

NIH GUIDE

for GRANTS and CONTRACTS

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

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RESEARCH PROJECTS INVOLVING

HUMAN SUBJECTS

ANNOUNCEMENT

The purpose of this notice is to provide clarification of that portion of the Instruction Sheet (Rev. 2-73) for Form NIH 398 pertaining to Research Involving Human Subjects.

DHEW regulations define "subject at risk" as "any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service."

DHEW is concerned with the protection of the rights and welfare of human subjects in all research, development, and related activities. The Department's regulations (45 C.F.R., Part 46) are concerned with protection of rights to privacy, the need for informed consent, protection of confidentiality of data, and protection against physical, psychological, sociological, or legal risks. The need for protection of rights and welfare and protection against risks to the individual is not limited to activities involving children and adults but also includes the fetus, the abortus and the dead. The uses of organs, tissues, body fluids, or graphic, written or recorded information, while they present no physical risks to the subjects, may create medico-legal risks, or expose the subject to public embarrassment or humiliation through break of confidentiality and invasion of privacy. The major focus of a project (for example, on a medical procedure) is not the sole determinant of the need for protections. The safeguarding and confidentiality of medical records and other forms of data collected on individuals and groups and the use of such data either by the investigator conducting the original research, concurrent use of the data by other investigators, or use of the data at a later time are considered within the scope of concern of this policy.

While safeguarding the rights and welfare of subjects at risk is primarily the responsibility of the organization conducting grant activities, the responsibility for determining the adequacy of proposed procedures is shared by organizational review committees and DHEW staff and advisory committees. Therefore, if the proposal involves human subjects, the principal investigator shall, under the heading HUMAN SUBJECTS at the end of the Methods of Procedure section of the application:

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.

- 1) Describe the requirements for a subject population and explain the rationale for using in this population special groups such as prisoners, children, the mentally disabled or groups whose ability to give voluntary informed consent may be in question.
- 2) Describe and assess any potential risks--physical, psychological, social, legal or other--and assess the likelihood and seriousness of such risks. If methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used.
- 3) Describe consent procedures to be followed, including how and where informed consent will be obtained.
- 4) Describe procedures (including confidentiality safeguards) for protecting against or minimizing potential risks and an assessment of their likely effectiveness.
- 5) Assess the potential benefits to be gained by the individual subject, as well as benefits which may accrue to society in general as a result of the planned work.
- 6) Analyze the risk-benefit ratio.

The statements are subject to review, approval, and modification by your local organizational review committee. To insure timely completion of this review, your application and any additional materials requested by the committee should be submitted for local review well in advance of Public Health Service deadlines. If this review is not completed in advance of the deadline, it will be your responsibility to see that any modifications of the Methods of Procedure or HUMAN SUBJECTS section as a result of the review are forwarded to the PHS. These should be sent directly to the Division of Research Grants, NIH, Bethesda, Maryland 20014, and should be identified by principal investigator's name, project title, and name of organization precisely as entered on the receipt of application card returned with the original application.

The regulations concerned with the protection of human subjects effective July 1, 1974, require that organizational review and approval be completed and certified prior to submission of proposals to DHEW. However, by separate notice, the DHEW will provide that for a period of one year from the effective date of these regulations, organizations may submit certifications no later than 30 days following the deadline for which the proposal was submitted, or, if no deadline is specified, 30 days following the submission of the proposal. If a certification is not received within the 30 days, as provided above, the application will be administratively withdrawn by the Division of Research Grants and returned to the applicant institution.

After July 1, 1975, organizational review and approval must be completed and certified prior to submission of proposals to DHEW.

CLINICAL VIROLOGY SPECIAL
EMPHASIS PROGRAM

ANNOUNCEMENT

A Clinical Virology Special Emphasis Program has been initiated by the National Institute of Allergy and Infectious Diseases to encourage research on the development of more effective methods for the prevention, diagnosis, and treatment of viral infections. Through this program the Institute hopes to support through grants investigations that will determine the most effective routes for administration of viral immunogens, clarify mechanisms of immunity to viral agents, and identify those which modify defense responses.

As antivirals are developed for clinical use, there is a special need for more rapid, sensitive, and economical methods of viral diagnosis. Although molecular virology is providing answers to a number of basic problems, knowledge remains deficient on the pathogenesis and clinical consequences of viral infection.

An important goal of the program is to seek out and support research environments which encourage close collaboration between the research virologist or immunologist and the clinician responsible for the diagnosis and care of patients with viral diseases. This interaction is usually best achieved in those institutions where hospital-based virus diagnostic laboratories are closely tied to clinical investigative programs in viral infections.

Applications for research grants in clinical virology will be accepted from eligible institutions in which the proposed principal investigator has a doctoral degree in medicine or in a scientific field such as molecular virology or immunology. For fiscal year 1975, applications should be submitted on or before October 1. Contact: Dr. Luz Froehlich (301) 496-7131, Assistant for Clinical Programs, Extramural Programs, NIAID, Bethesda, MD 20014.

INVITATION TO SUBMIT RESEARCH GRANT APPLICATIONS
ON THE PHYSIOLOGY OF AGING

ANNOUNCEMENT

The National Institutes of Health is responsible for the support of research on many of the biological, medical, and behavioral aspects of aging.

NIH wishes to expand its current program of research on physiological aspects of aging and therefore invites the submission of investigator-initiated grant applications in that area.

In order to be eligible for funding in fiscal year 1975, applications must be submitted by October 1, 1974. Award and funding of projects will depend on review through the usual NIH procedures.

Inquiries regarding this program may be addressed to Dr. Leroy E. Duncan, Jr., Chief, Adult Development and Aging Branch, NICHD, NIH, Bethesda, MD 20014. Telephone: (301) 496-1033. Applications, when in the final form, should be sent to the Division of Research Grants, NIH, Bethesda, MD 20014. That Division is responsible for the initial review of applications and their assignment to the appropriate institute.