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-21-040, “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. Genomic 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 Center has built a central portal where data and analysis tools are readily accessible to the research community to promote comprehensive and cross-cutting research and collaboration (<https://portal.kidsfirstdrc.org>).

In addition to complying with the NIH Genomic Data Sharing Policy ([NOT-OD-14-124](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html)), 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.
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:
   1. On the top of the second page, it is anticipated that the *individual-level* genomic data will be made available through controlled-access.
   2. 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.
   3. 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).
4. On the third page, the IRB, or equivalent body, is to select the appropriate data use limitations (DULs) and/or DUL modifiers based on the language of each site’s consent form. 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 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).

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.

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 and use (i.e. General Research Use), another cohort with broader sharing may be selected instead.

Kids First X01 applicants and their IRBs are welcome to contact [NCIOfficeofDataSharing@mail.nih.gov](mailto:NCIOfficeofDataSharing@mail.nih.gov) and [KidsFirstDAC@nih.gov](mailto:KidsFirstDAC@nih.gov) for questions.

Sincerely,

The Gabriella Miller Kids First Pediatric Research Program Working Group