What are the “Regulatory Criteria for the Approval of Research”

Main Criteria
(45 CFR §46.111/ 21 CFR §56.111)
(a)(1) - Minimization of risks
(a)(2) - Risk-benefit relationship
(a)(3) - Equitable selection
(a)(4) - Consent process
(a)(5) - Consent documentation
(a)(6) - Data monitoring
(a)(7) - Privacy/confidentiality
(b) - Vulnerable subjects

Consent Process
(45 CFR §46.116, 21 CFR §50.20, §50.25)
Intro - Consent process
(a)- Required disclosures
(b)- Additional disclosures
(c)- Waiver #1
(d)- Waiver #2

Consent Documentation
(45 CFR §46.117, 21 CFR §50.27, § 56.109)
(a) - General
(b)(1) - Long form
(b)(2) - Short form
(c)(1) - Waiver #1
(c)(2) - Waiver #2 (Not FDA)

The IRB must determine that criteria delineated in all three boxes are met.