3, 1999. Guidelines for preparing full CRADA proposals will be communicated shortly thereafter to all respondents who have been selected.

**SUPPLEMENTARY INFORMATION:**

### Technology Available

DHHS scientists in the Structural Biochemistry Program, NCI-Frederick Cancer Research and Development Center (SBP) have developed certain structural and biochemically-based technologies that are believed to be of value in the diagnosis and treatment of drug resistant HIV. Using these technologies, SBP scientists have developed strategies for designing inhibitors to multidrug resistant HIV, and for predicting resistance-potentials of HIV protease inhibitors. Recent evidence indicates that multidrug resistant HIV strains are appearing in the drug-naïve population at an increasing rate. Thus, the SBP research is believed to be at a stage that is ripe for the development of new treatments and diagnostic methods for the multidrug resistant HIV-infected population. SBP is interested in a multi-disciplinary but highly focussed approach to the biochemical and virologic evaluation of protease inhibitors against clinically-derived drug resistant mutant viruses, as well as in the structure-based design and chemical synthesis of new protease inhibitors for testing.

The successful Collaborator should possess experience in the following areas at a minimum: Experience with pre-clinical and clinical drug development for antiretroviral compounds; ability to generate site-directed mutant viruses for measurement of phenotypic resistance with specific expertise in HIV; application of automation and robotics technologies to cell culture-based antiviral assays and to enzyme-based biochemical assays with specific expertise in HIV; application of automation and robotics technologies to cell culture-based assays designed to measure phenotypic resistance; application of database and bioinformatics technologies for the manipulation, storage and analysis of high throughput assay data, including the development of software as required; and, the use of high throughput assay methods to evaluate protease inhibitors against multidrug resistant HIV mutants.

DHHS now seeks collaborative arrangements for the joint evaluation and development of methods to biochemical and virologic evaluate protease inhibitors against clinically-derived drug resistant mutant viruses, as well as in the structure-based design and chemical synthesis of new protease inhibitors for further analysis. For collaborations with the commercial sector, a Cooperative Research and Development Agreement (CRADA) will be established to provide equitable distribution of intellectual property rights developed under the CRADA. CRADA aims will include rapid publication of research results as well as full and timely exploitation of any commercial opportunities.

The role of the National Cancer Institute in this CRADA will include, but not be limited to:

1. Providing intellectual, scientific, and technical expertise and experience to the research project.
2. Providing the Collaborator with HIV drug resistant gene sequences and protease inhibitors for evaluation.
3. Planning research studies and interpreting research results.
4. Publishing research results.

The role of the CRADA Collaborator may include, but not be limited to:

1. Providing significant intellectual, scientific, and technical expertise or experience to the research project.
2. Planning research studies and interpreting research results.
3. Providing technical expertise and/or financial support (e.g. facilities, personnel and expertise) for CRADA-related Government activities.
4. Accomplishing objectives according to an appropriate timetable to be outlined in the CRADA Collaborator's proposal.
5. The willingness to commit best effort and demonstrated resources to the research, development and commercialization of this technology.
6. The demonstration of expertise in the commercial development, production, marketing and sales of products related to this area of technology.
7. The willingness to cooperate with the National Cancer Institute in the timely publication of research results.
8. The agreement to be bound by the appropriate DHHS regulations relating to human subjects, and all PHS policies relating to the use and care of laboratory animals.
9. The willingness to accept the legal provisions and language of the CRADA with only minor modifications, if any. These provisions govern patent rights to CRADA inventions.

Dated: March 25, 1999.

**Kathleen Sybert,**

*Director, Technology Development & Commercialization Branch, National Cancer Institute, National Institutes of Health.*

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**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Notice of Meeting of the Working Group To Advise the ACD on Guidelines and Oversight Process for Research Involving Human Pluripotent Stem Cells

Notice is hereby given that the Working Group of the Advisory Committee to the Director (ACD), NIH to advise the ACD on guidelines and oversight for research involving human pluripotent stem cells, will meet in public session at the Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, Maryland 20814, on April 8, 1999. The meeting will begin at approximately 9:00 a.m. and end at approximately 5:30 p.m.

The goal of the Working Group is to provide advice to the ACD about the scientific, ethical, legal, and social issues relevant to guidelines for the conduct of research utilizing human pluripotent stem cells (cells that can form most of the cells and tissues of the body) and to consider oversight options for this research.

A limited amount of meeting time will be allotted for public testimony. Individuals who wish to give five minute public testimony may sign up at the meeting site the morning of the meeting on a first come, first served basis. Written testimony may be submitted to: the Office of Science Policy, Bldg. 1, Room 218, NIH, 9000 Rockville Pike, Bethesda 20892.

Attendance may be limited to seat availability.

**Ruth L. Kirschstein,**

*Deputy Director, NIH.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Center For Scientific Review; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Center for Scientific Review 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