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who represent millions of patients and their families, researchers and clinicians, will be dramatically impacted by the Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care recently released for comment by the Office of Human Research Protections. We are writing to ask that you allow additional time in which to offer comments in response to this draft guidance you announced on October 24, 2014.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 Careful and intensive deliberation must be undertaken for us to make meaningful comment on this draft guidance.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
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
Parent Project Muscular Dystrophy
Parent to Parent USA
Parkinson's Disease Foundation/Parkinsons Creative Collective
Partners HealthCare System, Office of Human Research Affairs
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
Project DOCC - Delivery of Chronic Care
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
Sickle Cell Disease Association of America, 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
Sysmark Information Systems, Inc.
The Progeria Research Foundation
The Sickle Cell Association of New Jersey
The Sturge-Weber Foundation
The United Leukodystrophy Foundation
Translational Genomics Research Institute
Trisomy 18 Foundation
Turner Syndrome Foundation
U.S. Pain Foundation
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