PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

**Agenda**
**Strategies for Returning IRBs to their Subject Protection Roots**
**April 26, 2011**
**Renaissance Boston Waterfront Hotel**

## Meeting Objectives

What strategies are most likely to be workable to help return all the well-meaning people serving on, staffing, and overseeing IRBs to their subject protection roots? Our IRB system has grown over the decades in size and in scope, and in the number and variety of tasks assigned to it. When advances in research and in the concepts of relationships between "subjects" and researchers are changing and raising new and thorny ethical questions, the incentives for IRBs tend to push them towards documenting their actions more than towards the thoughtful consideration of the underlying ethical issues. We intend to develop strategies that will both be achievable and would make a positive difference.

## Agenda

| | |
|---|---|
| 8:30–8:45 AM | Welcome, Overview of the Project, Objectives for the Day, and Desired Deliverables<br>*- Robert J. Levine and C. K. Gunsalus* |
| 8:45–10:30 AM | Roundtable Discussion: Each participant speaks to the potential applications of the assigned readings to the following questions: What are the incentives that do not support subject protection, where does each come from, and where might there be leverage points to explore for achieving change? Principles of accomplishing effective change. Possible approaches that might have an effect on each. |
| 10:30–10:45 | Break |
| 10:45–12:00 PM | What's In the Regs? What's in the Ethical Canon? And What's Happening on the Ground? Three perspectives:<br>• The Regulatory View: Activities in which the IRB must be engaged; of these, which could be more effectively accomplished by others. Negative regulatory incentives: Accreditation, administrative loss-aversion, and general inertia. |

| | |
|---|---|
| | • The Ethics View: What kind of review is required to satisfy the ethical codes and principles, and what are the barriers to that level of review? And, what provisions of the ethical codes enforce irrational behavior?<br><br>• The *On the Ground* View: An identification of the bright spots, including best practices and other successful strategies for IRB administration and protocol review that are working and that are worth emulating.<br><br>What is the goal and/or the desired endpoint of any change? |
| 12:00–1:15 PM | Lunch |
| 1:15–2:30 PM | Areas in which systemic change, if achieved, might produce a measurable improvement in the IRB's ability to protect human subjects. [Discuss 2 or 3 major examples from each category, SBER, and Biomedical.] |
| 2:30-2:45 | Break |
| 2:45–4:00 | Script the Critical Moves (i.e., in areas in which there is a consensus that change is desirable, what concrete steps could be taken to reach the goal, keeping in mind that too many options and ambiguity about what steps to take can paralyze decision making?)* Who are the "change agents"? Attempt to identify them by name or by job description. |
| 4:00–5:00 | Next Steps: Recommendations, Writing, and Other Follow-Up Items<br>*- Robert J. Levine and C.K. Gunsalus* |
| 5:00–6:00 | Reception |

*These and other core concepts associated with this meeting are based on the book *Switch*, by Chip and Dan Heath.