

b. Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.)

2. Late Applications:

Applications that do not meet the criteria in 1.a. or 1.b. above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional written information call (404) 332-4561. You will be asked to leave your name, address, and telephone number and will need to reference to Announcement 716. You will receive a complete program description, information on application procedures, and applications forms.

If you have questions after reviewing the contents of all the documents, business management business management technical assistance may be obtained from Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Mailstop E-13, Atlanta, GA 30305, telephone (404) 842-6535 or internet address <jcw6@cdc.gov>.

Programmatic technical assistance may be obtained from David J. Thurman, M.D., M.P.H., Division of Acute Care, Rehabilitation Research, and Disability Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop F-41, Atlanta, GA 30341-3724, telephone (770) 488-4031 or internet address <dxt9@cdc.gov>.

This and other CDC announcements are available through the CDC homepage on the Internet. The address for the CDC homepage is <<http://www.cdc.gov>>.

CDC will not send application kits by facsimile or express mail.

Please refer to Announcement 716 when requesting information and submitting an application.

Potential applicants may obtain a copy of "Healthy People 2000" (Full Report, Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report, Stock No. 017-001-00473-1) referenced in the "INTRODUCTION" through the Superintendent of Documents, Government Printing

Office, Washington, DC 20402-9325, telephone (202) 512-1800.

Dated: February 6, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

Traumatic Brain Injury Surveillance References

Methods and Key Resources

Thurman DJ, Snieszek JE, Johnson D, Greenspan A, Smith SM. Guidelines for Surveillance of Central Nervous System Injury. Atlanta: Centers for Disease Control and Prevention, 1995.

Klaucke DN, Buehler JW, Thacker SB, et al. Guidelines for evaluating surveillance systems. MMWR 1988;37(s-5):1-18.

Health Care Financing Administration. International Classification of Diseases, 9th Revision, Clinical Modification, Third Edition. Washington, DC: U.S. Department of Health and Human Services, 1989.

Epidemiologic Studies and Reviews

Kraus, JF. Epidemiology of head injury. In Cooper, PR, ed., Head Injury, Third Edition. Baltimore: Williams and Wilkins, 1993; 1-25.

Sosin DM, Snieszek JE, Waxweiler RJ. Trends in death associated with traumatic brain injury, 1979 through 1992. JAMA 1995; 273:1778.

Published epidemiologic studies of TBI are also reviewed in the article "Epidemiology of Traumatic Brain Injury in the United States" located at the Internet website of the National Center for Injury Prevention and Control <<http://www.cdc.gov/ncipc/dacrrdp/tbi.htm>>.

Centers for Disease Control and Prevention. Traumatic Brain Injury—Colorado, Missouri, Oklahoma, and Utah, 1990-93. MMWR 1997; 46(1):8-11.

How to Obtain a Copy of the CDC Guidelines for Surveillance of Central Nervous System Injury:

A copy of these Guidelines can be obtained either by calling 770-488-4031, by submitting the "NCIPC Publications Order Form" through the Internet website of the National

Center for Injury Prevention and Control <<http://www.cdc.gov/ncipc/pub-res/pubsav.htm>>, or by writing to the Division of Acute Care, Rehabilitation Research, and Disability Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC),

4770 Buford Highway, NE., Mailstop F-41, Atlanta, GA 30341-3724.

[FR Doc. 97-3473 Filed 2-11-97; 8:45 am]

BILLING CODE 4163-18-P

Administration for Children and Families

Children's Bureau/National Center on Child Abuse and Neglect Proposed Research Priorities for Fiscal Years 1997-2001

AGENCY: Administration on Children, Youth and Families (ACYF), Administration for Children and Families (ACF), HHS.

ACTION: Notice of proposed child abuse and neglect research priorities for fiscal years 1997-2001.

SUMMARY: The National Center on Child Abuse and Neglect/Children's Bureau (NCCAN/CB) within the Administration on Children, Youth and Families (ACYF) announces the proposed priorities for research on the causes, prevention, assessment, identification, treatment, cultural and socio-economic distinctions, and the consequences of child abuse and neglect.

