

DrinkerBiddle

OHRP Research Community Forum 2013
Oakland University - Beaumont Health System
Strategies for Optimizing
Human Research Protections
May 2, 2013

“Best Practices for IRB Chairs and IRB
Members/Incidental Research Findings”
11:00 – 12:15

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- I. Background: Definition, Examples, Prevalence
- II. Key Issues
- III. Recommendations

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I. Background: Definition, Examples, Prevalence

> Definition:

- o Incidental Finding = finding concerning research subject for which are potential health implications that is discovered in course of research but that is beyond research aims (and perhaps researcher's expertise)
- o Can arise in collecting, analyzing data, images, samples in screening or research procedures

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- > Examples
 - o Neuroimaging/MRI of brain
 - o CT colonography
 - o Genetic studies

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- > Prevalence
 - o MRIs: Reports that IFs in 13-40% of subjects, up to 84% of scans
 - o CT colonography: Reports that IFs in 15-89% of subjects
 - o Genetic studies: Reports of misattributed paternity in 5-20% of subjects

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II. Key Issues

- > What should researcher do if identifies suspected IF?
- > Researchers have obligation to look for IFs?
- > Once suspected IF identified, what should be disclosed, to whom, by whom, and how?
- > What should ICFs say about IFs?

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- > How to manage underlying tension:
 - Maintaining distinction between research and clinical care, assuring that science is not slowed unjustifiably
 - vs.–
 - Subjects' rights to information about themselves, "duty to warn," reciprocity to subjects

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III. Recommendations

- > Possibility of IFs should be addressed in protocol and ICF
- > IRBs should oversee compliance with IF-related obligations
- > Guidance should be developed

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