

**Assessing the Value of Collecting Biomeasures in the PSID:  
Ethical and Legal Concerns  
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Introduction

**I. General Issues**

**A. Ethical Propriety of Expanding PSID to Biomeasures**

Weighing of personal or social benefits against personal risks in human subjects research  
Reinforces the need for thought-out potential benefits and not “fishing expeditions”

Biomeasures are trendy – are they worth it?

**B. Are Biomeasures Different from Already Collected PSID Measures?**

1. Ethics

No legal difference in the application of the Common Rule or ethics generally  
May be some difference in IRB review

2. Law

Possible legal differences

May be HIPAA-covered medical information

May involve various state laws on, for example, genetic privacy

Note the issue of application of different state laws to a multi-state project

3. Perception

Possible differences in public perception

Biomeasures may *seem* more private, intrusive, and dangerous

Whether they are or not

But they may be – e.g.

Mental illness, HIV, STDs, etc.

Which may lead to significant differences in participation

In quantity

In who participates

It may provide a new confounding variable for participation

Possibly skewing, for example, SES

**II. Specific Issues**

**A. Control over Subsequent Uses or Users**

1. The dilemma of “blanket consent”

Cannot give subjects detailed information about risks and benefits  
Because don't know what all research will be done

2. Issues in this context

Can be control over biological samples or of data from biomeasures

Subjects may want to be assured that their data and samples won't be used for some kinds of research

As a result of their personal or group sensitivities  
e.g. research on genetics and sexual preference  
e.g. research on race, genetics, and social outcomes

**B. Right to Withdrawal from Research**

Guaranteed by the Common Rule

What does it mean in this context?

For samples

For data

**C. Confidentiality and Anonymity**

What can be promised in terms of confidentiality?

Given data security problems that are hard, at best, to preclude  
Stolen laptops

Can anonymity be provided?

The serious problem of re-identification

The additional confidentiality risks of adding more kinds of measures

Re-identification through one method leads to revelation of cross-connected data from other spheres

e.g. identification through genetics reveals identity of the subject of social data

The issue of possible government requests for samples or data

e.g., use of a pap smear from his daughter to incriminate the BTK killer

The unclear power of certificates of confidentiality

**D. Return of significant information to research subjects**

1. Medical information

Examples

- genetic information about Huntington's disease
- genetic information about BRCA1 or APOe
- genetic information about hereditary non-polyposis colon cancer genes
- imaging data on brain abnormalities
- infectious disease information on presence of an infection

Factors to Consider

- degree of power of the information
  - penetrance of condition
  - certainty of link
- seriousness of the condition
- availability and usefulness of interventions

2. Non-medical information

Examples

- genetic information about non-disease traits
- genetic information about ethnic ancestry
- genetic information about "misattributed parenthood"

Factors to Consider

- degree of power of the information
  - penetrance of condition
  - certainty of link
- importance to the subject of the information
- availability and usefulness of non-medical interventions

**E. Special Issues**

1. Children

Their enrollment

The Common Rule standards for research with children

Appropriate to enroll children at all?

- i.e., consensus on not testing children for genetic conditions for which no treatment needed while a child

Their status when they reach their majority

Recontact for new consent?

- If cannot recontact?

2. Family members of subjects

Consequences of information on one family member for others

- Genetic information

- Other information

The Virginia Commonwealth case

Probably not a strong precedent  
But the concern is real  
Handle in consent?

**F. The Consent**

In light of all of the above special issues, how long will be the consent be?  
What percentage of the potential subjects will be able to understand it?  
How should the consent for a project like this be structured to maximize “truly” informed consent?

**Conclusion**

Not impossible, but requires special thought  
Especially given the high profile and proud position of PSID