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Robert S. Stone, Director
National Institutes of Health
Bethesda, Maryland 20014

Dear Dr. Stone:

I am fully in support of NIH and DHEW efforts in the protection of human subjects of research, and respond here to the invited comment on the November 16 draft. Having studied the currently proposed congressional legislation in this area I believe that the scientific community should support NIH efforts, as the generally more informed and constructive. The pending legislation is exceedingly oppressive and the regulatory agency proposed could effectively curtail human research, and with it needed improvements in medical care and disease prevention.

The DHEW draft policies published in the Federal Register on November 16 are very worthwhile. I have only these running comments and questions:

1a. How can any conventional medical or surgical procedure be performed or refused depending on consent of a 7 year old child? And how therefore can an experimental procedure be so performed or refused? Others than the child must represent the child's interest in balance with the benefit possible, and others than the child must give consent and refusal. If parental consent is insufficient it is clear that no consent is sufficient.

2a. I am not informed about fetal research and question some of its pursuits. On the other hand, it is clear that no research is possible at all if the investigator can neither prolong nor terminate the function of the fetal organism. Is this what society wants, and is society making an informed consent?

3 and 4. The prisoner and mentally infirm provisions are reasonable and important and they do not completely shut off the possibility of benefit to society from these sources of research participation, as pending legislation seems to threaten. If you want to tighten up Section 4 of the Summary, provision 4.a.1. should read the "mental or emotional disability from which they suffer." I am inclined to agree, despite much valuable research in the past from this laboratory performed on inmates of mental institutions, that researches unrelated to their problems are better performed elsewhere, even if less efficient.

In Section VII.C. there is a problem concerning overseas researches. We all know that ethical principles are neither a platinum meter nor a tablet of commandments but rather, ethics depend on time and place. Such review of overseas research by the DHEW Advisory Ethical Board is fine, but it constitutes in one sense, interference in the internal affairs of a foreign country. It is not evident that these questions are considered in the draft. I think I would be willing to see a prohibition of DHEW funded researches overseas which did not meet U.S. ethical standards--if they were administered by U.S. scientists. But I would like more discussion about what we can tell a foreign scientist about being ethical in his own community under his own organizational Review Committee. It is also clear, as I learned as delegate in a recent U.S.-U.S.S.R. Health Treaty negotiation, that many researches we approve here would be "unethical" and unacceptable in the Soviet Union. This is based on a low level of health awareness in the population, a technological lag, and a conceptual lag by the profession there, an inability as yet to accept the often "higher ethics" of randomized controlled design of therapeutic trials.

In Section III.B. the Ethical Review Board proposed is needed, and in an advisory capacity. Where its opinion is against a particular research, there must be an appeal mechanism and if possible a mechanism for dialogue and negotiation with those determining the scientific merits of the application. Moreover, any truly advisory or editorial board must have the charge of stating its objections and criticisms explicitly and of proposing possible modifications in a research procedure which might, on subsequent review, lead to approval. Compared to this DHEW Review Board, a regulatory commission having inspection and certification authority given in currently proposed congressional legislation on human experimentation is surely unnecessary and therefore undesirable.

Concerning the composition of an Ethical Review Board I have real concerns. Depending on the administration, and DHEW administrator, it would be quite possible to have Christian Scientists, Jehovah's Witnesses, anti-vivisectionists and others in a real position to suppress biomedical research in this country. What safeguards can be taken to avoid the appointment of cultists, etc?

Sincerely,

Henry Blackburn

Henry Blackburn, M.D.
Professor and Director and
Professor of Medicine

HB:mk
Dictated but not read
blind copies to: L. Stauffer, L. French, L. Pickrel, D. Chianchiano, H. Burchell, R. Ebert, W. Goldwater, H. L. Taylor, A. Leon, R. Prineas, Rep. Paul Rogers, Sen. E. Kennedy, M. Visscher