NOTE: The National Center on Child Abuse and Neglect (NCCAN) was established in 1974 to carry out the functions of the Child Abuse Prevention and Treatment Act (CAPTA). Pursuant to Pub. L. 104-235, the Child Abuse Prevention and Treatment Act Amendments of 1996, the Office on Child Abuse and Neglect (OCAN) will, in the near future, be established by the Secretary for the purpose of coordinating the functions and activities of CAPTA, replacing NCCAN.

Section 104(a)(2) of CAPTA, as amended by Pub. L. 104-235, requires the Secretary to publish proposed priorities for research activities for public comment and allow 60 days for public comment on such proposed priorities. The proposed priorities are being announced for the five year period that corresponds to the authorization period for CAPTA. Because the amount of Federal funds available for discretionary activities in Fiscal Years 1997-2001 is expected to be limited, respondents are encouraged to recommend how the proposed issues should be prioritized.

As research issues arise or new issues emerge through consultation with other entities, additional announcements of proposed priorities will be published for public comment.

The actual solicitation of grant applications will be published separately in the Federal Register for

each fiscal year. Solicitations for contracts will be announced, at later dates, in the *Commerce Business Daily*. No proposals, concept papers, or other forms of application should be submitted at this time.

No acknowledgment will be made of the comments submitted in response to this notice, but all comments received by the deadline will be reviewed and given thoughtful consideration in the preparation of the final funding priorities for the announcements. The names and addresses of all those who submit comments will be added to the mailing list for receiving copies of the final program announcements when they are published.

DATES: In order to be considered, comments must be received no later than April 14, 1997.

ADDRESSES: Comments should be sent to: James A. Harrell, Deputy Commissioner, Administration on Children, Youth and Families, Attention: CB/NCCAN, PO Box 1182, Washington, DC. 20013.

Electronic comments may be sent to: <comments@acf.dhhs.gov>

If you comment electronically and wish to be added to the mailing list, please include a street address.

SUPPLEMENTARY INFORMATION:

I. Background

In addition to projects funded under priority areas selected as a result of this announcement, NCCAN/CB may continue discretionary funding for:

- The National Clearinghouse on Child Abuse and Neglect Information;
- The National Resource Center on Child Maltreatment;
- Future phases of the Consortium for Longitudinal Studies of Child Maltreatment;
- The National Data Archive on Child Abuse and Neglect; and
- The National Child Abuse and Neglect Data System (NCANDS) technical assistance and technical support program.

NCCAN/CB will continue to pursue Interagency Agreements to develop collaborative research with other Federal agencies to carry out an interdisciplinary program of research that is designed to provide information needed to better protect children from abuse or neglect and to improve the well-being of abused or neglected children. NCCAN/CB also will continue to participate in the development of a Federal framework for child welfare research and an ACF strategic research agenda on child abuse and neglect.

In addition, NCCAN/CB explicitly acknowledges on-going analytic work

with the National Incidence Study (NIS), the National Child Abuse and Neglect Data System (NCANDS), and the Adoption and Foster Care Analysis and Reporting System (AFCARS) data collection projects that will inform several of the topics described below. Comments about research topics and future activities should be addressed in light of this ongoing work. The relevant topics include: recurrence (the numbers and characteristics of children and families in both substantiated and unsubstantiated reports that return to the system) and patterns of recurrence (repeat substantiations, as well as unsubstantiated cases that return as substantiated cases) which will be topics of analysis in the NCANDS Detailed Case Data Component (DCDC) in the coming year; the removal of children and abuse and neglect in foster care will be examined by cross-walking data between NCANDS and AFCARS; mandated reporter characteristics and child characteristics, as correlates, will be explored through further analysis of both NCANDS and NIS data; and court activity related to substantiated reporting will be explored through additional analyses of NCANDS data.

Information on these and other prior and continuing projects supported by NCCAN/CB as well as on other studies of child maltreatment are available through the National Clearinghouse on Child Abuse and Neglect Information, PO Box 1182, Washington, DC. 20013 (1-800-394-3366).

