

mechanisms that are designed to yield quantitative results.

The Agency received no comments in response to the 60-day notice published in the **Federal Register** on March 23, 2018 (vol. 83, No. 57, pages 12766–12768).

This is a Revision information collection request. The burden hours have decreased from the previous submission by 6,250 hours. This decrease accounts for the hours that were unused as well as the planned

efforts within the Institute during the next three years. NIOSH is also planning on discontinuing 0920–0940 (expiration 3/31/2018) which accounts for service delivery data collections within NIOSH’s Health Hazard Evaluation program. The current submission will account for all service delivery data collections within NIOSH.

During the past three years the information has been used by programs within NIOSH to collect feedback from

customers and stakeholders. Respondents will be screened and selected from Individuals and Households, Businesses, Organizations, and/or State, Local or Tribal Government. Below we provide NIOSH’s projected annualized estimate for the next three years. There is no cost to respondents other than their time. The estimated annualized burden hours for this data collection activity are 13,075.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Individuals and Households, Businesses, Organizations	Print Surveys	50,000	1	15/60
	Focus Groups	100	1	2
	Online Surveys	1,500	1	15/60

Jeffrey M. Zirger,
Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice; Children’s Bureau Proposed Research Priorities for Fiscal Years 2018–2020

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

ACTION: Notice of proposed priorities; request for comments.

SUMMARY: The Children’s Bureau (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, and solicits comments regarding the prioritization.

DATES: In order to be considered, comments must be received no later than August 24, 2018.

ADDRESSES: You may send comments, identified by the RIN or docket number in the subject line, by email: CBComments@acf.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Dori Sneddon, 202–205–8024, Dori.Sneddon@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 104(a)(4) of the Child Abuse Prevention and Treatment Act (CAPTA), as amended by the CAPTA Reauthorization Act of 2010, Public Law (Pub. L.) 111–320, requires the Secretary of the Department of Health and Human Services (HHS) to establish proposed priorities for research activities, provide an opportunity for public comment on those proposed activities, and maintain an official record of received public comment concerning the priorities. The proposed priorities are being announced for the 2-year period required by CAPTA. Because the amount of federal funds available for discretionary activities in fiscal years (FY) 2018–2020 is expected to be limited, respondents are encouraged to recommend how the proposed issues should be prioritized.

The actual solicitation of grant applications will be posted electronically each fiscal year and will be available online through <http://www.Grants.gov>. Solicitations for contracts will be announced at later dates, online at FedBizOps. No proposals, concept papers, or other forms of application should be submitted at this time.

No acknowledgement 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.

I. Background

As noted above, section 104(a)(4) of CAPTA requires the Secretary to publish proposed priorities for research activities for public comment every 2 years. In response to this legislative mandate, CB has undertaken a review of the current legislative language, the results of the CAPTA-funded research since the last CAPTA announcement of research priority areas, findings from other relevant research, and input from the field. Based on this review, this notice of proposed research is being disseminated for comment. The FY 2018 President’s Budget requested \$32,937,267 for child abuse discretionary activities to support efforts designed to assist and enhance national, state, and local efforts to prevent, identify, and treat child abuse and neglect. The program funds projects to compile, publish, and disseminate training materials; provide technical assistance; and demonstrate and evaluate improved methods and procedures to prevent and treat child abuse and neglect. Under discretionary funds, CB will continue to fund the following clearinghouse and technical assistance activities:

- The Child Welfare Information Gateway;
- Family Resource Information, Education, and Network Development Service (FRIENDS); and
- National Child Abuse and Neglect Data System (NCANDS) technical assistance and technical support program.

In addition, the child abuse discretionary activities’ account funds a number of research and demonstration

grants and contracts. For those members of the public interested in responding to this announcement, information on previous and continuing projects supported by CB are available through the following websites:

- The Child Welfare Information Gateway (<http://www.childwelfare.gov>); and
- Children's Bureau Reports/Publications (<http://www.acf.dhhs.gov/programs/cb/publications/index.htm>).

