DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Director
Office for Civil Rights
Washington, D.C. 20201

April 15, 2003

Mr. Stan Crosley
Chief Privacy Officer, Eli Lily & Company
Chair, International Pharmaceutical Privacy Consortium
1301 K St., N.W., Suite 900 East Tower
Washington, D.C. 20005-3317

Dear Mr. Crosley:

Thank you for your April 9, 2003, letter to the Secretary advising of concerns that clinical research trials may be impeded because Institutional Review Boards (IRB) are backlogged with requests to review thousands of authorizations. The Secretary has asked that I respond on his behalf, since the Office for Civil Rights (OCR) is charged with responsibility for compliance and implementation of the Privacy Rule. Given our desire to encourage compliance with the Rule and the importance of the issues you have raised, we have hastened to provide this reply.

We appreciate your concern about the International Council on Harmonization (ICH) provisions cited in your letter and understand that many IRBs believe they are required by these provisions to review all written materials or information provided to subjects, including HIPAA authorizations.[1] This misinterpretation is apparently leading some IRBs to refuse to allow continued enrollment of subjects in ongoing studies without first reviewing and approving stand-alone HIPAA authorizations. We understand your concern that this could result in effectively halting many ongoing studies and depriving subjects of access to those studies. In addition to responding to you, this letter is intended to correct any misinterpretation on the part of IRBs, investigators, or sponsors, and it will be posted on our website.

With respect to your request that we announce a "transition period" during which these requirements would be suspended in certain circumstances, we must advise that the April 14, 2003, compliance date for most covered entities is statutorily established. Thus, we are not able to suspend the Privacy Rule's requirements as your letter requests.

However, we wish to emphasize that the Privacy Rule does not require IRBs to review HIPAA authorizations for compliance with the Rule's requirements. From the point of view of Privacy Rule compliance and enforcement, all that is required is that HIPAA authorizations used for research or other disclosures comply with the requirements of the Rule, whether the HIPAA authorization form is created by the covered entity itself or by a third party. Under the Privacy

[1]The ICH Good Clinical Practice guidelines (E6) state, for example, "Before initiating a trial, the investigator/institution should have written and dated approval/favorable opinion from the IRB/IEC for the trial protocol, written informed consent form, consent form updates, subject recruitment procedures (e.g., advertisements), *and any other written information to be provided to subjects*" (Emphasis added.) (See ICH E6 4.4.1.)

Rule, a covered entity may disclose protected health information for research purposes with an authorization that is valid under the Rule, whether or not an IRB has approved the form.

In addition, the Food and Drug Administration (FDA) has authorized us to advise you of its position that the ICH Good Clinical Practice (GCP) guidelines are guidance and as such are not legal requirements subject to enforcement by U.S. authorities, including the FDA. This principle is stated in the FDA's publication of the Good Clinical Practice: Consolidated Guideline at 62 FR 25692, May 9, 1997. In particular the Guideline states, as is true of all FDA guidance, that "[it] does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations, or both." FDA advises that because IRB review and approval of a stand-alone HIPAA authorization is not required under the Privacy Rule, use of a stand-alone HIPAA authorization reviewed and approved by another entity, such as an investigator or sponsor, is an acceptable alternative approach. This approach complies with FDA requirements, so long as it is permitted by the IRB's written procedures.[2] Since the ICH GCP guidelines, including the E6 4.4.1 reference to review of "any other written information," are not requirements, federal regulations do not require IRBs to review and approve stand-alone HIPAA authorizations.

Finally, we wish to clarify how these requirements would apply to IRBs that are subject to the HHS Protection of Human Subjects Regulations at 45 C.F.R. Part 46. The HHS regulations at 45 C.F.R. Part 46 do not require that stand-alone HIPAA authorizations be reviewed or approved by the IRB. Under HHS regulations at 45 C.F.R. 46.117(a), IRB review and approval of HIPAA authorizations is only required if the authorization language is integrated in the informed consent document for human subjects research. The Office for Human Research Protections advises that it would not undertake any compliance action with respect to activities, including review of stand-alone HIPAA authorizations, that are not required by the regulations at 45 C.F.R. Part 46.

Thus, the Privacy Rule, FDA guidance, and the HHS Protections of Human Subject Regulations, all provide significant and broad flexibility for obtaining authorizations that comply with HIPAA. In light of the urgent circumstances identified by your letter, we encourage all entities concerned to avail themselves of this flexibility to permit continued enrollment of individuals in clinical trials.

Sincerely,

Richard M. Campanelli, J.D.
Director, Office for Civil Rights

[2]See 21 CFR 56.108(a). However, even where an IRB's written procedures may present an obstacle, the FDA has advised that it intends to consider exercising enforcement discretion with respect to the requirements of 21 C.F.R. 56.108(a) to the extent that may be necessary, and expects to address the matter in guidance as expeditiously as possible.