Week 2 (6/23): HHS/OHRP Regulations, Definitions, Guidances (Kristin Craun)

45 CFR 46 Subpart A

History of OHRP
Mission of OHRP
46.10: To what does this policy apply?
46.102: Definitions.
46.103: Assuring compliance with this policy--research conducted or supported by any Federal Department or Agency.
46.107: IRB membership.
46.108: IRB functions and operations.
46.109: IRB review of research.
46.110: Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
46.111: Criteria for IRB approval of research.
46.112: Review by institution.
46.113: Suspension or termination of IRB approval of research.
46.114: Cooperative research.
46.115: IRB records.
46.116: General requirements for informed consent.
46.117: Documentation of informed consent.
46.118: Applications and proposals lacking definite plans for involvement of human subjects.
46.119: Research undertaken without the intention of involving human subjects.
46.120: Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
46.122: Use of Federal funds.
46.123: Early termination of research support: Evaluation of applications and proposals.
46.124: Conditions.

OHRP Coded Data/specimen Guidance