

The History of Minority Inclusion in Clinical Trials – Civil Rights

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Tuskegee Study: (picture slide of lumbar puncture that subject was told was interventional therapy for “bad blood.”)



The last 100 years:

- Tuskegee Syphilis study begins: 1932
- Nazi experiments in WWII.
- Nuremburg Trial: 1946
- The Nuremburg Code 1947
- Helsinki Declaration 1957
- Thalidomide tragedy 1960s
- Tuskegee study exposé 1972
- The Belmont Report 1979
- Consolidated HHS/FDA regulations: 1981
- Common Rule: 1991

The Civil Rights Movement

- The Civil Rights Movement, along with the Women's Liberation Movement spawned a vigorous national debate about social justice and brought an awareness of minority group's historically unfair participation in clinical trials.
- Originally, minorities bore more than their fair share of the burden of human experimentation. Then, after scandals such as the Tuskegee Syphilis Study changed the human subject protection landscape, minority groups became underrepresented in potentially beneficial clinical trials.

The Pendulum Swing

- To address this pendulum swing, a variety of regulations and guidelines have been implemented to reverse this trend.
- Chief among these is the NIH Revitalization Act of 1993 which
 - mandates the inclusion of Women and Minorities in clinical trials in numbers large enough to measure differences between groups
 - cost cannot be a justification for not being inclusive