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 <u>all three boxes</u> are met.