EXPLORING THE BOUNDARIES BETWEEN PRACTICE AND RESEARCH IN PUBLIC HEALTH

Plenary session #8
Columbia University Human Research Protection Program Annual Educational Conference
May 8, 2012

EXPLORING THE BOUNDARIES WITH:

• Hugh Tilson, the Moderator and a distinguished panel comprising:
• Ron Otten, Director of the Office of Scientific Integrity, CDC
• Ivor Pritchard, Senior Advisor to the Director, Office of Human Research Protections
• AND Marjorie Speers, President and CEO, Association for the Accreditation of Human Research Protection Programs

OBJECTIVES for Exploring the Boundaries between Public Health Practice and Research

• Clarify the problem(s) we are trying to address
• Understand the perspective(s) and challenges of those walking/straddling the fence
• Contribute to the development of some “rules of engagement”
We regret that the program ... originally scheduled for this time ... could not be CANCELLED!!

But first, a word from our evil sponsors ...

THE PRIM&R ANNUAL ETHICAL RESEARCH MEETING 2011
Town Hall Meeting: Bumping into Things: What are the Boundaries of Research and Why Might We Want to Know?
Moderators: Hugh Tilson, Alexander Capron
Let's Scrimmage

- What challenges do you in the practice community face with IRBs or other ethics review?
- What challenges do you in the IRB/Ethics review world face with the practice community?
- What are the boundary conditions/criteria that support ethics review?
- What alternative ethics review mechanisms are in place for those activities that fall on the non-research side of the boundary? (i.e., if not the IRB, then what?)

Broad Criteria: To Review or Not to Review

- Activities that DO NOT significantly depart from standard practices
- Activities involving significant risk of irreversible harm and, conversely, those in which risk is minimal or potential harms remediable
- Activities that are new or incompletely supported by evidence but systematically applied or implemented
- Activities in which the purpose of the data is not primarily for the benefit of the individuals or the community from which it was collected
- Activities involving deception or a lack of full disclosure of the intent of the intervention
- Activities involving an imbalance of power relationship in which assent cannot be assured as freely given
- Activities in which the intervention deviates substantially and in unproven ways from the standard of care for the subjects

Alternative Review Mechanisms

- Ethics Consultations
- Collaborative Peer Review
- Internal Screening
- Science Advice Committees
- Community Advisory Boards
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• AND NOW ... YOU!!

The Way Forward