Protocol Development, Review, and Approval Process Module Part 1: Overview

Slides from: Elizabeth Ness, RN, MS
Nurse Consultant (Education)
Center for Cancer, NCI
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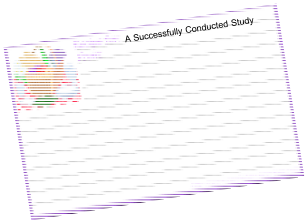
THE PROTOCOL

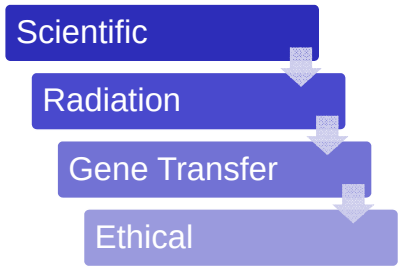


- Sponsor-initiated
- Investigator-initiated
- Combination

Basic Elements of a Protocol

- General information
- Background information
- Trial objectives and purpose
- Trial design
- Selection and withdrawal of subjects
  - Subject selection and accrual (inclusion/exclusion)
- Treatment of subjects
  - Investigational plan
- Assessment of efficacy and safety
  - Study assessments and procedures
  - Adverse events identification and reporting
- Statistical analysis
- Data handling and record keeping
- Supplements

Types of Protocol Reviews



Role of the IRB

- A committee charged with the review of human subject research
- Primary mandate is to protect and safeguard the rights and welfare of human subjects
  - Balance rights of individual subjects with development of knowledge to further society as a whole

Types of IRBs

- Local
- Commercial or independent
- Central

IRB Review

- Risks are minimized
- Risks are reasonable in relation to anticipated benefits
- Subject selection is fair
- Informed consent is obtained
- Protocol includes a plan for data and safety monitoring
- Privacy and confidentiality are protected
- Additional safeguards in place

Protocol Life Cycle