II. Proposed Child Abuse and Neglect Research Priorities for Fiscal Years 2016–2018

A. Legislative Topics

A number of research topics are suggested in the 2010 reauthorization of CAPTA, section 104 (42 U.S.C. 5105). The legislation states that the Secretary shall, in consultation with other federal agencies and recognized experts in the field, carry out a continuing interdisciplinary program of research, including longitudinal research, that is designed to provide information needed to better protect children from abuse or neglect and to improve the well-being of victims of abuse or neglect, with at least a portion of such research being field initiated. Suggested research includes:

- The nature and scope of child abuse and neglect;
- The causes, prevention, assessment, identification, treatment, cultural and socio-economic distinctions, and the consequences of child abuse and neglect, including the effects of child abuse and neglect on a child's development and the identification of successful early intervention services or other services that are needed;
- Effective approaches to improving the relationship and attachment of infants and toddlers who experience child abuse or neglect with their parents or primary caregivers in circumstances where reunification is appropriate;
- Appropriate, effective, and culturally sensitive investigative, administrative, and judicial systems, including multidisciplinary, coordinated decision making procedures with respect to cases of child abuse and neglect;
- The evaluation and dissemination of best practices, including best practices to meet the needs of special populations, consistent with the goals of achieving improvements in child protective services systems of the states in accordance with CAPTA, section 106(a), Grants to States for Child Abuse and Neglect Prevention and Treatment Programs [42 U.S.C. 5106a], paragraphs (1) through (14), which include:

- i. The intake, assessment, screening, and investigation of reports of child abuse and neglect;
- ii. Creating and improving the use of multidisciplinary teams and interagency, intra-agency, interstate, and intrastate protocols to enhance investigation, and improving legal preparation and representation; and improving legal preparation and representation;
- iii. Case management, including ongoing case monitoring and delivery of services and treatment provided to children and their families;
- iv. Enhancing the general child protective system by developing, improving and implementing risk and safety assessment tools and protocols, including the use of differential response;
- v. Developing and updating systems of technology that support the program and track reports of child abuse and neglect from intake through final disposition and allow interstate and intrastate information exchange;
- vi. Developing, strengthening and facilitating training;
- vii. Improving the skills, qualifications, and availability of individuals providing services to children and families, and the supervisors of such individuals, through the child protection system, including improvements in the recruitment and retention of caseworkers;
- viii. Developing, facilitating the use of, and implementing research-based strategies and training protocols for individuals mandated to report child abuse or neglect;
- ix. Developing, implementing, or operating programs to assist in obtaining or coordinating necessary services for families of disabled infants with life threatening conditions;
- x. Developing and delivering information to improve public education relating to the role and responsibilities of the child protection system and the nature and basis for reporting suspected incidents of child abuse and neglect, including the use of differential response;
- xi. Developing and enhancing the capacity of community-based programs to integrate shared leadership strategies between parents and professionals to prevent and treat child abuse and neglect at the neighborhood level;
- xii. Supporting and enhancing interagency collaboration between the child protection system and the juvenile justice system for improved delivery of services and treatment, including methods for continuity of treatment plans and services as children transition between systems;

xiii. Supporting and enhancing interagency collaboration among public health agencies, agencies in the child protective service system, and agencies carrying out private community-based programs

a. To provide child abuse and neglect prevention and treatment services (including linkages with education systems) and the use of differential response; and

b. To address the health needs, including mental health needs, of children identified as victims of abuse or neglect, including supporting prompt, comprehensive health and developmental evaluations for children who are the subject of substantiated child maltreatment reports; or

xiv. Developing and implementing procedures for collaboration among child protective services, domestic violence services, and other agencies in

a. Investigations, interventions, and the delivery of services and treatment provided to children and families, including the use of differential response, where appropriate; and

b. The provision of services that assist children exposed to domestic violence, and that also support the caregiving role of their non-abusing parents.

- Effective approaches to interagency collaboration between the child protection system and the juvenile justice system that improve the delivery of services and treatment, including methods for continuity of treatment plans and services as children transition between systems;

- Effective practices and programs to improve activities such as the identification, screening, medical diagnosis, forensic diagnosis, health evaluations, and services, including activities to promote collaboration between—

i. The child protective service system; and

ii. (I) The medical community, including providers of mental health and developmental disability services; and

iii. (II) Providers of early childhood intervention services and special education for children who have been victims of child abuse or neglect;

- An evaluation of the redundancies and gaps in services in the field of child abuse and neglect prevention in order to make better use of resources;

- Effective collaborations, between the child protective system and domestic violence service providers, that provide for the safety of children exposed to domestic violence and their non-abusing parents that improve the investigations, interventions, delivery of

services, and treatments provided for such children and families;

- The nature, scope, and practice of voluntary relinquishment for foster care or State guardianship of low-income children who need health services, including mental health services.

- The impact of child abuse and neglect on the incidence and progression of disabilities;

- The nature and scope of effective practices relating to differential response, including future analysis of the following:

- i. What is the underlying hypothesis about the need to engage a parent and/or family in order to achieve specific outcomes in Child Protective Services (CPS)? Which specific outcomes need to be considered?

