



Genetic Testing Registry
Public Meeting

Tuesday, November 2, 2010
9:00 a.m. – 12:00 p.m.



Walter E. Washington Convention Center, Room 147
801 Mount Vernon Place, N.W.
Washington, D.C. 20001

AGENDA

9:00 a.m. – 9:05 a.m.

Welcome and Opening Remarks

Francis Collins, M.D., Ph.D.
Director, National Institutes of Health

9:05 a.m. – 9:20 a.m.

**Overview of Public Comments Received in Response to NIH's
Request for Information on the Genetic Testing Registry**

Amy Patterson, M.D.
Acting Associate Director for Science Policy, NIH

9:20 a.m. – 9:35 a.m.

Prototype Data Elements for the Genetic Testing Registry

James Ostell, Ph.D.
Chief, Information Engineering Branch, NCBI, NLM, NIH

9:35 a.m. – 11:15 a.m.

Public Comments on the Following Questions:

- 1. Based on an analysis of RFI comments and other operational issues, NIH is considering a phased approach to developing the GTR in which some types of tests would be eligible for early entry in the GTR and other types of tests would be added later. If NIH adopts this approach, what criteria should be used to determine which genetic tests should be included in the first phase of the GTR, and what types of tests would meet these criteria?*
- 2. Several RFI responders, who are potential data submitters, noted that it makes more sense for clinicians and genetics professionals to be the source of clinical utility evidence rather than test developers and/or test providers. Given that data submitters are unlikely to have clinical utility information, how is this data element best addressed in the GTR?*

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3. *Among responders to the RFI question about including a data element for test cost, half were in favor of including cost information and half were opposed. What are the benefits, risks, and challenges of including cost information in the GTR?*
4. *What safeguards can be put in place to prevent GTR users from misunderstanding, misinterpreting, or misusing the information in the Registry?*
5. *What mechanisms can be used to provide materials that explain the GTR's data elements to audiences with varying technical expertise?*

11:15 a.m. – 11:55 a.m.

Panel Discussion

Kathy Hudson, Ph.D.

Deputy Director of Science, Outreach, and Policy, NIH

Question 1: Robert Nussbaum, M.D.
Chief, Division of Medical Genetics
University of California, San Francisco

Question 2: Victoria Pratt, Ph.D.
Chief Director, Molecular Genetics
Quest Diagnostics Nichols Institute

Question 3: Misha Angrist, Ph.D.
Assistant Professor
Institute for Genome Science and Policy
Duke University

David Mongillo
Vice President, Policy and Medical Affairs
American Clinical Laboratory Association

Question 4: Myrl Weinberg, M.A.
President
National Health Council

Question 5: Joanna Mountain, Ph.D.
Senior Director of Research
23andMe

11:55 a.m. – 12:00 p.m.

Concluding Remarks

Dr. Hudson