Diversity of Race and Ethnicity in Clinical Trial Participants

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Clinical Trials
Historical Context

- Nuremburg Code
  - 1940s Nazi experimentation of human subjects
- Belmont report
  - 1978 respect for persons, beneficence and justice
- US government implemented NIH guidelines
1993 NIH Revitalization Act

- Mandated the inclusion of “women and members of minority groups” in clinical research sponsored by the US National Institutes of Health for reasons of “fairness and scientific validity”
- Implementation has been challenging
Barriers

- Distrust of medical system and research
  - Historical
    - Tuskegee Syphilis
    - Human Radiation Experiments conducted by the US Government
    - Birth control studies on women of color
    - Lead toxicity in children
Barriers

- Provider
  - Lack of referral of minorities for clinical trials
  - Not explaining the trial
    - Language
    - Educational level
Barriers

- Socioeconomic
  - Lack of access to trials
Barriers

- Trial design
  - Exclusion criteria
  - Patient diagnosis
Barriers

- Group Specific
  - Cultural
  - Health beliefs
Barriers

- Institutional
  - Institutional racism
  - Protocol availability
  - Inter-organizational cooperation
  - Organization size
  - Staffing
Barriers

- Insurance and health system issues
  - State-mandated coverage for trials
Solutions

- Setting and population
  - Safety-Net Hospitals
  - Minority serving institutions
  - Minority Physician Practices
Solutions

- Research Specific Resources
  - Clinical Trials Support Unit
  - Electronic medical records
  - Clinical research coordinators or nurses
Solutions

- Private and public funding to support clinical trials in institutions and practices that treat minority patients
References

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