http://grants/nih.gov/guide/rfa-files/FRA-OD-99-06.html

RESEARCH ON CHILD NEGLECT

Release Date: March 16, 1999

RFA: OD-99-006

P.T.

Office of Behavioral and Social Sciences Research
National Institute on Alcohol Abuse and Alcoholism
National Institute of Child Health and Human Development
National Institute of Dental and Craniofacial Research
National Institute on Drug Abuse
National Institute of Mental Health
National Institute of Neurological Disorders and Stroke
Children's Bureau, Administration on Children, Youth and Families
National Institute of Justice, Office of Justice Programs, DOJ
Office of Juvenile Justice and Delinquency Prevention, Office of
Justice Programs, DOJ
Office of Special Education Programs, Department of Education

Letter of Intent Receipt Date: June 15, 1999 Application Receipt Date: September 14,1999

PURPOSE

The purpose of this five-year research grant program is to enhance our understanding of the etiology, extent, services, treatment, management, and prevention of child neglect. This Request for Applications (RFA) is intended to stimulate the development of programs of child neglect research at institutions that currently have strong research programs in related areas (e.g., child development, injury prevention, developmental neurobiology, child abuse, substance abuse, population research, craniofacial and dental public health, health services) but are not engaged in extensive research focusing on child neglect. A second goal of this RFA is to bring the expertise of researchers from the child health, education, and juvenile justice fields into the child neglect research field and to promote their collaborations with each other and with child neglect and child abuse researchers.

While increasing attention is being paid to the issue of child abuse, little research has yet addressed the equally significant problem of child neglect. Yet child neglect may relate to profound health consequences, including premature birth and perinatal complications, physical injuries (such as central nervous system and craniofacial injuries, fractures, and severe burns), disfigurement, disabilities, and mental and behavior problems (e.g., suicide, lowered IQ, depression, anxiety, post-traumatic stress disorder, delinquency and later adult criminal behavior, drug and alcohol abuse, and a greater likelihood of growing up to repeat the cycle of negative behaviors as a parent). Moreover, child neglect can place children at higher risk for a variety of diseases and conditions (e.g., through elevated exposure to toxins causing anemia, cancer, heart disease, poor immune functioning, and asthma; through inadequate health promoting behaviors--medical checkups, proper diet, etc. -- needed to prevent disease or manage chronic disorder). Child neglect can also interfere with normal social, cognitive, and affective development, including the development of language, social relationships, and academic skills.

Thus, child neglect is a serious public health, justice, social services, and education problem, not only compromising the immediate health of our nation's children, but also threatening their growth and intellectual development, their long-term physical and mental health outcomes, their propensity for pro-social behavior, their future parenting practices, and their economic productivity as eventual wage earners. The sponsoring organizations are jointly issuing this Request for Applications (RFA) because neglect is a multi-faceted problem involving many agencies in its consequences, prevention, and control. The RFA is intended to go beyond what any single organization would be likely to accomplish individually, since child neglect requires multi-disciplinary solutions which cross-cut the missions of NIH and these partner agencies.

Since studies of child neglect are constrained by myriad practical, legal, ethical, and methodological considerations, the funding partners sponsoring this RFA believe that, without special encouragement to the scientific community, the number of studies addressing child neglect will likely continue to lag behind that of studies addressing other forms of childhood trauma. Without an increase in child neglect research we will continue to lack the means to effectively prevent the occurrence of child neglect or to ameliorate its consequences. The need for more research to augment and expand the existing scientific knowledge base on child neglect provides the impetus for this RFA.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000" a PHS-led national activity for setting priority areas. This RFA, Research on Child Neglect, is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2000" at http://www.crisny.org/health/us/health7.html

ELIGIBILITY

Applications may be submitted by any domestic for-profit or non-profit organizations, public or private, such as universities, colleges, hospitals, laboratories, units of State and local governments, or eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators.

