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November 18, 2014

The Honorable Sylvia Burwell  
U.S. Department of Health & Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Secretary Burwell:

We, the undersigned, who represent millions of patients and their families, researchers and clinicians, will be dramatically impacted by the Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care recently released for comment by the Office of Human Research Protections. We are writing to ask that you allow additional time in which to offer comments in response to this draft guidance you announced on October 24, 2014.

The research-to-services continuum in the U.S. is at a crux moment in time. The learning healthcare system is nascent and will have far reaching implications for our entire health system. This guidance will impact the research that is of critical importance to all Americans and most specifically to the millions of individuals we here undersigned represent and/or care for: those who suffer from conditions and diseases that have burdened them greatly. Careful and intensive deliberation must be undertaken for us to make meaningful comment on this draft guidance.

A number of factors lead to a request for an extension of time: 1) the large number of people affected (everyone served by the US healthcare system); 2) the enormous complexity of the issues which must be considered; 3) comments are due in the midst of holidays when it is hard to respond; and 4) the short 60 day comment period. Therefore, we respectfully request that the comment period be extended by an additional 60 days until February 24, 2015.

Thank you very much.

Respectfully,

Sharon Terry  
President & CEO, Genetic Alliance

cc: Jerry Menikoff, Director, Office for Human Research Protections  
Jeffrey Botkin, Chair, Secretary's Advisory Committee on Human Research Protections

## **Organizations:**

22q Nation  
Academic Health Resources  
Adenoid Cystic Carcinoma Research Foundation  
Advocates for Recovery  
Alstrom Syndrome International  
American Multiple Endocrine Neoplasia Support  
American Occupational Therapy Foundation  
American Society of Human Genetics  
Amputee Coalition  
Amyloidosis Support Groups Inc.  
Anxiety and Depression Association of America  
Aplastic Anemia & MDS International Foundation  
Arbor Research Collaborative for Health  
ARPKD/CHF Alliance  
Association for Clinical and Translational Science  
Asthma and Allergy Foundation of America  
AXYS  
B-Corp Citizen Science Effort  
Batten Disease Support and Research Association  
Baylor Scott & White Health  
Beth Israel Deaconess Medical Center  
Bridge The Gap - SYNGAP Education & Research Foundation  
Brigham and Women's Hospital  
Broad Institute  
CADASIL Together We Have Hope  
Cambridge Health Alliance  
Canavan Foundation  
Cancer Information and Support Network  
CCFA Partners Patient-Powered Research Network  
Celiac Sprue Association  
Center for Medical Technology Policy  
Children's PKU Network  
Children's Cause for Cancer Advocacy  
The Cholangiocarcinoma Foundation  
Cleveland Clinic  
The Clinical Research Forum  
Clinical and Translational Science Institute at Children's National (CTSI-CN)  
Coalition Duchenne  
Coalition for Clinical and Translational Science  
Community Health Charities of America  
Comparative Effectiveness, Cost and Outcomes Research Center  
Congenital Hyperinsulinism International  
COPD-Alert  
Coriell Life Sciences  
Counsyl  
Cure HHT  
Cutis Laxa Internationale  
Dana Farber/Harvard Cancer Center Patient Advocate Committee  
Detroit Medical Reserve Corps  
DHHS Public Health  
DNA Digest  
Duke University  
EA | A Quintiles Company  
El Camino Hospital Genomics Medical Institute  
Fabry Support & Information Group  
Fibromuscular Dysplasia Society of America  
Fight Colorectal Cancer  
Florida Atlantic University  
FOD Family Support Group  
FORCE: Facing Our Risk of Cancer Empowered  
The Forsyth Institute  
Foundation for Prader-Willi Research  
Geisinger Health System  
Georgetown University Medical Center  
Global Genes  
Global Healthy Living Foundation  
Group Health Research Institute  
Harvard Pilgrim Health Care  
HealthPartners Institute for Education and Research  
Hebrew SeniorLife  
Hemophilia Federation of America  
Hepatitis Foundation International  
Hereditary Spherocytosis Support Group  
Hermansky-Pudlak Syndrome Network  
Hydrocephalus Association  
Hypertrophic Cardiomyopathy Association  
Immune Deficiency Foundation  
ImproveCareNow  
Inflammatory Breast Cancer Research Foundation  
InnoThink  
International Society for Mucopolysaccharidosis and Related Diseases  
International Society for Nurses in Genetics (ISONG)  
IVBE, Inc.  
John Paul II Medical Research Institute

Johns Hopkins University  
Joslin Diabetes Center  
Joubert Syndrome & Related Disorders  
Foundation  
K-T Support Group  
The Kanter Family Foundation  
The Life Raft Group  
Lipodystrophy United  
The Living Affected Corporation  
Loeys-Dietz Syndrome Foundation  
Louisiana Clinical Data Research Network  
Lupus and Allied Diseases Association, Inc.  
Lymphatic Education & Research Network  
(LE&RN)  
M-CM Network  
The Marfan Foundation  
Marshfield Clinic Research Foundation  
Mass. Eye and Ear  
Massachusetts General Hospital  
MLD Foundation  
Moebius Syndrome Foundation  
The Myelin Project  
Myotonic Dystrophy Foundation  
National Association of Chronic Disease  
Directors (NACDD)  
National Gaucher Foundation  
National Headache Foundation  
National Hemophilia Foundation  
National Neutropenia Network  
National Organization for Rare Disorders  
(NORD)  
National PKU Alliance  
NBIA Disorders Association  
NephCure Kidney International  
New England Baptist Hospital  
Noah's Hope Batten Disease Research Fund  
North American Malignant Hyperthermia  
Registry of MHAUS  
Organic Acidemia Association  
Palo Alto Medical Foundation Research  
Institute  
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Parent to Parent USA  
Parkinson's Disease Foundation/Parkinsons  
Creative Collective  
Partners HealthCare System, Office of Human  
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Patient Advocates In Research (PAIR)  
PatientsLikeMe  
Pediatric Congenital Heart Association  
PEDSnet: A Pediatric Learning Health System  
PFO Research Foundation

Phelan-McDermid Syndrome Foundation  
Powerful Patient Inc.  
The Praxis Project  
Prevent Cancer Foundation  
Private Access, Inc.  
Private Practice  
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PTEN World  
Purine Research Society  
PXE International  
Rare Disease Perspectives LLC  
RASopathies Network USA  
Research!America  
Rhode Island Parent Information Network  
SADS Foundation (Sudden Arrhythmia Death  
Syndromes)  
Sage Bionetworks  
Sanguine BioSciences  
SHARE  
Share & Care Cockayne Syndrome Network  
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Inc.-Eastern NC Chapter  
Sickle Cell Disease Association of America,  
Philadelphia/Delaware Valley Chapter  
Society for Public Health Education  
Solve ME/CFS Initiative  
Stickler Involved People  
Swedish Health Services  
Syndromes Without A Name USA  
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The Progeria Research Foundation  
The Sickle Cell Association of New Jersey  
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The United Leukodystrophy Foundation  
Translational Genomics Research Institute  
Trisomy 18 Foundation  
Turner Syndrome Foundation  
U.S. Pain Foundation  
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