Dear X01 Investigators,

The Gabriella Miller Kids First Pediatric Research Program (Kids First Program) is pleased to announce the Kids First Cohort Advancement FY 2026. We invite applications from investigators with previously awarded X01 cohorts to submit additional pediatric samples for data generation, including whole genome sequencing (WGS), RNA sequencing, long-read sequencing (DNA or RNA), and methylation profiling (e.g., EPIC arrays).

The aim of this opportunity is to advance the understanding of the genetic and molecular basis of childhood cancers and congenital anomalies. Samples from selected proposals will be sequenced and processed at a Kids First Genomic Sequencing Center (the Broad Institute), and resulting data will be shared through the Kids First Data Resource Center (Kids First DRC) in accordance with the NIH genomic data sharing policy (GDS).

Key Priorities:

1. Add study participants (cases or family members) to existing X01 cohorts or related conditions, such as Whole Genome Sequencing (WGS) from blood or saliva of pediatric cancer or congenital anomalies. Addition of tumor and/or affected tissue and/or longitudinal samples with data when available and justified. Specification of cases such as primary tumor, germline, and relapsed/metastatic tumors is encouraged.
2. Add data types to existing X01 cohorts with WGS data available.
3. Use of trio, quad, or family-based study designs when appropriate.

Proposals:

Applicants may request data generation services including WGS, RNA-seq, long-read sequencing (PacBio Revio), and/or methylation profiling (EPIC arrays). These requests will be reviewed administratively by NIH staff. Proposals with strong scientific rationale, ability to share rich clinical and phenotype data in a timely manner, and possession/rapid access to additional specimens are encouraged.

How to Apply:

Submit a proposal (maximum 3 pages) addressing the following:

1. **Scientific Question**: How will the proposed data generation add value to the existing X01 sequencing data? How does the project relate to original X01 and, if applicable, other Kids First datasets?

2. **Justification and Impact**: Summarize prior sequencing efforts and findings, relevance of proposed work to the field, and description of analysis plan. Describe commitment to sharing of the new data through the Kids First Data Resource Center.

3. **Sample Description**: Provide scientific justification of new requested samples. Describe the cohort (e.g. trios, duos), phenotypes, and clinical information. Describe the types of pediatric samples (e.g., blood, saliva, tumor types, affected tissues, matching samples).

   Confirm that all samples can be shipped by December 2026. Proposed samples should represent conditions identical or closely related to the condition(s) described in the original X01.

4. **Attachments:** Include the attachments itemized below to meet NIH requirements for application completion.

    1. Institutional Certification (Provisional Certification is not acceptable) or confirm that a previously provided Institutional Certification covers the participants represented in the proposal.

    2. Sample Information with sample priority list and estimated date of sample shipment. Please confirm the number of samples you are proposing for sequencing that are covered by the Institutional Certifications provided and that are currently ready for shipment. You may do this by providing a table summarizing this information and a full list of the sample IDs including DNA/RNA sources, subject/family mapping, the data use limitation or consent group to which they belong, and the estimated date by which they can be shipped. Please explain how samples will be prioritized if only part of the cohort can be supported for sequencing.

    3. Clinical/Phenotypic Data Description in the form of a Data Dictionary. Please provide a data dictionary or list of data elements describing the clinical and phenotypic data that will be provided to the Kids First DRC for sharing with the broader research community upon release of the dataset. Please note that these clinical and phenotypic data will be required for review by the Kids First DRC and program staff prior to approving access to the associated sequence data. The Kids First DRC will be able to ingest these data in a variety of formats, but for a template that can serve as a starting point see: https://commonfund.nih.gov/sites/default/files/Clinical%20Elements%20List%20-%202018%20X01_vJan19.xlsx
    4. Family Structure (Optional).

Email Submission Deadline: May 1, 2026, 5:00 PM (local time of applicant organization).

- **Submission Email:** KidsFirst@od.nih.gov
- **Subject Line for Submission:** *Kids First Cohort Advancement FY 2026 (PI Last Name)*
- **Email Notification of Results:** September 2026

Pre-Application Webinar:

Kids First program intends to hold a Pre-Application Webinar for all interested prospective applicants. The webinar date and other details will be announced by email.

Review Criteria:

1. Research plan:

    - Provides explanation of how the project relates to original X01 and other Kids First data.

    - Describes sample size, and family structures are sufficient to lead to genetic discovery. Large sample sizes are preferred. Consider collaborating with other investigators to pool samples together. Non-trio family designs: describe the number of probands and affected/unaffected family members proposed for sequencing.

    - Provides scientific justification of new requests, how additional characterization benefits the pediatric research community, and description of analysis plan. Researchers are encouraged to use the cloud-based infrastructure, including Cavatica, for their analysis.

