



DDR&E Updates to Human Subject Research Policy

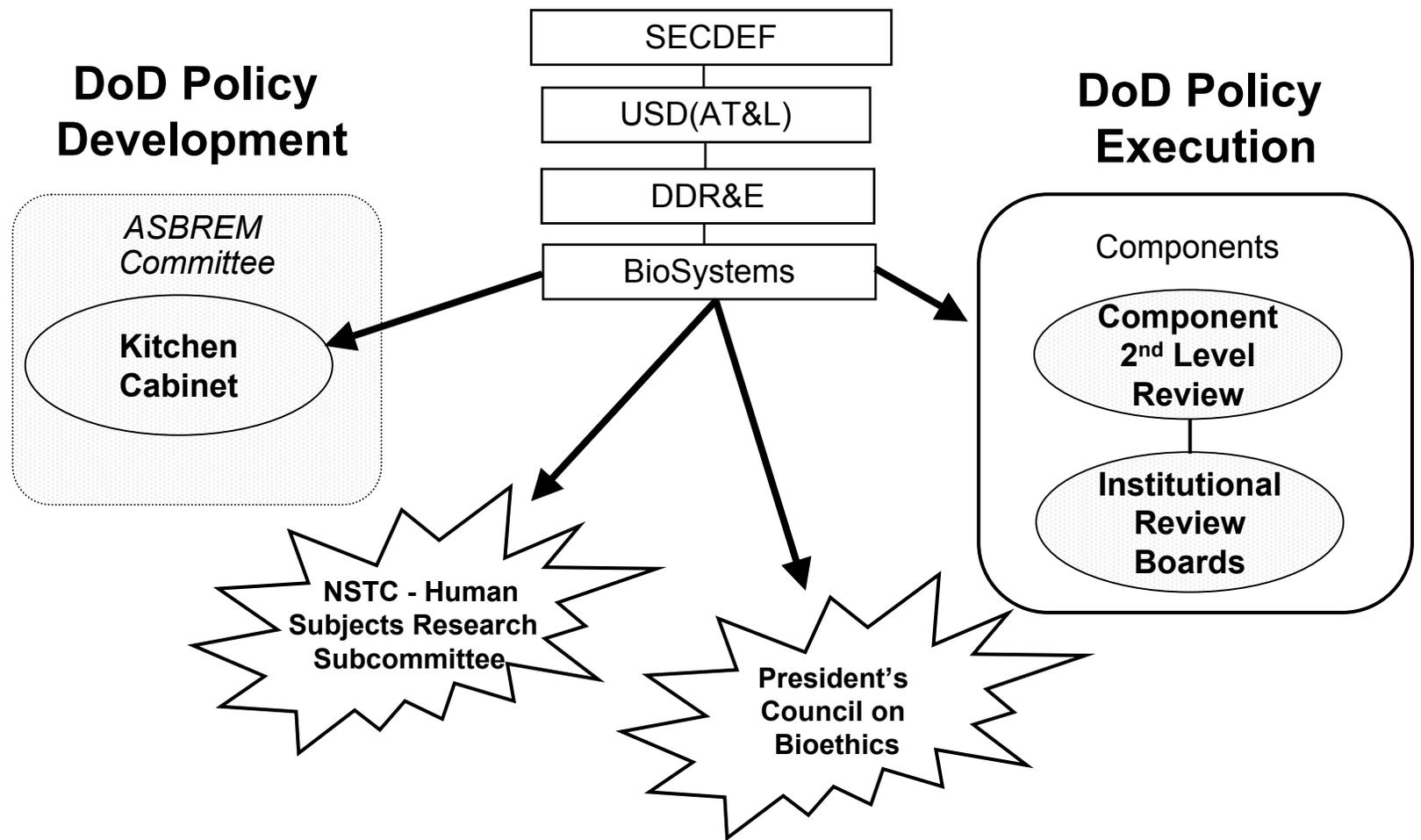
CIRO Meeting
San Antonio, TX
May 7, 2002

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Office of the Deputy Under Secretary of Defense for
Science and Technology
Office of the Director, Defense Research & Engineering