The proposed research priority areas which follow have been developed in consultation with several entities and from several sources.

- The 1996 reauthorization of CAPTA, section 104.
- The National Research Council (NRC), Commission on Behavioral and Social Sciences and Education (CBASSE), Panel on Research on Child Abuse and Neglect report, *Understanding Child Abuse and Neglect*. This report was produced by CBASSE in response to a request from ACYF to undertake a comprehensive review and synthesis of research on child abuse and neglect and to recommend research needs and priorities for the remainder of the decade. Over the last several years, NCCAN/CB has responded to individual recommendations as funding allowed. NCCAN/CB will continue to address the concerns raised in the NRC report, as appropriate.
- Reviews of current literature on child abuse and neglect.
- Findings from recently completed studies.
- Recommendations from the field.

- Meetings with other Departmental units and professional organizations.

NCCAN/CB will continue to examine the recommendations from these various sources in light of other ongoing efforts and the applicability of the recommendations to Federal research goals.

II. Proposed Child Abuse and Neglect Research Priorities for Fiscal Years 1997-2001

A. Legislative Topics:

A number of research topics are suggested in the 1996 reauthorization of CAPTA, section 104. Comments are requested on the feasibility of these topics for research, their pertinence to the field, and their likelihood to promote innovative research that increases our understanding of all aspects of child maltreatment.

The Research Frame: In general, all NCCAN/CB sponsored research must fit within an overall frame of research on the nature and scope of child abuse and neglect; the causes, prevention, assessment, identification, treatment, cultural and socio-economic distinctions, and consequences of child abuse and neglect; appropriate, effective and culturally sensitive investigative, administrative, and judicial procedures with respect to cases of child abuse; and the national incidence of child abuse and neglect. These areas of inquiry underlie all other questions and apply especially to inquiries that are investigator-initiated, as described below in section C.

Mandated Reporting: Because entry into the child protective services system may be affected by factors in addition to those specific to an incident, research which explores these other factors will elucidate the entry, service, re-entry, and flow processes experienced by children and their families. Mandated reporting, for example, affects the number of reports made, the gateways into child protective services, and the allocation of resources in relation to the number of reports accepted for investigation.

State child protective services (CPS) data show significant differences in the reporting patterns and substantiation rates for different reporting sources. For instance in an analysis of all reports investigated by CPS in 10 States in 1993, it was found that 60 percent of reports from legal and law enforcement professionals were substantiated or indicated versus 45 percent of reports from educators. (Child Abuse and Neglect Case Level Data 1993: Working Paper 1).

Questions about mandated reporting include those that explore the extent to which the lack of adequate resources and the lack of adequate training of individuals required by law to report suspected cases of child abuse have contributed to the inability of a State to respond effectively to serious cases of child abuse and neglect.

Unsubstantiated, unfounded, and false reports: Unsubstantiated, unfounded, and falsely reported cases of child abuse and neglect put considerable stress on the children and families who are the subjects of the reports, but also put stresses on the child protective service system itself. At this time, we have very little knowledge of the relationship between reports, however false, unsubstantiated or unfounded, and future maltreatment and system entry. Research questions might inquire about: the extent to which the number of unsubstantiated, unfounded, and falsely reported cases of child abuse or neglect contribute to the inability of a child welfare system or child protective services system to respond effectively to serious cases of child abuse or neglect; the extent to which and the pathways by which unsubstantiated reports return as more serious cases of child abuse or neglect.

Reports in the context of family court proceedings: Some reports occur in a context of divorce, custody or other family court proceedings. NCCAN/CB is interested in the interaction between this venue and the child protective services system. Research might be at the individual, case, or system level. Questions might include: How does family history with a child protective services system relate to family court proceedings? Does entry into the child protective services system via the family court gateway have a relationship to particular case outcomes? What is the relationship, if any, between unsubstantiated, unfounded, and false reports and families involved in divorce, custody, or other family court actions?

