Values Based Research
Understanding the Ethicality of Our Research

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• Course Director and Course Planner, Kevin Tracey, MD and Tina Chuck, MPH have nothing to disclose.

• Stephen Frattini DVM has nothing to disclose.
Objectives

• Introduce the concept of values-based research in both clinical and nonclinical studies.

• Discuss ethical issues encountered in biomedical research.
Agenda

1. What is values based research?
   • Whose values ought to be considered?

2. What impact can our values have on our research behavior?
   • Do our values predispose us to unethical behavior?

3. Can we predict unethical behavior?
   • Do values play a role?

4. How can we use values based research to understand our research behavior?
   • What are some methods?
Speaker Background

Shepaug Spartans

- Washington CT, Region 12
- Low Diversity

Cornell University College of Veterinary Medicine

- Ithaca, NY
- Aquatic Animal Health
- Moderate Diversity
- A Minority

• New York, NY
• Neuroscience/Philosophy
• Highly Diverse

January 24, 2017
Does Diversity On Research Team Improve Quality Of Science?

March 21, 2014 · 5:00 AM ET
Heard on Morning Edition

As science becomes more diverse, scientific collaborators are growing more diverse, too. New research exploring the effect of this change suggests the diversity of the teams that produce scientific research play a big role in how successful the science turns out to be.
. . . to better understand the contributions of regional cultural diversity and its misrepresentation within the scientific community, on the ethical conduct of research. . .
“Does diversity, during the conduct of scientific research act as a risk factor for, or a protective factor against unethical behavior?”

- **Planning**: Can lack of diversity (homogeneity) at the principal investigator level lead to ethical issues in proposing a research project?

- **Performance**: Does the lack of a diverse subject population or research team increase the likelihood that a researcher will engage in unethical behavior?

- **Evaluation**: Does the lack of diversity (homogeneity) of a subject population or research team increase the likelihood of unethical behavior such as research misconduct: falsification, fabrication or plagiarism (FFP)?
Values-Based Research

DIVERSITY IN RESEARCH TRIALS

Incidence of disease and response to treatment varies between genders and among racial and ethnic groups.

AFRICAN AMERICANS:
13% of population
5% of trial participants

HISPANIC/LATINO:
17% of population
1% of trial participants

BARRIERS TO PARTICIPATION:
Lack of awareness
Fear of research
Lack of access to trial
Health literacy/language issues

UNIVERSITY OF ROCHESTER:
Over 3,000 researchers
More than 1,000 clinical research projects

Minority researchers are more likely to conduct research in minority populations

$1.2 billion spent on patient recruitment for clinical trials each year

The University of Rochester CT$ is committed to diversity and inclusion in workforce development, community engagement, and research participant recruitment
What is values based research?
Whose values ought to be considered?

• Cultural norms play a role in the variability of a person’s reaction to any number of situations.

• Biomedical research is not immune to these effects.

• Doctors and patients, researchers and subjects, and regional communities, all harbor principles based on their culture, religion, local community, etc.

• Clinical or research relationships composed of different cultural backgrounds and values can create opportunity for unethical behavior, be it conscious or unconscious.

• A group may actively exploit another, it may be an implicit bias, or a misalignment of values and beliefs.
What is values based research?
Whose values ought to be considered?

• In clinical trials, research subjects are often not representative of the regional communities in regards to race, religion, gender, sexual orientation, socio-economic status, etc.

• Why?
  • Inherent biases in the design, conduct or reporting of research on the part of the researchers
  • Narrow scope of the research - studies may also not be designed with diversity or values-based considerations from communities impacted by the disease or condition under study
  • Difficulty in recruiting diverse subjects due to resource challenges (e.g. translations, transportation, etc.), distrust from the community or misaligned interests or values

• Though meeting enrollment criteria can be difficult, if a misrepresentation of regional culture exists it may contribute to unethical behavior.
What is values based research?
Whose values ought to be considered?

• Even outside of clinical trials, in the laboratory and at the bench, lack of consideration for diversity can be an issue.

• Many research institutes are composed of a moderately diverse work force when it comes to students, postdoctoral fellows, and junior faculty but at the faculty levels the composition becomes increasingly homogenous.

• This raises the following questions regarding researcher behavior:

  • Does the homogeneity at the faculty level empower the most senior faculty to behave in an unethical manner based on the composition of their lab personnel?
  • Does a lack of diversity in the faculty or workforce of an institute as a whole empower or disempower certain cultural groups in a manner whereby they must behave unethically to succeed?
  • Does the lack of diversity in faculty further narrow the scope of research that’s developed starting at the basic science level?
Values-Based Research
What is values based research?
Whose values ought to be considered?

• Research participants
• Communities (surrounding population, community and religious leaders and organizations)
• Students (Post-doctoral fellows, graduate students, interns, etc.)
• Researchers (clinical and laboratory-based PIs, Co-Is)
• Research staff (coordinator, nurse, lab and animal care staff, etc.)
• Workforce
• Public policy, regulatory, systems, micro/macro-economic levels
Can you think of a values basis for each of these reasons?
What impact can our values have on our research behavior?

Do our values predispose us to unethical behavior?

• Do you know anyone that espouses a different attitude towards research?

• Does/Do, religion, cultural norms, community pressure effect the way you think about science?
  • Interact with the nonscientific community?
  • Interact with your colleagues?
  • Conduct science?

• Do you every feel pressured to accept a different point of view (because it is value based)?

• Do you ever feel pressured to act in a certain way (based on values)?

Jay Taylor
Can we predict unethical behavior?
Do values play a role?

• How can you know that someone will behave unethically?
  • History
    • Personal
    • Community
    • Cultural
  • Bias
  • Data
    • What kind of data?

• Can you build a values-based framework for different value systems?
  • What are the core components of such a framework?
  • Where can you seek out these components?

• Do values systems change?

Jay Taylor
How can we use values based research to understand and affect our research behavior?

What are some methods?

- Potential themes:
  - Conceptions of the Body
  - The goals of science and relation to religious, moral and cultural worldviews
  - Individual and collective decision-making practices
  - Perspectives on Autonomy, Consent, Community and Coercion
  - Direct and Indirect Risks and Benefits to particular groups
  - The nature of the scientific and biomedical paradigms informing research agendas
  - The social value of particular research programs and why the research community and society may or may not value the intended outcomes
Thank You!

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