Letter on Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care

Author: Jackie Bendall and Costing Policies Committee

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COGR
an organization of research universities

COUNCIL ON GOVERNMENTAL RELATIONS
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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SUBJECT: Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care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.

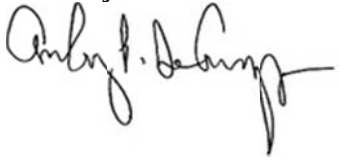
We and our members appreciate the opportunity that the Office for Human Research Protections (OHRP) has offered to provide comment on what risks to subjects are presented by research evaluating or comparing risks associated with standards of care and which of these risks are reasonably foreseeable and 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Lastly, we believe that verbiage related to the SUPPORT Trial should be removed from the draft guidance.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