

# Research Challenges in the HRPP: Planning for the Unexpected in DOD-Sponsored Research in Institutions outside the DOD

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# Overview

- Expectations of institutions engaged in DOD supported human subjects research
- Who is responsible for the oversight of human subjects research?
- DFAR clause
- What can go wrong?
- Expectations in addressing non-compliance in human subjects research
- DoD-Sponsor considerations

# What is expected in DOD-Sponsored Human Subjects Research (HSR) ?

- Awardee /Grantee/ Contractor institution engaged in HSR holds a current Assurance of Compliance
- Study described in funded proposal will be the study conducted
- DoD-sponsored HSR will be conducted IAW Federal, DoD, Component, state and host national regulatory requirements
- Work will be accomplished within agreed terms of cost, schedule and performance
- Problems will be reported as described in approval letters

# Who, in the DoD, is responsible for oversight of DoD-Sponsored Human Subjects Research?

- DoD institution that funded the awardee – follow the money
- Key DOD persons involved in oversight include:
  - Component Human Research Protection Office (HRPO) responsible for DOD institution funding the study
    - Initial and periodic review
    - Confirm that study is progressing in compliance with regulatory requirements
  - IO of the sponsoring organization
  - Contracting Officer's Representative (COR), Grant Manager, Program Manager
  - Contracting Officer
  - ???
- Methods of oversight vary
- All Components implement the DFAR clause provisions

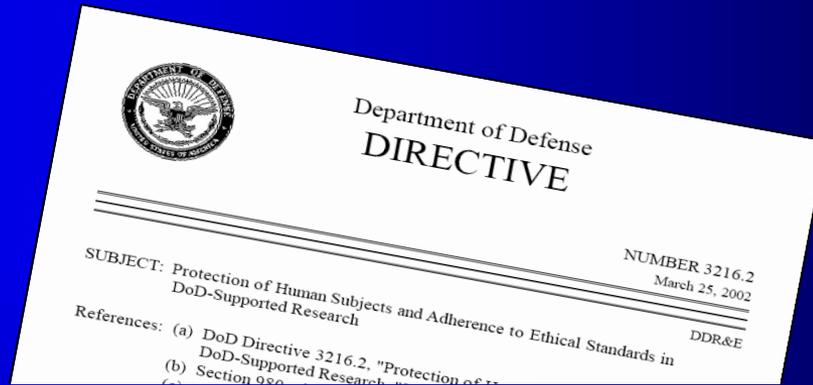
# DFAR Clause

- Holds contractor responsible for local oversight of execution of the research
- Requires 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

# DOD Requirements



## DOD Directive 3216.02

4.10. **Non-compliance.** Issues related to non-compliance with this Directive by any DoD Component, subordinate, or supported activity shall be referred initially to the next higher management echelon to take deliberate action to resolve. All findings of serious non-compliance under this section shall be reported to the Director, Defense Research and Engineering.

# Who at the Awardee Institution is responsible for oversight of DOD-Sponsored Human Subjects Research?

- Institution is the awardee (grant recipient, contractor, etc), not the PI

Institution's  
HRPP

- IO, Office of sponsored programs
- Awardee institution's IRB, compliance offices
- PI and study team

# What Could Go Wrong?

- Allegation of serious and/or continuing PI non-compliance
- Report of deviations in test product storage that invalidates one arm of a clinical trial
- Test article administration potentially associated with catastrophic health event
- Department of Health and Human Services Office of Human Research Protection shuts down all federally funded research at an institution holding a DHHS FWA

# Consequences of Non-Compliance

- Remedial action/Corrective action plan
  - Constructive and Positive
  - Education
  - Supervision
  - Shortened approval period
  - Limited participation in study
  - Additional activities as appropriate
- Suspension
- Termination
- Censure
- Limitations/restrictions to research activities
- Additional sanctions as indicated

# Institutional Actions

Fate of research data/specimens?

- Embargo
- Destruction
- Limit Publications

# Appeal

- The Principal Investigator and/or others involved in the allegations have the right to appeal after receipt of the report
- The appeal should be made to the appropriate office in the institution

# Reporting Findings of Serious/ Continuing Noncompliance

- DOD
    - Sponsor institution and then
    - Component HQ Office
    - DDR&E
  - FDA
  - OHRP
- As indicated

# DoD - Sponsor Considerations

- Accept local HRPP report and corrective action plan ( ideal option and likely if DoD sponsor and Institution have been in close contact during the process)
- Find HRPP actions inadequate and negotiate further actions
- Initiate DoD-lead investigation
- Limit /stop funding
- Censor investigator from serving as an investigator in future component sponsored studies
- Pursue legal remedies as indicated

Questions?