CRITERIA FOR CLINICAL INVESTIGATIVE USE
FOR THERAPEUTIC DEVICES UNDER CONTRACT
TO THE NATIONAL HEART AND LUNG INSTITUTE

ANNOUNCEMENT

The National Heart and Lung Institute wishes to call to the attention of the scientific community the criteria for clinical investigative use of therapeutic devices under its research contracts. The following statement of principles and criteria are to supplement, not to supersede, existing DHEW policies and requirements:

The clinical investigative use of any therapeutic device requires that on balance the patient has more to gain than to lose from the investigative use of the device and clinical use in a supported research project must offer promise of answering such significant questions as establishing the efficacy and net benefit of the device. Specifically:

1. The device is to be used only in a situation in which it offers at least as likely benefit as any known accepted technique or any experimental technique which is available for clinical trial in the same setting by the same group. Any exception to this—for example, a device which would have far greater availability with a minimal compromise of potential benefit—would have to be explicitly justified and the ethical, moral, and related issues discussed. Utilization of the device clinically should have the reasonable potential of improving the quality of life of the individual patient in whom it is applied.

2. There must be experimental evidence from laboratory animal studies of beneficial effect for the clinical circumstance in which it is to be used, or this must be clearly inferred from the laboratory investigations.

3. The expected reliability of the device in investigative clinical use must be stated; this reliability must be exceeded by a reasonable margin of safety in preclinical testing.

4. The functioning and the effects of the device must be characterized in detail in bench testing and in experimental animals where an animal test is feasible.

5. The device must be fully described as to construction, materials, and methods of use.

The GUIDE is published at irregular intervals to provide policy, program, and administrative information to individuals and organizations who need to be kept informed of requirements and changes in grants and contracts activities administered by the National Institutes of Health.
6. There must be evidence of reasonable safety against such potential ordinary hazards of devices as electrical shocks, as well as against any special hazards which may be associated with the device; whenever feasible, the device should be failsafe.

7. The investigative team must have specific and extensive familiarity and actual experience with the device.

8. The consequences and courses of action if the device fails or fails to achieve its expected results must be considered and a plan of action outlined in the protocol submitted.

9. The clinical investigative protocol must be such that it can produce maximum research information at minimum hazard to the patient, and it must be in the patient's best interest at all times. It must be designed to answer significant questions in a scientifically sound manner. Hypotheses, methods, sample sizes, end points and criteria for evaluation must be stated. The protocol must provide for careful patient characterization before, during, and after the use of the device; the settings and mode of use of the device must be specified; and standardized data must be recorded and analyzed systematically.

10. Definitive criteria for patient selection must be included in the investigation protocol.

11. The ethical, moral, and related issues of the clinical investigative procedure and the use of the device must be discussed in the protocol.

12. The principles of informed consent must be adhered to scrupulously; the protocol submitted must discuss this fully, including the procedures to be utilized and the information to be presented.

13. The approval of local institutional research committee and other appropriate committees and conformity to the Institutional Guide to DHEW Policy on Protection of Human Subjects is required.

14. The data to substantiate the fulfillment of these criteria must be presented to the National Heart and Lung Institute.

15. Prior to clinical use, the complete research protocol must be approved by NHLI.
NIH Guide for Grants and Contracts, Cumulative Contents (Continued)

Volume No. 3

Guide No. 1, January 4, 1974

Bladder Cancer Research ........................................... 1

Guide No. 2, January 23, 1974

NIGMS Molecular Pathology Centers ................................ 1
Decentralized Procedure for Announcement of Contract Proposals .... 3

Guide No. 3, February 21, 1974

"Student Unrest" Provisions of DHEW Appropriation Act, 1974 .......... 1
Use of Grant Funds for the Payment of Consultant Fees (NIH 5302) ...... 3
Grant Application Kits for Use by State and Local Governments ......... 5
Mass Spectrometry Resources Available to NIH Grantees ............... 7
Action to Cope with the Energy Crisis ................................ 9

Guide No. 4, March 13, 1974

Biomedical Engineering Centers ..................................... 1
Research Grant Support for Studies of Neurological, Neuromuscular
and Communicative Disorders; Research Grant Support in the Area
of Chiropracy .............................................................. 3

Guide No. 5, April 8, 1974

NIH Research Career Development Program ................................ 1

Guide No. 6, April 17, 1974

Minority Access to Research Careers .................................. 1

Guide No. 7, May 10, 1974

Special Dental Research Award ......................................... 1
Shared Biotechnology Resources Program .................................. 3
Treatment of Cost Transfers Between Projects .......................... 5

Guide No. 8, May 24, 1974

NIH Manpower Report ................................................... 1
Biotechnology Resource Centers Available to NIH
Grantees and Contractors ............................................. 3
Acupuncture Research ................................................... 7
PHS Grants Policy Statement Distribution and Applicability ......... 9

Guide No. 9, June 18, 1974

NIH and ADAMHA Institutional Research Fellowship Awards ............ 1
NIH Special Research Career Programs .................................. 5
Equalization of NIH Stipends ......................................... 7

Guide No. 10, July 3, 1974

Treatment of Cost Transfers Between Projects .......................... 1
Duplicated Copies of Grant Applications ................................ 1
Special Dental Research Award ......................................... 1
Development of Tests Suitable for Detecting Human Germinal and
Somatic Cell Mutations .................................................. 3

vii
Guide No. 11, August 7, 1974

Criteria for Clinical Investigative Use for Therapeutic Devices
under Contract to the National Heart and Lung Institute ............ 1