



# RETURN OF RESULTS

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## CURRENT CORE ELEMENTS OF LONGITUDINAL POPULATION STUDIES: 2005 - 2010

- Immediate feedback plus abnormal/critical values during initial assessment
- Bulletins & websites with aggregate findings
- Researchers who access data are required to return results of their studies to the database
- No individual results returned after initial assessment is completed



# TRADITIONAL ROLE OF POPULATION BIOBANKS

- Resources for research
- Healthy volunteers
- Potential benefits for future generations
- Participants are contributing to the public good with no personal benefit



# EMERGING TRENDS

- Clinically Validated Results
  - Biobanking is an adjunct to clinical trials or to medical care
- General Health Results
  - Individual results returned to participant/physician directly where relevant to health if so consented
- All Results



# IMPLICATIONS FOR POPULATION BIOBANKS

## ○ Positive:

- Self-determination
- Benefit-sharing with individuals for population health
- Increase in ambit of decision-making
- Potential benefit for family members/future generations



# IMPLICATIONS FOR POPULATION BIOBANKS (CONT.)

## ○ Negative:

- Creates therapeutic misconception
- Blurring of roles / responsibilities between researcher / physician
- Misinterpretation / confusion / stress
- Decrease in public trust
- Increase in liability
- Undermines public mission and nature
- Costs



# EXTERNAL DRIVERS

- Public Expectation – they do not want information withheld from them
- Reduced cost of sequencing
- DTC companies
- Potential litigation – what are the consequences of not informing?
- Society is changing
  - Social networking
  - Democratization of genomic information



# What do you think?



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# WHAT ARE RESULTS?

- “The ethical duty to disclose research results is inconsistently specified by available policies, legal instruments and scholarly commentary. It is further undermined by confused use of three core concepts.”
  - aggregate and individual results
  - definitive (validated) and preliminary (unvalidated) results
  - “types” of research for which specific duties of disclosure are relevant (genetic exceptionalism?)

○ FA Miller et al. Duty to disclose what? Querying the putative obligation to return research results to participants. *J Med Ethics* 2008;34:210-213

