



4301 Connecticut Avenue, NW
Suite 404
Washington, DC 20008
202.966.5557
info@geneticalliance.org
<http://www.geneticalliance.org>

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who represent millions of patients and their families, researchers and clinicians, will be dramatically impacted by the Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care recently released for comment by the Office of Human Research Protections. We are writing to ask that you allow additional time in which to offer comments in response to this draft guidance you announced on October 24, 2014.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 Careful and intensive deliberation must be undertaken for us to make meaningful comment on this draft guidance.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
DNAdigest
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 Mannosidosis 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
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
University of California, Davis
University of California, San Francisco
University of Chicago
University of North Carolina
University of Utah Center for Clinical and
Translational Science
University of Wisconsin-Madison
VHL Alliance
Vibrant Gene Consulting
Virginia Breast Cancer Foundation
VR Foundation
We Are Curious, Inc.
Wilson Disease Association
WNY Ovarian Cancer Project

Individuals:

Maritza Arroyo-Muniz, MD
University of Puerto Rico Medical Science
Campus
San Juan, Puerto Rico

Dawn Bare
International Cystinuria Foundation
Altoona, PA

Amy Basken
Director of Programs, Pediatric Congenital
Heart Association
Madison, WI

Alan H. Beggs
Boston Children's Hospital
Boston, MA

Gordon R. Bernard, MD
Melinda Owen Bass Professor of Medicine;
Associate Vice Chancellor for Research;
Director, Vanderbilt Institute for Clinical and
Translational Research, Vanderbilt University
Nashville, TN

Esteban Burchard
University of California, San Francisco
San Francisco, CA

Elizabeth A. Chrischilles, PhD
Professor of Epidemiology, The University of
Iowa
Iowa City, IA

Mr. and Mrs. William Clogston
Hurley, NY

Janis Creedon
Brockton, MA

Lesley H. Curtis, PhD
Duke University School of Medicine
Durham, NC

Marie Diehl
Pinellas Park, FL

Karen M. Emmons, PhD
VP for Research, Kaiser Permanente
Oakland, CA

William L. Freeman, MD, MPH, CIP
Program Director, Northwest Indian College
Center for Health; Human Protections
Administrator, Northwest Indian College
Bellingham, WA

Don Goldmann
Chief Medical and Scientific Officer
Institute for Healthcare Improvement
Cambridge, MA

James S. Goodwin, MD
Vice President and Chief Research Officer,
George and Cynthia Mitchell Distinguished
Chair in Geriatric Medicine, University of Texas
Medical Branch
Galveston, TX

Henry T. (Hank) Greely
Stanford Law School
Stanford, CA

Linda Hageman, RN
American Multiple Endocrine Neoplasia
Support
Louisville, TN

Sean Hennessy, PharmD, PhD
University of Pennsylvania Perelman School of
Medicine
Philadelphia, PA

Michael A. Horberg, MD MAS FACP FIDSA
Executive Director Research, Community
Benefit, and Medicaid Strategy, Mid-Atlantic
Permanente Medical Group
Director HIV/AIDS, Kaiser Permanente
Rockville, MD

Ralph I. Horwitz, MD
Sr. VP, Clinical Evaluation Sciences,
GlaxoSmithKline

Leslie Howes
Harvard School of Public Health
Boston, MA

Lisa James
Aliso Viejo, CA

Rainu Kaushal, MD, MPH
Chair, Department of Healthcare Policy and
Research, Weill Cornell Medical College
New York, NY

Wayne Ng Kwing King
Intern, Genetic Alliance
Washington, DC

Erika Lutins
Intern, Genetic Alliance
Washington, DC

Kathy McClelland
Stanford University
Palo Alto, CA

Peter A. Merkel, MD, MPH
Chief, Division of Rheumatology, Professor of
Medicine and Epidemiology, University of
Pennsylvania
Philadelphia, PA

Michelle N. Meyer
Union Graduate College-Icahn School of
Medicine at Mount Sinai Bioethics Program
Schenectady, NY

Celia Molvin
Stanford University
Palo Alto, CA

Federico A. Monzon
Invitae Corporation
Houston, TX

Bernard Munos
InnoThink
Indianapolis, IN

A. G. Newmyer III
President and Chief Executive Officer, The
Kanter Family Foundation
Palm Beach Gardens, FL

Fiona Nielsen
Founder and CEO, DNAdigest
Cambridge, UK

Linda Nichls
Desoto, TX

Selassie Ogyaadu
BRONXSCAN
Bronx, NY

Safiya Omari, PhD
Jackson State University
Jackson, MS

Susan R. Panny, MD
Hunt Valley, MD

Richard Platt, MD, MS
Professor and Chair, Department of Population
Medicine, Harvard Medical School; Executive
Director, Harvard Pilgrim Health Care Institute
Rockville, MD

Jan Porter
Palm Beach Gardens, FL

Debra Rider
Forsyth Institute
Cambridge, MA

Carlos F. Salinas, DMD
Professor, Medical University of South
Carolina, College of Dental Medicine,
Department of Pediatric Dentistry and
Orthodontics, Division of Craniofacial Genetics
Director, MUSC Craniofacial Anomalies and
Cleft Palate Team

Sharon Terry
President & CEO, Genetic Alliance
Washington, DC

Barry H. Thompson, MD
North Potomac, MD

Joanna Tierno
Immune Deficiency Foundation
Staten Island, NY

Lori Sames
Co-Founder & CEO, Hannah's Hope Fund
Rexford, NY

Blair Van Brunt
Rare Disease Perspectives LLC
Sherborn, MA

John Spertus
Saint Luke's Hospital of Kansas City and
University of Missouri - Kansas City
Kansas City, MO

Luciano Vittozzi, MSc
EPIRARE Project, National Centre for Rare
Diseases, National Institute of Health
Rome, Italy

Alexander M. Walker, MD, DrPH
World Health Information Science Consultants
Newton, MA

Andrea Williams
Children's Hospital of Pittsburgh

Susan L. Winterbottom
NPKUA Member, NPKUA
Milton, DE