Substitute care: NCCAN/CB is interested in the relationship between child protective service systems and other child welfare programs as well as a more detailed look at differentiated effects within substitute care experiences. Research interests include: What is the context, incidence, and prevalence of child physical, sexual, and emotional abuse and physical and emotional neglect occurring in substitute care? Because substitute care is itself a service, are children in substitute care referred for and receiving additional services related to the precipitating incident or additional

incidents of abuse and neglect? What is the efficacy of those additional services in terms of safety, permanency, and child well-being outcomes and does efficacy have a relationship to either the type of abuse precipitating the placement, demographic characteristics of the child (e.g., age, sex, disability), or characteristics of the substitute placement (e.g., relative care, licensing, certification).

Substantiated cases: Substantiated cases of child maltreatment represent a particular sector of the child protective service population. NCCAN/CB is interested in funding research that explores system and sequelae questions with substantiated case samples, which may answer such questions as: Can "system history" and "client characteristics" be used to make predictions about future service needs and system usage? What are the number and characteristics of substantiated cases that result in a judicial finding of child abuse or neglect or related criminal court convictions?

B. Other Topics

Child Safety and Child Fatality: NCCAN/CB is interested in research that explores ways to understand the nature and scope of child abuse and neglect that results in fatalities or permanent disabilities and systemic responses to child fatalities. Questions might include those which would explore reducing fatalities by asking questions about efficacious placement of siblings or termination of parental rights (TPR), as well as more prevention-oriented questions, including those which explore the context of home and community environments related especially to other forms of violence and the availability of a continuum of comprehensive community preventive and treatment services. Other research interests include: explorations of the relationship of child fatality or serious injuries to placement and TPR decisions; and "best practices" and model development for safety assessment. Recommendations are requested on the ability to sustain a research focus on, and the usefulness of a focus on, variables related to strengths-based programming and resiliency characteristics at the family level especially as they are related to placement and TPR.

Co-occurrence: Suggestions for additional research questions as well as comments are sought on research exploring the nature of the pathways between the co-occurrence of child maltreatment and substance abuse and/or domestic violence as those pathways relate to the prevention of child

maltreatment, assessment of co-occurrence, treatment or intervention, and system responses to co-occurrence (including demands on treatment, training, and resources). Preliminary questions might include: What are the variety of system responses to identifying, as a dynamic issue, and coordinating, as a structural issue, services for co-occurrence? Do treatment models which begin with one or the other symptom have more efficacious outcomes? Are there identifiable "best practices" for treatment or service?

Definitions: In the interest of supporting on-going work and encouraging new work in creating a consensus on definitions for research purposes, NCCAN/CB seeks recommendations for field tests in research settings and other applications of a set of working data elements developed by the research committee of the Interagency Task Force on Child Abuse and Neglect. The committee has been working with researchers over the past three years to identify the data elements that represent a core of consensus for research purposes about the experiences of child abuse and neglect. The overall goal of the work of the committee has been to present a common data collection set of attributes that explicitly describe the nature of maltreatment in a particular sample and allows samples to be compared, in terms of maltreatment experiences, across studies.

Graduate Student Research Fellowships: With a continuing interest in encouraging new investigators to select child maltreatment as an area of specialty, NCCAN/CB seeks comments comparing the two models of graduate student research support employed most recently. One model awarded funds directly to eligible institutions for specific eligible individual students. The second model awarded funds to eligible institutions for a group consisting of a faculty member and eligible students, or student. The goal of the Fellowships is to develop mechanisms which support the renewal of the research field by increasing the number of new researchers who elect to study child abuse and neglect.

Outcomes: Building on the work of the Children's Bureau regarding monitoring by outcomes and thinking ahead to the requirements for outcome-based performance partnerships, NCCAN/CB seeks comments on the socio-economic, cultural, and community variances which have bearing on the use of "safety," "permanency," and "child and family well-being" as outcomes, and tools for assessing the outcomes. Questions

might include: What is the relationship between the availability of tools for assessing particular outcomes and a community's efforts to achieve those outcomes? From a systemic perspective, how does the definition of outcomes, or the operationalization of them, have impact on the system's delivery of services and the success of particular populations achieving the outcomes?

