

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health ([NIH \(http://www.nih.gov\)](http://www.nih.gov))

Components of Participating Organizations

Office of Strategic Coordination ([Common Fund \(https://commonfund.nih.gov/\)](https://commonfund.nih.gov/))

This Notice of Funding Opportunity (NOFO) is a Common Fund initiative ([Common Fund \(http://commonfund.nih.gov/\)](http://commonfund.nih.gov/)) through the NIH Office of the Director, Office of Strategic Coordination (<https://dpcpsi.nih.gov/> (<https://dpcpsi.nih.gov/>)). All NIH Institutes and Centers participate in Common Fund initiatives. The NOFO will be administered by a cross-NIH team led by the National Cancer Institute ([NCI \(https://www.cancer.gov/\)](https://www.cancer.gov/)) and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development ([NICHD \(http://www.nichd.nih.gov/\)](http://www.nichd.nih.gov/)).

Funding Opportunity Title

Discovery of the Genetic Basis of Childhood Cancers and of Congenital Anomalies: Gabriella Miller Kids First Pediatric Research Program (X01 Clinical Trial Not Allowed)

Activity Code

[X01 \(http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=x01&Search.x=0&Search.y=0&Search.Type=Activity\)](http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=x01&Search.x=0&Search.y=0&Search.Type=Activity) Resource Access Award

Announcement Type

Reissue of [PAR-24-082 \(https://www.grants.gov/search-results-detail/351450\)](https://www.grants.gov/search-results-detail/351450)

Related Notices

- Check for any recent [Notices of NIH Policy Changes \(https://grants.nih.gov/grants/guide/url_redirect.php?id=11163\)](https://grants.nih.gov/grants/guide/url_redirect.php?id=11163) that may impact application requirements.

Funding Opportunity Number (FON)

PAR-27-071

Companion Funding Opportunity

None

Number of Applications

See Part 2, Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.310

Funding Opportunity Purpose

As part of the Gabriella Miller Kids First Pediatric Research Program ([Kids First Program \(https://commonfund.nih.gov/kidsfirst/\)](https://commonfund.nih.gov/kidsfirst/)), the NIH invites applications to submit samples from pediatric cohorts for whole genome sequencing at a Kids First Program supported genomic data generating centers. Applicants are encouraged to propose sequencing of existing pediatric cancer or congenital anomaly cohorts to elucidate the genetic contribution (somatic and/or germline) to childhood cancers, to investigate the genetic etiology of congenital anomalies, to study the molecular basis of the associations between congenital anomalies and increased cancer risk, or to expand the range of pediatric disorders included within the [Kids First Data Resource \(https://kidsfirstdrc.org/\)](https://kidsfirstdrc.org/). The program will accept applications that propose whole genome, exome, and transcriptome sequencing, as well as clinical-grade sequencing, long-read sequencing, proteomics, and epigenomic assays of tumor or affected tissue, when justified. Applicants are encouraged to propose cohorts to increase representation of existing [Kids First Program projects \(https://commonfund.nih.gov/kidsfirst/X01Projects\)](https://commonfund.nih.gov/kidsfirst/X01Projects). These data, and associated clinical and phenotypic data, will become part of the Kids First Data Resource Center for sharing with the research community.

Funding Opportunity Goal(s)

This listing covers the Common Fund, administered by the Office of Strategic Coordination (OSC) in the NIH Office of the Director which offers assistance awards or supplements to assistance awards.

Key Dates

Posted Date

June 18, 2026

Open Date (Earliest Submission Date)

December 11, 2026

Application Due Date(s)

Applications are due January 11th, 2027 (01/11/2027).

All applications are due by 5:00 PM local time of applicant organization.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

AIDS Application Due Date(s)

Not applicable.

Scientific Merit Review

A Scientific Merit Review will be performed by members of the Gabriella Miller Kids First Working Group in March 2027.

Advisory Council Review

Not applicable.

Earliest Start Date

April 2027.

Expiration Date

January 12, 2027

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), except where instructed to do otherwise (in this NOFO or in a Notice from [NIH Guide for Grants and Contracts \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164)).

Conformance to all requirements (both in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the [NIH ASSIST system \(https://public.era.nih.gov/assist/landing.era?tabId=0819b5fc-46b7-4f02-b6b7-127e5a4e19fa\)](https://public.era.nih.gov/assist/landing.era?tabId=0819b5fc-46b7-4f02-b6b7-127e5a4e19fa) to prepare, submit and track your application online.
2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and [eRA Commons \(https://public.era.nih.gov/commons/\)](https://public.era.nih.gov/commons/) to track your application. Check with your institutional officials regarding availability.
3. Use [Grants.gov \(https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PA-25-301\)](https://grants.gov/search-grants?oppStatuses=closed|archived|posted|forecasted&fon=PA-25-301) Workspace to prepare and submit your application and [eRA Commons \(http://public.era.nih.gov/commons/\)](http://public.era.nih.gov/commons/) to track your application.

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Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

The Gabriella Miller Kids First Pediatric Research Program (Kids First) was established by The Gabriella Miller Kids First Research Act, or Kids First (<https://www.congress.gov/bill/113th-congress/house-bill/2019/text>) (<https://www.congress.gov/bill/113th-congress/house-bill/2019/text>), for an initial 10 years, 2015-2024. The program was reauthorized as Kids First 2.0 by the 118th Congress for an additional five years, and the program was transferred from The Common Fund to the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI). DPCPSI and Common Fund have agreed that Common Fund would continue to administer Kids First on behalf of DPCPSI.

The overall goal of the Gabriella Miller Kids First Program is to help researchers uncover new insights into the biology of childhood cancer and congenital anomalies, including the discovery of shared genetic pathways between these disorders, to understand the underlying mechanisms of disease. This understanding would lead to novel and more refined prevention tools, diagnostics, and ultimately more targeted therapies and interventions for patients and families.

This funding opportunity builds upon prior NOFOs ([PAR-15-259 \(https://grants.nih.gov/grants/guide/pa-files/PAR-15-259.html\)](https://grants.nih.gov/grants/guide/pa-files/PAR-15-259.html), [PAR-16-150 \(https://grants.nih.gov/grants/guide/pa-files/PAR-16-150.html\)](https://grants.nih.gov/grants/guide/pa-files/PAR-16-150.html), [PAR-17-063 \(https://grants.nih.gov/grants/guide/pa-files/PAR-17-063.html\)](https://grants.nih.gov/grants/guide/pa-files/PAR-17-063.html), [PAR-18-583 \(https://grants.nih.gov/grants/guide/pa-files/PAR-18-583.html\)](https://grants.nih.gov/grants/guide/pa-files/PAR-18-583.html), [PAR-19-](#)

104 (<https://grants.nih.gov/grants/guide/pa-files/PA-19-104.html>), PA-19-390 (<https://grants.nih.gov/grants/guide/pa-files/PA-19-390.html>), PA-21-040 (<http://grants.nih.gov/grants/guide/pa-files/PA-21-040.html>), PA-22-054 (<http://grants.nih.gov/grants/guide/pa-files/PA-22-054.html>), PA-23-035 (<https://grants.nih.gov/grants/guide/pa-files/PA-23-035.html>), and PA-24-082 (<https://grants.nih.gov/grants/guide/pa-files/PA-24-082.html>)) and is intended to identify samples for germline whole genome sequencing (standard short-read whole genome sequencing or long-read sequencing, or clinical-grade sequencing, when justified), as well as genomic, exome, transcriptomic (RNA), and epigenomic (e.g., genome-wide methylation, chromatin accessibility) data generation for tumors and/or affected tissue that will help elucidate genetic contributions to childhood cancers and the etiology of congenital anomalies.

