

Exploring and Enhancing Diversity Within Our Compliance Committees

John A. Guidry, PhD

Dorotha Love Hall, PhD

Tuesday, November 15, 2016

PRIMER's
2016 **Advancing Ethical
Research Conference**
November 13-16 • Anaheim, CA



Disclosure: Dorotha Love Hall, PhD

*I have no relevant personal/professional/
financial relationship(s) with respect to this
educational activity*

Disclosure: John A. Guidry, PhD

*I have no relevant personal/professional/
financial relationship(s) with respect to this
educational activity*

Dorotha Love Hall, PhD

Dr. Dorotha Love Hall currently serves as a Senior Public Health Advisor in Port-au-Prince, Haiti. Prior to this assignment she was a Lead Policy Analyst in the CDC Office of Director for Policy. Before that she was Acting Country Director in Luanda, Angola for 2 ½ years. In her current position and as country director, she established significant relationships with the Minister of Health, the Director of the National AIDS Institute, other international officials and provided leadership assistance to the Ministry during multiple disease outbreaks. She was responsible for management and operations activities in the office and served as the technical expert for all science related activities. From 1997 – 2012, she was the Senior Public Health Advisor in the Division of Global HIV/AIDS Science office with management and operations responsibilities and responsibility for scientific review of documents for ethical issues. Also in that position she developed a comprehensive training curricula for the Protection of Human Subjects, which included development of institutional review boards and the process for protocol and scientific reviews.

John A. Guidry, PhD

Dr. John A. Guidry, PhD, is a consultant to community health organizations across the United States. He provides services in grant writing, evaluation, strategic planning, community research, and IRB development. He is also an Adjunct Professor with New York University's College of Global Public Health. He has published numerous peer-reviewed articles and two books on social movements and community engagement. He hails from New Orleans and has lived in Brooklyn since 2004.

Content Copyright (breakout)

All content included in this session is the property of the presenter(s), and is protected by United States and international copyright laws. Certain materials are used by permission of their respective owners, and those are marked accordingly. The course content may not be copied, reproduced, republished, linked, uploaded, posted, transmitted, or distributed in any way without the prior written permission of the presenter(s).

Access to this presentation should not be construed as a license or right under any copyright, patent, trademark or other proprietary interest of PRIM&R or third parties.

Learning Objectives – part 1

1. To understand how the Belmont Principles support considerations of diversity in the human subjects review process.
2. To understand how the Common Rule and its subparts provide for diversity on IRBs, research ethics committees, and other administrative bodies engaged in human research protection.
3. To evaluate the knowledge, attitudes, and beliefs of attendees working with institutional review board and research ethic committees.

Learning Objectives – part 2

4. To understand how diversity, or a lack of diversity, can impact the actions of IRBs and human protections committees.
5. Explore opportunities for the community boards to enhance diversity and representation during the review process.

Outline

1. Review responses to survey
2. The Common Rule and Diversity: The stated Regulation
3. The Belmont Report: The implications
4. Words have meaning: Diversity, Representation, Social Justice, Distributive Justice, Bias, and Implicit Bias
5. Case Studies
6. What We Can Do

The Survey

1. Which of the Belmont Principles addresses issues under the topic of what we call “diversity?”
 - Respect for persons
 - Beneficence
 - Justice
 - None of the above

The Survey

2. Which of the following attributes may be involved when considering issues of diversity?
- Age
 - Race
 - Gender
 - Place of birth
 - All of the above

The Survey

3. True or False: “IRB composition must always reflect the demographics of the general population.”
- True
 - False

The Survey

4. Which of the following statements is false?
- Ethnicity is a social, cultural, and historical phenomenon.
 - “Gender identity” is the personal experience of one’s own gender.
 - Race is genetically determined.
 - None of the above.

The Survey

5. Diversity is an important issue in research because:
- Research has historically exploited disadvantaged populations.
 - Research findings in one population may not apply to all populations.
 - Scientific advances should be available to all populations who might benefit from them.
 - All of the above.

The Survey

6. True or False: “Diversity is explicitly addressed by the federal regulations governing IRB composition.”
- True
 - False

The Survey

7. Please assess your level of agreement with the following statement using the scale provided:
"It is extremely difficult to create an IRB and human research protections staff who reflect the subject population in research."
- Strongly agree
 - Agree
 - Disagree
 - Strongly disagree

The Survey

8. Implicit bias refers to the impact of unconsciously held attitudes or stereotypes on our understanding, actions, and decisions about other people or things.
- True
 - False

The Survey

9. Are racial and ethnic minority groups, members of sexual minorities (LGBTQ), underserved individuals, or representatives for persons with diminished autonomy (such as sex workers, prisoners, disabled etc.) available as members of your IRB?
- Yes
 - No
 - Not applicable

The Survey

10. If your answer to the previous questions was “no” or “not applicable,” what are the major challenges for bringing them on board?.

The Survey

11. What process does your IRB use to select or invite members to the board?

The Survey

12. How does your board or committee ensure that the community is represented for research projects reviewed?

The Common Rule and Diversity

45 CFR 46, §46.107

“The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.”

