### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

# Office of the Secretary

### **Meeting of the National Human Research Protections Advisory** Committee

AGENCY: Office of Public Health and Science, Office for Human Research Protections.

**ACTION:** Notice of July 30–31, 2001 Meeting.

**SUMMARY:** Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Human Research Protections Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below. Individuals planning on attending the meeting and who want to ask questions must submit their requests in writing in advance of the meeting to the contact person listed below.

DATES: The Committee will hold its next meeting on July 30-31, 2001. The meeting will convene from 8:30 a.m. to its recess at approximately 5:30 p.m. on July 30 and resume at 8:30 a.m. to 5:00 p.m. EST on July 31.

ADDRESSES: DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD, (301)468-4972.

#### FOR FURTHER INFORMATION CONTACT: Ms.

Kate-Louise Gottfried, Executive Director, National Human Research Protections Advisory Committee, Office for Human Research Protections, 6100 Executive Boulevard, Room 310B (MSC 7507), Rockville, Maryland 20892-7507, (301)496-7005. The electronic mail address is kg123a@nih.gov.

SUPPLEMENTARY INFORMATION: The National Human Research Protections Advisory Committee was established on June 6, 2000 to provide expert advice and recommendations to the Secretary of HHS, Assistant Secretary for Health, the Director, Office for Human Research Protections, and other departmental officials on a broad range of issues and topics pertaining to or associated with the protection of human research subjects.

The draft agenda for the Committee's July meeting is below. Updates to this agenda will be posted on the NHRPAC website at http://ohrp.osophs.dhhs.gov/ nhrpac/nhrpac.htm.

### **Draft Agenda**

Monday July 30, 2001

- 8:30-8:45am HHS&Human Subject Protection, Arthur Lawrence, Ph.D., Acting Principal Deputy Assistant, Secretary for Health [15 minutes] 8:45am-9:15am The Perilous
- Intersection of Protection, Human Research Subjects and Conflicts, of Interest, Michael Wood, M.D., President and CEO The Mayo Foundation [30 minutes]
- 9:15am-9:30 Welcome: Overview of Meeting Mary Faith marshall, Ph.D. Chairperson NHRPAC [15 minutes
- 9:30am-10:00am Final Review & Approval of NHRPAC Response to Financial Relationships Interim Guidance Mark Barnes, J.D. Chair,
- Working Group [30 minutes] 10:00am–12:30pm Update: Children's Workgroup Alan Fleischman, M.D. Chair, Working Group [2 hours, 30 minutes]
- [10:30am-10:45am] BREAK [15 minutes
- 12:30-1:30pm LUNCH—On your own 1:30pm-3:30pm The Office for Human Research Protectiosn (OHRP) [2 hours
  - Introduction Greg Koski, Ph.D., M.D. Director, OHRP [10 minutes]
  - Education Jeffrey Cohen, Ph.D. Director, Division of Education [15 minutes]
  - Assuance George Gasparis, Acting Director, Division of Assurances and Quality Improvement [15] minutes
  - Compliance Kristina Borror, Ph.D. Division of Compliance [15 minutes]
  - International Melody Lin, Ph.D., Deputy Director and Director, Office for International Activities [10 minutes
  - Policy, Irene Stith-Coleman, Ph.D., Director, Office of Policy, Planning, and Special Projects [10 minutes]
- 3:30pm–3:45 BREAK [15 minutes] 3:45–5:30 Update and Discussion: Third Parties: Research Subjects? Mary Kay Pelias, J.D., Ph.D. Chair, Working Group [1 hour, 45 minutes]
- 5:30pm-5:pm Closing Comments/ ADJOURN [15 minutes]

Tuesday, July 31, 2001

- 8:30 am-8:45 am The Honorable Diane DeGette, Congresswoman, Colorado [15 minutes]
- 8:45 am-9:15 am Human Subject Protections, General Accounting Office (GAO), Marcia G. Crosse, Ph.D., Assistant Director, Health Care—Public Health Issues [30 minutes]

- 9:15 am-9:45 am National Bioethics Advisory Committee (NBAC), Marjorie Speers, Ph.D., Acting Executive Director, NBAC [30 minutesl
- 9:45 am-10:45 am HIPAA and the Privacy Regulation: The Implications for Research, Julie Kaneshiro, M.P.P., Policy Analyst, OSP, National Institutes of Health [1 hour]
- 10:45 am-11:00 am BREAK [15 minutes]
- 11:00 am-12:30 pm Informed Consent & Decisional Capacity Overview, Mary Faith Marshall, Jeremy Sugarman, MD, MPH, MA, Director, Center for the Study of Medical Ethics and Humanities, Professor of Medicine and Philosophy, Duke University Medical Center, Don Rosenstein, M.D., Chief Psychiatry Consultation-Liaison Service, National Institute of Mental Health, Adil Shamoo, Ph.D., Department of Biochemistry and Molecular Biology, University of Maryland School of Medicine, Jim McNulty, President, Depressive/Manic Depressive Association of Rhode Island [1 hour, 30 minutes]
- 12:30 pm-1:30 pm LUNCH—on your own [1 hour]
- 1:30 pm-2:30 pm Informed Consent
- (Continued) [1 hour] 2:30 pm-4:30 pm Update: Social Science, Felice Levine, Ph.D., Executive Officer, American Sociological Association; Jeffrey Cohen, Ph.D., Director, Education, OHRP [2 hours]
- [3:00 pm-3:15 pm] BREAK 4:30 pm-5:00 pm Recap of Meeting & Action Items, Mary Faith Marshall, Ph.D., Chairperson, NHRPAC 5:00 pm ADJOURN

# Kate-Louise Gottfried,

Executive Director, National Human Research Protections Advisory Committee.

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# **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

# **Centers for Disease Control and** Prevention

Disease, Disability, and Injury **Prevention and Control Special Emphasis Panel (SEP): Community Coalition Development Projects for** African American Communities, **Program Announcement 01033** 

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease