Registry (GTR) to provide access to information that enables informed decision making by patients, caregivers, health care professionals, clinical laboratory professionals, payers, and policy makers. The goals of the GTR are to promote transparency by encouraging test providers to share information about the purpose and validity of their tests; provide a resource for the public—including health care providers, patients, and researchers—to locate laboratories that offer particular tests; and facilitate genomic data sharing for research and new scientific discoveries.

The GTR project is overseen by the NIH Office of the Director. The National Center for Biotechnology Information (NCBI), part of the National Library of Medicine at NIH, is responsible for developing the registry, which is expected to be available in 2011. As part of the development process, the NIH issued a Request for Information (RFI) on July 12, 2010, to seek input from the public on its plan for this project. The RFI comment period ended August 2, 2010. NIH received 68 comments in response to the RFI, and these comments are available at http://oba.od.nih.gov/gtr/gtr_comments.html.

II. Public Meeting Focus

NIH will begin the November 2 public meeting with an overview of the public comments that were received in response to the RFI and a presentation of prototype data elements for the GTR. The remainder of the meeting will be dedicated to a moderated discussion of responses to specific questions about the GTR. The meeting agenda will be available on the Internet at http://oba.od.nih.gov/gtr/gtr_meetings.html.

The RFI comments have been helpful in the development of a prototype of registry data elements. However, NIH seeks further public input on specific aspects of the GTR and requests that comments address the questions below. If time permits, discussion of additional issues will be accommodated.

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?

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?


Amy P. Patterson,
Acting Associate Director for Science Policy, NIH.

[FR Doc. 2010–25411 Filed 10–7–10; 8:45 am]