Data obtained from these projects will be analyzed and processed, to generate derived files and summary data, which will be compiled and made accessible alongside raw data and metadata, through the [Kids First Data Resource Center's portal](https://portal.kidsfirstdrc.org/login?redirect_path=dashboard) (https://portal.kidsfirstdrc.org/login?redirect_path=dashboard)

Types of Research Projects

The Kids First Program seeks applications for sample sets that can be ready for whole genome sequencing (whether short-, long-, or clinical-grade sequencing) and other omic assays, as soon as possible after the application due date of this NOFO. In general, applications may aim to discover influential genetic variants underlying their targeted disorder using various study designs (e.g., trio-based, family-based, or other). An integrative -omics approach (e.g., transcriptomic) may also be taken. This NOFO offers a protocol of sequencing the whole genome from high quality genomic DNA by one of Kids First Program's genomic data generating centers, as well as protocols for exome, transcriptomic, and epigenomic sequencing and analyses of tumor/affected tissue specimens (if available and justified). As sequencing technologies are constantly evolving, additional or alternative approaches may be proposed. For example, applicants may propose long-read sequencing approaches based on evidence of structural variations from previous short-read sequencing and analysis. Clinical-grade sequencing may be proposed but must be justified. Proteomics may be proposed, with justification, and may be accommodated if available. Project design will be finalized in discussions among the X01 investigators, the genomic data generating centers, Kids First Data Resource Center, and NIH program staff.

For childhood cancer cohorts: This NOFO invites applications that propose sequencing of DNA samples from childhood cancer cohorts (as well as RNA samples from tumors) for which a genetic basis (germline or somatic) is suspected but not identified, or for which understanding of recurring somatic mutations may address important questions of biology and therapy, or that analysis may uncover relationships with conditions already represented in the Kids First Data Resource. Proposed study populations should address important questions about the genetic basis, predispositions, or genomic aberrations of childhood cancers that might be answered by the approach proposed (e.g., whole genome sequencing of germline DNA, as well as tumor genome, exome, transcriptome, and epigenomic sequencing when tumor tissue is available). Clinical-grade sequencing may be proposed but must be justified. Proteomics and/or metabolomics of tumor samples may be proposed, with justification; and may be accommodated if available. Studies where the probands were born with congenital anomalies and subsequently diagnosed with childhood cancer are also encouraged. All study designs, with appropriate scientific justification, will be considered. Investigators may consider a trio or quad study design with the study population consisting of germline and tumor samples collected from participants with childhood cancer and their parents or affected first degree relatives, including those where the proband has previously been sequenced. Note that submission of materials from tumor samples is encouraged when sequencing and analysis of the tumor will provide additional insight into the cancer(s) under study.

For congenital anomalies cohorts: This NOFO also invites applications that will propose sequencing of DNA samples from subjects with those categories of congenital anomalies that are appropriate for whole genome sequencing; that are not yet well represented in the Kids First dataset, or that analysis may uncover relationships with conditions already represented in the Kids First dataset. Proposed study populations should address important questions about the genetics/genomics of congenital anomalies that might be answered by whole genome sequencing, as well as genome, exome, transcriptome, and epigenomic sequencing of affected tissue. Clinical-grade sequencing may be proposed but must be justified. Proteomics of relevant tissue samples may be proposed, with justification; and may be accommodated if available. All study designs, with appropriate scientific justification, will be considered. One example is that of a trio study design with the study population consisting of samples collected from participants with congenital anomalies and their parents, including those where the proband has previously been sequenced. Strong justification for the proposed sample size is expected in each application. Study populations with defects that affect multiple organ systems, or that are associated with susceptibility to childhood cancers, are especially encouraged. Populations with syndromic conditions that exhibit intellectual or neurobehavioral disabilities as part of the phenotype are acceptable, as long as the focus of the project is on associated congenital anomalies. Note that submission of material from affected tissue samples is encouraged when sequencing and analysis of the tissue will provide additional insight into the structural birth defect(s) under study.

For all cohorts: Investigators with small cohort sizes are encouraged to collaborate with other investigators and pool samples together to establish adequate power to uncover variants with relevant implications to the cancer(s) or birth defects under study, or to improve representation of racial and ethnic diversity in the datasets. This approach is especially relevant for disease conditions that have not yet been sequenced by the Kids First Program. Investigators who have previously sequenced genomic DNA from probands and who have unsequenced nucleic acid samples from their parents, siblings, tumor, and/or affected tissue are also encouraged to apply to have those samples sequenced, if it will result in additional insights into the genetic contribution to the cancer(s) or birth defects under study.

Specific Requirements and Expectations for this Opportunity

The cohorts selected under this NOFO must have already extracted genomic DNA or samples that are ready to be extracted (DNA and RNA from tumors/affected tissue are desirable but optional). Participants must have given consent to allow broad sharing and use of individual-level sequence and associated clinical and phenotypic data through dbGaP or other NIH-approved repositories. Unless otherwise prohibited, clinical and phenotypic data will be openly shared through the [Kids First Data Resource Center's portal](https://portal.kidsfirstdrc.org/) (<https://portal.kidsfirstdrc.org/>). Consent groups and/or data use limitations (DULs) for proposed samples should be indicated on the submitted Institutional Certification using the current NIH template. Cohort samples that have consents allowing broad data sharing and use, to include combining and comparing datasets across disease areas, (i.e., for **General Research Use**) are of higher priority. Conditions not previously incorporated into the Kids First dataset are desirable. A list of [prior Kids First Program X01 projects](https://www.kidsfirstdrc.org/prior-kids-first-program-x01-projects) (<file:///C:/Users/nierrascr/AppData/Local/Microsoft/Windows/NetCache/Content.Outlook/8CFGF12D/prior%20Kids%20First%20Program%20X01%20projects>) is available for reference.

No funds will be provided through this opportunity for collecting samples, performing additional phenotyping, acquiring other data types, obtaining new consent for existing samples, or performing data analysis. However, other NIH initiatives may provide support for these activities. Cohorts that have provided consent to be re-contacted for additional studies are therefore encouraged.

