Rehabilitation Institute *of* Chicago

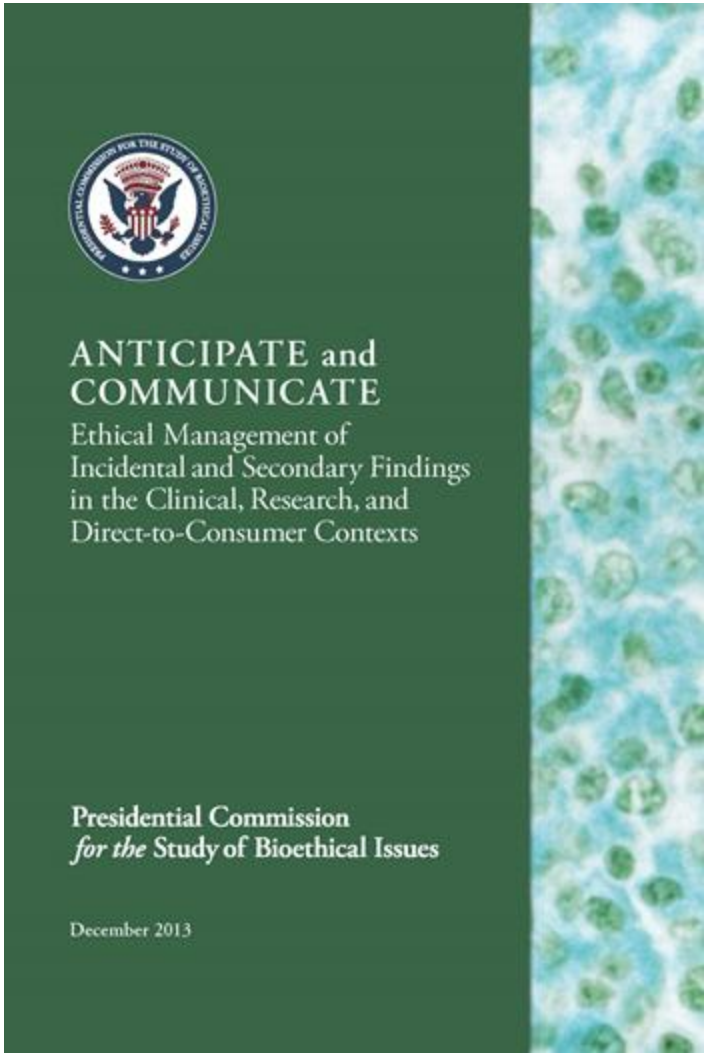
THE ETHICS OF INCIDENTAL FINDINGS: RECOMMENDATIONS FOR IRBS AND RESEARCHERS

Andy Kondrat, MA
Bioethicist, Donnelley Ethics Program

OVERVIEW

- In December 2013, the Presidential Commission for the Study of Bioethical Issues released *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts*

- The report reflects on the practical, legal, and ethical considerations that arise with incidental and secondary findings in the course of research, and provides recommendations based on these considerations



RIC
Rehabilitation Institute of Chicago

INCIDENTAL AND SECONDARY FINDINGS

Bioethics Commission Classification of Individualized Results of Medical Tests

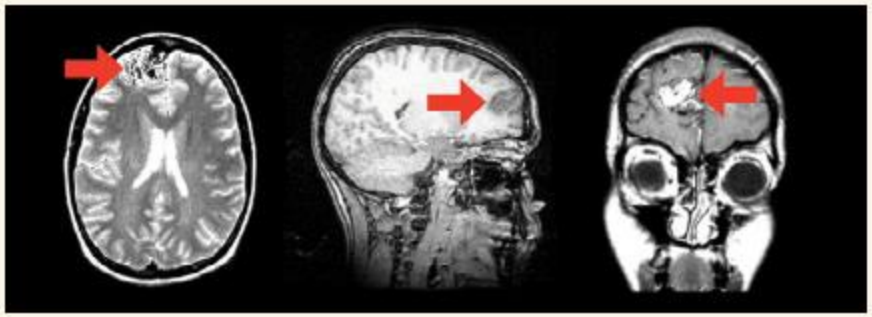
TYPE OF RESULT DISCOVERED	DESCRIPTION	EXAMPLE
Primary Finding	Practitioner aims to discover A, and result is relevant to A	In a child with unknown vaccine history, a test done to determine a child's immunity status before the chickenpox vaccine is administered
Incidental Finding: *Anticipatable*	Practitioner aims to discover A, but learns B, a result known to be associated with the test or procedure at the time it takes place	Discovering misattributed paternity when assessing a living kidney donor and potential recipient who believe they are biologically related
Incidental Finding: *Unanticipatable*	Practitioner aims to discover A, but learns C, a result not known to be associated with the test or procedure at the time it takes place	When a DTC genetic testing company identifies a health risk based on a newly discovered genetic association not knowable at the time a previous sample was submitted
Secondary Finding	Practitioner aims to discover A, and also actively seeks D per expert recommendation	ACMG recommends that laboratories conducting large-scale genetic sequencing for any purpose should actively look for variants underlying 24 phenotypic traits

Source: Presidential Commission for the Study of Bioethical Issues (PCSBI). (2013, December). *Anticipate and Communicate: Ethical Management of Incidental and Secondary Findings in the Clinical, Research, and Direct-to-Consumer Contexts.* Washington, DC: PCSBI, p. 27. Note: DTC = direct-to-consumer, ACMG = American College of Medical Genetics and Genomics.

