NIOSH

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

REPRODUCTIVE EFFECTS DUE TO WORKPLACE HAZARDS

RESEARCH GRANT PROGRAM ANNOUNCEMENT

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

June 30, 1980

PROGRAM ANNOUNCEMENT

GRANTS ADMINISTRATION AND REVIEW BRANCH
OFFICE OF EXTRAMURAL COORDINATION AND SPECIAL PROJECTS
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH,
CENTER FOR DISEASE CONTROL

TITLE: REPRODUCTIVE EFFECTS FROM OCCUPATIONAL HAZARDS

Application receipt dates: November 1, March 1, and July 1

Altered fertility, low birth weight, spontaneous abortion, transplacental carcinogenesis, congenital malformation, mutagenesis, and developmental abnormalities are among the effects on reproduction that have been recognized to result from toxic occupational exposure. Exposure of both men and women can produce these effects. The knowledge base in the area of toxic reproductive hazards is relatively small. The National Institute for Occupational Safety and Health (NIOSH) would like to expand its involvement in the identification and prevention of reproductive effects from occupational hazards. The scope of this announcement is flexible to encourage various interactive combinations of research approaches that might yield insight into the issues and problems surrounding reproductive effects as a consequence of physical and chemical occupational hazards. The Institute is seeking applications for research and demonstration grants concerned with basic and applied projects in areas such as epidemiology, toxicology, control technology, and health education.

I. BACKGROUND INFORMATION

The current responsibilities of NIOSH were established by the Public Health Service Act, the Occupational Safety and Health Act of 1970 and the Federal Mine Safety and Health Amendments Act of 1977. A major NIOSH responsibility under those Acts is to conduct research necessary to ensure, insofar as possible, that no worker will suffer diminished health, reduced functional capacity, or decreased life expectancy as a result of his or her work experience. As a part of this responsibility NIOSH is concerned with discovering the identity and, if possible, the prevalence of physical and chemical hazards to which male and female workers who are exposed that might affect the development of their unborn children. While a relatively few chemical and physical agents are generally accepted as proven mutagens, teratogens, or carcinogens in humans, over a thousand agents are reported to have these effects in animals. Furthermore, many of these agents are reported to be mutagenic

in biologic test systems and thus must be suspected as capable of causing reproductive effects in humans.

Over the past several decades there has been a threefold increase in the number of women employed in the U.S. workforce. During this period women have been employed in more hazardous occupations including those traditionally restricted to men. In recent years an increasing number of pregnant women have remained on the job until near the end of pregnancy. Thus, many more women and their unborn children are being exposed to chemical, physical, and psychological hazards of the workplace. Despite this fact, very little is known about the impact of such exposures on fetal wastage and growth and development.

Because of the unique role of women in the reproductive process, exposure to chemical and physical hazards has targetted attention on the risks to the offspring of maternal exposure. In so doing, we tend to forget that the working male exposed to mutagenic agents also places the health of his offspring at risk.

Other areas of concern are:

(1.) Recognition of the potential that exists for harm to the germ cells of parents of both sexes signals a need to investigate the possibility that occupational hazards might affect the fertility of both men and women;

(2.) The realization that significant quantities of industrial materials may be brought home in clothing resulting in the potential exposure of non-working pregnant women, makes studies of teratogenicity of agents to which male workers are exposed as important as studies of infertility and mutagenicity; and

(3.) The possibility that childhood cancers may be related to pre-natal environmental exposures.

NIOSH is offering both a challenge and an opportunity to talented researchers interested in the study of reproductive effects from occupational exposures.

II. AREAS OF RESEARCH INTEREST

The goal of this announcement is to stimulate and encourage high quality research and demonstration grants in the areas of research listed below. These areas are not mutually exclusive. It is anticipated that a given research study may cut across several areas. Included under each listed area are examples of the types of studies which would be of interest to NIOSH. They are not meant to be restrictive and are cited for illustrative purposes only.

A. EPIDEMIOLOGY AND BIOMETRY: Projects which consider the epidemiology of reproductive effects, including altered fertility, spontaneous abortion, fetal deaths, genetic diseases and disorders and childhood cancer, resulting from chemical and physical occupational hazards. Of particular interest are studies where dose-effect relationships are identified or determined. NIOSH is interested in epidemiological research using a variety of methods or approaches. Such methods include those which generate hypotheses and typically use registries, medical records or statistics as the primary data source and those methods which tend to confirm hypotheses by demonstrating dose-effect relationship or the prevention of an effect by interruption of exposure. Specific examples of epidemiology studies include:

- o Studies which identify groups of workers with abnormal reproductive experience and determine probable cause.
- o Studies to determine whether an incidence of infertility, spontaneous abortion, or fetal mortality in the reproductive experience of a specific group of workers and/or spouses is abnormal.
- o Studies to assess the parental employment relatedness of cancer in childhood.
- o Studies on known reproductive hazards to evaluate and compare methodologies and to determine association between endpoints of the methodologies.

