National Institute of Environmental Health Sciences

Returning Individualized Research Results to Participants: An IRB Perspective

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IRB Perspective

- Protect the rights and welfare of human research subjects.
- Help investigators conduct ethical research; work with them.

Beneficence

- Common Rule: 45 CFR 46.111(2) “Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.”
  - Also, general ethical duties of beneficence from the Belmont Report principle, the duty to rescue, and reciprocity.

Beneficence

- Returning results can **benefit** participants by providing them with information related to their health, health care (i.e. diagnosis, treatment), and options.
- However, returning results can also **harm** participants by causing them needless worry and stress and encouraging them to spend money for unnecessary medical tests.

Beneficence

- Is information useful, clinically relevant?*
- How does the information affect the person's absolute or relative risk?*
- Is there an available treatment or preventative measure for the disease?*
- Is the testing lab reliable, e.g. CLIA-certified?
- Are there resources to help the participants understand and apply the information?*

* **Community engagement can help address this question.**

Autonomy

- Returning results can promote the autonomy of participants by giving them information relevant to important life choices.
- Participants may want to know their results even if they have no clinical relevance.
- Some would argue that participants in some sense “own” their results because the information has come from them.
- However, some may not want to know their results to avoid needless worry or stress.

Consent

- 45 CFR 46.116c(8) “A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.” [NEW]
- Prior to this change, informing subjects about return of results was standard practice though not covered by the Common Rule.

Consent

- Will any results be returned? Which ones?*
- How, when, under what conditions?*
- In person, by phone, letter, email? To their doctor?*
- Will counseling be available?*
- Will treatment be available?*
- Can participants consent or not consent to return of results?*

*** Community engagement can help address this question.**

Consent

- Will participants be told that these are research results, not clinical test results?
- Will participants be encouraged to follow up results with their doctor, seek additional testing?*
- Would some results require immediate medical attention (e.g. dangerously high blood pressure or blood sugar)?
- Would some results be reported to public health authorities (e.g. HIV, other STDs, TB)?*
- How will confidentiality be protected?*

*** Community engagement can help address this question.**

Some Types of Results

- Clinical tests, e.g. bloodwork
- Physical exam
- STD testing
- Imaging tests (ultrasound, x-ray, MRI)
- Environmental sampling (e.g. chemical exposures)
- Genomic/genetic testing

Working with Investigators

- Correspond with investigators during protocol submission concerning issues related to return of results.
- Invite investigators to the IRB meeting to discuss plans to return results.
- Provide investigators with clear guidance concerning issues, including rationales for decision(s).
- Continuing dialogue with investigators, especially if they want the IRB to reconsider its decision.

Cases

- Studying effects of DDT exposure on pregnancy loss fertile women in an African country that is using DDT to reduce populations of mosquitoes that carry malaria.
- DDT metabolites will be measured in blood samples taken from the subjects but will not be analyzed for several months or more after the collection.
- Telling the subjects in the study about the risks of DDT and their personal exposure could cause the village to stop using DDT, which could do more harm than good, since the risk of malaria may be much worse than a small reduction in fertility.

Cases

- The study also involves HIV testing to control for the impacts of this virus on immune system cells, DDT metabolites, and other chemicals in the blood.
- Many women in the study do not want to receive their HIV results, due to concerns about stigma and discrimination.

Cases

- Observational study of environmental and genetic risk factors for breast cancer.
- The informed consent document stated that the subjects would not receive genetic test results but it did not include a provision allowing them to refuse to receive these results.
- Investigators have found that a few dozen subjects have two copies of a genetic mutation that increases the risk of hemochromatosis, a disease in which the body stores too much iron.
- The disease can cause fatigue, pain, weakness, diabetes, and problems with the liver, pancreas, and heart.

Cases

- Hemochromatosis is easy to diagnose and treat. The treatment involves periodically removing blood or donating it.
- People with two copies of the mutation (homozygotes) have a 25% chance of developing the disease. Those with only one copy (heterozygotes) have a 2% chance.
- Testing is done by a research lab that is reliable but not CLIA-certified.
- Should the investigators return results to homozygotes? Heterozygotes?