



Ethical Considerations: Designing Clinical Trials for AI-based Interventions

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SCRI Clinical Trials Symposium 2024

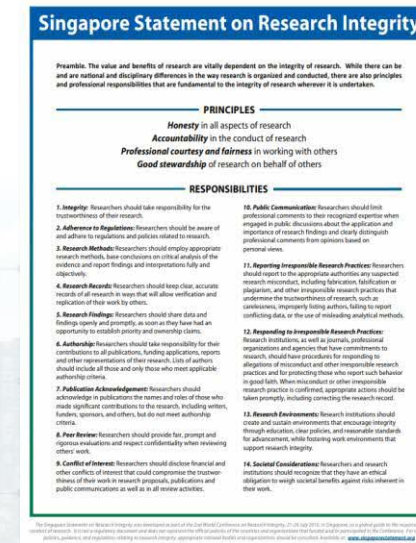
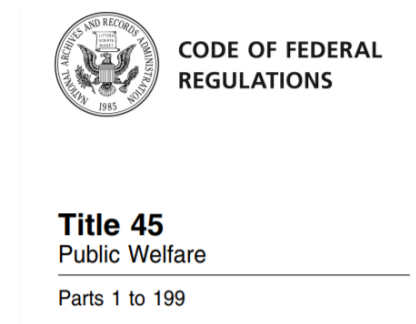
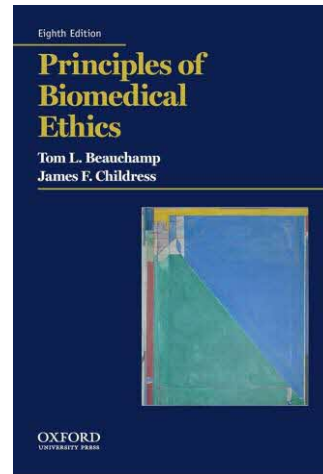
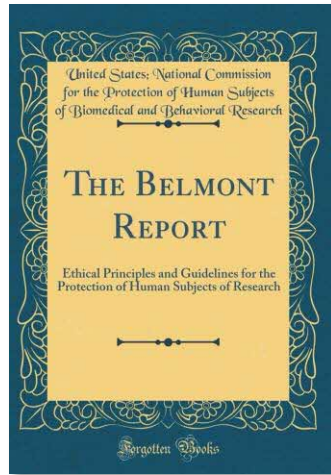
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Disclosure statement

- I am an employee and shareholder of Johnson & Johnson
- The views expressed in this presentation are mine alone and may not represent those of my employer

The basis for ethical conduct of research is well-established



- Respect for Persons
- Beneficence
- Justice

Source: The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. [Bethesda, Md.]: The Commission, 1978.

- Autonomy
- Non-maleficence
- Beneficence
- Justice

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My Goal: Avoid bioethics being viewed as a barrier to innovation

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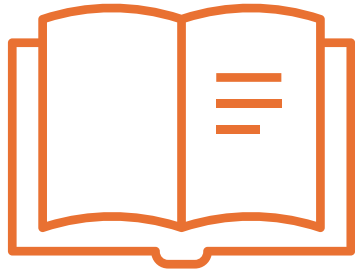
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Consider some of the top concerns expressed about AI in healthcare

- Right to know
- Explainability
- Biased datasets





Right to Know

How does using an AI-based intervention change the informed consent process?



Explainability

Are we expecting more of AI than we currently expect from our human decision makers?



Biased Datasets

We know data sets are biased, incomplete, insufficient

We routinely make decisions based on these data

When and how does AI make this more problematic?

Big Picture Takeaways

1

Look first to existing guidelines and practices that tell us what ethical research looks like

- Tenets of informed consent and enhanced process to ensure appropriate understanding of complex concepts and risks
- What would a reasonable patient want to understand? Have you asked patients what they want to know?
- Are the data fit for the purpose for which they are going to be used? Are you relying on inherently flawed data without any guardrails to avoid further misuse or marginalization?

2

Ensure training about ethical conduct of research – especially for fields that may not have that traditional exposure to patients

3

Healthcare is not the place to move fast and break things – can lead to bad outcomes and patient harm

Thank You

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