

Childrens Group  
Oncology  
U of M

Minnesota Department of Health  
Institutional Review Board

RECEIVED  
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Application for Approval of Research with Human Subjects

MINNESOTA DEPARTMENT OF HEALTH  
INSTITUTIONAL REVIEW BOARD

B. Explanation of subject involvement in the research (the who, what, when, and how of subject involvement),

The PI will initiate a request for 100 randomly selected, *anonymous* NBS from the most recent birth year available from the Minnesota Department of Health Laboratory. We will pay any fees associated with obtaining Guthrie cards.

C. Summary of data analysis or statistical methods to be used in the study;

DNA from banked NBS may be released for research on childhood cancer etiology after approval by the COG Epidemiology Committee. As an initial project, the frequencies of polymorphisms of the NQ01, GSTM1, MPO, and MTHFR genes among NBS will be compared to those among cases currently being recruited to two federally-funded COG studies of hepatoblastoma (R01CA111355) and infant leukemia (R01CA079940).

1. Concept proposal

Researchers requesting DNA from banked NBS must submit a one-page concept proposal to the COG Epidemiology Committee. The proposal should provide a brief rationale for the project, name the specific gene variants that will be studied, and include power calculations. Researchers should request the minimum number of samples needed accomplish the goals of a project in order to preserve the resources of the bank.

2. IRB approval

Researchers requesting DNA from banked NBS must submit proof of approval for the project from their local Institutional Review Board.

3. Sample selection and distribution

The University of Minnesota will select a stratified random sample of NBS, weighted for the number of births in each state, for release to researchers. In order to ensure consistent sample quality, DNA will be extracted at the Children's Cancer Research Fund Molecular Epidemiology Laboratory using standard techniques. Aliquots of DNA, in the minimum amount necessary, will then be sent to researchers labeled only with the ID number.

D. Specification of any inducements or rewards to be given subjects for their participation;

None

E. Specification of any research-related expenses to be charged to the subject or their third party payor.

None

III. RISKS Describe any reasonably foreseeable risks or discomforts to participants, including physical, emotional, economic, or social factors. Delineate any steps taken to minimize risks, as well as care of subjects in the event of an accident or complication.

There are no foreseeable risks to obtaining a random sample of NBS given that NBS involve existing anonymous specimens that cannot be identified or linked to the subjects.

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