

**Minnesota Department of Health
Institutional Review Board**

Application for Approval of Research with Human Subjects

**Minnesota Department of Health (MDH)
Center for Health Statistics**
SIDS database

- Providing the MDH Newborn Screening Program with a list of all infants who died of SIDS in the state of Minnesota between the years 1997-2006.

**Minnesota Department of Health (MDH)
Newborn Screening Program**
Archived newborn blood-spots (NBS)

- Retrieving available NBS of children who died of SIDS between 1997-2006 (Study group).
- Matching random NBS for age and gender (Control group).
- Assigning random key to all NBS from both the study and control groups.
- Sending the anonymized NBS from both groups to the CIDMTR laboratory

**Center for Infectious Diseases and
Microbiology, Translational
Research (CIDMTR)**

- Receiving NBS from MDH, being blinded for status (study vs control) and identity.
- Molecular analysis of all NBS to detect CMV DNA.

- MDH will unblind CIDMTR to status of NBS.

NBS from infants who died of SIDS (Study Group)

Random NBS, matched for age and gender (Control Group)

- Comparing the incidence of CMV DNA detected in NBS between the study and control groups.

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Figure 1: Study Design. MDH's Center for Health Statistics will provide the MDH Newborn Screening Program with the names of all infants who died of SIDS in the state of Minnesota between 1997 and 2006. The MDH Newborn Screening Program will retrieve all available NBS, match them for age and gender with a pool of randomized NBS and send them to the CIDMTR for molecular analysis. The CIDMTR laboratory will be blinded as to the identity and status of all NBS. Following DNA extraction and amplification the CIDMTR will be unblinded by the MDH Newborn Screening Program as to the status of the NBS (Study vs Control groups). The incidence of CMV DNA detected between NBS of infants who died of SIDS will be compared to the random cohort of control NBS.

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