

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