MECHANISM OF SUPPORT

This RFA will use the NIH individual research project grant (R01) mechanism of support. Although the R01 is the mechanism of support for this RFA, research projects not traditionally supported with this mechanism are also encouraged. These may include not only large scale research grants characteristic of more mature fields of study, but also exploratory, preliminary, or innovative research projects, with sound methodology and strong rationales, that provide a basis for future continuing or expanded research project applications. Also of interest are short-term projects, studies submitted by less experienced investigators, and feasibility studies testing methods or techniques new to child neglect

research. Because the nature and scope of the research proposed in response to this RFA will vary, it is anticipated that the size and length of the awards will also vary widely.

FUNDS AVAILABLE

It is anticipated that for fiscal year 2000, the co-sponsors of this initiative will provide total funds (direct and indirect costs) in the amount of \$ 3,315,000. Award of grants pursuant to this RFA is contingent upon receipt of both sufficiently meritorious applications and funds for this purpose. Between 11 and 15 awards are anticipated. The exact amount of funding awarded will depend on the quality of applications and the availability of funds.

Applicants should provide a detailed time frame describing what specific activities are to occur throughout the proposed grant period, justifying time estimates. Applicants may request support for up to 5 years. The usual PHS policies governing grants administration and management will apply. Annual awards will be made, subject to continued availability of funds and progress achieved. This RFA is a one-time solicitation. At the end of each project's official award period, a competitive renewal application may be submitted for peer review and competition for support through the regular grant programs of the participating agencies. It is anticipated that awards resulting from RFA OD-99-006 may begin as early as July 1, 2000. Administrative adjustments in project period or amount of support may be required at the time of the award. Since a variety of approaches would represent valid responses to this RFA, it is anticipated that there will be a range of costs among the grants awarded. All current policies and requirements that govern the research grant programs of the NIH will apply to grants awarded in connection with this RFA.

RESEARCH OBJECTIVES

Background

This initiative is responsive to the recent directive by the Committee on Appropriations (H.R. No. 104-659) that the NIH "convene a working group of its component organizations currently supporting research on child abuse and neglect." The NIH Child Abuse and Neglect Working Group (CANWG), was established in response to this mandate. The Appropriations Committee requested that this working group report on "current NIH research efforts in this area, the accomplishments of that research, and on plans for future coordination efforts at NIH at the fiscal 1998 hearings." The recommendations for future research noted in the CANWG's subsequent 1998 report were based on both an analysis of the NIH portfolio as well as on the 1993 National Academy of Sciences (NAS) report, "Understanding Child Abuse and Neglect." The NAS report outlined 17 research priority areas where research was especially needed, including (a) a better understanding of the nature and scope of child maltreatment, (b) increased knowledge about the origins and consequences of abuse and neglect, (c) improving treatments and prevention interventions, and (d) developing a science policy for research on child maltreatment. Child neglect was also noted as a high priority research area in the 1998 Institute of Medicine report, "Violence in Families: Assessing Prevention and Treatment Programs." This RFA is also

responsive to recommendations from the National Institute of Justice (NIJ) "Child Abuse and Neglect Interventions Strategic Planning Meeting," October 20-21, 1997, which included representatives from the government agencies of ACYF, NIH, CDC, and NIJ. The content of this RFA is also in line with the conclusions of a June 1993 National Center for Child Abuse and Neglectsponsored symposium on chronic neglect, which addressed consensusbuilding on definitions, strategies for change, research, treatment, and policy topics (Chronic Neglect Symposium Proceedings (1993) available from the NCCAN Clearinghouse, 800-394-3366).

Child abuse and child neglect have become endemic to our society, constituting major public health problems for all Americans, with consequences of severe psychological and social dysfunction as well as injury and death. Of these two serious problems affecting children, the one of abuse (both physical and sexual) has gained significantly greater attention. In contrast, the area of child neglect has not benefitted from any systematic study, despite the fact that neglect may be as deleterious, and even more widespread, than physical or sexual child abuse.