- ii. Given that “engagement” may vary according to the eyes of the beholder, can specific aspects of engagement be measured with greater consistency and replication, particularly between the two groups who are part of the relationship?

- iii. How should engagement be defined in future studies?

- iv. CPS systems, in general, may be providing training to their caseworkers, regardless of pathway, to help them better relate to families and caregivers. If Alternative Response (AR) and Investigative Response (IR) caseworkers receive the same training and use similar engagement practices, should one still expect differences in family or caseworker perceptions of engagement?

- v. Are there specific micro-practices that should be examined in more depth to determine if they make a difference for parents and families? As examples: Does setting an appointment to visit a family make a difference in engaging a family in early stages of relationship building? Does solution-focused casework result in parent willingness to engage with caseworkers?

- vi. Should all low-risk families receive AR?

- vii. Should the threshold for providing a family with AR be raised?

- viii. Should CPS caseworkers also have the discretion to reassign IR families to AR?

- ix. If families are encouraged to build relationships with their CPS caseworkers and are encouraged to contact them in the future, should re-referral still be considered a proxy for lack of safety?

- Child abuse and neglect issues facing Indians, Alaska Natives, and Native Hawaiians, including providing recommendations for improving the collection of child abuse and neglect data for Indian tribes and Native Hawaiian communities; or

- The information on the national incidence of child abuse and neglect specified in CAPTA, section 104(a) specified in clauses (i) through (x) of paragraph (1)(O).

B. Other Topics

Prevention Practices: CB is interested in research that builds on the existing body of knowledge of prevention practices, in particular primary prevention. This includes research to measure the efficacy and effectiveness of strategies to serve families across a spectrum of risk for child maltreatment, and strategies that aim to enhance the capacity of communities to address the physical, social, and emotional well-being of families before the occurrence of child abuse or neglect. In addition, CB is interested in research that examines innovative techniques for the assessment and detection of the risk of incidences of child abuse and neglect, including techniques for the detection of household opioid and other substance misuse, and interventions based on such risk detection which mitigate or eliminate the incidence of abuse and neglect.

CB has supported a number of research and demonstration projects to generate knowledge about effective early prevention strategies and interventions. Over 5 years, from 2009–2014, CB funded the Rigorous Evaluation of Existing Child Abuse and Neglect Prevention Programs grant programs. Through a competitive process, grants were made to conduct randomized controlled trials (RCTs) of four well-established, community-based child abuse and neglect prevention programs located in three regions across the U.S., garnering information on the effectiveness of interventions to increase child, parent, and family safety and well-being. Additionally, CB has funded research and demonstration grants to support initiatives to prevent maltreatment and increase the well-being of children and youth, including: Infrastructure-building grants between child welfare agencies, early education, and schools; supportive housing models for families; and interventions to address child trafficking. While this work is contributing to the body of knowledge about the type and range of early intervention strategies to prevent the occurrence of maltreatment, much more can and must be learned at the individual and population level to build the protective capabilities of families and communities.

Research interests may include: The development and demonstration of research methodologies that allow for valid and reliable measurement of

primary prevention activities and assessment of risk for child abuse and neglect at the individual, community, and population level; the innovative use of data, including administrative and secondary data, to inform our understanding of the implementation and outcomes of primary prevention strategies; and integrating child abuse and neglect research into prevention practices and techniques for the assessment and detection of risk for child abuse and neglect.

Child Protection Systems: CB is interested in research that examines effective state-level strategies employed to improve child protection systems. Questions may include: The degree to which changes in CPS systems’ policy and practice are tied to better outcomes; determining the variations in local agencies that result in different outcomes; and whether or not child safety and well-being are improved by privatizing part or all of the child welfare system. Other research interests may include: Effective responses for children at risk of being harmed; barriers to consistency in CPS operations, such as differences in the level of resources; lack of clear laws and policy and the competing desire for local autonomy in government functions; the means by which CPS agencies try to understand the standards of the community they serve through outreach to additional panels and review teams (fatality review team, citizen review panels, external case reviews); and collaborations between CPS and other agencies.

Services: CB is interested in research focused on the assessment of service needs and services provided. Research questions may include: What services are children and families receiving; to what degree are services responsive to the needs of the target population; and what are the outcomes that result from various services. Other research may focus on case planning and intervention, such as examining the development and implementation of comprehensive family assessment, safety planning, engaging families and monitoring risk assessment over the life of CPS cases, and increasing knowledge of parent and child engaging in the case planning process. In addition, topics of interest include services needs of families and children who are impacted by substance use disorders, trafficking, and inadequate housing including homelessness.