Cohorts proposed for sequencing must include a minimum amount of associated clinical and phenotypic data sufficient to enable association analysis with genomic variants. Applications with rich clinical and phenotypic data that can be shared to facilitate cross-disease research among the pediatric research community will be prioritized. Examples of other data types include other omics data, imaging data, and information from health records.

Projects selected under this NOFO will be expected to work in a collaborative manner with a designated Kids First Program genomic data generating center. These centers will produce sequence read and called variant data sets, as well as genome-wide methylation profiling and chromatin accessibility assay data (e.g., ATAC sequencing), where applicable. Some applicants may wish to further collaborate with the data generating center for custom analysis and validation of variants for a subset of cases. Such scientific collaboration will be arranged between the applicant and data generating center staff with oversight from the NIH; however, such services may reduce the total number of samples that can be sequenced.

Data from the studies selected under this NOFO will be submitted to the Kids First Data Resource Center. All Kids First data will be processed, harmonized, and made accessible through the cloud-based infrastructure of the Kids First Data Resource Center, where investigators are encouraged to interact with the data.

PDs/PIs of selected cohort projects will participate in a collaborative effort to inform the development of the integrated data resource to maximize its impact on the research community.

Investigators selected for this opportunity will be notified by NIH Kids First program staff with the estimated number of samples approved for sequencing. Approval to access the sequencing capacity is conditional on the submission of a completed Institutional Certification covering all samples to be submitted for sequencing. If the document does not meet the Kids First program's expectation for broad data sharing (i.e., **General Research Use**), another cohort with broader sharing may be selected instead. After approval, investigators will work with the NIH and the designated sequencing center to determine the final number of samples to be sequenced, as well as which sequencing technologies will be used. Details of sample and shipping requirements (amount, concentration, quality) will be provided to investigators.

Background

The intersection between human development and cancer is not a new concept. Multiple findings have substantiated the shared biology between congenital anomalies and childhood cancer. For example, *BRAF*, *MAPK*, and *ALK* mutations are found in both birth defects and cancers. These proteins are validated clinical oncology drug targets; thus suggesting potential new treatments for pediatric conditions. A 2019 publication showed increased cancer risks for kids born with birth defects in a large-scale study including 10 million live births.

Genetic alterations underlie etiologic contributors to pediatric disease, including childhood cancers as well as multiple congenital anomalies and related syndromes. Investigations of the genetic architecture of various diseases, by exome sequencing and other genome-wide interrogations, suggest that large sample sizes will be required to achieve a comprehensive understanding of the genetic etiology of these disorders. Those studies highlight the genetic heterogeneity of various developmental disorders and the genetic overlap between various diseases.

The Kids First Program has developed a data resource in the cloud to accelerate pediatric cancer and congenital anomalies research leading to better prevention, diagnosis, and treatments for patients and families. The program's goal is to grow a resource with Findable, Accessible, Interoperable, and Reusable (FAIR) data, promote data sharing, develop tools for data analysis and data visualization, and foster collaborative research. The Kids First Data Resource Center provides integrated data sets to increase study power; catalogs myriad data sets to enable rational organization of data resources; and facilitates cross-linking of diverse data sets to enable novel research collaborations and knowledge connections.

The contribution of genetic factors to human health due to the relative frequencies of both deleterious and beneficial alleles among human populations is an important area of interest.

Approximately 3% of all babies born in the United States has a birth defect, and these are the leading cause of death for infants during the first year of life, summing to 20% of all infant deaths. Next to accidents, congenital anomalies are the leading cause of death in children during the first four years of life and account for half of all pediatric hospitalizations. Technical advances (such as the decreased cost of genomic sequencing) have made powerful tools available to help researchers uncover the genetic variants, genes, and pathways that underlie congenital anomalies. Together with our ability to describe clinical characteristics in detail, there are emerging opportunities for research on genetic and environmental influences on development and for illuminating common pathways that may link different birth defects.

Cancer is the leading cause of death from disease among children. Kids First Program's workshops and symposia have emphasized the importance of further large-scale germline sequencing of well-annotated pediatric cancer patient and parent trios, as well as paired diagnostic and/or relapse tumor specimens when available and have emphasized the value of collecting and sharing rich clinical and phenotypic data. The causes of some pediatric cancers are not well understood. Many of the rare familial cancer syndromes include pediatric cancers in which tumor formation is directly related to a structural defect or mutation in the germline. Historically, germline alterations were identified in only a small fraction of children with cancer, even in those with a family history of cancer in 1st or 2nd degree relatives. However, with the advent of genome-wide sequencing, potentially causative germline alterations have been observed in approximately 10 percent of children with cancer.

Germline sequencing data from many more children with cancer and congenital anomalies are needed to fully elucidate the etiology of these conditions and accelerate the development of novel prevention, diagnostics, and treatments for patients.

Pre-Application Webinar

The Gabriella Miller Kids First Pediatric Research Program (Kids First) staff intends to hold a Pre-Application Webinar for all interested prospective applicants. Webinar date and other details will be posted on the Kids First website: <https://commonfund.nih.gov/kidsfirst> (<https://commonfund.nih.gov/kidsfirst>).

See [Section VIII. Other Information](#) for award authorities and regulations.

Section II. Award Information

Funding Instrument

Other: A financial assistance mechanism that is not a grant or cooperative agreement. Examples include access to research resources or pre-applications.

Application Types Allowed

New

The [OER Glossary](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the [How to Apply - Application Guide](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), provide details on these application types. Only those application types listed here are allowed for this NOFO.

Clinical Trial?

Not Allowed: Only accepting applications that do not propose clinical trials. Note: Applications may propose activities involving human subjects that are not deemed clinical trials.

[Need help determining whether you are doing a clinical trial?](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82370)

Funds Available and Anticipated Number of Awards

Not applicable; there are no funds associated with a resource access award.

Award Budget

Not applicable; there are no funds associated with a resource access award.

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is 1 year. Investigators are expected to ship samples to designated Kids First Program's data generating center within 6 months of the award notification. This period may be extended only in exceptional cases upon justification and approval.

NIH grants policies as described in the [NIH Grants Policy Statement](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) will apply to the applications submitted and awards made from this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions - Includes all types

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Local Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

Federal Governments

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Foreign Organizations/Foreign Collaborations

Non-domestic (non-U.S.) Entities (Foreign Organizations) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as [defined in the NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are not** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. Failure to complete registrations in advance of a due date is not a valid reason for a late submission, please reference [NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423) for additional information

- [System for Award Management \(SAM\) \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82390\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82390) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code. Foreign organizations must obtain a [NATO Commercial and Government Entity \(NCAGE\) Code \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11176) (in lieu of a CAGE code) in order to register in SAM.
 - Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- [eRA Commons \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=11123) - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registrations; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- [Grants.gov \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82300\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82300) – Applicants must have an active SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

All PD(s)/PI(s) must be registered with [ORCID \(https://orcid.org/\)](https://orcid.org/). The personal profile associated with the PD(s)/PI(s) eRA Commons account must be linked to a valid ORCID ID. For more information on linking an ORCID ID to an eRA Commons personal profile see the [ORCID topic in our eRA Commons online help \(https://era.nih.gov/erahelp/Commons/default.htm#orcid.htm%3FTocPath%3D29\)](https://era.nih.gov/erahelp/Commons/default.htm#orcid.htm%3FTocPath%3D29).

