**Optional tables for requirements described in “Other Attachments” (see Section IV.2 of** [**PAR-19-390**](https://grants.nih.gov/grants/guide/pa-files/PAR-19-390.html)**)**

You may use the tables below to help address the information requested in the “Other Attachments” section of PAR-19-390. The use of these tables is optional; applicants may choose to describe the data use limitations, samples, clinical/phenotypic data, and family structures in another format. The tables serve to help both applicants and reviewers by providing a uniform structure for organizing this information.

1. **Provisional Certification: Data Sharing and Data Use Limitations**

If you provided a Provisional Institutional Certification, because you are unable to provide a full Institutional Certification, please describe the anticipated data use limitations based on the language of the consent form(s) signed by the participants in the proposed cohort. For a description of standard DULs and modifiers, please review the Institutional Certification template (<https://osp.od.nih.gov/scientific-sharing/institutional-certifications>) and <https://osp.od.nih.gov/wp-content/uploads/NIH_PTC_in_Developing_DUL_Statements.pdf>.

|  |  |  |
| --- | --- | --- |
| **Site** | **Data Use Limitation** (GRU, HMB, DS) | **Data Use Limitation Modifiers** (IRB, PUB, COL, NPU, MDS, GSO) |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**2) Sample Information: Sample Sources and Details.** Please edit and fill-in the table below to describe the DNA (and RNA, for tumors and/or affected tissue) samples that you propose for sequencing.

Total Number of Samples proposed for sequencing:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **DNA (and RNA) tissue of origin** | **Number of Samples** | **Extraction Method** | **Concentration**  | **Quality (Metric used***:[edit here to specify])* | **Method of Quantitation** | **Number of Samples Ready to Ship by August 2020** | **Number of Samples Ready to Ship by January 2021** |
| Blood |  |  |  |  |  |  |  |
| Saliva or Buccal swab |  |  |  |  |  |  |  |
| [other tissue, edit here to describe]. **Note: cell lines will not be accepted** |  |  |  |  |  |  |  |
| Tumors or Affected Somatic Tissue  |
| DNA – Frozen Tissue |  |  |  |  |  |  |  |
| RNA – Frozen Tissue |  |  |  |  |  |  |  |
| DNA – Embedded Tissue |  |  |  |  |  |  |  |
| RNA – Embedded Tissue |  |  |  |  |  |  |  |
| **Total** |  |  |  |  |  |  |  |

\*For tumor specimens or affected tissue samples, please also describe the fixation methods and the pathology review to which the specimens were subjected, separate from the table. For tumors, describe the percentage of tumor cells within the specimen used for DNA and/or RNA isolation and % necrosis.

**Available Phenotype or Clinical Information (for #3 Clinical, Phenotypic, and Demographic Data).** Please edit or add to the table below to indicate what clinical and phenotypic information are available for the case/proband, parents, and/or other family members to be shared through the Kids First Data Resource. Please note this information can be provided as separate attachments, such as data dictionaries.

|  |  |  |
| --- | --- | --- |
| **Demographics** | Case/Proband/Affected | Unaffected family members/parents |
| o Age at enrollment or age at diagnosis |  |  |
| o Other age information (age at specimen collection, age at death etc.…) |  |  |
| o Sex |  |  |
| o Race |  |  |
| o Hispanic ethnicity |  |  |
| o List any other demographic information: |  |  |
|  |  |  |
| **Clinical information (e.g., diagnoses, type of birth defect, primary tumor type, vital status, age at last know vital status, treatment information). Indicate any data elements that are collected at multiple time points (longitudinally) with a \*.**  |
|  | Case/Proband/Affected | Unaffected family members/parents |
| List the variables:  |  |  |
| Are electronic health records available?  |  |  |
|  |  |  |
| **Other phenotypic information (e.g., other phenotypic measurements that may be related to the primary outcome). Indicate any data elements that are collected at multiple time points (longitudinally) with a \*.** |
|  | Case/Proband/Affected | Unaffected family members/parents |
| List the variables |  |  |
|  |  |  |
| **Family medical history (e.g., family history of birth defects, family history of cancer)** |
|  | Case/Proband/Affected | Unaffected family members/parents |
| List the variables: |  |  |

**Family Structures (for #4 Family Structure (Optional)).**

Descriptions of Family Structures: (e.g. proband-parent dyads, proband-parent-sibling quads, multiplex families, consanguineous families)

If your cohort includes a mix of family types/structures, you may use a table to describe how many families and samples belong to each type. Convey how many affected and unaffected family members will be sequenced. Reminder: you may also submit pedigree information.

|  |  |  |
| --- | --- | --- |
| **Family type** | **Number of families** | **Total Germline Samples** |
| Proband/Child + Parents (unaffected) Trios | XX | XX affected XX unaffected |
| Proband + 1 affected FDR + [Unaffected FDRs] | XX | XX affected XX unaffected |
| Proband + 2 affected FDR + [Unaffected FDRs] | XX | XX affected XX unaffected |
| **Total** | XXX | XXX |

FDR= First Degree Relative