

Ethics, Translational Science & the IRB: The Future is (Still) Not What It Used to Be

**University of Miami
IRB Grand Rounds**

December 10, 2013

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ETHICS PROGRAMS



History

- Beaumont (1820s)
- Neisser (1892; syphilis at Breslau)
- Osler (1907)
- Nuremburg (1946)
- Thalidomide (1950s-60s;
Kefauver, FDA)

History, continued

- Helsinki (1964, etc.)
- Beecher (1966)
- US Public Health Service (1996)
- Tuskegee (1932-72)
- 45 USC 46 (1981; cf. Helsinki 1975)

Consent, Probability

- Risks
- Harms
- Wrongs

Valid Consent

- Adequate information
- Voluntariness
- Capacity

Physical Risks

- Discomfort
- Injury
- Death

Behavioral Risks

- Anxiety
- Bad anxiety
- Really bad anxiety

Social Risks

- Privacy, confidentiality
- Stigma; group privacy
- Discrimination (social, financial)

Translational Science

- Decline in RDBPCTs (cf. increase in meta-analyses)
- Big data; EHRs; analytics; data mining
- Biobanks

Trusted Governance

- Pan-encounter consent
- Community consent
- IRB reviews scope, approach
- Governance boards as IRB's sisters

Now what?

- Ethics precedes regulation
- Focus on compliance is necessary, but if too narrow can fail
- IRBs (and their sisters) must make educated judgments

Chronology

- Post-atrocity era (1972-2002)
- Middle ages (2003-2013)
- Health literacy and bioscience renaissance (2014-2030)

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