To Kids First X01 applicants and their IRB(s),

The NIH Common Fund's Gabriella Miller Kids First Pediatric Research Program (Kids First) is soliciting applications for childhood cancer and structural birth defects cohorts to undergo whole genome sequencing through PAR-18-583, "Discovery of the Genetic Basis of Childhood Cancers and of Structural Birth Defects: Gabriella Miller Kids First Pediatric Research Program (X01 Clinical Trial Not Allowed)".

Kids First is a Congressionally mandated, trans-NIH effort focused on accelerating gene discovery in childhood cancers and structural birth defects. Controlled access genetic data and associated phenotypic data generated through this program will be made accessible through the Gabriella Miller Kids First Pediatric Data Resource (Kids First Data Resource) and the National Center for Biotechnology Information's database of Genotypes and Phenotypes (dbGaP). The Kids First Data Resource, which started development in 2017, will build a collection of curated genomic and phenotypic data from Kids First X01 projects and provide a central portal where data and analysis tools will be readily accessible to the research community in order to promote comprehensive and cross-cutting research and collaboration.

In addition to complying with the NIH Genomic Data Sharing Policy (NOT-OD-14-124), sequence data generated through Kids First are expected to be consented for broad data sharing that allows comparing and combining datasets for analyses, consistent with the goals of the program. Therefore, we ask that applicant PIs obtain an Institutional Certification following these steps:

1) Download the current NIH Institutional Certification template from: https://osp.od.nih.gov/scientific-sharing/institutional-certifications/
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. **Note: Investigators should not fill out the second page, which indicates the data use limitations and modifiers (these are for the IRB to determine).**
3) Provide the Institutional Certification to the IRB along with the participant consent forms for each site and any other pertinent information (e.g. protocols).
4) The IRB reviews the consent form(s) and supporting information to determine whether there are any data use limitations (DULs) and/or DUL modifiers for each "consent group". Unless the intent of the consent form language is determined to prohibit specific uses of the data generated from the samples collected from the participants, it is expected that the IRB will designate a dataset as "General Research Use".
5) After IRB review, the Institutional Certification needs to be counter-signed by the applicant PI and a senior official at the PI's institution 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.

While a full Institutional Certification is preferred for submission with the X01 application, a Provisional Certification is acceptable if there is not enough time to obtain a full Institutional Certification before submitting the application. However, approval to access the Kids First X01 sequencing capacity is conditional on the submission of a full 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.

X01 applicants and their IRBs are welcome to contact a Genomic Program Administrator from the appropriate NIH institute or center (https://osp.od.nih.gov/wp-content/uploads/IC_GPAs.pdf) for questions.

Sincerely,
The Gabriella Miller Kids First Pediatric Research Program Working Group