It is difficult to make any absolute statement about the extent of neglect since the literature is plagued by poorly defined samples and the tendency to aggregate physical abuse, sexual abuse, and neglect into a single category of child maltreatment. Perhaps the most influential nationally representative incidence survey, commissioned by ACYF, includes both harm and endangerment in its definition of neglect (National Incidence Study (NIS), Office of Human Development). Another ACYF survey, the "1996 Child Maltreatment Reports of the States to the National Child Abuse and Neglect Data System," indicated that 55% of the nearly one million documented cases of child maltreatment that year were cases of some form of neglect. This incidence figure is likely to be a significant underestimate. Other evidence suggests that less than half of recognized cases of maltreatment are actually reported to child protective services, and less than 20% of these cases are taken to court. While serious neglect may sometimes result in foster care placement, only a minority of cases result in removal of the child from the home. Interventions must therefore address the needs of both the child and the parents.

The NIS distinguishes among three primary forms of child neglect: physical neglect, educational neglect, and emotional neglect. In a 1985 report, the AMA suggested that routine examinations may reveal many indicators of physical neglect, including malnutrition; low birth weight; repeated pica; constant fatigue; poor hygiene; persistence of treatable medical conditions; lack of immunizations and appropriate medications; absence of dental care; absence of necessary prostheses such as eyeglasses and hearing aids; preventable injuries (e.g., craniofacial injuries resulting from failure to wear protective headgear during sports); and delays in physical, language, and cognitive development. While educational neglect (e.g., ignored or permitted truancy; failure to enroll children in school; failure to obtain recommended remedial or special education services) may also be relatively easy to detect, less readily apparent is emotional neglect, which can involve inadequate nurturance and affection, exposure to family violence, permitted abuse of drugs or alcohol, or refusal of psychological care. Intervention may be particularly difficult in the vast majority of the cases where neglect is chronic and insidious.

Parental factors that contribute to child neglect may include maternal depression, intellectual impairments, social isolation, financial problems, substance abuse, limited education, unemployment, marital problems, and mental illness. While the data are largely inconclusive, child-related risk factors for neglect may include prematurity, chronic illness, and hearing impairment. Consequences of neglect may include developmental delays such as lower IQs, growth problems, decreased readiness for learning, and speech and language impairment. Some studies show neglect to be associated with behavioral and psychological impairments as well, such as maladaptive peer interactions, insecure attachments, social isolation, depression, avoidance, low self-esteem, lowered tolerance for frustration, greater dependency, attention problems, and (for boys) conduct disorder, though the causal direction for many of these problems is still unclear. Neglected children under age 3 are also at high risk for child fatalities.

In 1993, the National Academy of Science "Report on Child Abuse and Neglect" noted that studies of child neglect were lacking in scientific rigor, and relied heavily on anecdotal evidence. Since these shortcomings remain, this RFA is intended to encourage research on the prevalence, causes, course, and consequences of child neglect, as well as evaluation of interventions designed to prevent its occurrence, and to reverse, ameliorate, or compensate for the short- and long-term effects of neglect on child victims.

This RFA, coordinated under the auspices of the NIH Child Abuse and Neglect Working Group, is a joint effort of several Institutes and Offices of the NIH, including the Office of Behavioral and Social Sciences Research, the National Institute on Alcohol Abuse and Alcoholism, the National Institute of Child Health and Human Development, the National Institute on Drug Abuse, the National Institute of Dental and Craniofacial Research, the National Institute of Mental Health, and the National Institute of Neurological Disorders and Stroke. This RFA is in line with NIH's overall mission to promote the nation's health, by increasing the scope of research on the causes, prevention, treatment, and physical and mental health consequences of child neglect.

Joining with the NIH are the Children's Bureau, within the Administration for Children and Families, Department of Health and Human Services; the National Institute of Justice (NIJ) and the Office of Juvenile Justice and Delinquency Prevention (OJJDP), both in the Department of Justice; and the Office of Special Education Programs (OSEP), within the Department of Education. Research on neglect fully supports the mission of the Children's Bureau, which is to provide for the safety, permanency and well-being of children and families through leadership, support for necessary services, and productive partnerships with states, tribes and communities. This RFA is consistent with NIJ's overall mission to sponsor research that strengthens the criminal justice system and reduces crime and delinquency, including studies that evaluate the effectiveness of criminal justice programs. The RFA is also consistent with OJJDP's commitment to foster all research which may potentially contribute toward the prevention and treatment of juvenile delinquency. Finally, the RFA furthers the mission of OSEP to encourage research useful to state and local efforts to educate children with disabilities, and to provide all such children and youth with early intervention services.

