# 14. ADVERSE EVENT REPORTING AND DATA MONITORING

## 14.1 Monitoring Subjects and Criteria for Withdrawal from the Study

The National Children's Study is relatively noninvasive, and the research protocol has no interventions. The Study and all procedures are also of no more than minimal risk. Thus, there are no conditions envisioned, either due to Study procedures or unrelated to Study procedures, which would preclude continuation in the Study. The only situation in which we would discontinue follow-up with the family is if there is a pregnancy loss or an enrolled child dies, and the occurrence is beyond the enrollment period (such that it is beyond the point when subsequent pregnancies would be eligible for enrollment in the Study). If Study subjects develop a condition that renders them incapable of providing the continuing informed consent required of the Study, continuing consent will be sought from the legally appropriate party.

Any participant may withdraw from participation in the NCS at any time. Declining participation or withdrawing from the Study will in no way affect their relationship with the local research sites or associated medical institutions. In the event a participant withdraws from the Study or the Study is unable to locate a participant (lost to follow-up), data and samples obtained to that point will be maintained for use in future analyses unless the participant requests the samples be discarded and not used in any future analyses. Participants will also be allowed to stop participation in the Study for brief periods and then rejoin in the future. If a participant dies, all data will be maintained in the data sets for all subsequent analyses. Participants will be informed of these policies.

## 14.2 Data and Safety Monitoring Board

A Data and Safety Monitoring Board (DSMB) consisting of 5 to 10 individuals not associated with the NCS will be created to review data periodically. The DSMB will have expertise in biostatistics, epidemiology, environmental toxicology, pediatrics, genetics, psychology, social determinants of health, ethics, and other appropriate disciplines. The DSMB will report to the Study Director and review standard process data such as accrual rates and adverse events and possibly other appropriate aspects of study data as determined by the Study Director and the Steering Committee. The DSMB will alert the Steering Committee if data become available that might require participants to be informed about the finding. An Ethics Advisory Committee (Subcommittee of the Federal Advisory Committee to the Study) will be established to review relevant situations at the request of the NCS Study Director or the NCS Steering Committee.

## 14.3 Ethics Advisory Committee

During the course of the NCS, environmental findings may reveal information that could be relevant not only to participants but also to members of the community from which participants have been recruited. The Ethics Advisory Committee of the NCS will assist in considering which information is of this type and will be available to assist the regional sites, in partnership with their local community advisors, to develop a strategy for dissemination of this information in an appropriate manner.