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Genetic Alliance Supports New NIH Policy on Clinical Trials

Washington, DC (September 16, 2016) – Today, the U.S. Department of Health and Human Services (HHS) issued a final rule specifying the registration and reporting requirements for clinical trials on drug, biological, and device products. It also provides a framework to implement a more efficient and effective compliance and enforcement program.

This ruling is extremely important for Genetic Alliance and the individuals, families, and communities with whom we work. Clinical trials are critical to medical advances. Increasing transparency about their processes and products, particularly in this age of participants as partners in biomedical research, is long overdue. This applies to all trials – successes and failures – since all of this information, and the immense contributions from participants, clinicians, investigators, and funders, must be in the public domain to accelerate discovery.

Clinical trials depend on volunteers, people who live with diseases or disorders. These people often participate knowing they are contributing to future discoveries, and may not benefit themselves. These participants need results reported back to them. This information should be reported in ways that make sense to them. The scientific community and potential or actual participants are very interested in clinical trials: more than 57,000 unique visitors visit ClinicalTrials.gov every day seeking information about trials that are open for recruitment, identifying ongoing studies of new therapies, or looking for results of studies that have been completed.

Recently a number of studies have been done to determine whether we, the public, are seeing the results of clinical trials. The results are atrocious and unacceptable, particularly when considered in light of the principles of transparency, openness, and ultimately offering everything the biomedical research enterprise can give for alleviating suffering and improving health. A 2014 analysis of 400 clinical studies revealed that 30% had not shared results through publication or through results reporting in ClinicalTrials.gov within 4 years of completion *[Saito H, Gill CJ. PLoS One. 2014;9(7):e101826].* A more recent study of the trial publication rate among 51 U.S. academic medical centers found that 43 percent of their clinical trials were unpublished two years after the trial was completed *[Chen et al., BMJ. 2016 Feb 17;352:i637].*

The final HHS rule specifies registration and results reporting requirements for certain clinical trials on drug, biological and device products, and provides a framework to implement a more efficient and effective compliance and enforcement program. This is good. However, Genetic Alliance is especially supportive of the National Institutes of Health (NIH) policy also released today. The NIH policy addresses registration and results information reporting for *all* NIH-funded clinical trials. Together, the final rule and the NIH policy will move the field toward the openness and transparency we believe is essential and significantly improve the availability of clinical trial information to the public.

The NIH policy applies to *all* NIH-funded clinical trials. The immediate goal is to have *all* NIH-funded trials in ClinicalTrials.gov.

- NIH has taken several other actions to ensure good stewardship in the conduct of the clinical trials it funds or conducts. These include:
    - Requiring Good Clinical Practice (GCP) training for investigators and NIH staff conducting or overseeing clinical trials;
    - Requiring all applications for clinical trials to be submitted in response to clinical trial-specific Funding Opportunity Announcements;
    - Encouraging the use of a clinical trial protocol template that was developed through a collaboration between the NIH and FDA and that meets International Council for Harmonisation (ICH) E6 Good Clinical Practice Guidance and FDA regulations;
    - Expecting the use of a single Institutional Review Board of record for the review of multi-site studies; and
    - Development of a standardized electronic system for NIH to use for management and oversight of NIH-funded clinical trials, and ensure accountability to stakeholders.

While we work together as a society to align incentives to make data and information sharing the normal default, it is important that policies have meaningful enforcement mechanisms. The NIH states that failure to comply with the final rule may have legal consequences, including civil monetary penalties assessed by the FDA. In addition, non-compliance may be made public through a posting on the clinical trial record. If the clinical trial is funded in whole or part by HHS, failure to submit all required registration and results information may jeopardize grant funding and future funding to the grantee institution.

In 2015, Genetic Alliance President and CEO, Sharon Terry, participated in an extensive study resulting the in the Institute of Medicine (now the National Academies of Science, Engineering, Medicine) report, *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk*. "My great hope when we wrote that report was that the recommendations in that report provide a framework for the culture change that we believe is critical. We know there is a great deal of inertia around reporting on clinical trials. But there are no excuses for not reporting everything. We are delighted and extremely supportive of the NIH policy announced today", said Sharon Terry. “We look forward to tracking the changes in available information and the resultant acceleration of research and development over time.”

For more information on HHS ruling see https://www.nih.gov/news-events/news-releases/hhs-take-steps-provide-more-information-about-clinical-trials-public.

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About Genetic Alliance

Genetic Alliance engages individuals, families, and communities to transform health. Founded in 1986, it is the world’s largest nonprofit health advocacy organization network. Genetic Alliance’s network includes more than 1,200 disease-specific advocacy organizations, as well as

thousands of universities, private companies, government agencies, and public policy organizations. For more information about Genetic Alliance, visit www.geneticalliance.org.