Research Goals and Topics

Studies responsive to this RFA should focus on: the adult caretaker and/or child victims of neglect; the dynamics of the relationship between caretaker and child; the family system in which neglect occurs; and the larger social contexts of neglect, such as individual or family support systems, socioeconomic factors, neighborhood, school, community programs and resources (e.g., health care providers and health care delivery systems), mandated community response agencies (e.g., the police or protective service agencies), and prosecution and judicial responses that address serious cases of neglect. Multidisciplinary approaches are encouraged. Studies in these areas can include, but are not limited to:

- 1) Research on the antecedents of neglect, including studies of:
- o individual and social risk factors for neglect, such as the influence of gender (mothers and mother-substitutes as primary caretakers), availability and quality of child care settings and providers; child disability; mental disorder and emotional problems (e.g., depression, loneliness), substance abuse, interpersonal situations, social/behavioral histories of caretakers (history of neglect, domestic violence, criminal activity), socioeconomic, family structure (e.g., single parent, alcoholic father), parenting knowledge, family isolation, family conflict resolution processes, chronic childhood illness, child disruptive behavior problems, and child temperament
- o cultural, social, religious, or ethnic differences in causes, patterns, and contexts of neglect, (e.g., different cultural views about behavior among kin, reporting of neglect, parental rights, and the definition and significance of neglect)
- 2) Research on the consequences of neglect, including studies of:
- o the educational consequences of neglect (e.g., need for and access to special education and related services, characteristics of children who have been neglected in the preschool years, school-readiness, school adaptation, and academic achievement of children who have suffered various degrees of neglect and/or environmental deprivation)
- o the impact of neglect on the socio-emotional behavior of children and youth, (e.g., antisocial behavior and delinquency, status offenses, alcohol and drug use, risk-taking behaviors, attachment relationships, peer relations, social competence, selfesteem, emotional development; and adult criminality)
- o the impact of neglect on short and long term health outcomes (e.g., SIDS, Pica, lead poisoning, anemia, AIDS, hepatitis, heart failure, asthma, reactive airway disease, cancer)
- o prenatal and postnatal influences on the developing brain, including studies of gene regulation; mechanisms of stress system activation on brain anatomic and functional development; ages of vulnerability to neglect on brain development; role of neuroimmune and neuroendocrine influences on brain development as a consequence of the neglect-stress environment

- o long-term neurobiological sequelae/morbidity of neglect (e.g., effect on immune system regulation, altered sleep patterns, changes in motor system activity, neurocognitive, and neuropsychiatric outcomes); factors that mitigate or protect the brain from adverse long-term outcomes
- 3) Research on processes and mediators accounting for or influencing the effects of neglect, including studies of:
- o psychosocial and psychobiological mechanisms by which neglect results in harmful effects; the impact of neglect on individual development and progress during infancy, childhood, adolescence, or adulthood; processes of risk and resilience in neglected populations; effect of neglect on exposure to environmental hazards (e.g., lead poisoning) affecting health, educational, or emotional outcomes
- o Individual and social protective factors, (e.g., teacher, extended family, and other formal and informal social support; coping style; quality child care; community resources; special education); and subgroups of at risk populations
- 4) Neglect research on treatment, preventive intervention, and service delivery, including studies of:
- o knowledge and behaviors of health care providers affecting early detection or evaluation of child neglect; development and validation of biomarkers, indices, or classificatory systems which aid health providers, teachers, or other community members recognize child neglect at earlier stages
- o theory-driven preventive strategies to reduce risk for child neglect, such as programs targeted toward at-risk individuals or families (e.g., early home visitation, parent training programs, low-income child care, family preservation services) as they are influenced by participant characteristics (e.g., poor or young mothers; child's developmental stage, individual cognition, coping responses, behavior patterns, substance abuse and/or emotional reactions of caretakers or victims), family structure, intervention processes, and extra-intervention factors
- o early intervention as a means of preventing long-term mental, oral, and other health problems and disorders
- o interventions tailored for use in different ethnic, social, and cultural groups, or different types of communities (e.g., urban versus rural)
- o intervention models in various social and community settings for ameliorating the effects of deprivation on antisocial behavior, delinquency, and school outcomes; the influence of setting (e.g., home, child care, institution, clinic, school, resource centers, foster care, special education) on program participation, and outcomes
- o population characteristics, societal values, or intervention components that may affect identification, help-seeking, or access to services; barriers to intervention availability, delivery, or effectiveness as a function of social group membership or factors