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with their organization to develop an application for support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

2. Cost Sharing

This NOFO does not require cost sharing as defined in the [NIH Grants Policy Statement NIH Grants Policy Statement Section 1.2 Definition of Terms. \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11126\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11126)

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time, per [NIH Grants Policy Statement Section 2.3.7.4 Submission of Resubmission Application](#) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=82415). This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see [NIH Grants Policy Statement 2.3.9.4 Similar, Essentially Identical, or Identical Applications](#) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423)).

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in [Part 1](#) of this NOFO. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the [How to Apply - Application Guide](#) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) except where instructed in this notice of funding opportunity to do otherwise (in this NOFO, in a [policy notice](#) (https://grants.nih.gov/grants/guide/url_redirect.php?id=11163), or other notice from [NIH Guide for Grants and Contracts](#) (https://grants.nih.gov/grants/guide/url_redirect.php?id=11164)). Conformance to the requirements in the [How to Apply - Application Guide](#) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Page Limitations

All page limitations described in the [How to Apply - Application Guide](#) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) and the [Table of Page Limits](#) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=61134) must be followed

, with the following exceptions or additional requirements: For this specific NOFO, the Research Strategy section is limited to **6 pages**.

Instructions for Application Submission

The following section supplements the instructions found in the [How to Apply - Application Guide](#) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

All instructions in the [How to Apply - Application Guide](#) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

Total Federal Funds Requested: Enter \$0.

Total Federal & Non-Federal Funds: \$0.

Estimated Program Income: Enter 0.

SF424(R&R) Project/Performance Site Locations

All instructions in the [How to Apply - Application Guide](#) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

SF424(R&R) Other Project Information

All instructions in the [How to Apply - Application Guide](#) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

Other Attachments: The application must include the following attachments.

1) Institutional Certification for Genomic Data Sharing:

Provide the Institutional Certification(s) using the current NIH template (<https://grants.nih.gov/policy-and-compliance/policy-topics/sharing-policies/gds/completing-institutional-certification-form> (<https://grants.nih.gov/policy-and-compliance/policy-topics/sharing-policies/gds/completing-institutional-certification-form>)), which demonstrates that it is permissible to share individual-level genomic data to be generated for all samples proposed, consistent with achieving the goals of the program. Institutional Certifications specify the data use limitations and data use limitation modifiers, as determined by the institution's IRB (or equivalent body) after reviewing the informed consent agreed to by the participants. If the Institutional Certification is not available, provide a [Provisional Certification](#) (https://grants.nih.gov/sites/default/files/flmngn/IC9_Provisional_Institutional_Certification.pdf) and describe the anticipated data use limitations and associated modifiers separately. If submitting a Provisional Certification with the application, please note that a completed Institutional Certification will be required before a final selection can be made. For guidance on obtaining an Institutional Certification, see: <https://commonfund.nih.gov/kidsfirst/FAQ> (<https://commonfund.nih.gov/kidsfirst/FAQ>).

2) Sample Information:

- Describe the characteristics and number of specimens proposed for sequencing in computer readable table format.
- Describe the number of specimens currently ready to ship to a genomic data generating center, and those that could be shipped at a later date in the same fiscal year (please provide a timeline if all proposed samples are not currently ready for shipment).
- Provide a detailed inventory of the sources of the DNA (and RNA or other material if available for tumors and/or affected somatic tissue): number of samples from blood, number of samples from saliva or buccal swabs, and number of samples from frozen tissue versus embedded tissue (including fixation method). Please note that costs associated with assaying/processing saliva samples contaminated with bacteria could reduce the total number of samples that can be sequenced; therefore, blood- or tissue-derived nucleic acids are preferable. DNA or other material from patient-derived cell lines will not be accepted due to the possible introduction of mutations that could confound the identification of disease-causing rare variants. Additionally, DNA or RNA from samples that have undergone decalcification will not be accepted.
- Describe the status of the DNA, RNA, and other samples and their storage/preservation formats that will be provided, including the extraction methods used for each source and the approximate nucleic acid concentrations. Address their quantity and quality in terms of suitability for whole genome sequencing and/or other technology proposed. Describe the quality metric and method of quantification used.
- Describe sample availability for shipment to the genomic data generating center(s) per cohort or sub-cohort proposed.
- For applications proposing chromatin accessibility assays, such as ATAC-seq, describe the tissue source and material that will be provided.
- For tumor specimens, describe the pathology review to which the specimens were subjected and the percentage of tumor cells within the specimen used for DNA and/or RNA isolation.

3) Clinical, Phenotypic, and Demographic Data:

Describe what clinical, phenotypic, and demographic information was collected from all study participants and what is available for submission to the Kids First Data Resource to be shared with the wider research community. At a minimum, the following data elements are expected:

- sex,
- race,
- ethnicity,
- age at enrollment and/or age at diagnosis,
- diagnoses (e.g., type of birth defect, primary tumor type),
- phenotypes for affected cases (list all variables collected),
- phenotypes for unaffected family members (list all variables collected),
- vital status,
- age at last known vital status,
- clinical information (list all available clinical data elements),
- and family medical history (e.g., family history of cancer or congenital anomalies).

Describe whether other data types are available. Describe whether electronic health records may be available for additional data extraction.

For an example template of clinical and phenotypic data elements, visit <https://commonfund.nih.gov/kidsfirst/FAQ> (<https://commonfund.nih.gov/kidsfirst/FAQ>).

If appropriate, describe any available environmental or exposure data.

If a proposed cohort is selected, a data dictionary or additional data elements may be requested.

4) Family Structure (if applicable):

If proposing a non-trio design, provide any additional information that will help explain the family structures for your proposed cohort (e.g., pedigrees). Convey the total number of affected and unaffected family members proposed for sequencing.

For optional tables to facilitate organizing and providing sample information, clinical and phenotypic data information, and family structure visit, <https://commonfund.nih.gov/kidsfirst/FAQ> (<https://commonfund.nih.gov/kidsfirst/FAQ>).

SF424(R&R) Senior/Key Person Profile

All instructions in the [How to Apply - Application Guide](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

PHS 398 Cover Page Supplement

All instructions in the [How to Apply - Application Guide](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

PHS 398 Research Plan

All instructions in the [How to Apply - Application Guide](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) (https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed, with the following additional instructions:

Specific Aims: The Specific Aims should refer directly to the goals of this Notice of Funding Opportunity.

Research Strategy: Cohorts for childhood cancers and congenital anomalies have distinct requirements as indicated below. Applicants should note requirements that apply to all cohorts.