2. Sample readiness, quality and quantity:
    - Provides evidence that samples have sufficient quantity for each available assay with appropriate quality metrics such as meeting DNA concentration requirements for WGS or long read PacBioRevio. RNA samples (for tumor/affected tissue) must be of sufficient quality and concentration for RNA-seq.
    - Provides strong evidence that samples will be ready to ship by the end of 2026 calendar year.
3. Data sharing:
    - Samples from participants have consented to allow broad data access and use, including combining and cross-analyzing datasets.
    - Institutional Certifications (ICs) are updated to include additional participants, if applicable.
    - ICs with less restrictive data use limitations (DULs) such as General Research Use, or Health/Medical/Biomedical will be prioritized.

Important Notes:

- No funding is provided through this opportunity; sequencing and data processing will be supported by the Kids First Program.
- Participants must have given consent for broad data sharing as documented on the associated Institutional Certification(s).
- Applications not following the submission instructions may be delayed or rejected.
- Provisions regarding data sharing, sample information, research strategy remain the same as describe in PAR-24-082 (https://grants.nih.gov/grants/guide/pa-files/PAR-24-082.html).

We encourage all eligible investigators to apply and contribute to this important effort to accelerate discoveries in pediatric health through shared data and collaborative science.

Best regards,

The Kids First WG Leadership
Gabriella Miller Kids First Pediatric Research Program

Gabriella Miller Kids First Pediatric Research Program

Institutional Certification General recommendations:

If your group has provided **a Provisional Certification** or **an Institutional Certification that is on a template other than the current NIH GDS template**, we ask that you obtain a full/new Institutional Certification following these steps:

1) Download the current NIH Institutional Certification template from: https://sharing.nih.gov/genomic-data-sharing-policy/institutional-certifications/completing-an-institutional-certification-form
2) Fill out the first page of the Institutional Certification to include the sites that would contribute samples for sequencing. One document can list multiple sites; alternatively, multiple Institutional Certifications, one for each site, can be submitted.
3) Provide the Institutional Certification to the IRB, or equivalent body, along with the participant consent forms for each site and any other pertinent information (e.g. protocols), to complete the second and third pages:
    a. On the top of the second page, it is anticipated that the *individual-level* genomic data will be made available through controlled-access.
    b. The lower section of the second page addresses "*genomic summary results (GSR)*." This box is to be left unchecked, unless unrestricted access to GSR is not permitted due to the study's designation as "sensitive" by the institution. Please note that it is anticipated that unrestricted access to GSR will be appropriate for the majority of Kids First genomic datasets. For additional information see "Update to NIH Management of Genomic Summary Results Access" (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-023.html). For data that are designated as sensitive, a justification must be provided in the text box. If unrestricted access is allowable for GSR, then both the GSR checkbox and the associated text box should be left blank.
    c. On the third page, the IRB, or equivalent body, is to select the appropriate data use limitations (DULs) and DUL modifiers based on the language of each site's consent form(s). Unless the intent of the consent form language is determined to prohibit specific uses of the data to be generated from the samples collected from the participants, it is expected that the dataset will be designated as "General Research Use (GRU)". Please note that cohorts with data use limitations and/or modifiers that impede the ability to access, use, combine, or cross-analyze data will not be prioritized for sequencing by the Kids First program (e.g., datasets consented for disease-specific research only, datasets that require a letter of collaboration ("COL"), or datasets that require local "IRB" approval for access).
4) Finally, the Institutional Certification needs to be counter-signed by the applicant PI and the Institution Signing Official who is authorized to enter the institution into a legally binding contract and sign on behalf of the investigator who plans to submit the data to NIH, e.g. Dean, Vice President for Research.

If your group has provided an Institutional Certification letter that indicates a consent group **other than General Research Use (with no additional modifiers)**, Kids First respectfully requests that IRBs consider whether the consent language for the proposed cohort may support broader data sharing consistent with goals of the program (e.g., datasets consented for disease-specific research only, datasets that require a letter of collaboration ("COL"), or datasets that require local "IRB" approval for access are not prioritized for sequencing). The program will provide you the opportunity to consult with your IRB, and any other necessary parties to include the Kids First GPA, and subsequently resubmit a new Institutional Certification, using the current NIH GDS template (https://sharing.nih.gov/genomic-data-sharing-policy/institutional-certifications/completing-an-institutional-certification-form).You may also find it helpful to provide this letter to your IRB.

X01 applicants and their IRBs are welcome to contact NCIOfficeofDataSharing@mail.nih.gov and KidsFirstDAC@nih.gov for questions. Additionally, more information about Kids First data sharing expectations can be found at: https://commonfund.nih.gov/kidsfirst/FAQ.