in the setting (e.g., special education, foster care, child care, home) in which the intervention occurs

- o different types of integration, coordination, and organization of services on the effectiveness of preventive and treatment strategies in real world settings; the relative effectiveness of different community-level comprehensive service system approaches to neglect (e.g., case management systems, interagency panels)
- o legal processes, protective services, and mental health services both separately and in combination with court-ordered interventions (e.g., mandatory reporting, foster care, termination of parental rights, kinship care, police response and involvement) as the means of preventing or ending neglect, and reversing, ameliorating, or compensating for the short- and long-term effects of neglect on child victims
- 5) Other topics/special issues, including studies of:
- o issues related to specific neglect populations and their caretakers (e.g., co-occurrence with substance abuse, sexual or physical abuse, exposure to community violence, culturally/ethnically diverse samples) to determine similarities and differences within and across groups and their implications for intervention
- o studies of the effect of non-residential, parental involvement as either a causative or preventative factor in neglect. Involvement may take the form of financial support, visitation, or specific types of interactions with the child or residential caretaker
- o issues related to the impact of welfare reform on quality and availability of child care and the frequency and severity of child neglect in communities
- o the co-occurrence of child neglect with domestic violence, including studies of the incidence and prevalence of child neglect in families experiencing domestic abuse, impact of domestic violence on parenting abilities and behaviors, consequences of neglect within the context of domestic violence, effect of court response to domestic violence, and effectiveness of interventions for domestic violence in reducing the risk of child neglect or in ameliorating its consequences
- o The co-occurrence of child neglect with disabling conditions, including studies of neglected children with disabilities which adversely affect educational performance; disabilities which require special services under the Individuals with Disabilities Education Act; delivery of special education services to neglected children and youth with disabilities
- o instrument development to determine the utility, reliability and validity of standard physical and mental health assessments when used with neglected children, as well as assessment of other effects of neglect (e.g., social attributions, world view, selfesteem)

SPECIAL REQUIREMENTS

It is anticipated that a successful grant application will address the following considerations (see also Chapter 3 of the 1998 Institute of Medicine report, "Violence in Families: Assessing Prevention and Treatment Programs," as a source of recent guidance for conducting research in this sensitive field):

Definition of the Sample and Subject Selection Criteria

The samples for study must be rigorously defined to permit complete independent replication at another site. Within this context, the ascertainment/referral sources should be described in detail, including the definitions and criteria employed to identify and report child neglect. It is expected that not all victims of child neglect will be identified according to the same definitions and criteria. Consequently, applicants should provide clearly documented and operationalized definitions of the criteria employed in the identification of neglect. Description of subjects as neglected according to vague referral sources (i.e., "agencyidentified" neglect victims) is discouraged unless accompanied by the explicit identification criteria employed by the protective service agency/health care provider, etc. Because state statutes vary in their criteria for designating a case as "neglected", applicants should also identify and discuss the effects of legal context on the sample selection or composition.

In addition, all study samples should be defined, to the maximum extent possible, with reference to age, gender, grade level (if appropriate), race, ethnicity, SES, geographic region, presence of disabling/handicapping condition, socio-emotional behavioral status (e.g., antisocial behavior, delinquency, alcohol and drug use, etc), caretaker status, characteristics of home/family environment, and primary type of neglect (physical, emotional, educational) and combinations of types if present.

