

July 9, 2010

NIH GTR RFI Comments
National Institutes of Health
Office of Science Policy
6705 Rockledge Drive
Room 750
Bethesda, MD 20892

RE: RFI on the National Institutes of Health Plan to Develop the Genetic Testing Registry

Cleveland Clinic (CC) is a not-for-profit, integrated healthcare system dedicated to patient care, teaching and research. Our health system is comprised of a main campus, ten community hospitals and 14 family health centers with over 2,100 salaried physicians and scientists. Last year, our system had more than four million patient visits and over 165,000 hospital admissions. Within our system, we have a Genomic Medicine Institute that is a multidisciplinary platform for translational genetics and genomic medicine research, academic clinical practice of both traditional medical genetics and 21st century genomic medicine and education. As with most multidisciplinary genetics practices, we rely on well curated, web-based resources for a variety of relevant information such as genetic testing resources.

We read with great interest the RFI for the NIH plan to develop a genetic testing registry (GTR). While we acknowledge the multiple questions posed on the Federal Register, we would like to address one general area along with three specific questions which we feel are particularly important in clinical care. The question numbers below are in accordance with the numbers posted in the Federal Register.

There is currently a robust resource, Gene Tests, that currently funded by the NIH and described as “a publicly funded medical genetics information resource developed for physicians, other healthcare providers, and researchers, available at no cost to all interested persons.” Today, this valuable resource is widely utilized by genetics and non-genetics professionals. We believe that NIH should consider utilizing this existing resource and perhaps enhancing by including the additional proposed information it in order to develop the GTR. We do not believe it would be in the best interests of patients or health care professionals to develop a duplicative tool.

1. Are there types of genetic tests that should not be included in the GTR?

While we acknowledge the importance of being inclusive, we feel that genetic testing that is both appropriate and validated be included. When information such as this is hosted by an NIH site, NIH needs to be cognizant that the public will view the information as being endorsed by the NIH and U.S. Government.

6. To describe adequate and accurately a genetic test, which of the following data elements should be included in the GTR?

We would like to acknowledge the insightful comments provided at the June meeting of the Secretary's Advisory Committee on Genetics, Health and Society and would like to emphasize the balance between quantity and quality. An ideal resource should have multiple fields. In the stated example, the majority of these fields would likely remain empty and thereby limit the quality of the entry. We believe that choosing a finite number of data elements would result in more fields being completed, thereby creating a more robust GTR.

9. In addition to the data elements would it be helpful to reference other resources and if so, which ones?

We acknowledge the insightful comments at the June meeting of the Secretary's Advisory Committee on Genetics, Health and Society and would like to emphasize the importance of curation. We are cognizant that there may not be harmonization among known, well-curated resources (which are also NIH funded) and the proposed GTR modifications. We feel strongly that a vetting process similar to that which is currently in place for other NIH genetic testing resources should be employed with this new GTR as this process will provide the necessary analysis to ensure quality.

The American Society of Human Genetics (ASHG) submitted a letter on July 19, 2010 to the NIH that addressed a variety of issues including those stated above. We agree with all of the insightful comments that the ASHG provided in their letter.

Thank you for conducting a thoughtful process that allows us to provide input on such an important issue, and for your consideration of this information. Please do not hesitate to contact me if you need additional information.

Sincerely,

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