Appendix B

METHOD OF THE STUDY

The general process for studies in the Office of Technology Assessment (OTA) is to have an advisory panel of experts for the study. Panel members suggest source materials and experts; assist in data collection and interpretation; review staff drafts for accuracy and validity; suggest conclusions based on the facts; suggest options for the consideration of Congress; and give arguments for and against specific options. However, the panel does not determine the content of the report and is not responsible for the conclusions and options.

Such a panel was formed for the study on biomedical research and development of medical technology. Dr. Eugene Stead was selected as panel chairman. Other panel members were then selected with the help of Dr. Stead to represent a wide range of disciplines, viewpoints, and expertise. Two members of the Health Program Advisory Committee, who had expressed particular interest in this study, were made members of the panel.

The first meeting of the Panel on Biomedical Research and Medical Technology was convened in Washington, D. C., on January 23, 1976. At this meeting, the Panel discussed the scope of the study. In addition, the Panel endorsed the use of specific cases of development and diffusion of medical technology to illustrate some general points, as well as the complexities of the process. Specific cases were recommended by the Panel for inclusion in the final report, and the points illustrated by each case were discussed.

Between the first and second meetings of the Panel, the staff initiated discussions with selected individuals and groups, including:

Office of the Assistant Secretary of Health, Department of Health, Education, and Welfare
Office of the Assistant Secretary for Planning and Evaluation, Department of Health, Education, and Welfare
The Director and other officials, National Institutes of Health, Department of Health, Education, and Welfare
Officials of the National Center for Health Services Research, Department of Health, Education, and Welfare
Officials of the Food and Drug Administration, Department of Health, Education, and Welfare
Officials of the Office of Research and Statistics, Social Security Administration, Department of Health, Education, and Welfare
The President's Biomedical Research Panel
The Commission for the Protection of Human Subjects
Officials of the National Science Foundation
Staff of the Institute of Medicine, National Academy of Sciences

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Some **voluntary associations were also contacted and gave informal assistance.** In particular, the American Association of Bioanalysts and the American College of Radiology were helpful in furnishing factual information about their respective fields.

At the second meeting of the Panel on February 23, a draft outline developed by the staff for the final report was presented and discussed. There was also more general discussion of the complexities of the charge and of the field under study. Some possible conclusions and options began to emerge from the discussion.

Between the second and third meetings, the staff reviewed materials relating to the subject, received copious materials from certain Panel members, and developed drafts of chapter IV ("A Framework for Medical Technology Assessment") and chapter V ("Findings and Options"). Ms. Sherry Arnstein of the National Center for Health Services Research and Dr. Robert Ringler, Deputy Director of the National Heart and Lung Institute of the National Institutes of Health, were particularly helpful in suggesting references and reacting to drafts of these chapters.

At the third Panel meeting on March 16, three guests made comments and answered questions from the Panel and staff: Dr. Donald Fredrickson, Director of the National Institutes of Health; Dr. Clifton Gaus, Director of Health Insurance Studies for the Social Security Administration; and Dr. Robert Ringler, Deputy Director of the National Heart and Lung Institute and staff to the NIH Totally Implantable Artificial Heart Assessment PaneI. These witnesses were very helpful in suggesting ways technology assessment or other types of assessment could help the process of biomedical research and development of medical technology. The remainder of the meeting was used to discuss conclusions of the study and policy options to be presented.

Between the third and final meetings, the staff continued to collect materials, including helpful comments from Panel members, and completed a draft of the report. At the final meeting of the Panel on March 31, an essentially complete draft report was presented and discussed. The Panel reviewed the report page by page and made many helpful comments and criticisms.

A revised draft was then prepared and submitted to the OTA Board. The Board approved release of the report, subject to final editing and revision, at its meeting of April 13. The draft was then sent to members of the Technology Assessment Advisory Council, the Health Program Advisory Committee, and the Advisory Panel to this study, and to approximately 40 interested individuals both within and outside of the Federal Government, including officials at NIH. During May and June, the staff considered a variety of comments and criticisms received from these people, and prepared a final version of this report for publication.

Although members of the Advisory Panel had enormous impact on the report, the staff takes full responsibility for its contents. Indeed, several Panel members object strenuously to some of the policy options, and inclusion of an option should in no way be construed as indicating approval of the Panel for that option.