RECOMBINANT DNA ADVISORY COMMITTEE

EMBASSY SUITES HOTEL
CHEVY CHASE ROOMS 1 & 2
4300 MILITARY ROAD
WASHINGTON, D.C.

REVISED AGENDA[1]

MAY 30, 1991

I. Call to Order..... 9:00 a.m.

Dr. McGarrity

II. Minutes of February 4, 1991, Meeting..... 9:15 a.m.

Tab #1436 (Page 1329) Dr. Post
Mr. Mannix

III. Proposed Amendment to Appendices B-I-B-1 and B-I-B-2 of the *NIH Guidelines* regarding the Bacterial Order, *Actinomycetales*/ Dr. Fleming..... 9:30 a.m.

Tabs #1429/VII (Page 1132) Dr. Schaechter
1427 (Page 1004) Dr. Krogstad
1432 (Page 1230) Dr. Brinckerhoff

(Coffee Break.....10:15-10:30 a.m.)

IV. Proposed Addition to Appendix D of the *NIH Guidelines* Regarding a Human Gene Transfer Protocol entitled *The Administration of Interleukin-2, Interleukin-4, and Tumor Infiltrating Lymphocytes to Patients with Melanoma*/Dr. Lotze..... 10:30 a.m.

Tabs #1429/I (Page 1119) Dr. Gellert
1422 (Page 1) Dr. Carmen
1434 (Page 1309) Dr. Post

(Lunch.....12-1:30 p.m.)

V. Proposed Amendment to the *Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA into the Genome of Human Subjects* regarding Preclinical Studies/ Dr. McIvor..... 1:30 p.m.

Tabs #1429/VI-B (Page 1131) Dr. McIvor

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[1]All times on this agenda are estimates. The actual time for consideration of an item may be earlier or later than indicated.

1. Proposed Addition to Appendix D of the *NIH Guidelines* Regarding a Human Gene Transfer Protocol entitled *Hepatocellular Transplantation in Acute Hepatic Failure and Targeting Genetic Markers to Hepatic Cells*/Drs. Ledley and Woo..... 2:00 p.m.

Tabs #1429/IV	(Page 1122)	Dr. McIvor
1425	(Page 482)	Dr. Bourquin
		Mr. Barton

(Coffee Break..... 2:45-3:00 p.m.)

VII. Proposed Amendment to the *Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA into Genome of Human Subjects* regarding the Human Gene Therapy Subcommittee be Eliminated from the Review Process Involving Human Gene Therapy Protocols/Dr. Anderson..... 4:00 p.m.

Tabs #1429/VII-A	(Page 1126)	Dr. Gellert
1426	(Page 1001)	Dr. Walters
1433	(Page 1302)	Dr. R. Murray

May 31, 1991

VIII. Proposed Additions to Appendix D of the *NIH Guidelines* Regarding Human Gene Transfer Protocols entitled *A Phase I/II Trial of High-Dose Carboplatin and Etoposide with Autologous Marrow Support for Treatment of Stage D Neuroblastoma in First Remission: Use of Marker Genes to Investigate the Biology of Marrow Reconstitution and the Mechanism of Relapse; and A Phase II Trial of High-Dose Carboplatin and Etoposide with Autologous Marrow Support for Treatment of Relapse/Refractory Neuroblastoma Without Apparent Bone Marrow Involvement: Use of Marker Genes to Investigate the Biology of Marrow Reconstitution and the Mechanism of Relapse*/Dr. Brenner..... 9:00 a.m.

Tabs #1429/II	(Page 1120)	Dr. Kelley
1423	(Page 164)	Dr. Atlas
1431	(Page 1139)	Mr. Brewer
1435	(Page 1324)	

(Coffee Break.....10:15-10:30 a.m.)

IX. Proposed Addition to Appendix D of the *NIH Guidelines* Regarding a Human Gene Transfer Protocol entitled *Autologous Transplantation for Chronic Myelogenous Leukemia: Retroviral Marking to Discriminate Between Relapses Arising from Residual Systemic Disease vs. Residual Contamination of Autologous Marrow*/Dr. Deisseroth..... 11:00 a.m.

Tabs #1429/III	(Page 1121)	Dr. Leventhal
1424	(Page 299)	Dr. R. Murray
		Mr. Capron

(Lunch.....12-1:30 p.m.)