

Background Document for Pediatric Oncology Subcommittee Meeting

March 17, 2004
**Room 1066, 5630 Fishers Lane
Rockville, MD**

Document Prepared by:

**Steven Hirschfeld, M.D.
HSM 755
1401 Rockville Pike
Rockville, MD 20857**

Submitted To:

**Johanna Clifford, MS, RN, BSN
HFD 21, Room 1085
5630 Rockville Pike
Rockville, MD 20857**



Table of Contents

1. Points to Consider	Page 1
-----------------------------	--------

APPENDICES

Appendix A. Safety monitoring in clinical studies enrolling children with cancer.

1. HHS Report to Congress Protecting Children in Research
2. FDA Adaptation of Subpart D
3. NIH Guidelines for Research Involving Children
4. Belmont Report
5. Helsinki Declaration
6. ICH E11
7. ICH E6

Appendix B. Non-clinical data to complement clinical data for pediatric oncology.

1. Animal Imaging
2. Animal Models and Osteoporosis
3. Golub DNA Microarrays
4. Limitations of Animal Models
5. Mice as Drug Models
6. Rat Genome Sequence
7. Science Mouse Standards
8. Scientific and Ethical Considerations of Animal Studies:
The Role of Xenografting in Pediatric Brain Tumors with
Specific Emphasis on Medulloblastoma/Primitive Neuroectodermal
Tumors of Childhood
9. Childhood testing of new agents