

ACS Cancer Conference 2025

March 12-14 | Phoenix, AZ

Ethics in Cancer Research

Erica Carlisle MD, FACS

University of Iowa Stead Family Children's Hospital

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- No disclosures

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Overview

- Ethical Issues in Cancer Research
 - Equipoise
 - Informed Consent
 - Inclusiveness
 - Participant Welfare
 - Data Sharing
 - Biospecimens
- Children in Cancer Research

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Types of Cancer Research

- National Cancer Institute and the American Association for Cancer Research group cancer research into 4 categories:
 - Basic – preclinical study of cells, genes, animal models, etc
 - Clinical – testing interventional approaches with goal of improving patient care
 - Observational – measuring occurrence and risk for varying populations
 - Translational – applying basic research findings to clinical care

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Ethical Issues for each Type of Cancer Research

Belmont Concepts	Translational Research	Observational Studies	Clinical Trials
Respect for persons	Complex consent	Straightforward consent	Complex consent
	Low personal utility	Low personal utility	High personal utility
Justice	Mid equitable subject selection	High equitable subject selection	Low equitable subject selection
Beneficence	Mid analytic validity (susceptible in subgroup analysis)	High analytic validity	High analytic validity (susceptible in subgroup analysis)
	High clinical significance	Mid clinical significance	High clinical significance
	Low availability of results for participants	Low availability of results for participants	High availability of results for participants
	Low privacy/confidentiality	High privacy/confidentiality	Low privacy/confidentiality

- Behring M et al. Inclusiveness and Ethical Considerations for Observational, Translational, and Clinical Cancer Health Disparity Research. Cancer. 2019. Sept 10;125(24):4452.4461.

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RCTs and Equipoise

- Randomized Control Trials are typically thought of as the gold standard
- Equipoise = uncertainty about the relative merit of one treatment over another- study drug v standard of care
- Challenge during design and conduct of the study

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Challenges with Equipoise

- Practically, we often lack the “true” equipoise needed for an RCT
 - Example: placebo arm is only ethical for conditions in which there is no known treatment
- “Clinical Equipoise” = the clinical community is undecided over which of two or more treatments to prefer
- If equipoise is disturbed during study- terminate trial and give subjects in inferior arm the superior treatment
- Review of data during trial by data monitoring committees to prevent data from being available to investigators and avoid disturbing their equipoise

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Recruitment: Informed Consent

- Informed consent requires:
 - Decision making capacity
 - Information
 - Understanding
 - Voluntariness
- Voluntariness may be impacted by incentives, feeling of obligation to physicians who are also researchers, desperation
- If treatment is only offered through RCT- coercion
- Assent for children/adolescents

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Recruitment: Informed Consent

- Therapeutic misconception = occurs when those who consent to a clinical trial believe they are being treated primarily as patients rather than research participants
- Research Ethics Committees designed to determine if research is ethical
 - Scientific validity, appropriate balance of risks and benefits, etc required prior to conducting a study. Participant consent is not sufficient.
- Is it ethical to limit access to a treatment arm (due to randomization) for a patient with a strong preference for a given arm
 - Does this pressure a patient to participate
 - Patients can refuse but not demand a treatment

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Recruitment: Inclusiveness

- Of US adults, 2-4% participate in clinical trials
 - Generalizability? Equitable representation of various populations?
- In the US, racial/ethnic minorities with cancer experience higher incidence, prevalence, higher stage at diagnosis, higher cancer-related mortality, and decreased survival.
- Health disparities in cancer relate to how cancer research is conducted.
 - Clinical trials have been shown to be unequitable in subject selection related to race/ethnicity
 - Lack of inclusion of underserved patients in clinical research is well documented
- Equitable inclusion of patients is critical

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Ethical Conduct During a Trial

- Privacy and confidentiality
 - Are research results recorded in the research record, medical record, both?
 - Disclosure

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Ethical Conduct During a Trial

- Welfare of patients - adjusting or abandoning a given therapy may not be compatible with continuation of the trial
 - Review by care staff outside of study
 - Study design that allows for early withdrawal but the possibility of using data collected up to the point of withdrawal
 - Ensuring feasibility studies prior to clinical trials
 - Data Safety Monitoring Board
 - Stopping trial on basis of early benefit or futility

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Data Sharing

- Failing to report data is unethical – nonpublication of negative results
- Research registries attempt to overcome

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Biospecimens

- Collection, storage, research use of biospecimens and data
- Informed consent, oversight, large-scale data sharing, privacy, confidentiality, commercialization, access to research results, ability to withdraw

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Children in Cancer Research

- Why do we need children in research?
 - Different pathologies
 - Unique physiology
 - Lifetimes

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Children in Cancer Research: Assent/Consent

- Assent
 - Comprehension increased with grade/developmental level
 - 15-16 yr olds similar to adults
 - Most under 10yr had difficult understanding
 - IRB: 7-12 yr simplified assent form; 13-17 fully informed assent
 - Variable success- in one study of children 7-18 yr with cancer who participated in research, 51% did not know their treatment was considered research and 86% did not understand their doctor when the trial was discussed (similar to adults)
- Common Rule Subpart D; Balance of Risk v Benefits
 - Common Rule is the Federal Policy for the Protection of Human Subjects
 - Influenced by the Belmont Report (1979- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research)
 - Common Rule 1981 - addn'l protections for (subpart B) pregnant women, human fetuses, neonates, (subpart C) prisoners, (subpart D) children

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Children in Cancer Research: Perspectives

- Trust is important...Children more willing to participate in research when they feel safe
- Have realistic perception of research risks
- Believe that if researcher acts unethically or causes harm, will have personal/professional consequences
- Age dependent ability to weigh risks and benefits
- Adolescents very concerned with how their data will be used and how it will be communicated with parents

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Children in Cancer Research: Perspectives

- Generally felt research participation had a positive impact
 - Learned something new
 - Helped others, helped others learn
 - Felt empowered
 - Enjoyed talking about themselves, procedures, filling out forms
 - Thought they participated in clinical improvement
 - Would participate again
- 4-6% reported negative experiences
 - Anxiety, bored, worry about being high risk, painful
 - Not associated with a particular demographic
- Prefer to be involved with decision making regarding their participation
 - Age-appropriate information, direct communication with the child/adolescent, choices

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Research Integrity

- Dr. Puneet Singh

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Increasing Access and Diversity in Clinical Trials

- Dr. Allison Martin

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