Tradition of Professional Dominance in Research Ethics

- Nuremberg Code – created by physicians, adopted by judges
- Helsinki Declaration – World Medical Association
- First NIH Guidelines – Researchers and Officials
- U.S. Regulations – Professionals
- IRBs (Mostly) Professionals
Problems with Subject Exclusion

- Professionals, patient advocates, and public members may have values and interests that differ from individuals actually considering and participating in research.

- Such groups also lack knowledge of on-the-ground realities of research participation.
Background

- Challenges to & support for consulting subject population on ethical issues
- Over time, professional acceptance re: returning aggregate research results
- Professional support for returning ‘clinically actionable’ individual results
Return of Results

- Fisher: “What research community needs to understand is that . . . we gave a gift to advance human health.”

- “Tell me what you know . . . even if you do not know what it means. Tell me because we are both human beings.”
Return of Results

- Survey and focus groups –
  
  - majority want to know about individual results, including health risks “even if there [is] nothing they could do about them”
Return of Results

- Also want to know information relevant to family risk, reproductive decisions, environmental risks, life & financial planning, & potential future research participation

- Participant definition of utility = broader than professional definition
Survey of sample donors’ preferences

- Substantial portion wanted to know genetic risk for Alzheimer’s disease

- One subject: “Not to let us know would be like the overprotective mother who doesn’t let her kids grow up”
Concerns Raised by Participant Preferences

- Are participants adequately informed?
- Increased research costs
- Justified paternalism?
Positive Dimensions

- Promotes egalitarian vision of research: subjects as partners
- Shows respect for people most affected by research rules and policies
- More inclusive process for research policy development