THE ST. JUDE CHILDREN'S RESEARCH HOSPITAL – WASHINGTON UNIVERSITY PEDIATRIC CANCER GENOME PROJECT

Access to Genomic Data

1. General principles

The St. Jude Children's Research Hospital – Washington University Pediatric Cancer Genome Project (PCGP) Data Access Committee will consider applications for access to de-identified and anonymized genomic sequence data generated as a result of the PCGP activities. Access to data will be granted to qualified researchers for appropriate use. A qualified researcher refers to a scientist who is employed, or a student enrolled at or legitimately affiliated with an academic, non-profit, or government institution, or a commercial company.

The data will be deposited in the European Genome-Phenome Archive (EGA) and access will be by application to the PCGP Data Access Committee (PCGP DAC). Access to data will be granted to researchers for appropriate use and will be governed by the provisions in the associated informed consent for each cohort or collection, and the terms contained in the Data Access Agreement.

The PCGP Data Access Committee is concerned with access to de-identified anonymized genomic data generated by this PCGP, and associated phenotypic information published by the PCGP in reports of the analyses of each tumor subtype. The Committee will not consider requests for more detailed phenotypic information which is held by the principal investigators for the individual case collections. Access to this data should be by arrangement with the relevant principal investigator.

Access is conditional upon availability of data and signed agreement by the researcher(s) and the responsible employing Institution to abide by policies related to publication, data disposal, ethical approval, confidentiality, and security.

2. Application procedure

Applicants requesting access to data from the PCGP will be asked to complete a basic application form and to agree to the terms and conditions laid out in the Data Access Agreement (DAA). Applications must be made by a Laboratory Head, Principal Investigator, or Departmental Chair. Both the applicant and an authorized representative of the applicant's institution, e.g., the relevant Head of Department, Head of Institute, or equivalent, must sign the DAA.

Successful applicants who have access to data will be designated "Registered Users" and will be issued a username and password by the EGA to enable access to the database.

The PCGP DAC will consider applications that include named collaborators, but each Institution must sign a separate Data Access Agreement. Should you wish to share the data with additional collaborators not previously approved, they must make a separate application for access to the Data.

Applicants agree to use the data for the approved purpose and project described in the application; use of the data for a new purpose or project will require a new application and approval.

3. Membership of Consortium Data Access Committee

Dr. Suzanne Baker, Co-Leader, Brain Tumor Program, St Jude Children's Research Hospital, Memphis, Tennessee
Dr. James R. Downing, Scientific Director, St Jude Children's Research Hospital, Memphis, Tennessee
Dr. Michael A. Dyer, Co-Leader, Developmental Therapies for Solid Tumors, St Jude Children's Research Hospital, Memphis, Tennessee
Dr Tim Ley, Division of Oncology, Washington University, St. Louis, Missouri

Dr. Amar Gajjar, Co-Leader, Brain Tumor Program, St Jude Children's Research Hospital, Memphis, Tennessee
Dr. Charles G. Mullighan, Co-Leader, Hematologic Malignancies Program, St Jude Children's Research Hospital, Memphis, Tennessee
Dr. Alberto Pappo, Co-Leader, Developmental Therapies for Solid Tumors, St Jude Children's Research Hospital, Memphis, Tennessee
Dr. Ching-Hon Pui, Chair, Department of Oncology and Co-Leader, Hematologic Malignancies Program, St Jude Children's Research Hospital, Memphis, Tennessee
Dr Richard Wilson, Director, The Genome Institute at Washington University, St Louis, Missouri

4. Assessment Criteria

Each application will be assessed to determine if:

- it has been submitted by a qualified researcher or researchers and is embedded in a recognized research institution that can provide institutional responsibility for appropriate research governance;
- the project described constitutes 'biomedical research' in the context of the consent process, and is likely to be understood as such by the sample donors;
- it does not breach any of the ethical permissions or restrictions in the consent forms for any component cohort or collection;
- it does not have the potential to produce information that will enable identification of individual participants or other individually identifiable information;
- Research Trainees (including PhD students and post-doctoral fellows) include details of their research supervisors, and that a laboratory head, principal investigator or departmental chair requests access to the data; and

In considering applications, the PCGP DAC has clarified policies in regard to specific data access requests and agrees that:

- The PCGP DAC does NOT attempt to peer review the scientific quality of proposals. However, it does ask for a brief summary of the research to be undertaken, to judge whether it falls within the scope of the consents. It also considers whether the research is grossly inadequate or ethically questionable, and reserves the right to require clarification for those requests that do not appear to attain even a minimal standard of competence;
- the use of data by commercial companies for commercial purposes is prohibited; and
  use of de-identified and anonymized data in teaching is permissible; and to protect participant confidentiality the data may not be removed from the teaching laboratory.

5. Data Available

To view the data available, please visit:

http://explore.pediatriccancergenomeproject.org
https://www.ebi.ac.uk/ega/dacs/EGAC00001000044

Genomic sequence information will be accompanied by phenotype data published in manuscripts from the PCGP, including (for example):

- Age at diagnosis
- Ethnicity
- Tumor characteristics, including site and stage
- Treatment outcome

Apart from tumor type, these phenotype data will NOT be provided prior to nine months from initial data deposition and release at EGA OR publication of the first manuscript from the PCGP for each tumor type.