Over-represented populations and special populations (i.e., racial and ethnic groups, children with disabilities): With continuing concern about over-representation, research questions might include: What are the characteristics of the system or the context that may contribute to the over-representation of some populations in child protective service caseloads? How do systems achieve a better understanding of the dynamics of the communities that are over-represented? How are clients assessed in order to generate knowledge about these populations that is formed from appropriate cultural and sociological perspectives?

NCCAN/CB is interested in the safety and well-being of immigrant children and their families, as a special population. Questions might include explorations of service utilization, outreach, and cultural context. More specific examples of research questions might include: What are the relationships between child safety and well-being, child protective services, the characteristics and needs of the children and families themselves, and the communities in which they reside? How are the needs of immigrant children and their families identified and assessed? What are effective maltreatment prevention and treatment program models for these populations?

Secondary Analysis: NCCAN/CB seeks comments regarding the interest of the field for funding of secondary analyses of federally-financed data collections and existing datasets. Opportunities here exist in the analysis of, for example, Head Start data, data from the Adoption Foster Care Analysis and Reporting System (AFCARS), the 1994 National Study of Protective, Preventive and Reunification Services Delivered to Children and their Families, the National Child Abuse and Neglect Data System (NCANDS), and the National Incidence Study (NIS), regarding specific field-generated or federally-generated research inquiries related to child maltreatment. Comments should include (1) suggestions for minimal award sizes and (2) suggestions for application strategies that reduce the burden of applying for these small-amount grants.

Triage: Triage, here, is used to describe a differentiated response service-entry or resource allocation model for handling child abuse and neglect reports. Some triage models include assignment to service prior to investigation for some classes of reports. Research interests include questions about: The effects of a triage process on child safety and child and family well-being, caseload sizes, and resource allocation; and evaluations of the impact and efficacy of criteria, tools, and protocols for case assignment, safety and risk assessment. Does a triage approach result in changes in system responses, client behavior (i.e., recidivism), changes in public perception of CPS, or changes in clients' perceptions of CPS responsiveness to their needs or to the perception of a punitive nature of CPS service?

Welfare Reform and System Changes: The impact of recent changes in family support entitlements, block granting of welfare funds, work requirements, child care needs, and other systemic changes is unknown. NCCAN/CB is interested in research which explores the interactions of these changes in welfare policy at the state and local level with child safety in general and the protective needs of children in particular. States have a range of options available to them as they implement new welfare programs. Questions might include: How do these policy choices affect child protective services agencies' ability to protect children? What are the impacts on case loads, case characteristics, and system entry and exit, for example, of family caps, time limits, and the transition to work?

C. Field Initiated Research on Child Abuse and Neglect

The generation of new knowledge for understanding critical issues in child abuse and neglect improves prevention, identification, assessment, and treatment. Research areas to be addressed may be those that will expand the current knowledge base, build on prior research, contribute to practice enhancements, inform policy, improve science, and provide insights into new approaches to the assessment, prevention, intervention, and treatment of child maltreatment (i.e., physical abuse, sexual abuse, emotional maltreatment, or neglect) on any of the topics listed in (A) Legislative Topics, (B) Other Topics, above, or any other child maltreatment topic.

In addition to the topics cited above, practitioners and researchers are encouraged to propose other relevant subjects for research topics.

(Catalog of Federal Domestic Assistance Program Number 93.670, Child Abuse and Neglect Prevention and Treatment)

Dated: February 7, 1997.

James A. Harrell,

Deputy Commissioner, Administration on Children, Youth and Families.

[FR Doc. 97-3469 Filed 2-11-97; 8:45 am]

BILLING CODE 4184-01-P

Food and Drug Administration

[Docket No. 96E-0385]

Determination of Regulatory Review Period for Purposes of Patent Extension; ULTIVA™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ULTIVA™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts