



Presidential Commission *for the* Study of Bioethical Issues

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Staff Presentation on Incidental Findings

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Scope

- Definition
- Practical, legal, and ethical considerations

Modalities

- Genetic and genomic testing
- Imaging
- Biological samples

Contexts

- Clinical
- Research
- Direct-to-consumer



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Working definition

- Information gathered in a clinical, research, or direct-to-consumer medical setting that was not the intended aim of the test
 - *Potential clinical, reproductive, or health significance*



Practical considerations

- Return of results

Legal considerations

- CLIA
- Liability and defensive medicine

Ethical considerations

- Ethical challenges of emerging technologies in clinical, research, and direct-to-consumer contexts
- Ethical principles give rise to specific duties in each context



Overview

6

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Description

- Includes whole genome sequencing, whole exome sequencing, and other large-scale genomic testing

Types of incidental findings

- Known (e.g., predisposition to Alzheimer's disease)
- Unknown (thousands of variants)

Specific considerations

- For example, additional genomic or diagnostic testing less likely necessary



Description

- Includes scans, x-rays, ultrasounds, and other radiographic techniques

Types of incidental findings

- Likely to reveal masses that indicate potential causes of concern

Specific considerations

- Some percentage of the masses are benign
- Smaller percentage indicate something harmful



Description

- Includes urine, blood, tissue, or other samples from the body

Types of incidental findings

- For example, resulting from a comprehensive metabolic panel, or chemistry screen

Specific considerations

- Often finite set of incidental findings anticipated given panel of tests to be done



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Context-specific concerns

- Incidental findings arise when a health care provider conducts a test with the goal of diagnosing the patient's symptoms

Ethical considerations

- Fiduciary duty to act in a patient's best interest

Legal considerations

- Concerns about liability and defensive medicine

Practical considerations

- Reimbursement for follow-up testing



Context-specific concerns

- Variety of research protocols give rise to a variety of researcher-participant relationships

Ethical considerations

- Types of obligations researchers owe participants beyond the scope of the research

Legal considerations

- Implications of CLIA
- Potential liability

Practical considerations

- Varying degree of expertise among researchers to detect, interpret, and communicate incidental findings
- Re-identification of data



Context-specific concerns

- Intersection of medical ethics and business ethics

Ethical considerations

- What are the ethical principles that could give rise to a DTC company's ethical responsibility to their customers

Legal considerations

- Contract law, state law, FDA, CLIA

Practical considerations

- Returning results not defined in the scope of the contractual relationship



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