Measurement Criteria

Interviews, surveys, questionnaires, observational measures, standardized measures, and other assessment procedures used for the identification of child neglect across physical, emotional, and academic domains must be described in sufficient detail to permit independent replication. Measures with known reliability, validity, and appropriateness for the population under study should be employed when available. If reliability and validity characteristics are not yet known for a particular assessment procedure, the application should contain specific plans for establishing these features.

Opportunities for Definition and Classification of Neglect

A critical public health task for amelioration of child neglect is the development of a set of operational definitions and a classification system for different types of neglect. Definitional clarity and classification are necessary to develop prevention, early intervention, and treatment programs, to identify distinctions and interrelationships between types of neglect, to ascertain the antecedents and consequences of each neglect type, and to understand the relationship between each type of neglect and individual, familial, social, cultural, and geographic variables. Applicants should consider research protocols that are capable of

identifying well defined subgroups that exist within the neglected population. Within this context, investigators may wish to cast the sampling net wide enough to ensure a representative number of children across physical neglect, emotional neglect, educational neglect, and combined neglect domains.

Secondary Data

It is acceptable to propose analyses of data collected for other purposes that might yield insight on neglect. In these instances, investigators should be specific about how neglect is operationalized, limitations of the data, and how the analysis will be structured. Investigators should also be clear when such analysis is descriptive or designed to model a process or test an hypothesis.

Feasibility

Feasibility issues must be clearly addressed. Plans for implementation of interventions should include procedures for: obtaining and maintaining the necessary community relations, training and supervising staff, insuring implementation fidelity, securing ongoing access to the subject population pool, recruiting a representative sample of the target population, recruiting minorities for the staff of the research intervention, and monitoring subject participation over time.

Applicants are encouraged to document the commitment, support, cooperation, and nature of proposed collaboration of community agencies or other entities or settings outside the applicant organization whose support is essential for the conduct of the research.

Annual Meetings

Successful applicants will be asked to participate in yearly meetings to report progress, discuss problems, and share information related to the conduct of their grants. It is recommended that costs associated with attendance at these meetings, to be held in the Washington DC area, be included as a part of the budget proposal.

Publication of Study Findings

All publications ensuing from these grants should acknowledge the joint support of the agencies participating in this RFA, by citing the "Federal Child Neglect Research Consortium" as the funding source.

The statutory mandate of the NIJ is to both support research and disseminate the results of the research. Given this, the NIJ intends to publish the results of these research projects. It is therefore expected that at the completion of the project, in addition to any publications specified in the application, the grant recipient will submit a brief (2,500 to 4,000 words) summary highlighting the findings and their implications for research and policy.

In addition, OJJDP requires that grantees produce documents ranging from 900 to 6,000 words suitable for publication as OJJDP Fact Sheets or OJJDP Bulletins. These publications are intended to

summarize the goals and objectives of the research effort, describe the study, and discuss findings.

Participation in Data Archive

Because the pool of money for this RFA includes funding from NIJ and ACF, grant recipients will be expected to conform to the data archiving requirements of both of these agencies. Archiving requirements will be determined on a case by case basis, with the potential for joint listing and linkage. However, applicants should bear in mind that OCAN/Cornell requirements permit researchers 2 years after the completion of the grant to archive their data, whereas NIJ requires that data be archived with the final report.

NIJ is committed to ensuring the public availability of research data and to this end has established a Data Resources Program. Recipients who collect data are required to submit a machine-readable copy of the data and appropriate documentation to NIJ prior to the conclusion of the project. A variety of formats are acceptable; however, the data and materials must conform with requirements detailed in Depositing Data within the Data Resources Program of the National Institute of Justice: A Handbook. For further information about NIJ's Data Resources Program, contact Dr. Jordan Leiter, (202) 616-9487.

