CITI PROGRAM
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Revisions to Research Roles Under the Final Rule

How does the new Final Rule affect my role?

Researchers and Key Study Personnel	• Exempt research (46.104) • IRB review of research (46.109) • Criteria for IRB approval of research (46.111) • Cooperative research (46.114) • General requirements for informed consent (46.116) • Documentation of informed consent (46.117)
IRB Members and Chairs	• Exempt research (46.104) • IRB review of research (46.109) • Expedited review procedures (46.110) • Criteria for IRB approval of research (46.111) • Cooperative research (46.114) • IRB records (46.115) • General requirements for informed consent (46.116) • Documentation of informed consent (46.117)
HRPP Professionals (IRB Administrators and Staff)	• Definitions for purposes of this policy (46.102) • Assuring compliance with this policy—research conducted or supported by any federal department or agency (46.103) • Exempt research (46.104) • Membership (46.107[a]) • IRB functions and operations (46.108) • IRB review of research (46.109) • Criteria for IRB approval of research (46.111) • Cooperative research (46.114) • IRB records (46.115) • General requirements for informed consent (46.116) • Documentation of informed consent (46.117)
Organizational Leadership	• To what does this policy apply? (46.101) • Cooperative research (46.114) • Federalwide Assurances (FWA) and IRB Registrations (46.103)

Reference

• *U.S. Department of Health and Human Services (HHS). 2017. "Federal Policy for the Protection of Human Subjects." Federal Register 82(12):7149-274.*