RIC
Rehabilitation Institute *of* Chicago

SOURCES OF INCIDENTAL OR SECONDARY FINDINGS

- Large-scale genetic sequencing
- Behavioral studies/questionnaires
- Testing of biological specimens
- Imaging



As indicated in the image above, researchers incidentally discovered an arteriovenous malformation in Sarah Hilgenberg's brain on a scan during a memory research study.

Source: Hilgenberg, S., Recipient of a finding incidental to research. (2013). Incidental Findings in Research. Presentation to the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission), April 30. Retrieved from http://bioethics.gov/node/1617.

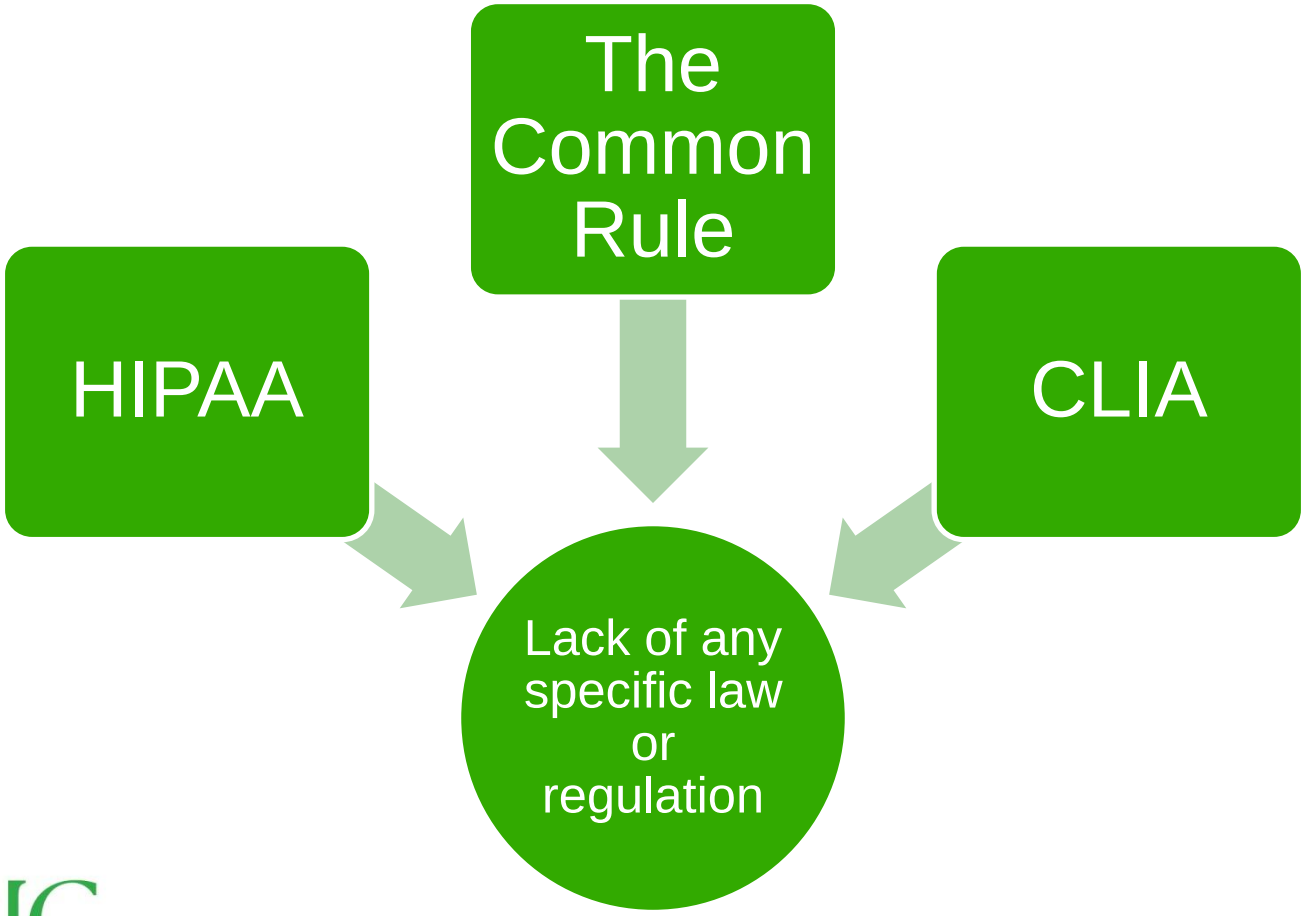
RIC
Rehabilitation Institute *of* Chicago