It is also expected that grant recipients will commit to using data processing and documentation practices in accordance with the needs of the National Data Archive on Child Abuse and Neglect and to providing study data to the Archive at the conclusion of the project, as applicable. A manual describing such practices, The Preparation of Data Sets for Analysis and Dissemination: Technical Standards for Machine-Readable Data, can be obtained free of cost from the National Data Archive on Child Abuse and Neglect located at Cornell University, Family Life Development Center, G20 MVR Hall, Ithaca, New York 14853-4401, Phone: 607-255-7799; FAX:

DataCAN@cornell.edu; Web site: www.ndacan.cornell.edu. Applicants must confirm that the final report will be prepared in the suggested format to ensure its readiness for dissemination by the Children's Bureau and ACYF, if desired.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide to Grants and Contracts, Volume 23, Number 11, March 18, 1994, and is also available on the web at:

http://grants.nih.gov/grants/guide/1994/94.03.18/notice-nih-guideline008.html

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

INCLUSION OF CHILDREN AS PARTICIPANTS IN THE RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-024.html

LETTER OF INTENT

Prospective applicants are asked to submit, by June 15, 1999 a letter of intent that includes a descriptive title of the proposed research, the name, address, telephone, and email of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows staff of the participating Institutes and Agencies to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Cheryl A. Boyce, Ph.D.
National Institute of Mental Health
6001 Executive Boulevard, Room 6200, MSC 9617
Bethesda, MD 20892-9617
Telephone: (301) 443-0848
FAX: (301) 480-4415
Email: cboyce@nih.gov

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 4/98) must be used in applying for these grants. However, since applications are expected to vary considerably in scope, this RFA will NOT follow the new modular grant application, review, and award procedures. Application kits are available at most institutional offices of sponsored research and from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone (301) 435-0714, E-mail: GrantsInfo@nih.gov. Applications are also available on the World Wide Web at

http://grants.nih.gov/grants/forms.htm.

The RFA label available in the PHS 398 (rev. 4/98) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. To identify the application as a response to this RFA, the RFA title, "Research on Child Neglect" and number OD-99-006 must be typed on Line 2 of the face page of the application form and the YES box must be marked.

Submit a signed, original of the application, including the Checklist, and four signed photocopies of the application in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, send one additional copy of the application to:

Cheryl A. Boyce, Ph.D.
National Institute of Mental Health
6001 Executive Boulevard, Room 6200, MSC 9617
Bethesda, MD 20892-9617
Telephone: (301) 443-0848
FAX: (301) 480-4415
Email: cboyce@nih.gov

It is important to send this copy at the same time that the original and four copies are sent to the Center for Scientific Review (CSR).

All applicants must provide a Protection of Human Subjects Assurance Identification/Certification/Declaration as specified in the policy described on the Optional Form 310. If there is a question regarding the applicability of this assurance, contact the Office for Protection from Research Risks of the National Institutes of Health at (301) 496-7041. Applicants who have been selected for funding may also wish at that time to apply for a Certificate of Confidentiality as part of their plan to maintain confidentiality for research participants. To obtain more information and to apply for a Certificate of Confidentiality, under the authority of Section 301(d) of the Public Health Service Act (42 U.S.C. 82421(d) to protect against involuntary disclosure of the identities of research subjects, the appropriate contact is Olga Boikess, J.D., National Institute of Mental Health, 6001 Executive Boulevard, Room 8102, MSC 9653, Bethesda, MD 20892-9653; (301) 443-3877. For certificates of confidentially related to studies of substance abuse, the appropriate contact is Jackie Porter, Office of Extramural Program Review, National Institute on Drug Abuse, 6001 Executive Blvd, Bethesda, MD 20892-9547; 301/443-2755. Specific questions concerning protection of human subjects may be directed to the program staff listed under INQUIRIES.

Applications must be received by September 14, 1999. If an

application is received after that date, it will be returned to the applicant. The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications previously reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by CSR, and for responsiveness by NIH program staff. Incomplete and/or non-responsive applications will be returned to the applicant without further consideration. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by a special emphasis panel convened by CSR in accordance with NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score; those with the potential for funding will receive a second level review by the National Advisory Council of the relevant NIH institute.

