



Document Downloaded: Tuesday November 10, 2015

**Letter on Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research
Evaluating Standards of Care**

Author: Jackie Bendall and Costing Policies Committee

Published Date: 01/23/2015

COGR

an organization of research universities

COUNCIL ON GOVERNMENTAL RELATIONS

1200 New York Avenue, N.W., Suite 750, Washington, D.C. 20005
(202) 289-6655/(202) 289-6698 (FAX)

BOARD OF DIRECTORS

SUSAN CAMBER, Chair
University of Washington

SARA BIBLE
Stanford University

LOIS BRAKO
University of Michigan

PAMELA CAUDILL
Harvard University

KELVIN DROEGEMEIER
University of Oklahoma

JOSEPH GINDHART
Washington University in St. Louis

CYNTHIA HOPE
University of Alabama

CINDY KIEL
University of California, Davis

MICHAEL LUDWIG
University of Chicago

JAMES LUTHER
Duke University

LYNN MC GINLEY
University of Maryland, Baltimore

ALEXANDRA MC KEOWN
The Johns Hopkins University

KIM MORELAND
University of Wisconsin

KERRY PELUSO
Emory University

CORDELL OVERBY
University of Delaware

SUZANNE RIVERA
Case Western Reserve University

PATRICK SCHLESINGER
University of California, Berkeley

JAMES TRACY
University of Kentucky

PAMELA WEBB
University of Minnesota

DAVID WINWOOD
Louisiana State University

KEVIN WOZNAK
Georgia Institute of Technology

ANTHONY DE CRAPPEO
President

January 22, 2015

Irene Stith-Coleman, Ph.D.
Office for Human Research Protections,
Department of Health and Human Services
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

SUBJECT: Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research
Evaluating Standards of Care

Dear Dr. Stith-Coleman:

The Council on Governmental Relations (COGR) is an association of 190 research universities and their affiliated academic medical centers and research institutes. COGR concerns itself with the influence of federal regulations, policies, and practices on the performance of research conducted at its member institutions.

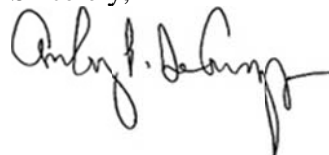
We and our members appreciate the opportunity that the Office for Human Research Protections (OHRP) has offered to provide comment on what risks to subjects are presented by research evaluating or comparing risks associated with standards of care and which of these risks are reasonably foreseeable and should be disclosed to prospective research subjects as part of their informed consent. We affirm the importance of a meaningful and informed consent process, but caution against unnecessarily long and complex consent forms that may have an adverse impact on participant understanding. While we also agree that boilerplate language may be useful in crafting a consent form, care should be taken to keep the informed consent an understandable portrayal of real risk to the participants utilizing understandable terminology and keeping the document to a comprehensible length.

We also believe that identifying additional known risks which are not being evaluated in the study is not reasonable as they may differ by physician practice and may unnecessarily complicate the informed consent and confuse the study participants.

Lastly, we believe that verbiage related to the SUPPORT Trial should be removed from the draft guidance. The guidance as currently written is overly complicated and confusing to read, and should be scaled back to the basic principles and current realities of clinical care.

Thank for you giving us the opportunity to provide comment on what we believe will be a more meaningful consent process. We realize the importance of providing the utmost respect and protection to human subjects while furthering the scientific discoveries that will save lives and keep our citizens healthy.

Sincerely,



Anthony P. DeCrappeo
President