

February 7, 2001

Eric M. Meslin, Ph.D.  
Executive Director,  
National Bioethics Advisory Commission  
6705 Rockledge Drive, Suite 700  
Bethesda, MD 20892-7979

Dear Dr. Meslin:

As president of the Federation of American Societies for Experimental Biology (FASEB), I thank you for the opportunity to submit comments on the NBAC report, *Ethical and Policy Issues in Research Involving Human Participants*. FASEB is comprised of 21 societies with more than 60,000 members, making it the largest coalition of biomedical research associations in the United States. The mission of FASEB is to enhance the ability of biomedical and life scientists to improve, through their research, the health, well-being and productivity of all people.

FASEB highly commends the commission for its thoughtful and well-reasoned approach to ensuring the protection of human participants in all research regardless of funding source. The report provides a comprehensive and integrative set of recommendations to enhance the organization and execution of research oversight, while improving efficiency and reducing redundancy in the existing system. We strongly believe that a single office with final oversight authority, as proposed in the report, will best achieve these important goals. FASEB is in complete agreement that there should be fewer regulations, with emphasis placed on more guidance for the various policy issues. Furthermore, it fully supports NBAC's assertion that the level of protection should be commensurate with the level of risk and believes that the report's recommendations reflect this critical tenet.

FASEB was also pleased that the report highlights an important change needed in the area of informed consent for research involving human participants: shifting the emphasis from documentation to information. This request appropriately reflects the principle of respect for persons, which is strongly embraced by our scientists. The sound ethical framework on which the report's recommendations are constructed makes the document an enduring guide for optimizing human participant protection, while ensuring that groundbreaking biomedical research will continue in the future. This is especially evident in the sections detailing the definitions of research and of a human participant.

#### Centralized Oversight Office

Whereas FASEB is solidly in agreement with the majority of the report's recommendations, it has serious reservations about the necessity of a National Office of Human Research Oversight (NOHRO). Nevertheless, we do support the idea of a centralized office to oversee all research involving human participants, regardless of funding source. Therefore, rather than creating an entirely new entity, FASEB proposes that the mission of the recently established Office for Human Research Protections (OHRP) in

the Department of Health and Human Services (DHHS) be expanded to include these additional responsibilities. This structure would produce multiple benefits including the protection of human participants involved in non-Federally funded research, the elimination of overlapping and sometimes conflicting policies from different government agencies and the reduction of regulatory burden. This solution would also avoid any duplication in the oversight of HHS-funded research and the coordination of Federally-sponsored research and prevent administrative confusion between the two offices. Certainly the advantages of expanding the role of OHRP are persuasive B greater effectiveness, avoidance of conflicts, and increased accountability B but FASEB does recognize that there are practical concerns to be addressed regarding any changes to its administration. In this regards, insight from the commission would be beneficial. One specific concern would be the selection process for the senior personnel of this office. If directors and other high-level administrators were to become political appointees, the policy directions of the office in terms of both federal regulations and day-to-day guidance could shift every time there is a change of administration. **FASEB would therefore like NBAC to carefully consider this proposal for a more encompassing role for OHRP and possibly recommend mechanisms to ensure its effective operation and the long-term continuity of its major policies.**

FASEB is also troubled by the commission's recommendation that the central office issue new regulations requiring that at least fifty percent of IRB members should be people not affiliated with the institution and at least fifty percent of IRB members should be non-scientists (even though a single person could meet both qualifications). While we support the primary rationale behind this recommendation B reduction of institutional influences on IRB decision-making B the consequences of increasing the representation of nonscientists on IRB panels could be detrimental to the advancement of scientific research. In addition, the practicality of fulfilling both requirements is questionable, given the potential difficulties of recruiting, training and retaining qualified people from the community.

A final concern regarding oversight is whether private IRBs would have a special oversight mechanism different from university IRBs under a centralized office and seeks explanation from NBAC. We are also uncertain how this office would ensure that the standards for IRB operation elucidated in the report would be faithfully put into practice by these private entities.

### Rights of Individuals Involved in Research

FASEB commends NBAC for including a section on the compensation for research-related injuries, which is a fundamental component of this report and reinforces the ethical principle of respect for persons. FASEB fully supports the commission's recommendation that Congress should pass legislation establishing a compensation system for medical and rehabilitation costs caused by research participation. However, we recognize that this type of reimbursement would likely prove very expensive and are concerned about the appropriate mechanism for financial support.

FASEB appreciates that NBAC has chosen to address the issues of privacy and confidentiality in research. It is certainly fitting to charge investigators and IRBs with designing research procedures to protect privacy and ensure confidentiality in research studies. We are concerned, however, about the feasibility of these proposals because of a) the potential costs to institutions that could be associated with complying with these requirements and b) the possible conflicts that might arise between applicable

state and federal legislation.

Finally as a practical matter, an Executive Summary would provide a useful tool for reviewing the complete set of recommendations and would direct readers to the relevant sections in the report where they are described, along with their supporting text, in further detail.

In summary, FASEB is very pleased to see that the Commission has:

- 1) Acknowledged the importance of protecting all human participants involved in research, regardless of the source of funds supporting that research
- 2) Clearly defined the terms *research* and *human participants* within a solid ethical framework
- 3) Called for a strengthening of the rights of human participants in terms of informed consent, compensation for injury, and privacy and confidentiality.

Thank you for this opportunity to comment on this outstanding draft report. This comprehensive and detailed document will prove indispensable for leading the Nation as it strives to address the ethical and policy issues associated with research involving human participants.

Respectfully yours on behalf of the FASEB member societies,

Mary J. C. Hendrix, PhD  
FASEB President

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