PRACTICAL CONSIDERATIONS

- Range of researcher expertise
- Participant preferences
- Clinical significance of potential finding
- Cost of discovering and/or returning findings

RIC
Rehabilitation Institute *of* Chicago

LEGAL CONSIDERATIONS



RIC
Rehabilitation Institute of Chicago

ETHICAL CONSIDERATIONS

- Respect for Persons
- Beneficence
- Justice and Fairness
- Intellectual Freedom and Responsibility

RIC
Rehabilitation Institute *of* Chicago

RESPECT FOR PERSONS

"Researchers…demonstrate respect for participants by informing them about the possibility of discovering incidental or secondary findings and the plan for their disclosure or management…including letting participants know that, in some circumstances, certain findings might not be disclosed at all" (82-3).

RIC
Rehabilitation Institute *of* Chicago

BENEFICENCE

"[B]eneficence calls upon researchers and IRBs to consider whether the benefits of disclosing a finding outweigh the risks of disclosure" (84).

Rehabilitation Institute *of* Chicago

JUSTICE AND FAIRNESS

"Allocating research resources to returning large numbers of incidental or secondary findings could burden the research enterprise and the ability to create generalizable knowledge" (85).

RIC
Rehabilitation Institute *of* Chicago

INTELLECTUAL FREEDOM AND RESPONSIBILITY

"Researchers must take responsibility for their actions…In this spirit, policies concerning the return of incidental or secondary findings should avoid excessively restrictive rules that might jeopardize and hinder progress in science, medicine, and health care" (86).

RIC
Rehabilitation Institute *of* Chicago

RECOMMENDATIONS FOR RESEARCHERS

- Consent in the research context
- Planning for incidental findings
- No duty to look for secondary findings

Rehabilitation Institute *of* Chicago

CONSENT IN THE RESEARCH CONTEXT

During the informed consent process, researchers should convey to participants the scope of potential incidental or secondary findings, and whether and how participants might opt out of receiving certain types of findings

Rehabilitation Institute *of* Chicago

Photo Credit: Waag Society, https://www.flickr.com/photos/waagsociety/

PLANNING FOR ANTICIPATABLE INCIDENTAL FINDINGS

Researchers should develop a plan to manage anticipatable incidental findings based on a balancing of the risks and benefits of disclosure, analytical and clinical validity, and clinical significance

Rehabilitation Institute *of* Chicago

PLANNING FOR UNANTICIPATABLE INCIDENTAL FINDINGS

Researchers should develop a process for evaluating and managing unanticipatable findings, including the researchers' responsibilities post-finding and method of disclosure to participants

Rehabilitation Institute *of* Chicago

NO DUTY TO LOOK FOR SECONDARY FINDINGS

- Both society at large and participants engaged in research have a vested interest in completed research that furthers scientific knowledge
- Prioritizing a duty to look for secondary findings over the creation of generalizable knowledge has the potential to undermine the research enterprise

Rehabilitation Institute of Chicago

Photo credit: Jonathan Bennett,
http://www.flickr.com/photos/jonanime/

RECOMMENDATIONS FOR IRBS

IRBs should consider the following elements when reviewing plans to manage incidental findings:

- Informed Consent
- Researcher Expertise
- Participant Preferences
- Researcher Responsibilities

RIC
Rehabilitation Institute *of* Chicago

INFORMED CONSENT

IRBs should evaluate whether the following elements have been considered and included in the consent material:

- Secondary Findings
- Anticipatable Incidental Findings
- Unanticipatable Findings

RIC
Rehabilitation Institute *of* Chicago

RESEARCHER EXPERTISE

IRBs should verify that researchers either have the expertise to manage incidental findings, or have considered sources of additional expertise, including:

- Adding members to the research team
- Relying on research ethics consultants or the IRB
- Seeking consultation from experts on findings of uncertain clinical significance

RIC
Rehabilitation Institute *of* Chicago

PARTICIPANT PREFERENCES

IRBs should review researcher plans for how they will return certain types of incidental or secondary findings, and how researchers will respect the wishes of those participants who wish to opt out of receiving findings

RIC
Rehabilitation Institute *of* Chicago

RESEARCHER RESPONSIBILITIES

When reviewing a study application and consent form, an IRB should look to see that the researcher has described the team's responsibilities following disclosure of a finding

RIC
Rehabilitation Institute *of* Chicago

Photo Credit: Helen K, https://www.flickr.com/photos/helenk/

CONCLUSIONS

- Have a plan for incidental findings, both those that are anticipatable and those that aren't
- As part of the informed consent process, inform potential participants of this plan, even if it includes not returning findings to them
- Manage any findings according to that plan

RIC
Rehabilitation Institute *of* Chicago

EXAMPLE 1: JOHNS HOPKINS MEDICINE

Incidental Finding

The (INSERT SPECIFIC TYPE OF IMAGING, e.g., MRI).you are having as part of this research study will be reviewed by a qualified person just as it would be if you were having the (INSERT SPECIFIC TYPE OF IMAGING, e.g., MRI) as part of your routine medical care.

