**DATABASE PROJECT REQUEST FORM**

*This form has been revised with input of COG investigators and statistical staff. The additional project, data, and personnel details now required are intended to create a more efficient project review and data curation process and shorten the typical timeline from request submission to data acquisition.*

**To be completed by Project Principal Investigator**

**Title of research proposal:**

**Project Principal Investigator(s) and contact information:**

**Project Statistician and contact information:**

**Has the Project Principal Investigator confirmed whether any or all requested data are available through the NCTN Data Archive? (https://nctn-data-archive.nci.nih.gov)**

**[ ] YES [ ] NO**

**Has the Project Principal Investigator confirmed whether any or all requested images are available through the NCI Cancer Imaging Archive? (https://www.cancerimagingarchive.net/)**

**[ ] YES [ ] NO**

**Is the Project Principal Investigator (or any project Co-Investigator) a COG member with access to protocols and Case Report Forms (CRFs) via the COG website?**

**[ ] YES [ ] NO**

**If YES above, have the relevant protocols and CRFs been reviewed in detail to support this data request?**

**[ ] YES [ ] NO**

**COG protocol(s) from which project data elements are being requested:**

*List all relevant COG protocols by protocol number.*

**Project Background:**

*What is already known or published about this research topic?*

**Project Significance:**

*How will the proposed research add significantly to the literature in this research area?*

**Project Aims:**

*Briefly state the scientific questions to be addressed by this research project that will require the use of COG data. Include 1 Primary Aim and up to 3 Secondary Aims. If additional Primary or Secondary Aims exist such that the scope of work will likely yield multiple project manuscripts, it is recommended to submit separate/additional Database Project Request Forms, one for each anticipated manuscript.*

***Primary Aim:***

***Secondary Aim 1:***

***Secondary Aim 2:***

***Secondary Aim 3:***

**Project Patient Population: Inclusion/Exclusion**

*(To be completed by the Project Principal Investigator and Project Statistician)*

*For each Project Aim, describe in detail which patients are to be included in corresponding analyses (e.g., by protocol number, risk stratum, treatment arm, or other clearly identifiable factors), and which patients should be excluded (if any). If some patients will be excluded from analyses for a given Aim, please provide rationale for exclusion.*

**Data Elements or Variables Requested:**

*(To be completed by the Project Principal Investigator and Project Statistician)*

*If COG CRFs are accessible to the Project Investigator or co-Investigator through the COG website, please list the exact elements by CRF Name and CRF Item. Otherwise, please complete the table below in as much detail as possible for each study, patient, demographic, disease, treatment, or outcome measure that will be needed.*

*Note: Patient demographic data are collected on COG registry studies (rather than therapeutic studies) and may be listed below without referencing specific COG study CRFs. Similarly, calculated/derived outcome data (such as event-free survival and overall survival) may be named without reference to specific CRFs, and the COG statistician will supply the appropriate calculated variables.*

|  |  |  |
| --- | --- | --- |
| **CRF NAME** | **CRF Question or Demographic/Outcome Data Element** | **Applicable Aim** |
| *AREN0532 On Study* | *What is patient’s disease stage?\**  | *Aim 1* |
| *Demographics* | *Age, sex, race, ethnicity* | *Aim 1, Aim 2* |
| *Outcomes* | *Event-free survival* | *Aim 1, Aim 2* |

**Statistical Analysis Plan:**

*(To be completed by the Project Statistician)*

*For each Project Aim named above, describe in detail how the requested COG data will be analyzed to support the Aim. Aim-specific details should include:*

* *The exact patient cohort to be analyzed (inclusion/exclusion) and corresponding known or anticipated cohort sample size (e.g., inferred from primary publications)*
* *The data elements to be used in each analysis (referenced directly from COG CRFs if access is available), including those that will need to be reported as descriptive statistics, or those that will be included as independent or dependent variables (or variables for adjustment or stratification) in regression models*
* *The statistical tests, models, or other methodology that will be used to address the Aim (for non-standard methodology, please provide a citation to a book or article describing the method)*

***Once the sections above are complete, please return this form to COG: datarequest@childrensoncologygroup.org***

**To be completed by COG Committee/Study Chair**

**Are there concerns or suggestions regarding the scientific merit of the request?**

**Does the database request project overlap substantially with an existing protocol objective (already published or to be published), or an existing committee project?**

**To be completed by COG Committee/Study Statistician**

**Are the requested data available? Indicate whether certain data elements are definitely not available, or where there is lack of clarity regarding the requested data.**

**Are there concerns or suggestions regarding the statistical analysis plan? If so, provide a summary of these concerns/suggestions.**