

National Organization for Rare Disorders, Inc.®



out of the darkness
into the light

NATIONAL MEMBER ORGANIZATIONS

Alagille Syndrome Alliance
Alpha 1 Association
Alpha 1 Foundation
American Brain Tumor Association
American Laryngeal Papilloma Foundation
American Porphyria Foundation
American Syringomyelia Alliance Project
Amyotrophic Lateral Sclerosis Association (ALS)
Aplastic Anemia & MDS International Foundation, Inc.
Association for Glycogen Storage Disease
Association of Gastrointestinal Motility Disorders, Inc. (AGMD)
Batten Disease Support & Research Association
Benign Essential Blepharospasm Research Foundation
Charcot-Marie Tooth Association
Chromosome 18 Registry Research Society
Cleft Palate Foundation
Cornelia De Lange Syndrome Foundation
Cystinosis Foundation, Inc.
DEBRA of America
Dysautonomia Foundation, Inc.
Dystonia Medical Research Foundation
Ehlers Danlos National Foundation
Epilepsy Foundation
Families of Spinal Muscular Atrophy
Foundation for Ichthyosis and Related Skin Types
Genetic Alliance
Guillain Barre Syndrome Foundation International
Hemochromatosis Foundation
Hereditary Colon Cancer Association
Hereditary Disease Foundation
HHT Foundation International, Inc.
Histiocytosis Association of America
Huntington's Disease Society of America
Immune Deficiency Foundation
International FOP Association, Inc.
International Joseph Diseases Foundation, Inc.
International Rett Syndrome Association
Interstitial Cystitis Association
Lowe Syndrome Association, Inc.
Mastocytosis Society, Inc.
Mucopolysaccharide Type IV Foundation, Inc.
Myasthenia Gravis Foundation of America, Inc.
Myeloproliferative Disease Research Center
Myositis Association of America, Inc.
Narcolepsy Network, Inc.
National Adrenal Disease Foundation
National Alopecia Areata Foundation
National Ataxia Foundation
National Foundation for Ectodermal Dysplasias
National Hemophilia Foundation
National Marfan Foundation
National MPS Society, Inc.
National Multiple Sclerosis Society
National Neurofibromatosis Foundation
National PKU News
National Spasmodic Torticolis Association
National Tay Sachs & Allied Diseases Association
National Urea Cycle Disorders Foundation
Neurofibromatosis, Inc.
Osteogenesis Imperfecta Foundation
Parkinson's Disease Foundation, Inc.
Platelet Disorder Support Association
Prader Willi Syndrome Association, USA
Pulmonary Hypertension Association
PXE International, Inc.
Reflex Sympathetic Dystrophy Syndrome Association
Scleroderma Foundation
Sickle Cell Disease Association of America
Stevens Johnson Syndrome Foundation
Sturge-Weber Foundation
The Erythromelalgia Association
The Oxalosis and Hyperoxaluria Foundation
The Paget Foundation
Tourette Syndrome Association
Trigeminal Neuralgia Association
United Leukodystrophy Foundation
United Mitochondrial Disease Foundation
VHL Family Alliance
Wegener's Granulomatosis Association
Williams Syndrome Association
Wilson's Disease Association

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April 8, 2003

Dockets Management Branch (HFA-305)

Docket No. 02N-0475

Food & Drug Administration

5630 Fishers Lane

Room 1061

Rockville, MD 20852

Re: **Docket Number 02N-0475
Financial Relationships and
Interests in Research Involving
Human Subjects: Draft Guidance**

Dear Sir or Madam:

In response to publication of your draft guidance on financial conflicts of interest in human subject research, we are very pleased to note that the guidance will apply to all human research involving funding from DHHS, as well as privately funded human research that is regulated by the Food & Drug Administration (FDA). However, we are disappointed that the proposal is issued as non-binding "points to consider" rather than mandatory regulations. We believe this issue is of maximum importance to the human research protection system, and it should be a mandatory component of that system.