Human Use Policy Oversight Groups



FEDERAL REGULATORY OMISSION



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THAVES 2-6



Kitchen Cabinet Members



- Army
 - COL Jim Lamiell
 - COL Julie Zadinski
- Air Force
 - Lt Col Pat Bradshaw
 - Major Donnamarie Robinson
- DARPA
 - CDR Kurt Henry
- Navy
 - CAPT Harry Tillman
 - CAPT Tim Singer
 - CDR Dave McGowan
- USUHS
 - LTC Kathy Knudson
- ASD(HA)
 - Dr. Sal Cirone



Regulatory Affairs-Human Use Looking Forward--Near Term

- Human Subjects Issues:
 - SECDEF approval of revised DoDD 3216.2
 - Full use of revisions to 10 USC 980 to enhance medical product development
 - Revalidation of approval process for classified research



New DoD Directive 3216.2



- Updates the Directive to reflect 32 CFR 219 (“The Common Rule”)
- New title: “Protection of Human Subjects and Adherence to Ethical Standards in DoD Supported Research”
- Located at the DoD web site for directives:
www.dtic.mil/whs/directives/corres/pdf/d32162_032505/d32162p.pdf



Outline of Changes to DoDD 3216.2

- Enhanced Protection of Research Subjects
- Better Definition of Medical Monitor
- New Policies
- Training



Enhanced Protection of Subjects

- Minimizing command influence on subject recruitment:
 - Individual recruitment: No unit officers or senior NCOs in chain of command present
 - Unit recruitment: Ombudsman with no connection to the unit or to the research must be present
- Subjects are protect from expenses not otherwise provided or reimbursed if primary support of research is from the DoD

THAT'S LIFE , MIKE TWOHY



Close to Home runs Mon., Wed., Fri., and Sat. in this space;
That's Life runs Tue. and Thu.



Medical Monitor

- Better definition of the medical monitor
- Appointed if risk is more than minimal
- Defines who may function as such
- Shall be independent of the research team
- May be assigned responsibilities by the IRB



New Policies

- Modifications to 10 USC 980
- All human subjects research conducted or supported by DoD shall have an assurance of compliance that is acceptable to the funding agency
- DoD Supported International Research:
 - Shall comply with 32 CFR 219
 - Shall comply with all applicable requirements
- Research misconduct requires all components to establish procedures to monitor and review the ethical conduct of research
 - Based on recent OSTP federal policy
 - DoD Instruction has been drafted by DUSD(Lab & BS)



Training

- All DoD personnel involved in human subject research are required to be aware of policies
- Awareness of requirements for protection of subjects commensurate with involvement and compatible with OHRP policies
- Research ethics training incorporated in continuing education program



Classified Research

- OSTP requesting comment from Departments and Agencies on Clinton Memorandum of March 27, 1997 (see Federal Register, Volume 62, Number 92)
- Policy directed the DoD and other Departments and Agencies to amend the Common Rule to cover classified research
- Secretary Cohen endorsed Clinton policy in December 13, 1999 memorandum
- Policy is still in effect but was not incorporated into the revised DoDD 3216.2
- Policy currently undergoing review

“STAY TUNED”



HHS Federal Wide Assurance



You tell me!



Human Use Regulatory Affairs Advisor



- Focus on Training & Education for decision makers above IRB (e.g. COs and OSD Senior Staff)
- Developed as a research effort in Advanced Distributed Learning
- Research product deliverable 4Q/FY02



HSRS Work

- Focus on consistent interpretation of Common Rule and resulting policies
- Determination of Annual Review date
- Non-Biomedical Issues
 - Public Use Data Files
 - Confidentiality
- Decision Tree to help determine if work is human subjects research
- Financial Conflict of Interest
- Policy governing classified research
- Conference to simplify and unify policies and interpretations from Federal offices



Issues in DoD Human Subject Research Policy



- Adverse publicity
 - Ethics
 - Conflict of interest
 - Fraud
 - Genetics research
- HHS's Office of Human Research Protection - revised assurance process (Federal Wide Assurance)
- Institutional Review Board (IRB) accreditation
- Education requirements
 - IRB members
 - DCI staff
 - Scientists/Investigators
 - Approving officials
- National capital region collaboration -- WRAMC, NNMC, MCMC, USU
- HIPAA



Points of Contact

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