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NIH GUIDE for GRANTS and CONTRACTS

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Vol. 3, No. 11, August 7, 1974

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

ANNOUNCEMENT

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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.

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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.

Volume No. 3

GPO 879-404