As you mentioned in the *Federal Register* notice of March 31, 2003, the draft guidance does not impose any new requirements. However, the need for guidance on conflicts-of-interest in human research arises because such conflicts have repeatedly biased research results, negatively affected the human subject protection system, and undermined the public's trust in the clinical trials system because of repeated scandals. If these abuses had not occurred, there would be no need for Guidance on financial relationships in human research. Logically, new requirements are needed and should be mandatory so these abuses will not continue to occur in the future.

The draft Guidance notes that, "financial interests may be managed by eliminating them or mitigating their potentially negative impact." We believe the language should say, "Financial interests MUST be managed by....." In other words, it should not be the IRB's choice to ignore potential conflicts of interest, nor should IRBs be allowed to minimize their importance. The government must make it clear that such financial interests MUST be managed. However, since the IRB is normally composed of employees of the institution, investigators may not want their private financial information to be known by their colleagues. Thus a separate conflict-of-interest panel, rather than the IRB, might be assigned the task of reviewing all confidential financial information, and send only relevant information to the IRB when it is directly related to the trial.

Associate Member Organizations

Acid Maltase Deficiency Association (AMDA)	Chromosome Deletion Outreach Inc	Hydrocephalus Association	Osteoporosis and Related Bone Diseases National Resource Center	Sotos Syndrome Support Association
Alternating Hemiplegia of Children Foundation	Chronic Granulomatous Disease Association	Incontinentia Pigmenti International Foundation	Parent to Parent New Zealand Inc	St. Claire's Health Services
American Autoimmune Related Disease Association	CLIMB	K-T Support Group	Parent to Parent New Zealand Inc	Tawana Foundation for Rare Disorders
American Bencaet's Disease Association	Consortium of Multiple Sclerosis Centers	Late Onset Tay-Sachs Foundation	Rare & Expensive Disease Management Program (REM)	Takayasu's Arteritis Association
Amyotrophic Lateral Sclerosis (ALS) of Greater Philadelphia Chapter	Contact A Family	Les Turner ALS Foundation Ltd	Recurrent Respiratory Papillomatosis Foundation	
A-T Children's Project	Cooley's Anemia Foundation Inc	Mercy Medical Airlift	Restless Legs Syndrome Foundation	
(The) CDG Family Network Foundation	Cushing Support & Research Foundation Inc	National Lymphedema Network Inc	Sarcoid Networking Association	Associations are joining continuously For newest listing please contact the NORD office
Canadian Organization for Rare Disorders (CORD)	Family Caregiver Alliance	National Niemann-Pick Disease Foundation	Shwachman - Diamond Syndrome International	
Children's PKU Network	Family Support Network of North Carolina	National Spasmodic Dysphonia Association	Society for Progressive Supranuclear Palsy Inc	
	Freeman Sheldon Parent Support Group	Organic Acidemia Association		

02N-0475

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We also believe that financial information that may constitute a conflict-of-interest should be shared with human subjects through the Informed Consent document so that people can determine for themselves whether a particular financial matter might influence their decision to participate in a trial. For example, if an institution or an investigator owns stock in the company that manufactures the investigational drug that is being tested, this should be disclosed to each patient in advance.

In summary, we believe that separate conflict-of-interest panels should be created at each institution, and only relevant information should be sent to IRBs by the COI panels. If a COI panel finds a problematic conflict, they should manage it before the IRB makes its final determination. The rules should be binding (not a "Guidance"), and no IRB should be allowed to ignore conflicts-of-interest.

Very truly yours,

A handwritten signature in black ink, appearing to read "Abbey S. Meyers". The signature is fluid and cursive, with the first name "Abbey" and last name "Meyers" clearly distinguishable.

Abbey S. Meyers
President

ASM:aa

cc: Diane Dorman, NORD Vice President for Public Policy