DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Office of Global Health Affairs
Washington, DC 20201

May 10, 2011

Directorate General for Health and Consumer Protection
Unit SANCO/C/8, BREY 10/114,
BE-1049 Brussels
Belgium

Re: Comments on the Revision of the 'Clinical Trials Directive' 2001/20/EC Concept Paper

The U.S. Department of Health and Human Services is grateful for the opportunity to comment on the Concept Paper concerning the Revision of the Clinical Trials Directive 2001/20/EC. We commend efforts of the European Commission to improve legislation, regulations, directives and policies that govern clinical trials across the European Union.

Collaborations with the European Union account for approximately one-third of the National Institutes of Health's (NIH) annual international funding with an estimated $160 million awarded to institutions in the EU member and associate states. As an active third country funder, sponsor (via a legal representative), and clinical research collaborator with institutions within the European Union, the Department of Health and Human Services, is keen to help facilitate cooperative multi-site clinical trials involving collaborations between sponsors and investigators of our nations.

Comments on the 18 consultation items in the Concept Paper were prepared by a working group comprised of senior officials and represent the position of the Department of Health and Human Services. As you will note, our responses are inserted into the original consultation document (attached).

Our primary comments fall into the general categories of harmonization, risk-based regulatory approaches and the clarification of definitions. It is important to note that some important proposals are described broadly in the Commission's concept paper, and we are uncertain whether the necessary level of detail exists to be able to comment definitively. In these instances we have provided our understanding of the scenario(s) and our respective responses to each. We would provide more detailed responses if we were certain we understood the potential framework that is envisaged.

NIH has previously provided input on the major problems investigators encounter when conducting studies funded by the NIH. These are in the areas of single sponsorship, legal representative of the sponsor, insurance/indemnity, and GMP/QP issues. We are very pleased to see that the Concept Paper proposes options that work to resolve these current challenges.

We wish to emphasize the growing importance of US-EU cooperation for accelerating our collective capacity to create innovative therapeutic agents and to enhance diagnostic capabilities. Collectively, we have a need for larger samples to enroll adequate numbers of volunteers with rare or less prevalent diseases and to appropriately power trials in the face of novel technologies and new inclusion criteria such as genetic and molecular characteristics, requiring greater numbers of volunteers. International cooperation is essential to help ensure that clinical trial findings are broadly applicable to patients worldwide.

The Clinical Trials Directive is critically important legislation to clinical trialists, sponsors, patients and other stakeholders in the European Union and to third country partners who perform collaborative studies in the EU. We are pleased to have this opportunity to comment upon a set of proposals that has great promise for improving the ability of our clinical researchers to perform potentially life-enhancing and life-saving clinical studies in the European Union.

Please contact Dr Susan Shurin, Acting Director of the National Heart, Lung and Blood Institute (shurinsb@nhlbi.nih.gov) if you have any questions about our submission or would like to discuss any of our comments in more detail.

Sincerely,

Nils Daulaire, M.D., M.P.H.
Director