Specific Mandates: 45 CFR 46, §46.107

- Members have “professional competence necessary to review specific research activities”
- Represents “vulnerable category of subjects”
- Not “entirely of men or entirely of women”
- Not “entirely of members of one profession.”
- Includes scientific / non-scientific members
- Includes affiliated / unaffiliated members
- May invite non-voting consultants

The Belmont Report

- Respect for Persons
- Beneficence
- Justice
- The principles of respect for persons, beneficence, and justice within the Belmont Report are *based on the fact that considering the ethics of research involving human subjects is generally accepted in our cultural tradition.*

Respect for persons

- The principle: Individuals should be treated as autonomous agents.
- Mechanism: informed consent.
- Implies: diverse values, beliefs, and interests must be respected.
- Implies: that individuals have a voice, and that voice should be heard and respected.
- Outcome: scientific advancement within a democratic tradition.

Beneficence

- The principle: (1) do not harm, and (2) maximize possible benefits and minimize possible harms.
- Mechanism: relation of risk to subject experiences; weigh social and individual benefit
- Implies: IRBs must consider how individuals and communities are impacted by research
- Outcome: IRB/REC must reflect or represent the community it serves.

Justice

- The principle: To each person ...
 - an equal share
 - according to individual need
 - according to individual effort
 - according to societal contribution
 - according to merit

Justice

- Mechanism: examine the subject pools of research.
- Implies: recognition of diversity among individuals and groups in society
- Implies: taking action related to difference and representation

Justice

- Outcome: researchers and IRBs must actively consider and account for how research involves and impacts different groups in society.
- Outcome: research should not unduly involve persons from groups unlikely to be among the beneficiaries of the research.
- Outcome: research should not create subject pools for reasons of convenience or individuals whose agency is compromised.
- Outcome: research should not provide advantages only to those who can afford them.

Diversity and Representation

- Diverse: To be composed of different types or categories.
- Representative:
 - (a) typical of a particular group of people or of a particular thing
 - (b) including examples of the different types of people or things in a group

Social and Distributive Justice

- Social justice: How and on whom burdens are imposed.
- Distributive justice: How a good is distributed in society, with the implication that goods be distributed either equally, or in accord with what individuals deserve.

Bias and Implicit Bias

- Objective bias: Impact of Overt Intentionality
- Implicit bias: Impact of unconsciously held attitudes or stereotypes on our understanding, actions, and decisions about other people or things

Vulnerability

- The Common Rule recognizes “vulnerable populations” with specific needs for protection.
- Brown says that “IRB oversight and concern increase in proportion to their perception of subject vulnerability.”
- The inference is that IRBs that lack diversity, in class and age, etc. may have difficulty recognizing vulnerabilities of some populations in research.

What institutions can do

How can we proactively address potential biases???

- IRB membership
- Human protections staff
- Consultants
- Training

Case Study: St. Crispin Community Hospital

St. Crispin Community Hospital is a teaching hospital that serves a community that is 45% Black, 30% Hispanic, 3% Asian/Pacific Islander, and 20% white. Sixty-five percent (65%) of the hospital's medical doctors are white and 20% are of Indian and West Indian descent; but the nursing and support staff are predominantly persons of color, majority Black. St. Crispin's faculty is routinely engaged in research funded both by the NIH and also by private foundations and corporate concerns.

Question 1

Does the hospital have an obligation to ensure that the IRB members reflect the patient and human subject community the hospital serves?

Question 2

What kind of balance should the IRB reflect?

Question 3

What can the hospital do to ensure its IRB best represents all of the community members involved in research?

Question 4

St. Crispin's has created a committee to address diversity on its IRB and how it relates to the hospital's community.

What does this committee need to achieve?

Questions?

PRIM&R's
**2016 Advancing Ethical
Research Conference**
November 13-16 • Anaheim, CA



References

- The Common Rule 45 CFR 46, DHHS Regulations are provided in 45 CFR, Part 46. http://www.access.gpo.gov/nara/cfr/waisidx_99/45cfr46_99.html.
- The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research" Bethesda, Md.: The Commission. APA (6th Ed.) United States. (1978). <http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/>.
- Brown R, Hinkle S, Ely PG, Fox-Cardamone L, Maras P, Taylor L. Recognizing group diversity: individualistic-collectivistic and autonomous-relational social orientations and their implications for intergroup processes. *Br J Soc Psychol*. 1992;31:327–342.
- De Vries RG Forsbert CP. What do IRBs look like: what kind of support do they receive? *Account Res*. 2002;9: 1999–1216.
- Hayes GJ, Hayes SC, and Dykstra T. A survey of university institutional review boards: characteristics, policies and procedures, *IRB* 1995);17:1-621.
- Klitzman, R, Institutional Review Board Community Members: Who Are They, What Do They Do, and Whom Do They Represent? *Academic Medicine*, 2012 Jul; 87(7): 975–981.
- Lickona, Tolerance, Diversity, and Respect for Conscience: The Neglected Issue. In *Managing Diversity in the Workplace*, http://www2.cortland.edu/centers/character/images/sex_character/Tolerance%20Diversity%20and%20Respect%20for%20Conscience%20april%202006.pdf.

Thank you!!

Contact: jguidry.7@gmail.com

PRIM&R's
2016 **Advancing Ethical
Research Conference**
November 13-16 • Anaheim, CA

