

PUBLIC POLICYMAKING FOR BIOMEDICAL RESEARCH:
THE CASE OF HUMAN EXPERIMENTATION

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of experience, the institutional review committees would mature and could be largely left alone. However, on the basis of random and periodic reviews of research protocols and some forty site visits to the institutions, officials at the NIH discovered a serious lack of uniformity in the application of the PHS policy. For example, there was an "unwillingness of [sic] the part of some institutions to accept responsibility for cooperative or collaborative work being done outside the institution."⁵⁴ They also reported that the "committees are not uniformly making an effort to determine if the information being given to the subject is adequate and fair in the light of the subjects' probable intelligence, command of the English language, and the nature of the project."⁵⁵ Institutions were also confused by the "risks and benefits" clause of the policy. What was meant by these terms and what type of balance had to be achieved? To many, it was "an entirely new and strange concept,"⁵⁶ and the PHS policy provided few guidelines for them. Finally, under the policy institutions were permitted to review proposals at any time prior to their actual acceptance. Understandably, many institutions followed the practice of reviewing only after the actual awarding of a grant. While this was an administrative advantage for the institution as well as the investigator, it was a cause for concern among NIH officials.

Uncertainty as to the institutional review status of applications has always been very disturbing to initial review groups and to the National Advisory Councils. It has been impossible to tell whether some proposed procedures represented the considered opinion of the institution or whether they had been submitted in the absence of any degree of careful consideration.⁵⁷

It also placed review committees in the unenviable position of having to question a project which had already been reviewed and approved at the national level. The dangers of such haphazard review procedures were made more evident by a report elsewhere that shortly after the adoption of the PHS policy "a sizeable number of clinical investigators took the requirement lightly. Some were frankly annoyed at what they considered a needless imposition, or, worse, an infringement of their rights as physicians."⁵⁸

These problems led Dr. Philip Lee, DHEW Assistant Secretary for Health and Scientific Affairs, to appoint a PHS-NIH Task Force to review and revise previous policy statements with the intention of creating greater consistency in their interpretation and implementation. While there was some reluctance to expand "so much effort... on behalf of so few projects," officials found it "necessary to face up to the growing public awareness and concern with questions of the ethical conduct of medical research, and with the invasions of privacy inherent in a lot of our public data gathering."⁵⁹ Eighteen months after its initial meeting on October 28, 1968, the findings of the Task Force were summarized by its chairman: "The review confirmed the utility of the policy, but recommended changes in the policy statement to provide better understanding of the requirements."⁶⁰

Once again the changes were more procedural than substantive, and were consistent with previous policy statements in emphasizing that protecting the rights and welfare of human subjects was the responsibility