B. TOXICOLOGY: Projects to identify reproductive (mutagenic, teratogenic, etc.) hazards of chemicals to workers and to provide an early warning of the possible deleterious effects. Specific examples include:

- o Research which develops test systems to detect mutagenic activity of air particulates, chemical mixtures or complexes found in the workplace.
- o Projects which study the possible synergistic effect of mutagenic and teratogenic chemicals produced in workplaces.
- o Research to validate human cell mutagenic assay systems.
- o Studies which evaluate the usefulness of body fluid analysis and cytogenic assay systems for the assessment of the mutagenic hazard of chemicals to workers.

C. EXPERIMENTAL LABORATORY INVESTIGATIONS: Projects to elucidate the biochemical and physiological mechanisms of activity and nature of reproductive hazards in the workplace. Examples include:

- o Studies to develop and validate screening systems based upon biochemical, enzymatic, or hormonal components of body fluids (e.g., blood, urine, semen) that can be used as reliable indices of the functional state of the reproductive system.
- o Investigations to develop, improve, or validate short-term or in vitro methods for teratogenesis testing.
- o Studies of mechanisms of teratogenesis, with the goal to improve the ability to predict relative teratogenic potential of chemically related compounds or to make inter-species extrapolations of teratogenesis data.
- o Research on the mechanisms by which abnormalities are induced in sperm head morphology and the implications of morphological changes as indicators of induced mutations or of impaired reproductive capacity

D. CONTROL TECHNOLOGY: Projects to develop new and improved methods or equipment to prevent reproductive effects from occupational hazards

- o Studies which identify workers potentially or actually exposed to reproductive hazards and design new or improved controls for the hazards.
- o Research which adapts existing methods, as well as develop new methods of monitoring and controlling reproductive hazards in the workplace.
- o Research which seeks to use innovative approaches, such as alternative materials, engineering controls, process modification and protective equipment to prevent known or suspected reproductive problems.

E. HEALTH EDUCATION RESEARCH AND DEMONSTRATION PROJECTS: Projects to increase awareness of the importance or reproductive hazards in the workplace. Examples include :

- o Development of educational programs for health professionals, and worker educators to increase their awareness of the issues and problems surrounding reproductive effects from occupational hazards.

MECHANISM OF SUPPORT

The traditional grant-in-aid mechanism will be used to support grants pursuant to this Program Announcement.

Nonprofit organizations and institutions, State and local governments and their agencies, are eligible to apply.

Grants may be supported for up to three years, and may be renewed for an additional period, subject to the competitive review procedure and availability of funds.

Awards will be made based on priority score ranking, as well as availability of funds for this Program.

Grantees will be required to cost share a minimum of five percent.

Grants will be made under the legislative authorization in Section 20(a)(1) of the Occupational Safety and Health Act of 1970 (29 USC 669 (a)(1), Public Law 91-596. The Catalogue of Federal Domestic Assistance Citation is Section 13.262.

REVIEW PROCEDURES AND CRITERIA

The initial review of applications responsive to this Program Announcement will be arranged by the Division of Research Grants. Major factors considered in evaluating each application include:

- o training, experience, and research competence, or promise, of the applicant(s) to carry out the proposed investigations, and the adequacy of effort (time) to be devoted to the project
- o the scientific merit of the proposal: the questions proposed for study, the research design, the proposed methodology, the proposed methods for analysis and interpretation of data
- o adequacy and suitability of the existing and proposed facilities and resources.
- o appropriateness of the requested budget relative to the work proposed.
- o adequacy of collaborative arrangement(s), if applicable.

A secondary review process will be conducted by NIOSH. Factors considered in this review include:

- o the results of the initial review;
- o the significance of the proposed research to the research program of NIOSH.
- o national needs and program balance, and
- o policy and budgetary considerations.

Applications responsive to this Program Announcement are not subject to OMB Circular A-95 Clearinghouse and/or Health Systems Agency review.

Proposals considered to be non-responsive to the terms outlined in this Program Announcement will be appropriately reassigned for review or returned to the investigator, as indicated. Returned proposals may be revised and resubmitted.

METHOD OF APPLYING

Applications should be submitted on a form PHS 398 (State and local governments use form PHS 5161-1). Application kits may be obtained from:

Office of Grants Inquiries
Division of Research Grants
National Institutes of Health
Westwood Building, Room 448
Bethesda, Maryland 20205
Telephone: (301) 496-7441

Care should be taken in following the instructions included with the application form making certain to fulfill the points identified under the heading "REVIEW CRITERIA."

An original and six copies (original and two copies for State and local governments) must be received no later than: November 1, March 1, and July 1 as applicable. Applications received after the designated deadline will be considered with the applications received for the following deadline. Completed applications must be sent or delivered to:

Application Receipt
Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, Maryland 20205

A brief covering letter must accompany the application indicating that it is submitted in response to this program announcement. A carbon copy of this covering letter along with an additional copy of the application should be sent to the Chief, Grants Administration and Review Branch (see below).

IDENTIFICATION OF CONTACT POINT

Questions related to this announcement should be addressed to:

Faye Calhoun
Chief, Grants Administration and Review
Branch, National Institute for Occupational
Safety and Health
Parklawn Bldg., Room 8-63
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Rockville, Maryland 20857
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or

Mr. Joseph West
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