracts
- Allows DoD representatives to independently review and inspect the contractor's research
- Allows DoD representatives to prohibit research that is determined to present unacceptable hazards or is non-compliant

DFAR Clause (cont.)

- The contractor must furnish to the HRPO and the CO:
  - Documentation of an assurance of compliance and IRB approval, or
  - A determination that the human research proposed meets the exemption criteria
- HRPO must approve documents prior to funds being expended on human research activities
- HRPO retains final judgment on what is and is not exempt
- Failure of contractor to comply may result in stop-work order

IO Responsibilities

- Ensure Contracting Officers (COs) and CO Representatives (CORs) are trained
  - If approvals will be required, factor into timeline of deliverables
  - Provide up front guidance to awardees on Component requirements – refer to appropriate HRPO
- Work with Component headquarters to ensure appropriate approvals are in place and current
  - Prior to award
  - Prior to initiation of human subjects research
  - Through lifetime of award
- Stop payments if continuing non-compliance is identified

Helpful Hints

- Solicitations should clearly outline the human research regulatory requirements for applicants
- Include requirements for approval by the HRPO in COR training
- COs and CORs should inform contractors of Component requirements <u>as early as possible</u>
- Small businesses often do not have Assurances and should begin the Assurance application process as soon as it is identified that they will be conducting human subjects research funded by DoD

Helpful Hints (cont.)

- Consider timelines for review and Assurance acceptance and build into Statements of Work (SOWs)
- Consider limitations for short term funding mechanisms (e.g., no human research in phase I of SBIR)
- When multiple institutions are involved, encourage awardees to consider institutional agreements for IRB review. Component HRPO can provide guidance to awardees on acceptable mechanisms to streamline review processes.
- If multi-center, factor coordination and oversight responsibilities, reviews, and data management into budget planning. Ensure adequate personnel (e.g., study coordinator).

Funding other Federal Departments

- You must ensure recipient organization has appropriate oversight mechanism for human subjects research
- If the other Federal Department or Agency is a:
  - Signatory to the Common Rule: Recipient may provide oversight under their own implementing regulations
  - Not a signatory to the Common Rule: You must retain the responsibility to ensure compliance with 32 CFR 219

Economies in Reviews

- DoDD 3216.02 states that "In research undertakings in which more than one DoD Component is involved, the heads of the Components shall determine and jointly assign executive responsibility for Compliance"
- "A DoD Component may delegate headquarters-level research review responsibility to another DoD component for purposes of efficiency and consolidation of functional offices"
- In other words, we can defer to each other to streamline the process for the awardees – and we do!

Supporting Human Subjects Research
(Not Through Grants, Contracts and other Agreements)

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Supporting Research

- You are providing:
  - Your personnel as subjects (or identifiable data)
  - Equipment
  - Facilities
  - Subject matter experts as advisors or consultants
- You are not engaged (for this discussion)
- You do not need an assurance or DoD IRB Review
- 32 CFR 219 and DoDD 3216.02 apply to the research
- Your institution has a responsibility to ensure you are supporting ethical, quality research

Supporting Research: The Check List

- Much like research supported through an agreement (e.g., DFARS requirements)
- Performing institution must have an assurance and the research must be approved by their IRB (i.e., compliance with the Common Rule and DoDD 3216.02)
- When DoD subjects are involved, make sure their rights and welfare are protected (i.e., compliance with DoDD 3216.02)
- A second DoD IRB review is not required

Supporting Research: The Check List (cont.)

- Take care in writing your institution's letter "approving the study"
  - You may state that the study complies with all federal and DoD requirements
  - You may state that the study supports the DoD mission
  - You may allow subjects to participate on duty time
  - You may not encourage participation

Other Types of Collaborative or Supported Human Subjects Research

Students and “Off-site” Employees

- Your employee is a student and wants to conduct job-related research for his/her studies
  - Wants access to employees as subjects
  - Wants time or resources for study
- Employee is assigned to another institution
  - Employee is engaged in the other institution’s research
  - Who’s assurance, who reviews, who oversees the employee and the research?

Summary

- When collaborating
  - Plan the work, and work the plan
  - Look hard for economies and leveraging expertise
- When supporting
  - You are responsible for working with your headquarters office to ensure the engaged institution and research protocol are compliant with DoDD 3216.02
  - You may defer oversight to another DoD Component or agency that is a signatory to the Common Rule
- When in doubt, call your headquarters office

Questions?