There is a possibility that while reviewing your (INSERT SPECIFIC TYPE OF IMAGING, e.g., MRI) we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

We will let you know (INSERT or your legal representative if appropriate for the study) if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail or by phone. In the case of a potential serious emergency, someone may go to your home.

A qualified person (usually a member of the research team) will talk to you if there is an incidental finding. You do not have an option to decline information about an incidental finding.

If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

An incidental finding may cause you to feel anxious.

Since an incidental finding will be part of your medical record, it may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved.

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

RIC Rehabilitation Institute of Chicago

JOHNS HOPKINS MEDICINE

http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/incidental_findings.html

EXAMPLE 2: UNIVERSITY OF KENTUCKY

Will you be given individual results from the research tests?

Generally, tests done for research purposes are not meant to provide clinical information. Because the researchers will not have access to information that identifies you, the research findings will generally not be provided to you. There is a slight possibility that during a research project, a researcher could discover something that could affect the health of you or your family.

If this occurs, the finding will be reviewed by _____ (*specify review by a special committee, an expert consultant) to determine if it is in your best interest to contact you.*

If so, _____(*the bank, your primary/clinical care provider) will contact you at the contact information you provided. With the help of a (medical specialist, a genetic counselor), they will present possible risks or benefits of receiving the information. At that time you can choose to receive or refuse the result or finding. If you would like more information about this call_____.*

OR

Do you give permission for (*the bank, researchers) to contact you with information about research results or incidental findings that are determined to be important to you/your family's health? (Incidental findings are unforeseen findings discovered during the course of the research that may affect you or your family's health).*

___ Yes ___ No _____Initials

You may also withdraw your consent to be contacted with information about research results or incidental findings by sending a written request to ___(*provide bank phone and mailing address).*

RIC
Rehabilitation Institute *of* Chicago

UK

http://www.research.uky.edu/ori/ORIForms/D58-Issues-to-Address_Informed-Consent-for-Tissue-Specimen.pdf

EXAMPLE 3: DUKE UNIVERSITY

Incidental Findings: It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. There are no plans to provide this information to you or your physician unless the information indicates that you may be at risk for a serious illness known at the time of testing to be treatable. In that case, we will attempt to notify you using the contact information you have provided, so that you can speak with Dr. _____ at Duke University Health System (DUHS). DUHS staff will not provide this information in a voice mail, email, or otherwise prior to contacting you. Please notify us of any change in your contact information.

If you do not want to be notified of any incidental findings, please initial below.

_____ Please do not notify me of any incidental findings obtained from this research.

If you prefer, we can ask you at the time of notification whether or not you want to receive incidental findings information. In this case, please initial below.

_____ Please ask me at the time of notification whether or not I want to receive incidental findings information.

If at any time during or after the study you change your mind about whether or not you would like to be notified, you can contact us at _____.

After providing the information to you, Dr. _____ may arrange for you to meet with him/her and/or a genetic counselor or refer you to another appropriate health care provider to review the incidental findings information with you or your physician.

RIC Rehabilitation Institute of Chicago

DukeMedicine

http://irb.duhs.duke.edu/modules/irb_stdlng/index.php?id=1

EXAMPLE 4: NORTHWESTERN

Disease testing and genetic research may produce results about your medical condition. One question for you to consider is whether you should know the results of the testing and research. Knowing the results has risks. The results may cause you anxiety and other psychological distress. Also, if you tell the results to your doctor, they may become part of your medical record. If released, the information could lead to health or life insurance discrimination, job or social discrimination. Knowing the results could also affect your future relationships with family members

If applicable add:
Because your family members are also part of this study, there is a risk that the results may show that some are your family members are not genetic relatives. (There is also a risk that other family members may learn private genetic information about you.) Not knowing results also has risks. It could mean that you will not have enough information regarding the need for treatment or the availability of a cure for a particular disease.

RIC
Rehabilitation Institute *of* Chicago

http://irb.northwestern.edu/templates-forms/consent/genetic

RIC
Rehabilitation Institute *of* Chicago

THANK YOU!
QUESTIONS? COMMENTS?

Andy Kondrat
akondrat@ric.org