Research teams who have previously been approved to have cohorts sequenced through Kids First may submit a new application, provided that the required elements, described below, are addressed in the application. In addition, these applicants must provide scientific justification for why further sequencing should be supported (e.g., analysis of a different subpopulation, analysis of racial or ethnic groups, the addition of long read sequencing to confirm suspected structural variants, the addition of epigenomic profiling), and demonstration of what progress, if any, has been made on analyzing the data from the previously submitted cohort.

For cohorts with childhood cancers:

Applicants should:

- 1) Describe the proposed cohort of children with cancer for which a genetic predisposition to cancer is suspected, but not yet identified, or for which understanding of recurring somatic mutations may address important questions of biology and therapy.
- 2) Clearly explain why genome sequencing (as well as genome, exome, transcriptome, and/or epigenomic sequencing for tumors) is likely to reveal previously unknown variants underlying cancer predisposition or previously unrecognized associations between known variants and specific childhood cancers. Describe previous germline and somatic genomic sequencing that has been done on the samples proposed. Have known cancer predisposition genes been excluded? This is especially relevant where the proband has previously been sequenced, and sequencing the parents is proposed.
- 3) Present evidence that the number and type of DNA and RNA samples proposed are likely to be sufficient to detect genetic variants affecting cancer risk for the population under study.
- 4) If this request is a direct follow up of an earlier study, describe those results.
- 5) Proteomics and/or metabolomics of tumor samples may be proposed, with justification, and may be accommodated if available. Provide the rationale for doing proteomics and/or metabolomics characterization, as well as a prioritized list of available samples.
- 6) Provide any additional background that supports the value of the samples proposed for genomic sequencing.
- 7) Provide information on the value of adding data from this cohort to the Kids First Data Resource. This includes highlighting potential relationships with cohorts already represented in the Kids First Data Resource.

Applicants with cancer cohorts are strongly encouraged to address all the following points in their application:

1) **Study Population:** Describe the cohort and the characteristics that define it as a distinctive population that is likely to have a genetic basis for cancer predisposition or is a population for which understanding of recurring somatic mutations may address important questions of biology and therapy. Describe current understanding of the genetic contribution (germline and somatic) to the cancer(s) affecting the proposed cohort. Describe the rationale for the proposed cohort as one that will provide key contributions to answering important questions about the genetics/genomics of childhood cancers through the application of whole genome sequencing to the cohort. Describe how the study design will be likely to lead to the discovery of variants contributing to the development and/or progression of the cancer of interest, or to an enhanced understanding of the contribution of known variants to the development and/or progression of the cancer of interest. Submission of nucleic acids from tumor samples is encouraged. Applicants proposing submission of tumor samples should describe whether both DNA and RNA are available for sequencing.

2) **Data Analysis:** Provide a plan for analyzing the data to be generated under this NOFO (note that no funds are provided under this NOFO to support analysis or other activities). Including methods for variant filtering and follow up. If there is a plan to analyze the data obtained from earlier data, describe the strategy for that process. Describe why the number of samples proposed for whole genome sequencing as well as the associated clinical and phenotypic data are adequate to draw reliable conclusions about the contribution of genetic

alterations to the condition. Use power analyses to describe the range of effect sizes detectable by the study. If RNA sequencing or other –omics are proposed for tumors, describe how the results will be analyzed to better understand key biological and clinical characteristics of the cancer under study.

3) Contribution to Data Resource and value to the pediatric research community: Describe how the overall study design, sample size, available clinical and phenotypic, and the sequence data to be generated will contribute to the Kids First Data Resource and empower research and collaborations among the pediatric research community. For example, how do the cancers of this study intersect with other cancer or birth defect phenotypes, and what types of genetic and/or phenotypic overlap have been identified between the proposed cancer and other cancers or birth defects? Describe willingness to participate in a collaborative effort to inform the development of the Kids First Data Resource. Describe a willingness to contribute secondary results to the Data Resource, upon acceptance of publication of associated findings. [Describe willingness to participate in the Childhood Cancer Data Initiative \(CCDI\), as applicable \(https://www.whitehouse.gov/presidential-actions/2025/09/unlocking-cures-for-pediatric-cancer-with-artificial-intelligence/\).](https://www.whitehouse.gov/presidential-actions/2025/09/unlocking-cures-for-pediatric-cancer-with-artificial-intelligence/)

4) Consent and Data Sharing: Confirming the consent used to obtain the samples allows sharing of individual level sequence data through a controlled access, NIH-approved repository such as dbGaP (dbgap.ncbi.nlm.nih.gov/home/ (<https://dbgap.ncbi.nlm.nih.gov/home/>)) and allows for sharing of the associated clinical and phenotypic data. Describe whether the consents allow for broad use of the data including combining and comparing datasets of various disease phenotypes. It includes information such as the ability to re-contact participants for additional phenotyping or collection of additional samples. If submitting a provisional certificate because the full Institutional Certification is not available, describe the anticipated data use limitations based on the consent.

5) Data Management: Investigators are encouraged to use the cloud-based infrastructure of the Kids First Data Resource Center wherever possible; however, if the investigative team intends to download the data to an institutional computing environment, describe how the data and security will be managed.

For cohorts with congenital anomalies:

Applicants should:

1) Describe the phenotype and explain its biological, biomedical, and/or public health significance. Include details about whether multiple organ systems are affected or whether there are significant co-morbidities.

2) Document the evidence for a genetic component of this phenotype and the likely strength of that component including the heritability, complexity, and a description of any earlier genetic studies on this disorder. Describe previous genotyping that has been done on the samples proposed. If proposing the sequencing or epigenomic profiling of affected tissue, clearly describe the evidence for somatic mutations, mosaicism, or epigenomic factors.

3) Present evidence that the study design (e.g. family structure) and sample size proposed are likely to be sufficient to detect genetic variants underlying the condition under study.

4) Describe other identified risk factors, including any known environmental risk factors and the evidence for their involvement. Also, discuss any evidence for gene-environment interactions.

5) If this request is a direct follow up of an earlier study, describe those results.

6) Provide any additional background that supports the value of the samples proposed for genomic sequencing. This may include information on the ability of the investigator to obtain additional samples for follow-up studies or to acquire additional data such as exposure data.

7) Proteomics of relevant tissue samples may be proposed, with justification, and may be accommodated if available. Provide the rationale for doing proteomics characterization, as well as a prioritized list of available samples.

8) Provide information on the value of adding data from this cohort to the Kids First Data Resource. This includes highlighting potential relationships with cohorts already represented in the Kids First dataset.

Applicants with congenital anomalies cohorts are strongly encouraged to address the following points in their application:

1) Study Population: Clearly describe the study population. Include detailed information about how subjects were identified and sampled and the method(s) of phenotypic characterization. If the subjects provided for this study are a subset of a family population, explain which individuals were included and how they were selected. Highlight special features of the study population that would enhance success. Describe the ancestry, if known, of the individuals whose samples will be submitted for genome sequencing and how this information will factor into the design of the study. Describe how the study design will be likely to lead to discovery of variants contributing to your phenotype of interest.

