Appendix M–VII–D. New Site/New Investigator

This category includes the following: (1) initiation of a protocol at an additional site other than the site that was originally approved by the RAC, and (2) the investigator at the new site is different than the investigator approved for the original site.

Appendix M–VII–E. ''Umbrella'' Protocols

This category includes initiation of a RAC-approved protocol at more than one additional site (the Principal Investigator may be the same or different than the Principal Investigator approved for the original site).

Appendix M–VII–F. Modifications Related to Gene Transfer

This category includes experiments involving a modification to the clinical protocol that is not related to the gene transfer portion of study.

Appendix M–VII–G. Gene Marking Protocols

This category includes human gene marking experiments involving vector constructs that have previously been approved by the RAC and: (1) minor modifications to the vector constructs, or (2) a different tumor cell target.

Appendix M–VIII. Reporting Requirements—Human Gene Transfer Protocols

Appendix M–VIII–A. Semiannual Data Reporting

Investigators who have received approval from the FDA to initiate a human gene transfer protocol (whether or not it has been reviewed by the RAC) shall be required to comply with the semiannual data reporting requirements. Semi-annual Data Report forms will be forwarded by NIH/ORDA to investigators. Data submitted in these reports will be evaluated by the RAC, NIH/ORDA, and the FDA and reviewed by the RAC at its next regularly scheduled meeting.

Appendix M–VIII–B. Adverse Event Reporting

Investigators who have received approval from the FDA to initiate a human gene transfer protocol (whether or not it has been reviewed by the RAC) must report any serious adverse event immediately to the local IRB, IBC, NIH Office for Protection from Research Risks, NIH/ORDA, and FDA, followed by the submission of a written report filed with each group. Reports submitted to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, 6006 Executive Boulevard, Suite 323, Bethesda, Maryland 20892–7052, (301) 496–9838.

Appendix M–IX. Footnotes of Appendix M

Appendix M–IX–A. Human studies in which the induction or enhancement of an immune response to a vector-encoded microbial immunogen is the major goal, such an immune response has been demonstrated in model systems, and the persistence of the vector-encoded immunogen is not expected, may be initiated without RAC review if approved by another Federal agency.

OMB's ''Mandatory Information Requirements for Federal Assistance Program Announcements'' (45 FR 39592, June 11, 1980) requires a statement concerning the official government programs contained in the *Catalog of Federal Domestic Assistance.* Normally, NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers not only virtually every NIH program but also essentially every Federal research program in which DNA recombinant molecule techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the *NIH Guidelines.* In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the *Catalog of Federal Domestic Assistance* are affected.

Effective Date: April 17, 1995.

Harold Varmus,

Director, National Institutes of Health.

[FR Doc. 95–10381 Filed 4–26–95; 8:45 am]

BILLING CODE 4140–01–P

Public Health Service

National Institutes of Health; Notice of Meeting of the Panel to Assess the NIH Investment in Research on Gene Therapy

Notice is hereby given that the Panel to Assess the NIH Investment in Research on Gene Therapy, a fact-finding group reporting to the Advisory Committee to the Director (ACD), National Institutes of Health (NIH), will meet in public session at the William H. Natcher Building (Building 45) Conference Center, Board Room, National Institutes of Health, Bethesda, Maryland 20892, on May 15–16, 1995. The meeting will begin at approximately 9:00 a.m. to recess on May 15, and from approximately 9:00 a.m. to 1:00 p.m. on May 16.

The goal of the Panel is to make recommendations to the ACD about the scientific areas that NIH should emphasize and the funding mechanisms that should be employed in order best to advance the development of gene therapy. The purpose of the meeting is to provide the Panel with an opportunity to hear presentations regarding the current and anticipated research activities relevant to gene therapy that are supported by the various components of NIH, and to discuss how to proceed with its assessment of NIH's investment in gene therapy.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other special accommodations, should contact the person named below in advance of the hearing.

Attendance may be limited to seat availability. If you plan to attend the meeting as an observer or if you wish additional information, please contact Ms. Janice Ramsden, National Institutes of Health, Shannon Building, Room 235, 1 Center Drive MSC 0159, Bethesda, Maryland 20892–0159, telephone (301) 496–0959, fax (301) 496–7451, by May 10.

Ruth L. Kirschstein,

Deputy Director, NIH.

[FR Doc. 95–10382 Filed 4–26–95; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ-020–05–1330–00]

Notice of Availability of the Cyprus Tohono Corporation Proposed Mine Expansion Final Environmental Impact Statement, Phoenix District, Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Final environmental impact statement.

SUMMARY: In compliance with the Federal Land Policy and Management Act of 1976, section 102(2)(c) of the National Environmental Policy Act of