What: Post-Trial Responsibilities Conference: Ethics and Implementation

When: September 18, 2014: 7:30 AM – 5:30 PM

Where: Harvard Law School, Wasserstein Hall, Milstein East AB, 1585 Massachusetts Avenue, Cambridge, MA 02138

Who: Clinical research sponsors, investigators, funders, regulators, trial participants, and other stakeholders

Introduction / Background:

The term "post-trial access" is used broadly to connote a wide range of possibilities for providing continued access to study interventions (and potentially other care) once a trial is over, or a subject's participation has ended. For the purposes of this conference, we will focus discussions on the following:

1. Continued access to study intervention(s) and/or other care for **people who were enrolled in the clinical trial** and were benefitting (whether between the end of the trial and product approval or indefinitely)
2. Provision of the study intervention(s) and/or other care to **people who were enrolled in the clinical trial but did not get the intervention** and would like to try it (whether between the end of the trial and product approval or indefinitely)
3. Provision of the study intervention, other care, or other resources to the **community** in which the trial was conducted

Law, policy, and guidance are vague, sometimes conflicting, and generally lacking in concrete solutions for questions regarding post-trial responsibilities. The issues are complex and demand thoughtful discourse to move the clinical trial enterprise towards meaningful solutions. Areas that currently lack clarity include:

1. How are recommendations regarding post-trial responsibilities influenced by the trial phase and/or prior experience with the intervention?
2. What types of interventions or resources should be included within post-trial responsibilities? Do recommendations include ancillary care, treatment of side effects and adverse events, etc.?
3. What is a reasonable duration for post-trial responsibilities to extend?
4. What is the mission and purpose of various stakeholders (sponsors, governments, investigators, etc.) in the conduct of clinical research and how do these roles intersect with post-trial access responsibilities? In particular, how do government and sponsor responsibilities relate to each other? Do recommendations change when research is sponsored by non-profit entities?

This conference will bring together diverse stakeholders to address some of these questions.

Objectives:

- To discuss implications of international guidance on post-trial responsibilities for clinical research sponsors, governments, investigators, and other stakeholders
- To articulate and understand the range of perspectives on post-trial responsibilities
- To draw lessons from successful and unsuccessful attempts to implement post-trial access policies
- To discuss potential scenarios and practical solutions for post-trial responsibilities that may inform policy in this important area moving forward

- To identify key priorities for a Post-Trial Responsibilities Working Group to be launched by the Multi-Regional Clinical Trials Center at Harvard

Agenda:

7:30 8:00 am	Participants Arrive, Breakfast, and Registration	
8:00-8:05	Welcome Remarks	Mark Barnes (Ropes & Gray, MRCT), Barbara Bierer (MRCT), I. Glenn Cohen (Petrie-Flom, Harvard Law School)
8:05-8:15	The Potential Scope of the Post-Trial Access Issue	Mark Barnes

Session I: Setting the Stage (Moderator: I. Glenn Cohen)

Objective: To introduce current ethical and regulatory approaches, as well as key controversies.

8:15-8:35	The Ethics of Post-Trial Responsibilities: History, Models, Agreement, and Controversy	Christine Grady (NIH)
8:35-8:55	World Medical Association (WMA) Declaration of Helsinki – Process and Perspectives	Jeff Blackmer (University of Ottawa)
8:55-9:15	The Council for International Organizations of Medical Sciences (CIOMS) Approach	Alex John London (Carnegie Mellon University)
9:15-9:35	Policy Approaches Around the Globe	Seema Shah (NIH)
9:35-10:00	Panel Discussion and Q & A	Panel and Audience
10:00-10:15	Break	

Session II: Important Perspectives (Moderator: Barbara Bierer)

Objective: To convey the range of stakeholder perspectives and current approaches from sponsors, regulators, patients, and investigators, and identify areas of convergence and divergence

10:15-10:35	FDA Perspective	Richard Klein (FDA)
10:35-10:55	Governmental requirements	Daniel Wang (London School of Economics)
10:55-11:15	Industry perspective	Jocelyn Ulrich (PhRMA)
11:15-11:35	Investigator perspective	Ramadhani Noor
11:35-11:55	Participant/community perspective	Mitchell Warren (AVAC)
11:55-12:15 pm	Panel Discussion and Q & A	Panel and Audience
12:15 - 12:45	Short break to pick up lunch, reseat for next session	

Session III: Lessons Learned: Case Studies on Implementing Post-Trial Responsibilities (Moderator: Holly Fernandez Lynch, Petrie-Flom Center)

Objective: To better understand real world experiences implementing post-trial responsibilities, including both successes and failures, and to more clearly articulate and assess the complexities involved.

12:45-1:05	NIH Global HIV Research Case Study	Joseph Millum (NIH)
1:05-1:25	Investigator Case Study	Nancy Padian (UC Berkeley)
1:25-1:45	Industry Case Study #1	Walter L. Straus (Merck)
1:45-2:05	Industry Case Study #2	TBA
2:05-2:35	Panel Discussion and Q & A	Panel and Audience
2:35-2:45	Break	

Session IV: Working Toward Solutions: Group Discussion of Hypothetical Post-Trial Scenarios (Moderator: Mark Barnes)

2:45-3:00	Objectives for panel discussion of scenarios Presentation of scenarios and key questions
3:00-4:00	Panel Discussion: Christine Grady, Mitchell Warren, Richard Saver (UNC Law), and Luann Van Campen
4:00-4:30	Audience discussion

Session V: Wrap Up (Moderator: Barbara Bierer)

4:30-5:30	Group discussion to identify key priorities for new Post-Trial Responsibilities MRCT Working Group