

## **Administrative Supplements for the NCI P30 Cancer Center Support Grants to develop the National Childhood Cancer Registry**

### **Background**

Childhood cancer patients comprise a special and understudied population of cancer patients. Approximately 15,000 childhood cancer patients are diagnosed in the United States annually, compared with the 1.7 million new cancer cases diagnosed each year. Due to their rare nature, it has been challenging to collect substantial and vital information on a large scale to study and understand the needs for this unique population of cancer patients.

The Childhood Cancer Data Initiative (CCDI) symposium hosted by the National Cancer Institute (NCI) in July 2019 identified a critical need to collect, analyze, and share data to address the burden of cancer in children, adolescents and young adults. Currently, cancer registries in the United States hold structured information on every cancer case, including childhood cancers, within their respective catchment area. For childhood cancer patients and survivors, issues of late effects, recurrence, subsequent primary cancers, and follow-up are critically important to consider while addressing common instances of survivors moving to different states as these survivors mature and become adults. Using the data from registries as a base, an infrastructure that brings together key information on every childhood cancer patient is being constructed and will be maintained to support research on childhood cancer patients and survivors.

The National Childhood Cancer Registry (NCCR) is envisioned as a connected data infrastructure to enable sharing of childhood cancer data from multiple and heterogeneous data sources. Incorporating available data on genomic and tumor characterization, residential history, social determinants of health and measures of financial toxicity, longitudinal treatments including oral agents, and longitudinal outcomes data including recurrence and subsequent cancers can enhance the core infrastructure of registry data on pediatric patients. Because the basis for the NCCR is existing central cancer registries, personally identifiable information (PII) is reportable to the central registry to permit longitudinal linkage and reporting to central registries is HIPAA exempt. The NCCR will 1) support relevant research on childhood cancers; 2) provide a potential sampling frame for additional research; and 3) provide a population level set of data on all childhood cancer patients, including patients who do not participate in clinical trials.

### **Purpose and Goals**

The National Cancer Institute (NCI), Division of Cancer Control and Population Sciences (DCCPS), announces the opportunity for supplemental funding for NCI-designated cancer centers to participate in the development of an infrastructure of combined data to establish a National Childhood Cancer Registry (NCCR). Supplemental funding will enable the cancer centers to aggregate, integrate, and submit their existing data beyond traditional cancer abstracts on childhood cancer patients under 19 years of age receiving care at the cancer center to the NCCR in order to expand that infrastructure and ultimately support research on childhood cancer. It will also facilitate the development of an ongoing submission process to the NCCR database for the continued submission of data on pediatric cancer patients.

The main goals of the one-year supplement are to 1) identify extensive detailed treatment and clinical data on pediatric patients not currently being reported to cancer registries, 2) complete an assessment of the quality of the data, and 3) to develop a data packaging and transfer mechanism to report the data to the NCCR. The expectation is to develop an ongoing data linkage with the NCCR that will supplement the data already being reported to the cancer registries.

Once the NCCR is established, we anticipate collaborations between cancer centers, local area providers, public health practitioners, and other public health professionals to utilize the centralized infrastructure to address questions related to childhood cancer patients with special attention to long term outcomes including recurrence and second primary cancers, detailed treatment information, and further characterization of the cancers.

### **Eligibility and Budget**

- This opportunity is open to all P30 Cancer Center Support Grants.
- Only one supplement request per center will be considered.
- Supplement requests may not exceed \$300,000 total costs, and the project period is for one year.
- Cancer centers whose P30 Cancer Center Support Grant will be in an extension at the time the award is made in FY20 are not eligible for this supplement.
- It is anticipated that awards for this supplement opportunity will be made in September 2020.

### **Application Submission Format**

Applications should be submitted as a signed, scanned PDF to Clara Lam ([clara.lam@nih.gov](mailto:clara.lam@nih.gov)) and Stacey Vandor ([stacey.vandor@nih.gov](mailto:stacey.vandor@nih.gov)) no later than COB May 4, 2020.

Email confirmation of application receipt from Stacey Vandor must be obtained to be officially considered and evaluated.

Requests must include the following:

- The Standard PHS 398 Face Page
- A detailed Budget and Budget Justification
- NIH Biographical Sketches for new key personnel proposed in the supplement
- Summary of the Project, not to exceed 5 pages (references are excluded from the 5-page limit; no appendices, please)

The 5-page summary must:

- Provide a detailed list and format of data items (including common data elements), data categories, and any other relevant information and documentation that are currently being collected by the cancer center. Examples of key data types would include but are not limited to: genomic and germline test results, detailed treatment information, participation in clinical trials, measures of social determinants of health related to the patient and family, longitudinal treatment including oral agents, longitudinal outcomes data including recurrence and subsequent cancers, other relevant patient information.
- Provide a background statement that explains how these existing data would provide important supplemental information to traditional cancer registry abstracts that will serve as the basis for the NCCR.
- Provide a work plan to complete data packaging and transfer from the cancer center to the NCCR database within the year of the supplement.
- Outline a work plan that provides a timeline for development of a process that would support submission of the data to the NCCR on an ongoing basis (e.g., staff involved, IT integration). It should include milestones (e.g., data completion assessment, data quality review, data packaging for transfer, data transfer completion) for tracking the progress of the work in the one year of the supplement.
- Include agreement to attend two in-person meetings during the supplement period to establish and participate in working groups to address standardization of common data elements, data

harmonization, specific research and clinical questions that can be addressed by the NCCR, and other relevant topics.

- Describe the qualifications of the individual(s) who will conduct the work. Briefly elaborate on each person's CV in the narrative response.

### **NCI Evaluation of Supplement Requests**

Administrative supplements do not receive peer review. Instead, NCI staff with expertise in cancer prevention and control will evaluate supplement requests to determine overall merit. Proposals will be reviewed for quality and for responsiveness to application criteria outlined in the requirements for the five-page summary described above.

### **Reporting Requirements**

As part of the progress report for the parent cancer center grant, information must be included on what has been accomplished via the administrative supplement (program details such as workflow incorporation, sustainability actions, progress on timeline tasks, and other noted measures). Project leaders will participate in calls and meetings where they will be expected to present their progress and findings to NCI, other supplement awardees, and representatives from other NCI-Designated Cancer Centers. Award recipients are expected to provide data to NCI evaluators when requested.

### **Pre-Submission Informational Webinar:**

An informational webinar will be held as noted below:

Time: Wednesday, March 18, 2020, 12:00 PM Eastern Time (US and Canada)

The registration link is as follows:

<https://cbiit.webex.com/cbiit/onstage/g.php?MTID=efd5d082d707e740d9e21c3b1a67209c1>

Dial-in information:

Call-in toll number (US/Canada)

1-650-479-3207

Meeting Number/Access Code: 739 299 805

Event password: J2d5pEBZw\$6

### **Questions**

For technical inquiries (including eligibility), please contact your cancer center support grant administrator or your NCI program director. For inquiries about the scientific objectives and goals, please contact Clara Lam (clara.lam@nih.gov).