

2008-R-06

**CIO Name:** National Center on Birth Defects and Developmental Disabilities

**Project Title:** Evaluating the Risk for Development of Childhood Cancer among Infants with Birth Defects

**Project Description and Objectives:** An increased risk for later development of childhood cancer for infants with birth defects has been recognized, but has not been well studied. In a recent study from Canada (Agha et al., 2005) infants with birth defects were nearly six times as likely to develop cancer in the first year of life. Increased rates of cancer were noted among infants with certain types of birth defects (e.g., Down syndrome, nervous system defects, and defects of the urinary system). Better understanding the risk of malignancy development for infants with certain birth defects will have several benefits.

If substantially increased risks for infants with certain defects are identified, increased monitoring of these infants may be warranted. In addition, improved understanding of the relation between birth defects and cancer will result in better understanding of the genetic and environmental factors involved in their causation, possibly leading to prevention of these conditions. The focus of this project is to link population-based data on birth defects (ideally from one or more birth defects surveillance systems) to population-based data on childhood malignancies. The project should be a multi-state effort and include a diverse population.

The proposed project should have the capacity to include at a minimum:

1. All types of structural birth defects included in the National Birth Defects Prevention Network annual report ([http://www.nbdpn.org/current/2007pdf/4\\_Dec06appendix.pdf](http://www.nbdpn.org/current/2007pdf/4_Dec06appendix.pdf)); and
2. Childhood cancers diagnosed up through at least 10 years of age.

**Awardee Activities:**

1. The awardee will identify and obtain access to population-based data for both structural birth

- defects and childhood cancers and develop methods to link these data.
2. The awardee will be responsible for human subjects approval for the study.
  3. Following linkage of these datasets, the awardee will analyze data and publish results in the peer-reviewed literature.

**CDC Activities:**

CDC staff will be substantially involved in the programmatic and scientific activities of the project beyond that routinely associated with grant monitoring.

CDC scientists will:

1. Provide technical assistance, as needed, in the development, implementation, and conduct of the research; and
2. Provide subject matter expertise.

**Special Requirements:** The following criteria specific to this PEP will be used to determine the applicant's eligibility:

1. Access to the population-based datasets that will be used to study the association between structural birth defects and childhood cancer.
2. Evidence must be provided in the form of Letters of Support assuring access to the data and any restrictions or limitations to access.

**Additional Review Criteria:** In addition to the standard review criteria used to evaluate the scientific and technical merit of research applications (Significance, Approach, Innovation, Investigators, and Environment) the following additional review criteria specific to this PEP will be considered in the review process:

1. Expertise in research related to childhood cancer and structural birth defects.
2. Experience in linkage of datasets from population-based systems.
3. Adequacy of the statistical power.

**Funding Preferences:** The following factors may affect the funding decision:

1. Study site with a diverse population.
2. Data from multiple states.

**Project Period Length:** 1 year

**Approximate Total Project Period Funding:** \$200,000 (This amount is an estimate, and is subject to availability of funds and **includes direct and indirect costs, excluding the additional academic partner administrative costs.**)

**Approximate Average Award:** \$200,000 (This amount is for the first 12-month budget period, and **includes both direct and indirect costs, excluding the additional academic partner administrative costs.**)

**Approximate Number of Awards:** 1

**NOTE:** Applications must not exceed either the stated Project Period Length or the Approximate Total Budget Period funding per year. Applications in excess of these limits will be considered non-responsive and therefore will not be reviewed.