

SACHRP Meeting
Return of Research Results – Points to Consider
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I. Background

Current practice – consent forms largely state will not return anything

New research findings versus findings of known risks versus incidental findings of known risks

The transformative power of multiplexing

II. The Case for Return

A. Participants' Expectations

Expect important results to be returned, regardless of the consents they signed

B. Legal Arguments

Plausible but not certain arguments

Fiduciary duty

Implicit contract

Implicit in consent form

C. Ethical Analysis

Duty of rescue

Not legal duty but ethical duty

Reciprocity from gift

D. Practical Issues

Terrible publicity and settlement liability

Terrible publicity for research overall

E. Researcher Wishes

Researchers often want to provide information, which their protocol doesn't allow

III. Problems – and Solutions

A. Problems

1. What Kinds of Findings Should Be Returned?

How certain/accurate is the test?
How well-established is the diagnosis/medical knowledge?
How penetrant/how high risk is the indication?
How serious is the disease?
How actionable is the disease?

2. To Whom Should They Be Returned?

Everyone in the study?
Only those who agree to the return/ask for return up front?
Only those who, when told there is some concrete information, say they want it?
Do you tell participants or their physicians?
 What if they have no physicians?
Do you tell their relatives?
 Either to help the participant (who may not be competent)
 Or because they may also be at risk

3. Inform them after what?

Should replication be required?
Should analysis in a CLIA lab be required?
 For providing any information (you should get this tested at a CLIA lab) or
 just the end results?

4. How long should the requirement last?

What is the analysis of the sample/revelation of the risk came after the initial study was done?
What if the risky interpretation of the data is discovered after the initial study?
If so, how hard do you have to try to find the (former) participant?

5. How hard should one review the results for findings?

The non-MD problem
The MD not-specialized-in-this-disease problem
Who pays for the review?

B. The Way Forward

The tyranny of where and how to start
 Fears of slippery slopes
 But the slopes will stay slippery instead we work on them.

Researchers need use some guidance to help them

SACHRP should carve out a minimum standard that says that sometimes, some information *must* be returned

That saying flatly “no information will ever be returned” is *not* ethical

C. A Proposed Minimum Standard

When the researcher has actual knowledge

Of a medically or scientifically well-established risk or condition

That is a substantial risk

For a serious condition

For which they is some reasonable intervention

I would prefer any intervention, including life planning

One could limit it to medical interventions

In areas that are known to involve many such findings (brain scans, genome sequencing, etc.), the researchers must take reasonable efforts to have their data examined for such findings

The obligation is to at least offer to inform someone – without specifying participant or doctor

With whatever CLIA conditions may be legally required

D. Proposed Even More Minimum Statement

Just state that

It is NOT ethical to say we will never return results

Very powerful information must be offered or shared, subject to reasonable limitations

All to be worked out later

But say something, and say it **now**.