2) Data Analysis: Provide a plan for analyzing the data to be generated under this NOFO (note that no funds are provided under this NOFO to support analysis or other activities). Include methods for variant filtering and follow up. If there is a plan to analyze the data obtained with earlier data, describe the strategy for that process. Describe why the number of samples proposed for whole genome sequencing as well as the associated clinical and phenotypic data are adequate to draw reliable conclusions about the contribution of genetic alterations to the condition. Use power analyses to describe the range of effect sizes detectable by the study. If RNA sequencing is proposed for affected tissue, describe how the results will be analyzed to better understand key biological and clinical characteristics of the structural birth defect under study.

3) Contribution to Data Resource and value to the pediatric research community: Describe how the overall study design, sample size, available clinical and phenotypic, and the sequence data to be generated will contribute to the Kids First Data Resource and empower research and collaborations among the pediatric research community. For example, how do the phenotypes of this study intersect with other birth defect or cancer phenotypes and what types of genetic and/or phenotypic overlap have been identified between the proposed birth defect and other congenital anomalies or cancers? Describe willingness to participate in a collaborative effort to establish the Kids First Data Resource. Describe a willingness to contribute secondary results to the Data Resource, upon acceptance of publication of associated findings.

4) Consent and Data Sharing: Confirm the consent used to obtain the samples allows sharing of individual level sequence data through a controlled access, NIH-approved repository such as dbGaP (dbgap.ncbi.nlm.nih.gov/home/ (<https://dbgap.ncbi.nlm.nih.gov/home/>)) and allows for sharing of the associated clinical and phenotypic data. Describe whether the consents allow for broad use of the data including combining and comparing datasets of various disease phenotypes. Include information such as ability to recontact participants for additional phenotyping or collection of additional samples. If submitting a provisional certification because the full Institutional Certification is not available, describe the anticipated data use limitations based on the consent.

5) Data Management: Investigators are encouraged to use the cloud-based infrastructure of the Kids First Data Resource, wherever possible; however, if the investigative team intends to download the data to an institutional computing environment, describe how the data and security will be managed.

For all applications:

The overall goal of the Kids First Program is to create a data resource that makes individual and integrated datasets broadly accessible to the research community to help researchers to effectively mine data across diverse pediatric conditions, understand the underlying mechanisms of disease, uncover shared pathways, and develop more refined diagnostic capabilities and more targeted therapies or interventions for childhood diseases. All applications should include an Institutional Certification which indicates the data use limitations and/or modifiers stating how individual level sequence data can be shared with and used by secondary users, consistent with the terms of the NIH Genomic Data Sharing policy <https://grants.nih.gov/policy-and-compliance/policy-topics/sharing-policies/gds> (<https://grants.nih.gov/policy-and-compliance/policy-topics/sharing-policies/gds>). Applicants are expected to agree that all sequence data generated by Kids First and associated clinical and phenotype data will be deposited in repositories designated by the Kids First Common Fund staff, in a manner consistent with NIH policy <https://grants.nih.gov/policy-and-compliance/policy-topics/sharing-policies> (<https://grants.nih.gov/policy-and-compliance/policy-topics/sharing-policies>) and achieving the goals of the program.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

Other Plan(s):

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed, with the following additional instructions:

- A Data Management and Sharing Plan is not applicable for this NOFO.

Appendix: Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

- No publications or other material, with the exception of blank questionnaires or blank surveys, may be included in the Appendix.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400), with the following additional instructions:

If you answered "Yes" to the question "Are Human Subjects Involved?" on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

Delayed Onset Study

Note: [Delayed onset \(https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy\)](https://grants.nih.gov/grants/glossary.htm#DelayedOnsetStudy) does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

PHS Assignment Request Form

All instructions in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400) must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 2, Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

[Part I](#), contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or [Federal holiday \(https://grants.nih.gov/grants/guide/url_redirect.html?id=82380\)](https://grants.nih.gov/grants/guide/url_redirect.html?id=82380), the application deadline is automatically extended to the next business day.

Organizations must submit applications to [Grants.gov \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11128\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the [eRA Commons \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the [NIH Grants Policy Statement Section 2.3.9.2 Electronically Submitted Applications \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82423).

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the [How to Apply – Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to [intergovernmental review. \(https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm\)](https://grants.nih.gov/grants/policy/nihgps/html5/section_10/10.10.1_executive_orders.htm)

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Pre-award costs are allowable only as described in the [NIH Grants Policy Statement Section 7.9.1 Selected Items of Cost \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11143\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11143).

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400). Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit [How to Apply – Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400). If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the [Dealing with System Issues \(https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm\)](https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/dealing-with-system-issues.htm) guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this NOFO for information on registration requirements.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the [How to Apply - Application Guide \(https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400\)](https://grants.nih.gov/grants/guide/url_redirect.htm?id=82400).

See [more tips \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11146\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by components of participating organizations, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Mandatory Disclosure

Recipients or subrecipients must submit any information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award. See Mandatory Disclosures, [2 CFR 200.113](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113) (<https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-B/section-200.113>) and [NIH Grants Policy Statement Section 4.1.35](https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.35_mandatory_disclosures.htm) (https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.35_mandatory_disclosures.htm).

Send written disclosures to the NIH Chief Grants Management Officer listed on the Notice of Award for the IC that funded the award and to the [HHS Office of Inspector Grant Self Disclosure Program](https://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/) (<https://oig.hhs.gov/compliance/self-disclosure-info/hhs-oig-grant-self-disclosure-program/>) at grantdisclosures@oig.hhs.gov (<mailto:grantdisclosures@oig.hhs.gov>).

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in [the policy](http://grants.nih.gov/grants/guide/url_redirect.htm?id=82299) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=82299).

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the [NIH mission](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11149) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11149) are evaluated for scientific and technical merit through the NIH peer review system.

For this particular NOFO, note the following:

The X01 Resource Access Program invites eligible institutions to seek access to NIH research resources, which are specified in each X01 NOFO. This includes programs where institutions will request access to submit to the resource (e.g., high throughput screening assays) as well as programs where access to a specific NIH research resource is needed to conduct certain research. Important factors in the peer review of X01 applications are the need for, and potential benefit of, gaining access to the resource, specifications for any assays proposed, timelines for completion and plans for follow-on studies.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Specific to this NOFO,

- Is the trait under study significant to human health and/or the understanding of biology?
- Is there strong evidence for a genetic component? Are the proposed studies likely to provide important new information about genetic variants that contribute to congenital anomalies, address important questions about the genetics (germline and somatic) of childhood cancers, and/or to reveal shared genetic pathways? Is the cohort likely to strengthen the impact of the Kids First Data Resource and empower research and collaborations among the pediatric research community? For cancer cohorts for which there is tumor DNA and/or RNA from multiple time points available, will an understanding of recurring somatic mutations within the cohort address important questions about the biology and therapy for the cancer under study?
- Is there an ability to re-contact participants for additional phenotyping or collection of additional samples?
- Is there additional information (e.g., environmental exposure data) that is likely to add value for further studies?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance, and organizational structure appropriate for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

Specific to this NOFO:

Although this NOFO does not provide financial support for analysis, PD/PI(s) should put forth a rational and feasible plan for future analyses. Question to be considered:

- Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?

- Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project?
- Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate, for the work proposed?
- Are potential problems, alternative strategies, and benchmarks for success presented?
- If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed?
- Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

Additionally,

- Does the proposed cohort consist of highly informative cases?
- Are the specific phenotypic measures appropriately chosen and carefully determined?
- Is the depth of available clinical and phenotypic data sufficient to support the analysis plan and overall genetic discovery?
- Is the study design appropriate for the cancer or birth defect under study?
- Are the sequencing services requested appropriate for the questions posed?
- In the context of other data available through the Kids First Data Resource, is the cohort likely to reveal previously unknown variants associated with pediatric cancer and/or congenital anomalies?
- If the applicants have previously been approved to have cohorts sequenced by Kids First, is there compelling justification for why further sequencing should be supported?
- Have the applicants demonstrated what progress, if any, has been made on analyzing the data from the previously submitted cohort?
- Does the proposal include an Institutional Certification which indicates the data use limitations and/or modifiers stating how individual level sequence data can be shared with and used by secondary users, consistent with the terms of the NIH Genomic Sharing policy, <https://grants.nih.gov/policy-and-compliance/policy-topics/sharing-policies/gds> (<https://grants.nih.gov/policy-and-compliance/policy-topics/sharing-policies/gds>)? (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html>?) Applicants are expected to agree that all sequence data generated by Kids First Program and associated clinical and phenotype data will be deposited in repositories designated by the Kids First Common Fund staff, in a manner consistent with NIH policy.

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Study Timeline

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the [Guidelines for the Review of Human Subjects](http://grants.nih.gov/grants/guide/redirect.htm?id=11175) (<http://grants.nih.gov/grants/guide/redirect.htm?id=11175>).

This NOFO only accepts applications that do not propose clinical trials. Note: Applications may propose activities involving human subjects that are not deemed clinical trials.

Inclusion of Human Subjects Policies

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for inclusion. For additional information on review of the Inclusion section, please refer to the [Guidelines for the Review of Inclusion in Clinical Research](http://grants.nih.gov/grants/guide/redirect.htm?id=11174) (<http://grants.nih.gov/grants/guide/redirect.htm?id=11174>).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following three points: (1) a complete description of all proposed procedures including the species, strains, ages, sex, and total numbers of animals to be used; (2) justifications that the species is appropriate for the proposed research and why the research goals cannot be accomplished using an alternative non-animal model; and (3) interventions including analgesia, anesthesia, sedation, palliative care, and humane endpoints that will be used to limit any unavoidable discomfort, distress, pain and injury in the conduct of scientifically valuable research. Methods of euthanasia and justification for selected methods, if NOT consistent with the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals, is also required but is found in a separate section of the application. For additional information on review of the Vertebrate Animals Section, please refer to the [Worksheet for Review of the Vertebrate Animals Section](http://grants.nih.gov/grants/guide/redirect.htm?id=11150) (<http://grants.nih.gov/grants/guide/redirect.htm?id=11150>).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

Not applicable.

Renewals

Not applicable.

Revisions

Not applicable.

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Applications from Foreign Organizations

Not applicable.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the Resource Sharing Plan(s) (e.g., [Sharing Model Organisms \(https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview\)](https://sharing.nih.gov/other-sharing-policies/model-organism-sharing-policy#policy-overview)) or the rationale for not sharing the resources, is reasonable.

Authentication of Key Biological and/or Chemical Resources

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the Kids First Working Group, in accordance with [NIH peer review policies and practices \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11154\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

[Requests for reconsideration of initial peer review \(https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.4.2_appeals_of_initial_scientific_review.htm\)](https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.4.2_appeals_of_initial_scientific_review.htm) will not be accepted for applications submitted in response to this NOFO.

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) convened by the Kids First Working Group. The following will be considered:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Relevance of the proposed project to program priorities.
- Value of incorporating the dataset into the Data Resource to empower research among the pediatric research community.
- Compliance with resource sharing policies as appropriate and ability to broadly share and use data from the cohort in line with the goals of the program (i.e. combining and cross-analyzing genomic datasets). Kids First program staff reserves the right to not include cohorts that cannot be broadly shared or cross-analyzed with other Kids First datasets.
- Program balance: Kids First seeks to ensure that a broad diversity of both childhood cancer studies and congenital anomalies studies are well represented. Cohorts representing conditions not previously sequenced under Kids First may be prioritized. Criteria that will be considered include the following:
 - Informative study design and sufficient clinical and phenotypic data.
 - Availability of samples in timely manner.
 - Sample quality in terms of suitability for whole genome sequencing (as well as exome, transcriptome, and epigenome sequencing if applicable).

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the [NIH Grants Policy Statement Section 2.5.1. Just-in-Time Procedures \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82418\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82418). This request is not a Notice of Award nor should it be construed to be an indicator of possible funding.

Prior to making an award, NIH reviews an applicant's federal award history in SAM.gov to ensure sound business practices. An applicant can review and comment on any information in the Responsibility/Qualification records available in SAM.gov. NIH will consider any comments by the applicant in the Responsibility/Qualification records in SAM.gov to ascertain the applicant's integrity, business ethics, and performance record of managing Federal awards per 2 CFR Part 200.206 "Federal awarding agency review of risk posed by applicants." This provision will apply to all NIH grants and cooperative agreements except fellowships.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the [eRA Commons \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11123\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=11123). Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the [NIH Grants Policy Statement Section 2.4.4 Disposition of Applications \(http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82416\)](http://grants.nih.gov/grants/guide/uri_redirect.htm?id=82416).

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the [NIH Grants Policy Statement \(https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm\)](https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.5.1_just-in-time_procedures.htm).

An X01 does not result in a Notice of Award (NoA). Rather, selected applicants will receive access to resources described in this NOFO. Successful applicants will receive instructions for next steps.

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the recipient must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

2. Administrative and National Policy Requirements

An X01 does not result in a Notice of Award. Instead, successful applicants will receive instructions on accessing the resources described in this NOFO.

Applicants and recipients are strongly encouraged to refer to the [NIH Director's Statement of Priorities \(https://www.nih.gov/about-nih/nih-director/statements/advancing-nih-mission-through-unified-strategy\)](https://www.nih.gov/about-nih/nih-director/statements/advancing-nih-mission-through-unified-strategy), entitled "Advancing NIH's Mission Through a Unified Strategy."

Recipients are responsible for ensuring that their activities comply with all applicable federal regulations. Pursuant to 2 CFR 200.340, by accepting an NIH award, the recipient agrees that continued funding for the award is contingent upon the availability of appropriated funds, recipient satisfactory performance, compliance with the Terms and Conditions of the award, and may also otherwise be terminated, to the extent authorized by law, if the agency determines that the award no longer effectuates the program goals or agency priorities, in line with 2 CFR 200.340(a)(4).

