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June 4, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 01N-0322, Institutional Review Boards: Requiring Sponsors and Investigators to Inform IRBs of Any Prior IRB Reviews

Dear Sir or Madame:

We are writing today to express our opposition to the plan to require sponsors and investigators to inform IRBs of any prior IRB reviews as proposed in the Notice of Proposed Rulemaking recently published in the Federal Register. We believe that such a system could prove to be a bureaucratic mess for IRBs that are already overworked – distracting them from their more important pursuit of protecting the human subjects who volunteer for research studies.

IRB Shopping Is Not a Significant Problem.

To address the first question, our IRB does not perceive IRB shopping to be a significant problem. In our experience, sponsors and investigators do not decide whether to use a particular IRB based on perceptions of how difficult the Committee's review may be. Rather, we have found that sponsors tend to first choose investigators and institutions for reasons such as the reputation of the investigator or institution, unique characteristics of the local population, and resources available for the research at that particular site. Then they are required to use the IRB with which the investigators are affiliated. Further, investigators often have no choice of which IRB they use because of their affiliation with a hospital or academic medical center and therefore do not have the ability to engage in IRB shopping. Finally, as you observe in your Notice, the OIG was only able to point to "a few situations" where IRB shopping supposedly occurred, but does not offer any quantitative estimate. We urge you to not impose an additional regulatory burden before the scope of any potential problem can be documented and assessed.

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Proposal Is Not the Correct Solution to This Problem.

Furthermore, we believe that the solution to preventing any IRB shopping that might occur is to help raise the standards for all IRBs to the same minimum levels. This would eliminate any perceived advantage to be gained by IRB shopping. We concur with the comments submitted by the Association of American Medical Colleges and believe that voluntary accreditation of IRBs will establish a high standard for IRBs and will reduce the variability among IRBs. However, the FDA should not expect that either their proposal or accreditation will eliminate the differences among IRBs entirely. State law inconsistencies and regional variations will persist and as a result the IRB playing-field will never be entirely level.

We appreciate this opportunity to comment, and hope that you will take our concerns into consideration. If you have any questions or would like additional information, please feel free to contact us.

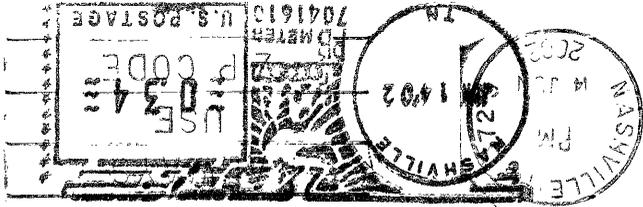
Sincerely yours,

A handwritten signature in black ink that reads "Alastair Wood". The signature is written in a cursive style with a horizontal line underneath the name.

Alastair J. J. Wood, M.D.
Assistant Vice Chancellor for Research
Professor of Medicine
Professor of Pharmacology

AJJW/tj

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