Review Criteria

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

- (1) Significance: How does the application address the goals of the RFA? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?
- (2) Approach: Are the conceptual framework, design, methods, and analyses adequately developed, and appropriate to the aims of the project and state of the art? Is the most rigorous research design possible proposed, given that a full range of research proposals, from preliminary research to large scale studies, has been encouraged? Does the applicant acknowledge potential problem areas and consider alternative tactics? Are measures used for the identification of child neglect across physical, emotional, and academic domains described in sufficient detail to permit independent replication? If reliability and validity characteristics are not yet known for a particular assessment procedure, does the application contain specific plans for

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establishing these features? Are proposed study and/or intervention designs well grounded in theory? If an analysis of secondary data is proposed, how is neglect operationalized, and how are limitations of the data addressed?

- (3) Ethical Issues: What provision has been made for reporting suspected abuse and/or neglect as governed by applicable laws and regulations? How does the applicant plan to handle issues of confidentiality and compliance with mandated reporting requirements?
- (4) Study Samples: Are the samples sufficiently rigorously defined to permit complete independent replication at another site? Have the ascertainment/referral sources been described, including the definitions and criteria employed to identify and report child neglect?
- (5) Innovation: Does the project employ novel concepts, approaches or method? Are the aims original and innovative?
- (6) Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?
- (7) Feasibility: Do plans for implementing interventions (if any) include procedures for: obtaining and maintaining the necessary community relations, training and supervising staff, insuring implementation fidelity, securing ongoing access to the subject population pool, recruiting a representative sample of the target population, recruiting minorities for the staff of the research intervention, and monitoring subject participation over time?
- (8) Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Does the proposed experiment take advantage of unique features of the scientific and community environment, or employ useful collaborative arrangements? Is there evidence of institutional support?
- (9) Dissemination: What plans have been articulated for disseminating findings and participating in a data archive?

In addition to the criteria listed above, the initial review group will examine the appropriateness of the proposed budget and duration; the adequacy of plans to include both genders, minorities (and their subgroups), and children as appropriate for the scientific goals of the research, and plans for the recruitment and retention of subjects; the provisions of the protection of human and animal subjects; and the safety of the research environment.

Schedule

Letter of Intent Receipt Date:
Application Receipt Date:
Initial Review:
Advisory Council Review:
Earliest Start Date:

June 15, 1999 September 14, 1999 January/February 2000 May 2000 July 1, 2000

AWARD CRITERIA

Funding decisions will made by the sponsoring organizations, based on scientific and technical merit as determined by peer review, program priorities, content area balance, policy and practice relevance, and the availability of funds.

INQUIRIES

Inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. Program staff of the NIH and other sponsoring organizations are available for consultation before and during the process of preparing an application. Potential applicants should contact program staff as early as possible for information and assistance in initiating the application process and developing an application.

Inquiries regarding programmatic issues may be directed to:

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In addition, the National Heart, Lung, and Blood Institute (NHLBI), although not a formal co-sponsor, is interested in supporting mission-relevant (i.e., with implications for sleep disorders and cardiovascular, respiratory, and blood diseases) applications submitted in response to this initiative that receive a peer review assessment within NHLBI funding levels.

Direct inquiries regarding fiscal matters to:

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AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, Numbers 93.273 (NIAAA), 93.865 (NICHD), 93.279 (NIDA), 93.121 (NIDCR), 93.242 (NIMH), 93.853 (NINDS), 93.670 (ACYF), 16.560 (NIJ), and 84.329 (OSEP-ED). Awards are made under authorization of section 301 and Title IV (42 U.S.C. 241 and 281) of the Public Health Service Act, and are administered under PHS grants policies and Federal Regulations 42 CAR Part 52, and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive order 12372, or Health Systems

Agency Review. Awards by PHS agencies will be administered under PHS grants policy as stated in the Public Health Service Grants Policy Statement (April 1, 1994).

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the nonuse of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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Department of Health and Human Services (HHS)



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