Pursuant to the Cybersecurity Act of 2015, Div. N, § 405, Pub. Law 114-113, 6 USC § 1533(d), the HHS Secretary has established a common set of voluntary, consensus-based, and industry-led guidelines, best practices, methodologies, procedures, and processes.

Successful recipients under this NOFO agree that:

When recipients, subrecipients, or third-party entities have:

- ongoing and consistent access to HHS owned or operated information or operational technology systems; and
- receive, maintain, transmit, store, access, exchange, process, or utilize personal identifiable information (PII) or personal health information (PHI) obtained from the awarding HHS agency for the purposes of executing the award.

Cybersecurity plans and procedures **must** at minimum include the following:

- Develop cybersecurity plans and procedures, modeled after the [NIST Cybersecurity framework \(https://www.nist.gov/cyberframework\)](https://www.nist.gov/cyberframework), to protect HHS systems and data:
 - **Identify:**
 - Develop an inventory of all assets and accounts with access to HHS owned and operated information or operational technology systems or which obtain PII or PHI for the purposes of the award.
 - **Protect:**
 - Limit access to HHS owned and operated systems to only those in need of access to complete reward activities.
 - Require all staff to complete annual cybersecurity and privacy awareness training. Visit [405\(d\): Knowledge on Demand \(hhs.gov\) \(https://405d.hhs.gov/kod/five-threats\)](https://405d.hhs.gov/kod/five-threats) to obtain free trainings, if needed.
 - Enable multifactor authentication for all employees, subrecipients, and third-party entities to access HHS owned and operated information or operational technology systems.
 - Regularly backup sensitive data and test backups.
 - **Detect:**
 - Install anti-virus or anti-malware software on all devices, servers, and accounts used to connect to HHS owned and operated systems.
 - **Respond:**
 - Develop an incident response plan. See [Incident-Response-Plan-Basics_508c.pdf \(cisa.gov\) \(https://www.cisa.gov/sites/default/files/publications/Incident-Response-Plan-Basics_508c.pdf\)](https://www.cisa.gov/sites/default/files/publications/Incident-Response-Plan-Basics_508c.pdf) to learn about developing incident response plans.
 - Have cybersecurity incident reporting procedures that ensure the relevant HHS awarding agencies are notified of a cybersecurity incident within 48 hours of discovery. A cybersecurity incident is defined as an unplanned interruption to a technology service or reduction in the quality of a technology service, or an occurrence that actually or potentially jeopardizes the confidentiality, integrity, or availability of an information system or the information the system processes, stores, or transmits.
 - **Recover:**
 - Investigate incidents and plug any security gaps identified.

All activities proposed in your application and budget narrative must align with applicable law, including but not limited to statutes, executive orders, federal regulations and applicable judicial holdings. Accordingly, discretionary awards shall not be used to fund, promote, encourage, subsidize, or facilitate; racial preferences or other forms of racial discrimination by the recipient, including activities where race or intentional proxies for race will be used as a selection criterion for employment or program participation; denial by the recipient of the sex binary in humans, or the belief that sex is a chosen or mutable characteristic; illegal immigration; or any other initiatives that compromise public safety. If an application does not align, the application will not receive funding to the extent permitted by law and applicable court orders.

For applications involving substance abuse, the application must not support harm reduction. Please see [Updated Funding Guidance for Recipients on Supplies and Services \(https://www.samhsa.gov/sites/default/files/dear-colleague-letter-updated-hr-funding-guidance.pdf\)](https://www.samhsa.gov/sites/default/files/dear-colleague-letter-updated-hr-funding-guidance.pdf).

For applications involving funding Medication-Assisted Treatment (MAT) or medications for opioid use disorder (MOUD), this funding should be used to provide comprehensive treatment and recovery support services rather than medication-only models for opioid use disorder. Services should include medications, where clinically indicated, in conjunction with psychosocial and other treatment and recovery support services. Funding can also be used to support individualized tapering and discontinuation of medications when clinically indicated. Please see [Updated Funding Guidance for Recipients on MAT/MOUD \(https://www.samhsa.gov/sites/default/files/dear-colleague-letter-mat-moud-guidance.pdf\)](https://www.samhsa.gov/sites/default/files/dear-colleague-letter-mat-moud-guidance.pdf).

As of October 1, 2025, HHS has adopted [2 CFR Part 200 \(https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200\)](https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200), with some modifications included in 2 CFR Part 300. These regulations replace those in 45 CFR Part 75. However, for NIH, under the Consolidated Appropriations Act for FY 2026, ([P.L. 119-75 \(https://www.congress.gov/bills/119th-congress/house-bill/7148\)](https://www.congress.gov/bills/119th/congress/house-bill/7148)), Division B, Title II, Sec. 224), the provisions relating to indirect costs in 45 CFR 75 continue to apply to NIH awards. Consistent with the statute, NIH will not apply updated thresholds outlined within 2 CFR Part 200, at this time.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Data Management and Sharing

A Data Management and Sharing Plan (DMS Plan) is not applicable to this NOFO. An X01 does not result in a Notice of Award. Instead, successful applicants will receive instructions on accessing the resources described in this NOFO

4. Reporting

Not applicable. An X01 does not result in a Notice of Award. Instead, successful applicants will receive instructions on accessing the resources described in this NOFO.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

[eRA Service Desk \(https://www.era.nih.gov/need-help/\)](https://www.era.nih.gov/need-help/) - Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues.

[Grants.gov Support Center \(https://gcc02.safelinks.protection.outlook.com/?](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fgrants.gov%2Fsupport&data=05%7C02%7Cantoinette.caliman%40nih.gov%7Caf6dde64d644478d4e8b08dde6700581%7C14b77578977342d58507251ca2dc2b)

[url=https%3A%2F%2Fgrants.gov%2Fsupport&data=05%7C02%7Cantoinette.caliman%40nih.gov%7Caf6dde64d644478d4e8b08dde6700581%7C14b77578977342d58507251ca2dc2b](https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fgrants.gov%2Fsupport&data=05%7C02%7Cantoinette.caliman%40nih.gov%7Caf6dde64d644478d4e8b08dde6700581%7C14b77578977342d58507251ca2dc2b)

- Questions regarding Grants.gov registration and services (e.g., Workspace, subscriptions).

Scientific/Research Contact(s)

Gabriella Miller Kids First Program

kidsfirst@od.nih.gov (<mailto:kidsfirst@od.nih.gov>)

Peer Review Contact(s)

Examine your eRA Commons account for review assignment and contact information (information appears two weeks after the submission due date).

Financial/Grants Management Contact(s)

Not Applicable.

Section VIII. Other Information

Recently issued trans-NIH [policy notices \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the [NIH Guide for Grants and Contracts \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the [NIH Grants Policy Statement \(http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120\)](http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 2 CFR Part 200.