The findings from the most recent Child and Family Service Reviews (CFSR) identify strengths and needs within state programs, as well as areas where technical assistance can lead to

program improvements. CB encourages research on underlying issues in practice areas contributing to poor performance on CFSR outcomes. State performance on identifying, assessing, and addressing children's mental needs, in particular, was found as an area needing improvement in the CFSRs. Areas of interest for research may include examining CPS procedures for identifying, assessing, and responding to children's mental health challenges, as well as the prevalence, type, and severity of mental health needs among children identified in state child welfare systems. In addition, findings from the National Survey of Child and Adolescent Well-Being show that high rates of mental health needs among parents, coupled with low rates of identification, assessment, and referral, is a serious issue. CB is interested in research that examines support services to strengthen families, including mental health services to parents and children.

Secondary Data Analysis: CB encourages the utilization of existing data sources, particularly the use of service data through the National Child Abuse and Neglect Data System (NCANDS) and other child welfare data available through the National Data Archive on Child Abuse and Neglect. CB is interested in secondary data analyses using NCANDS, focusing on service utilization, recurrence, and perpetrators.

Service utilization: While not all states provide complete service data to NCANDS, for those states that do provide complete service data, the following areas could be examined: The services that are provided to Substance Exposed Newborns and their families; services to victims of human trafficking; differences in service patterns that exist between child victims who remain in their homes and those who are removed; and the variations in service patterns within states according to county characteristics.

Perpetrators: CB continues to be interested in perpetrators, with the notion that understanding who this group is and what their characteristics are can help to inform more effective intervention and prevention efforts. According to the most recent analysis of NCANDS data, female caregivers between the ages of 18–30 are most often identified as maltreaters of children ages birth–3. Further exploration of these phenomena is necessary to identify subgroups within this population of female caregivers, to identify services that mitigate risk to infants and toddlers of young adult parents, and to develop targeted prevention strategies.

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 in child abuse and neglect.

Dated: June 19, 2018.

Jerry Milner,

Acting Commissioner, Administration on Children, Youth and Families.

[FR Doc. 2018–13526 Filed 6–22–18; 8:45 am]

BILLING CODE 4184–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Mutant IDH1 Inhibitors Useful for Treating Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: National Center for Advancing Translational Sciences, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the Patent Applications listed in the Summary Information section of this notice to Apexx Oncology, Inc., located in New York, NY.

DATES: Only written comments and/or applications for a license which are received by the National Center for Advancing Translational Sciences on or before July 10, 2018 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Sury Vepa, Ph.D., J.D., Senior Licensing and Patenting Manager, National Center for Advancing Translational Sciences,

NIH, 9800 Medical Center Drive, Rockville, MD 20850, Phone: 301–217–9197, Fax: 301–217–5736, or email sury.vepa@nih.gov. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. International Application No. PCT/US15/067406 filed on 12/22/2015 which is entitled “Mutant IDH1 Inhibitors Useful for Treating Cancer” (HHS Ref. No: E–243–2014/0–PCT–02), and

2. U.S. Provisional Application No. 62/353298 filed on 06/22/2016 which is entitled “Mutant IDH1 Inhibitors Useful for Treating Cancer” (HHS Ref. No. E–189–2016/0–US–01).

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America and the University of North Carolina at Chapel Hill.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for the following: “Therapeutics for cancers in humans which result from or characterized by the presence of mutant IDH1.”

The inventions relate to a series of novel compounds that potently and selectively inhibit mIDH1. These compounds reduce 2–HG levels in cell lines *in vitro* as well as in human cancer cells grown in mouse xenografts *in vivo*. These compounds show greater than 250-fold selectivity for the mutant enzyme over the wild-type, show favorable *in vitro* stability (in mouse, rat, dog and human hepatocyte exposure studies), are AMES negative, and exhibit no significant metabolic CYP liabilities. These compounds possess very favorable *in vivo* rodent pharmacokinetics and bioavailability and are well tolerated in rodents, even when dosed at high levels.

Thus, the compounds of the subject inventions can be used individually or in combination to develop new therapies to treat diseases which result from mutant IDH1 activity. The diseases caused by mutant IDH1 activity include cancer (*e.g.*, acute myeloid leukemia, glioma, cholangiocarcinoma and potentially other solid tumors) and selected rare diseases, such as Ollier Disease.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless