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## Study Design

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# Overview

- Ethical theory
  - Principle of beneficence
  - Principles specific to study design
- Study design
  - Types of trials
  - Oversight



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## Section A

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### Ethics Review

# Ethical Theory: Review

- Deontology: An action is right (or wrong) in and of itself
  - You want your physician to give you the treatment that you and your physician decide is best for you
- Utilitarianism: An action is right that leads to the greatest balance of good over bad consequences
  - One's chances of getting the best treatment is highest if one lives in a society where treatment choices are governed by well-designed trials

# Principle of Beneficence: Review

- Beneficence
  - Moral requirements
    - ▶ Do no harm
    - ▶ Maximize benefits/minimize harms
  - Practical applications
    - ▶ Study design
    - ▶ Risk/benefit ratio

# Ethical Principles: Study Design

- Legitimate research question
  - Has it already been answered?
- Valid design and analytic plan to address the research question
  - Is RCT best design?
- Independent review
  - Peer review

# Ethical Principles: Study Design

- Design executed as described in approved protocol
  - Oversight
- Study findings must be reported completely and promptly
  - During trial
  - After trial